

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

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§ 1500.1 Scope of subchapter.

Set forth in this subchapter C are the regulations of the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act as amended (see §1500.3(a)(1)).

§ 1500.2 Authority.

Authority under the Federal Hazardous Substances Act is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1500.3 Definitions.

(a) *Certain terms used in this part.* As used in this part:

(1) *Act* means the Federal Hazardous Substances Act (Pub. L. 86-613, 74 Stat. 372-81 (15 U.S.C. 1261-74)) as amended by:

(i) The Child Protection Act of 1966 (Pub. L. 89-756, 80 Stat. 1303-05).

(ii) The Child Protection and Toy Safety Act of 1969 (Pub. L. 91-113, 83 Stat. 187-90).

(iii) The Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74).

(2) *Commission* means the Consumer Product Safety Commission estab-

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lished May 14, 1973, pursuant to provisions of the Consumer Product Safety Act (Pub. L. 92-573, 86 Stat. 1207-33 (15 U.S.C. 2051-81)).

(b) *Statutory definitions.* Except for the definitions given in section 2 (c) and (d) of the act, which are obsolete, the definitions set forth in section 2 of the act are applicable to this part and are repeated for convenience as follows (some of these statutory definitions are interpreted, supplemented, or provided with alternatives in paragraph (c) of this section):

(1) *Territory* means any territory or possession of the United States, including the District of Columbia and the Commonwealth of Puerto Rico but excluding the Canal Zone.

(2) *Interstate commerce* means (i) commerce between any State or territory and any place outside thereof and (ii) commerce within the District of Columbia or within any territory not organized with a legislative body.

(3) *Person* includes an individual, partnership, corporation, and association.

(4)(i) *Hazardous substance* means:

(A) Any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(B) Any substance which the Commission by regulation finds, pursuant to the provisions of section 3(a) of the act, meet the requirements of section 2(f)(1)(A) of the act (restated in (A) above).

(C) Any radioactive substance if, with respect to such substance as used in a particular class of article or as packaged, the Commission determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with the act in order to protect the public health.

(D) Any toy or other article intended for use by children which the Commission by regulation determines, in accordance with section 3(e) of the act,

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presents an electrical, mechanical, or thermal hazard.

(ii) *Hazardous substance* shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house. "Hazardous substance" shall apply, however, to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of section 2(f)(1) of the Federal Hazardous Substances Act (re-stated in paragraph (b)(4)(i) of this section) by reason of bearing or containing such a pesticide.

(iii) *Hazardous substance* shall not include any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

(5) *Toxic* shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

(6)(i) *Highly toxic* means any substance which falls within any of the following categories:

(A) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered; or

(B) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or 2 milligrams per liter by volume or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or

(C) Produces death within 14 days in half or more than half of a group of 10 or more rabbits tested in a dosage of 200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.

(ii) If the Commission finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages and concentrations specified in paragraph (b)(6)(i) of this section, the human data shall take precedence.

(7) *Corrosive* means any substance which in contact with living tissue will cause destruction of tissue by chemical action, but shall not refer to action on inanimate surfaces.

(8) *Irritant* means any substance not corrosive within the meaning of section 2(i) of the act (re-stated in paragraph (b)(7) of this section) which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(9) *Strong sensitizer* means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(10) The terms *extremely flammable*, *flammable*, and *combustible* as they apply to any substances, liquid, solid, or the contents of any self-pressurized container, are defined by regulations issued by the Commission and published at §1500.3(c)(6).

(11) *Radioactive substance* means a substance which emits ionizing radiation.

(12) *Label* means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the cases of an article which is unpackaged or is not packaged in an

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immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto. A requirement made by or under authority of the act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (i) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (ii) on all accompanying literature where there are directions for use, written or otherwise.

(13) *Immediate container* does not include package liners.

(14) *Misbranded hazardous substance* means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance, except as otherwise provided by or pursuant to section 3 of the act (Federal Hazardous Substances Act), fails to bear a label:

(i) Which states conspicuously:

(A) The name and place of business of the manufacturer, packer, distributor, or seller;

(B) The common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name;

(C) The signal word “DANGER” on substances which are extremely flammable, corrosive, or highly toxic;

(D) The signal word “WARNING” or “CAUTION” on all other hazardous substances;

(E) An affirmative statement of the principal hazard or hazards, such as

“Flammable,” “Combustible,” “Vapor Harmful,” “Causes Burns,” “Absorbed Through Skin,” or similar wording descriptive of the hazard;

(F) Precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Commission pursuant to section 3 of the act;

(G) Instruction, when necessary or appropriate, for first-aid treatment;

(H) The word *Poison* for any hazardous substance which is defined as “highly toxic” by section 2(h) of the act (restated in paragraph (b)(6) of this section);

(I) Instructions for handling and storage of packages which require special care in handling or storage; and

(J) The statement (1) “Keep out of the reach of children” or its practical equivalent, or, (2) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard; and

(ii) On which any statements required under section 2(p)(1) of the act (restated in paragraph (b)(14)(i) of this section) are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

Misbranded hazardous substance also means a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in section 2(f)(1) of the Federal Hazardous Substances Act (restated in paragraph (b)(4)(i)(A) of this section) and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(15)(i) *Banned hazardous substance* means:

(A) Any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or

(B) Any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as

a “banned hazardous substance” on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under the act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce; *Provided*, That the Commission by regulation (1) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section) articles, such as chemistry sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved, or necessarily present an electrical, mechanical, or thermal hazard, and which bear labeling giving adequate directions and warnings for safe use and are intended for use by children who have attained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings, and (2) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section), and provide for the labeling of, common fireworks (including toy paper caps, cone fountains, cylinder fountains, whistles without report, and sparklers) to the extent that the Commission determines that such articles can be adequately labeled to protect the purchasers and users thereof.

(ii) Proceedings for the issuance, amendment, or repeal of regulations pursuant to section 2(q)(1)(B) of the act (restated in paragraph (b)(15)(i)(B) of this section) shall be governed by the provisions of section 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act: *Provided*, That if the Commission finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, the Commission may by order published in the FEDERAL REGISTER give notice of such finding, and thereupon such substance when intended or offered for household use, or when so packaged as to be suitable for such use, shall be deemed to be a “banned hazardous substance” pend-

ing the completion of proceedings relating to the issuance of such regulations.

(16) “Electrical hazard”—an article may be determined to present an electrical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock.

(17) “Mechanical hazard”—an article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness:

(i) From fracture, fragmentation, or disassembly of the article;

(ii) From propulsion of the article (or any part or accessory thereof);

(iii) From points or other protrusions, surfaces, edges, openings, or closures;

(iv) From moving parts;

(v) From lack or insufficiency of controls to reduce or stop motion;

(vi) As a result of self-adhering characteristics of the article;

(vii) Because the article (or any part or accessory thereof) may be aspirated or ingested;

(viii) Because of instability; or

(ix) Because of any other aspect of the article’s design or manufacture.

(18) “Thermal hazard”—an article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces.

(c) *Certain statutory definitions interpreted, supplemented, or provided with alternatives.* The following items interpret, supplement, or provide alternatives to definitions set forth in section 2 of the act (and restated in paragraph (b) of this section):

(1) To provide flexibility as to the number of animals tested, and to emphasize *in vitro* testing methods, the following is an alternative to the definition of “highly toxic” in section 2(h) of the act (and paragraph (b)(6) of this section); *Highly toxic* means:

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(i) A substance determined by the Commission to be highly toxic on the basis of human experience; and/or

(ii) A substance that produces death within 14 days in half or more than half of a group of:

(A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams or less per kilogram of body weight is administered orally;

(B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or

(C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours or less by the method described in §1500.40.

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

(iii) A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(2) To give specificity to the definition of "toxic" in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition. "Toxic" applies to any substance that is "toxic" (but not "highly toxic") on the basis of human experience. The following categories are not intended to be inclusive.

(i) The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharma-

cological practices. *Toxic* also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(ii) *Chronic toxicity*. A substance is toxic because it presents a chronic hazard if it falls into one of the following categories. (For additional information see the chronic toxicity guidelines at 16 CFR 1500.135.)

(A) *For Carcinogens*. A substance is toxic if it is or contains a known or probable human carcinogen.

(B) *For Neurotoxicological Toxicants*. A substance is toxic if it is or contains a known or probable human neurotoxin.

(C) *For Developmental or Reproductive Toxicants*. A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant.

(3) Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if a weight-of-evidence analysis suggests that it is corrosive, or validated *in vitro* test method suggests that it is corrosive, or if, when tested by the *in vivo* technique described in §1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis

comprising all of the following that are available: Existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; and/or a substance that can be considered a primary irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(5) The definition of *strong sensitizer* in section 2(k) of the Federal Hazardous Substances Act (restated in paragraph (b)(9) of this section) is supplemented by the following definitions:

(i) *Sensitizer*. A sensitizer is a substance that is capable of inducing a state of immunologically mediated

hypersensitivity (including allergic photosensitivity) following a variable period of exposure to that substance. Hypersensitivity to a substance will become evident by an allergic reaction elicited upon reexposure to the same substance.

(ii) *Significant potential for causing hypersensitivity*. (A) Before designating any substance a "strong sensitizer," the Commission shall find that the substance has significant potential for causing hypersensitivity. *Significant potential for causing hypersensitivity* is a relative determination that must be made separately for each substance. The determination may be based on documented medical evidence of hypersensitivity reactions upon subsequent exposure to the same substance obtained from epidemiological surveys or case histories; controlled *in vivo* or *in vitro* experimental studies; susceptibility profiles (*e.g.*, genetics, age, gender, atopic status) in non-sensitized or allergic subjects; and chemical or functional properties of the substance.

(B) In determining whether a substance is a "strong" sensitizer, the Commission shall consider the available data for a number of factors, following a weight-of-evidence approach. The following factors (if available), ranked in descending order of importance, should be considered: well-conducted clinical and diagnostic studies, epidemiological studies, with a preference for general population studies over occupational studies, well-conducted animal studies, well-conducted *in vitro* test studies, cross-reactivity data, and case histories.

(C) Additional consideration may be given to Quantitative Structure-Activity Relationships (QSARs), *in silico* data, specific human sensitization threshold values, other data on potency and sensitizer bioavailability, if data are available and the methods validated. Bioavailability is the dose of the allergen available to interact with a tissue. Bioavailability is a reflection of how well the skin or another organ can absorb the allergen and the actual penetrating ability of the allergen, including factors such as size and composition of the chemical.

(D) Criteria for a “well-conducted” study would include: validated outcomes, relevant dosing, route of administration, and use of appropriate controls. Studies should be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP).

(E) Before the Commission designates any substance as a “strong” sensitizer, frequency of occurrence and range of severity of reactions in exposed subpopulations having average or high susceptibility will be considered. The minimal severity of a reaction for the purpose of designating a material as a “strong sensitizer” is a clinically important reaction. A clinically important reaction would be considered one with a significant impact on quality of life. Consideration should be given to the location of the hypersensitivity response, such as the face, hands, and feet as well as persistence of clinical manifestations. For example, strong sensitizers may produce substantial illness, including any or all of the following: substantial physiological effects, such as discomfort and distress, substantial hardship, functional or structural impairment, persistent morbidity, or in rare cases, mortality.

(iii) *Normal living tissue.* The allergic hypersensitivity reaction occurs in normal living tissues, including the skin, mucous membranes (*e.g.*, ocular, oral), and other organ systems, such as the respiratory tract and gastrointestinal tract, either singularly or in combination, following sensitization by contact, ingestion, or inhalation.

(6) The Consumer Product Safety Commission, by the regulations published in this section, defines the terms *extremely flammable*, *flammable*, and *combustible*, appearing in section 2(1) of the Federal Hazardous Substances Act, as follows:

(i) The term *extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F (–6.7 °C) as determined by the test method described at §1500.43a, except that, any mixture having one component or more with a flashpoint higher than 20 °F (–6.7 °C) which comprises at least 99

percent of the total volume of the mixture is not considered to be an extremely flammable substance.

(ii) The term *flammable* shall apply to any substance having a flashpoint above 20 °F (–6.7 °C) and below 100 °F (37.8 °C), as determined by the method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint at or above 100 °F (37.8 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a flammable substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be flammable if the mixture does not present a significant flammability hazard when used by consumers.

(iii) The term *combustible* shall apply to any substance having a flashpoint at or above 100 °F (37.8 °C) to and including 150 °F (65.6 °C) as determined by the test method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint higher than 150 °F (65.6 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a combustible hazardous substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be combustible if the mixture does not present a significant flammability hazard when used by consumers.

(iv) To determine flashpoint temperatures for purposes of enforcing and administering requirements of the Federal Hazardous Substances Act applicable to “extremely flammable,” “flammable,” and “combustible” hazardous substances, the Commission will follow the procedures set forth in §1500.43a. However, the Commission will allow manufacturers and labelers of substances and products subject to those requirements to rely on properly conducted tests using the Tagliabue open-cup method which was in effect prior to the issuance of §1500.43a (as published at 38 FR 27012, September 27, 1973, and set forth below), and the definitions of the terms “extremely flammable,” “flammable,” and “combustible” in

this section before its amendment (as published at 38 FR 27012, September 27, 1983, and amended 38 FR 30105, November 1, 1973, set forth in the note following this section) if all of the following conditions are met:

(A) The substance or product was subject to and complied with the requirements of the Federal Hazardous Substances Act for “extremely flammable,” “flammable,” or “combustible” hazardous substances before the effective date of §1500.43a; and

(B) No change has been made to the formulation or labeling of such substance or product after the effective date of §1500.43a, prescribing a closed-cup test apparatus and procedure.

(v) *Extremely flammable solid* means a solid substance that ignites and burns at an ambient temperature of 80 °F or less when subjected to friction, percussion, or electrical spark.

(vi) *Flammable solid* means a solid substance that, when tested by the method described in §1500.44, ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

(vii) *Extremely flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening and the flashpoint, when tested by the method described in §1500.43a is less than 20 °F (−6.7 °C).

(viii) *Flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flame projection exceeding 18 inches is obtained at full valve opening, or flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening.

(7) The definition of *hazardous substance* in section 2(f)(1)(A) of the act (restated in paragraph (b)(4)(i)(A) of this section) is supplemented by the following definitions or interpretations or terms used therein:

(i) A substance or mixture of substances that “generates pressure through decomposition, heat, or other means” is a hazardous substance:

(A) If it explodes when subjected to an electrical spark, percussion, or the flame of a burning paraffin candle for 5 seconds or less.

(B) If it expels the closure of its container, or bursts its container, when held at or below 130 °F. for 2 days or less.

(C) If it erupts from its opened container at a temperature of 130 °F. or less after having been held in the closed container at 130 °F. for 2 days.

(D) If it comprises the contents of a self-pressurized container.

(ii) *Substantial personal injury or illness* means any injury or illness of a significant nature. It need not be severe or serious. What is excluded by the word “substantial” is a wholly insignificant or negligible injury or illness.

(iii) *Proximate result* means a result that follows in the course of events without an unforeseeable, intervening, independent cause.

(iv) *Reasonably foreseeable handling or use* includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

(8) The definition of “radioactive substance” in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following: *Radioactive substance* means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter. Source materials, special nuclear material, and byproduct materials described in section 2(f)(3) of the act are exempt.

(9) In the definition of “label” in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, “accompanying literature” is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that

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is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(10) The definition of “misbranded hazardous substance” in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein:

(i) *Hazardous substances intended, or packaged in a form suitable, for use in the household* means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed. The term includes articles, such as polishes or cleaners, designed primarily for professional use but which are available in retail stores, such as hobby shops, for nonprofessional use. Also included are items, such as antifreeze and radiator cleaners, that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled as, and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household; the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning’s prominence and conspicuousness are: Location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warn-

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ing might be the effect of the package contents if spilled on the label.

NOTE: The definitions of *extremely flammable*, *flammable*, and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10, 1987. The definitions remaining in effect until August 10, 1987, as published at 38 FR 27012, Sept. 27, 1973, and amended at 38 FR 30105, Nov. 1, 1973, are set forth below. Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F. as determined by the Tagliabue Open Cup Tester; *flammable* shall apply to any substance which has a flashpoint of above 20 °F., to and including 80 °F., as determined by the Tagliabue Open Cup Tester; and *combustible* shall apply to any substance which has a flashpoint above 80 °F. to and including 150 °F., as determined by the Tagliabue Open Cup Tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found by the Commission to be generally applicable to such materials or containers, respectively, and established by regulations issued by the Commission, which regulations shall also define the terms *flammable*, *combustible*, and *extremely flammable* in accord with such methods.

* * * * *

(c)(6)(i) *Extremely flammable* means any substance that has a flashpoint at or below 20 °F. as determined by the method described in §1500.43.

(ii) *Flammable* means any substance that has a flashpoint of above 20 °F., to and including 80 °F., as determined by the method described in §1500.43.

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 30105, Nov. 1, 1973; 49 FR 22465, May 30, 1984; 51 FR 28536, Aug. 8, 1986; 51 FR 29096, Aug. 14, 1986; 51 FR 30209, Aug. 25, 1986; 57 FR 46669, Oct. 9, 1992; 77 FR 73293, Dec. 10, 2012; 79 FR 8831, Feb. 14, 2014]

§ 1500.4 Human experience with hazardous substances.

(a) Reliable data on human experience with any substance should be taken into account in determining whether an article is a “hazardous substance” within the meaning of the act. When such data give reliable results different from results with animal

data, the human experience takes precedence.

(b) Experience may show that an article is more or less toxic, irritant, or corrosive to man than to test animals. It may show other factors that are important in determining the degree of hazard to humans represented by the substance. For example, experience shows that radiator antifreeze is likely to be stored in the household or garage and likely to be ingested in significant quantities by some persons. It also shows that a particular substance in liquid form is more likely to be ingested than the same substance in a paste or a solid and that an aerosol is more likely to get into the eyes and the nasal passages than a liquid.

§ 1500.5 Hazardous mixtures.

For a mixture of substances, the determination of whether the mixture is a "hazardous substance" as defined by section 2(f) of the act (repeated in §1500.3(b)(4)) should be based on the physical, chemical, and pharmacological characteristics of the mixture. A mixture of substances may therefore be less hazardous or more hazardous than its components because of synergistic or antagonistic reactions. It may not be possible to reach a fully satisfactory decision concerning the toxic, irritant, corrosive, flammable, sensitizing, or pressure-generating properties of a substance from what is known about its components or ingredients. The mixture itself should be tested.

§ 1500.12 Products declared to be hazardous substances under section 3(a) of the act.

(a) The Commission finds that the following articles are hazardous substances within the meaning of the act because they are capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use:

(1) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating.

(2) Metal-cored candlewicks that have a lead content of more than 0.06 percent of the total weight of the

metal core, and candles made with such wicks.

(b) [Reserved]

[38 FR 27012, Sept. 27, 1973, as amended at 68 FR 19147, Apr. 18, 2003]

§ 1500.13 Listing of "strong sensitizer" substances.

On the basis of frequency of occurrence and severity of reaction information, the Commission finds that the following substances have a significant potential for causing hypersensitivity and therefore meet the definition for "strong sensitizer" in section 2(k) of the act (repeated in §1500.3(b)(9)):

(a) Paraphenylenediamine and products containing it.

(b) Powdered orris root and products containing it.

(c) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200.

(d) Formaldehyde and products containing 1 percent or more of formaldehyde.

(e) Oil of bergamot and products containing 2 percent or more of oil of bergamot.

§ 1500.14 Products requiring special labeling under section 3(b) of the act.

(a) Human experience, as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, and opinions of informed medical experts establish that the following substances are hazardous:

(1) Diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol.

(2) Ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol.

(3) Products containing 5 percent or more by weight of benzene (also known as benzol) and products containing 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates such as kerosine, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates.

(4) Methyl alcohol (methanol) and mixtures containing 4 percent or more by weight of methyl alcohol (methanol).

(5) Turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and mixtures containing 10 percent or more by weight of such turpentine.

(b) The Commission finds that the following substances present special hazards and that, for these substances, the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act, the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

(1) *Diethylene glycol*. Because diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word “warning” and the statement “Harmful if swallowed.”

(2) *Ethylene glycol*. Because ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word “warning” and the statement “Harmful or fatal if swallowed.”

(3) *Benzene, toluene, xylene, petroleum distillates*. (i) Because inhalation of the vapors of products containing 5 percent or more by weight of benzene may cause blood dyscrasias, such products shall be labeled with the signal word “danger,” the statement of hazard “Vapor harmful,” the word “poison,” and the skull and crossbones symbol. If the product contains 10 percent or more by weight of benzene, it shall bear the additional statement of hazard “Harmful or fatal if swallowed” and the additional statement “Call physician immediately.”

(ii) Because products containing 10 percent or more by weight of toluene, xylene, or any of the other substances listed in paragraph (a)(3) of this section

may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word “danger,” the statement or hazard “Harmful or fatal if swallowed,” and the statement “Call physician immediately.”

(iii) Because inhalation of the vapor of products containing 10 percent or more by weight of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard “Vapor harmful” in addition to the statements prescribed in paragraph (b)(3)(ii) of this section.

(4) *Methyl alcohol (methanol)*. Because death and blindness can result from the ingestion of methyl alcohol, the label for this substance and for mixtures containing 4 percent or more by weight of this substance shall include the signal word “danger,” the additional word “poison,” and the skull and crossbones symbol. The statement of hazard shall include “Vapor harmful” and “May be fatal or cause blindness if swallowed.” The label shall also bear the statement “Cannot be made nonpoisonous.”

(5) *Turpentine*. Because turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and products containing 10 percent or more by weight of such turpentine, in addition to oral toxicity resulting in systemic poisoning, may be aspirated into the lungs with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word “danger” and the statement of hazard “Harmful or fatal if swallowed.”

(6) *Charcoal*. Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating.

(i)(A) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas may cause serious injury or death, containers of such products packaged before November 3, 1997, shall bear the following bordered statement:

WARNING: Do Not Use for Indoor Heating or Cooking Unless Ventilation Is Provided for Exhausting Fumes to Outside. Toxic Fumes May Accumulate and Cause Death

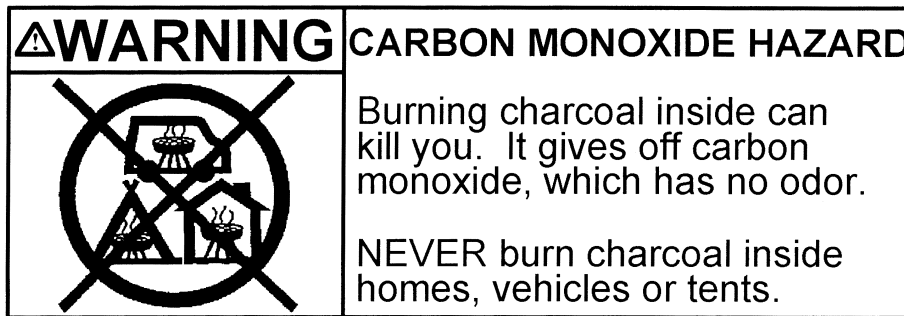
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(B) For bags of charcoal packaged before November 3, 1997, the statement specified in paragraph (b)(6)(i) of this section shall appear within a heavy borderline in a color sharply contrasting to that of the background, on both front and back panels in the upper 25 percent of the panels of the bag at least 2 inches below the seam, and at least 1 inch above any reading material or design elements in type size as follows: The signal word "WARNING"

shall appear in capital letters at least three-eighths inch in height; the remaining text of the warning statement shall be printed in letters at least three-sixteenths inch in height.

(ii)(A) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas can cause serious injury or death, containers of such products packaged on or after November 3, 1997, shall bear the following bordered label.



(B) Except as provided in paragraph (b)(6)(ii)(C) of this section, the following requirements apply to bags of charcoal subject to paragraph (b)(6)(ii)(A) of this section. The label specified in paragraph (b)(6)(ii)(A) of this section shall appear within a heavy borderline, in a color sharply contrasting to that of the background, on both the front and back panels in the upper 25 percent of the panels of the bag, and with the outer edge of the borderline at least 2.54 cm (1 inch) below the seam and at least 2.54 cm (1 inch) above any other reading material or design elements. The signal word "WARNING" shall be in bold capital letters in at least 7.14 mm (9/32 inch) type. The remaining text of the warning statement shall be in at least 4.763 mm (3/16 inch) type. The phrase "CARBON MONOXIDE HAZARD" shall be in bold. This phrase and the word "NEVER" shall be in all capital letters. The lettering shall have a strokewidth-to-height ratio of 1:6 to 1:8. The label shall be at least 50.8 mm (2 inches) high and 147.5 mm (5 13/16 inches) wide. The label's lettering,

spacing between the bottom of the letters of one line and the top of the letter of the next line, and pictogram shall have the size relation to each other and to the remainder of the label shown in paragraph (b)(6)(ii)(A) of this section.

(C) For bags of charcoal subject to paragraph (b)(6)(ii)(A) of this section that are 6 inches or less wide, the minimum label height may be reduced to 38 mm (1.5 inches) and the minimum width may be reduced to 139.7 mm (5.5 inches). The signal word "WARNING" shall be in capital letters in at least 6.32 mm (0.249 inch) type. The remaining text of the warning shall be in at least 4.23 mm (0.166 inch) type. All other requirements of paragraphs 6(b)(ii) (A) and (B) of this section shall apply to these bags.

(7) *Fireworks devices.* Because of the special hazards presented by fireworks devices if not used in a certain manner, the following listed fireworks devices shall be labeled as indicated:

- (i) *Fountains.*

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WARNING (OR CAUTION)

FLAMMABLE (or EMITS SHOWERS OF SPARKS, if more descriptive).

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place on level surface.

Light fuse and get away.

(ii) *California candles.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Hold in hand at bottom of tube.

Point away from body so that neither end points toward body.

(iii) *Spike and handle cylindrical fountains.*

(A) *Spike fountains.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Stick firmly in ground in an upright position.

Do not hold in hand.

Light fuse and get away.

(B) *Handle fountains.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Hold in hand—point away from body.

Light fuse.

(iv) *Roman Candles.*

WARNING (OR CAUTION) SHOOTS FLAMING BALLS

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Stick butt end in ground.

Do not hold in hand.

Light fuse and get away.

(v) *Rockets with sticks.*

WARNING (OR CAUTION) FLAMMABLE

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place in wooden trough or iron pipe at 75° angle, pointing away from people or flammable material.

Do not hold in hand.

Light fuse and get away.

(vi) *Wheels.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Attach securely by means of a nail through the hole (or place on hard flat surface, for ground spinners).

Light fuse and get away.

(vii) *Illuminating torches.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Hold in hand—point away from body, clothing, or other flammable material (or place upright on level ground. Do not hold in hand, if more descriptive).

Light fuse (or light fuse and get away, if more descriptive).

(viii) *Sparklers.*

On the front and back panels:

WARNING (OR CAUTION) FLAMMABLE

On the side, front, back, top, or bottom panel.

CAUTION

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Do not touch glowing wire (or do not touch hot plastic, wood, etc., if more descriptive). Hold in hand with arm extended away from body.

Keep burning end or sparks away from wearing apparel or other flammable material.

(ix) *Mines and shells.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS (OR SHOOTS FLAMING BALLS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place on hard smooth surface (or place upright on level ground, if more descriptive).

Do not hold in hand.

Light fuse and get away.

(x) *Whistles without report.*

WARNING (OR CAUTION) FLAMMABLE

SHOOTS WHISTLE IN AIR (if applicable)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Do not hold in hand.

Light fuse and get away.

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(xi) *Toy smoke devices and flutter devices.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision.

(Use of the word close is optional.)

For outdoor use only.

Do not hold in hand.

Light fuse and get away.

(xii) *Helicopter-type rockets.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision.

(Use of the word close is optional.)

For outdoor use only.

Place on hard, open surface.

Light fuse and get away.

(xiii) *Party poppers.*

WARNING (OR CAUTION) FLAMMABLE

Use only under [close] adult supervision.

(Use of the word close is optional.)

Do not point either end toward face or other person.

Hold in hand—jerk string.

(xiv) *Missile-type rockets.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision.

(Use of the word close is optional.)

For outdoor use only.

Place on hard, open surface.

Light fuse and get away.

(xv) *Labeling—General.* Any fireworks device not required to have a specific label as indicated above shall carry a warning label indicating to the user where and how the item is to be used and necessary safety precautions to be observed. All labels required under this section shall comply with the requirements of §1500.121 of these regulations. (See also §1500.17(a) (3), (8) and (9); §1500.83(a)(27); §1500.85(a)(2); and part 1507).

(8) *Art materials.*

NOTE: The Labeling of Hazardous Art Materials Act ("LHAMA"), 15 U.S.C. 1277 (Pub. L. 100-695, enacted November 18, 1988) provides that, as of November 18, 1990, "the requirements for the labeling of art materials set forth in the version of the standard of the American Society for Testing and Materials ["ASTM"] designated D-4236 that is in effect on [November 18, 1988] * * * shall be deemed to be a regulation issued by the Commission under section 3(b)" of the Federal Hazardous Substances Act, 15 U.S.C. 1262(b). For the

convenience of interested persons, the Commission is including the requirements of ASTM D-4236 in paragraph (b)(8)(i) of this section, along with other requirements (stated in paragraph (b)(8)(ii) of this section) made applicable to art materials by the LHAMA. The substance of the requirements specified in LHAMA became effective on November 18, 1990, as mandated by Congress.

(i) *ASTM D-4236—(A) Scope—(1)* This section describes a procedure for developing precautionary labels for art materials and provides hazard and precautionary statements based upon knowledge that exists in the scientific and medical communities. This section concerns those chronic health hazards known to be associated with a product or product component(s), when the component(s) is present in a physical form, volume, or concentration that in the opinion of a toxicologist (see paragraph (b)(8)(i)(B)(1) of this section) has the potential to produce a chronic adverse health effect(s).

(2) This section applies exclusively to art materials packaged in sizes intended for individual users of any age or those participating in a small group.

(3) Labeling determinations shall consider reasonably foreseeable use or misuse.

(4) Manufacturers or repackagers may wish to have compliance certified by a certifying organization. Guidelines for a certifying organization are given in paragraph (b)(8)(i)(H) of this section.

(B) Descriptions of Terms Specific to This Standard. (1) Art material or art material product—any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and suitable for users as defined herein.

(2) Users—artists or crafts people of any age who create, or recreate in a limited number, largely by hand, works which may or may not have a practical use, but in which aesthetic considerations are paramount.

(3) Chronic adverse health effect(s)—a persistent toxic effect(s) that develops over time from a single, prolonged, or repeated exposure to a substance. This effect may result from exposure(s) to a substance that can, in humans, cause sterility, birth defects, harm to a developing fetus or to a nursing infant,

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cancer, allergenic sensitization, damage to the nervous system, or a persistent adverse effect to any other organ system.

(4) chronic health hazard(s) (hereafter referred to as "chronic hazard")—a health risk to humans, resultant from exposure to a substance that may cause a chronic adverse health effect.

(5) Analytical laboratory—a laboratory having personnel and apparatus capable of performing quantitative or qualitative analyses of art materials, which may yield information that is used by a toxicologist for evaluation of potentially hazardous materials.

(6) Label—a display of written, printed, or graphic matter upon the immediate container of any art material product. When the product is unpackaged, or is not packaged in an immediate container intended or suitable for delivery to users, the label can be a display of such matter directly upon the article involved or upon a tag or other suitable labeling device attached to the art material.

(7) Producer—the person or entity who manufactures, processes, or imports an art material.

(8) Repackager—the person or entity who obtains materials from producers and without making changes in such materials puts them in containers intended for sale as art materials to users.

(9) Sensitizer—a substance known to cause, through an allergic process, a chronic adverse health effect which becomes evident in a significant number of people on re-exposure to the same substance.

(10) Toxic—applies to any substance that is likely to produce personal injury or illness to humans through ingestion, inhalation, or skin contact.

(11) Toxicologist—an individual who through education, training, and experience has expertise in the field of toxicology, as it relates to human exposure, and is either a toxicologist or physician certified by a nationally recognized certification board.

(12) Bioavailability—the extent that a substance can be absorbed in a biologically active form.

(C) Requirements. (1) The producer or repackager of art materials shall submit art material product formula-

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tion(s) or reformulation(s) to a toxicologist for review, such review to be in accordance with paragraph (b)(8)(1)(D) of this section. The toxicologist shall be required to keep product formulation(s) confidential.

(2) Unless otherwise agreed in writing by the producer or repackager, no one other than the toxicologists shall have access to the formulation(s); except that the toxicologists shall furnish a patient's physician, on a confidential basis, the information necessary to diagnose or treat cases of exposure or accidental ingestion.

(3) The producer or repackager, upon advice given by a toxicologist in accordance with paragraph (b)(8)(i)(D) of this section and based upon generally accepted, well-established evidence that a component substance(s) is known to cause chronic adverse health effects adopt precautionary labeling in accordance with paragraph (b)(8)(i)(E) of this section.

(4) Labeling shall conform to any labeling practices prescribed by federal and state statutes or regulations and shall not diminish the effect of required acute toxicity warnings.

(5) The producer or repackager shall supply a poison exposure management information source the generic formulation information required for dissemination to poison control centers or shall provide a 24-hour cost-free telephone number to poison control centers.

(6) The producer or repackager shall have a toxicologist review as necessary, but at least every 5 years, art material product formulation(s) and associated label(s) based upon the then-current, generally accepted, well-established scientific knowledge.

(7) Statement of Conformance—"Conforms to ASTM Practice D-4236," or "Conforms to ASTM D-4236," or "Conforms to the health requirements of ASTM D-4236." This statement may be combined with other conformance statements. The conformance statement should appear whenever practical on the product; however, it shall also be acceptable to place the statement on one or more of the following:

(i) The individual product package,
(ii) a display or sign at the point of purchase,

(iii) separate explanatory literature available on requirements at the point of purchase,

(iv) a response to a formal request for bid or proposal.

(D) Determination of Labeling. (1) An art material is considered to have the potential for producing chronic adverse health effects if any customary or reasonably foreseeable use can result in a chronic hazard.

(2) In making the determination, a toxicologist(s) shall take into account the following:

(i) Current chemical composition of the art material, supplied by an analytical laboratory or by an industrial chemist on behalf of a manufacturer or repackager.

(ii) Current generally accepted, well-established scientific knowledge of the chronic toxic potential of each component and the total formulation.

(iii) Specific physical and chemical form of the art material product, bio-availability, concentration, and the amount of each potentially chronic toxic component found in the formulation.

(iv) Reasonably foreseeable uses of the art material product as determined by consultation with users and other individuals who are experienced in use of the material(s), such as teachers, or by market studies, unless such use information has previously been determined with respect to the specific art material(s) under review.

(v) Potential for known synergism and antagonism of the various components of the formulation.

(vi) Potentially chronic adverse health effects of decomposition or combustion products, if known, from any reasonably foreseeable use of the hazardous art material product.

(vii) Opinions of various regulatory agencies and scientific bodies, including the International Agency for Research on Cancer and the National Cancer Institute, on the potential for chronic adverse health effects of the various components of the formulation.

(3) Based upon the conclusion reached in conformance with review determinations set forth herein, the toxicologist(s) shall recommend precautionary labeling consistent with paragraph (b)(8)(i)(E) of this section.

(E) Labeling Practices—(1) Signal Word. (i) When a signal word for an acute hazard(s) is mandated and a chronic hazard(s) exists, the signal word shall be that for the acute hazard.

(ii) When only a chronic hazard(s) exists, the signal word WARNING shall be used.

(iii) The signal word shall be prominently visible and set in bold capitals in a size equal to or greater than the statement of potential chronic hazards.

(2) List of Potentially Chronic Hazards—Potentially chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be stated substantially in accordance with the statements listed in paragraph (b)(8)(i)(F) of this section. Potentially chronic hazards noted shall be those that are clinically significant and that might be expected with any reasonably foreseeable use of the art material. The hazards should be grouped in the order of relative descending severity.

(3) Name of Chronically Hazardous Component(s)—All components and known decomposition products of the formulation with a potential for chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be listed prominently. Generically equivalent names may be used.

(4) Safe Handling Instructions—Appropriate precautionary statements as to work practices, personal protection, and ventilation requirements shall be used substantially conforming with those listed in paragraph (b)(8)(i)(G) of this section.

(5) List of Sensitizing Components—To protect users from known sensitizers found within art materials, each label shall contain a list of those sensitizers present in sufficient amounts to contribute significantly to a known skin or respiratory sensitization.

(6) Combined Statement—If an art material contains more than one component capable of causing a chronic adverse health effect, or if a single chemical can cause several different chronic adverse health effects, the potential effects may be combined into one statement.

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(7) Information Sources—The precautionary label shall contain a statement identifying a source for additional health information substantially in conformance with one of the phrases listed below:

(i) For more health information—(24 hour cost-free U.S. telephone number),
(ii) Contact a physician for more health information, or

(iii) Call your local poison control center for more health information.

(8) Labeling Content, Product Size—Any art material product in a container larger in size than one fluid ounce (30 ml) (if the product is sold by volume) or one ounce net weight (28 g) (if the product is sold by weight) shall have full precautionary labeling, as described in paragraph (b)(8)(i) (E) of this section. Any art material product in a container equal to or smaller than one fluid ounce or one ounce net weight shall have a label that includes a signal word in conformance with paragraph (b)(8)(i)(E)(I) of this section and a list of potentially harmful or sensitizing components in conformance with paragraphs (b)(8)(i)(E) (3) and (5) of this section.

(9) The information described in paragraph (b)(8)(i)(E) of this section must appear on:

(i) The outside container or wrapper, if any, unless it is easily legible through the outside container or wrapper and

(ii) All accompanying literature where there are directions for use, written or otherwise. Where a product that requires warning labels under paragraphs (b)(8)(i) (D) and (E) of this section is packed within a point-of-sale package that obscures the warning statement(s), the point-of-sale package shall carry the signal word conforming to paragraph (b)(8)(i)(E)(I) and the following wording: “Contains: (list hazardous product(s)) that may be harmful if misused. Read cautions on individual containers carefully. Keep out of the reach of children.”

(10) Statements required under paragraphs (b)(8)(i) (D) and (E) of this section must be in the English language and located prominently in conspicuous and legible type in contrast by topography, layout, or color with other printed matter on the label.

(11) Supplemental Information—Where appropriate, more detailed information that relates to chronic hazard(s), such as physical properties, decomposition products, detailed safety instructions, or disposal recommendations, shall be included in supplemental documents, such as Material Safety Data Sheets, technical brochures, technical data sheets etc.

(F) chronic Hazard Statements
MAY CAUSE STERILITY.

CONTACT MAY CAUSE PERMANENT EYE DAMAGE.

MAY BE HARMFUL BY BREATHING VAPORS/DUSTS.

MAY BE HARMFUL IF SWALLOWED.
MAY BE HARMFUL BY SKIN CONTACT.

MAY PRODUCE BIRTH DEFECTS IN THE DEVELOPING FETUS.

MAY BE EXCRETED IN HUMAN MILK.

MAY CAUSE HARM TO THE NURSING INFANT.

CANCER AGENT! EXPOSURE MAY PRODUCE CANCER.

CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.

POSSIBLE CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.

MAY PRODUCE ALLERGIC REACTION BY INGESTION/INHALATION/ SKIN CONTACT.

MAY PRODUCE NUMBNESS OR WEAKNESS IN THE EXTREMITIES.

EXPOSURE MAY CAUSE (SPECIFY THE ORGAN(S)) DAMAGE.

HEATING/COMBUSTION MAY CAUSE HAZARDOUS DECOMPOSITION PRODUCTS.

(G) Precautionary Statements

Keep out of reach of children.

When using do not eat, drink, or smoke.

Wash hands immediately after use.

Avoid inhalation/ingestion/skin contact.

Avoid fumes from combustion.

Keep container tightly closed when not in use.

Store in well-ventilated area.

Wear protective clothing (specify type).

Wear protective goggles/face shield.

Wear NIOSH-certified mask for dusts/mists/fumes.

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Wear NIOSH-certified respirator with an appropriate cartridge for (specify).

Wear NIOSH-certified supplied-air respirator.

Use window exhaust fan to remove vapors and ensure adequate cross ventilation. (Specify explosion-proof if necessary.)

Do not heat above (specify temperature) without adequate ventilation.

Use (specify type) local exhausting hood.

Do not use/mix with (specify material).

(ii) The following shall apply with respect to the standard for art materials set forth in §1500.14(b)(8)(i).

(A) The term *art material or art material product* shall mean any substance marketed or represented by the producer or repackager as suitable for use in any phase of the creation of any work of visual or graphic art of any medium. The term does not include economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act or drugs, devices, or cosmetics subject to the Federal Food, Drug, and Cosmetics Act.

(B) The standard referred to in paragraph (b)(8)(i) of this section applies to art materials intended for users of any age.

(C) Each producer or repackager of art materials shall describe in writing the criteria used to determine whether an art material has the potential for producing chronic adverse health effects. Each producer or repackager shall submit, to the Commission's Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207, the written description of the criteria described above and a list of art materials that require hazard warning labels under this section. Upon request of the Commission, a producer or repackager shall submit to the Commission product formulations.

(D) All art materials that require chronic hazard labeling pursuant to this section must include on the label the name and United States address of the producer or repackager of the art materials, an appropriate United States telephone number that can be contacted for more information on the hazards requiring warning labels under this section, and a statement that such

art materials are inappropriate for use by children.

(E) If an art material producer or repackager becomes newly aware of any significant information regarding the hazards of an art material or ways to protect against the hazard, this new information must be incorporated into the labels of such art materials that are manufactured after 12 months from the date of discovery. If a producer or repackager reformulates an art material, the new formulation must be evaluated and labeled in accordance with the standard set forth §1500.14(b)(8)(i).

(F) In determining whether an art material has the potential for producing chronic adverse health effects, including carcinogenicity and potential carcinogenicity, the toxicologist to whom the substance is referred under the standard described above shall take into account opinions of various regulatory agencies and scientific bodies, including the U.S. Consumer Product Safety Commission (CPSC), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).

(iii) Pursuant to the LHAMA, the Commission has issued guidelines which, where possible, specify criteria for determining when any customary or reasonably foreseeable use of an art material can result in a chronic hazard. These guidelines include criteria for determining when art materials may produce chronic adverse effects in children and adults, criteria for determining which substances contained in art materials have the potential for producing chronic adverse effects and what those effects are, criteria for determining the bioavailability of chronically hazardous substances contained in art materials when the products are used in a customary or reasonably foreseeable manner, and criteria for determining acceptable daily intake levels for chronically hazardous substances contained in art materials. Because these guidelines apply to hazardous substances in general as well as to hazardous substances in art materials, the guidelines are set forth in §1500.135 and a definition of "chronic toxicity" is provided in §1500.3(c)(2)(ii) as part of supplementation of the term "toxic" in section 2(q) of the FHSA.

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(iv) *Policies and interpretations.*

(A) For purposes of enforcement policy, the Commission will not consider as sufficient grounds for bringing an enforcement action under the Labeling of Hazardous Art Materials Act (“LHAMA”) the failure of the following types of products to meet the requirements of §1500.14(b)(8) (i) through (iii).

(1) Products whose intended general use is not to create art (e.g., common wood pencils, and single colored pens, markers, and chalk), unless the particular product is specifically packaged, promoted, or marketed in a manner that would lead a reasonable person to conclude that it is intended for use as an art material. Factors the Commission would consider in making this determination are how an item is packaged (e.g., packages of multiple colored pencils, chalks, or markers unless promoted for non-art materials uses are likely to be art materials), how it is marketed and promoted (e.g., pencils and pens intended specifically for sketching and drawing are likely to be art materials), and where it is sold (e.g., products sold in an art supply store are likely to be art materials). The products described in this paragraph do not meet the statutory definition of “art material.”

(2) Tools, implements, and furniture used in the creation of a work of art such as brushes, chisels, easels, picture frames, drafting tables and chairs, canvas stretchers, potter’s wheels, hammers, air pumps for air brushes, kilns, and molds.

(3) Surface materials upon which an art material is applied, such as coloring books and canvas, unless, as a result of processing or handling, the consumer is likely to be exposed to a chemical in or on the surface material in a manner which makes that chemical susceptible to being ingested, absorbed, or inhaled.

(4) The following materials whether used as a surface or applied to one, unless, as a result of processing or handling, the consumer is likely to be exposed to a chemical in or on the surface material in a manner which makes that chemical susceptible to being ingested, absorbed, or inhaled: paper, cloth, plastics, films, yarn, threads,

rubber, sand, wood, stone, tile, masonry, and metal.

(B) For purposes of LHAMA enforcement policy, the Commission will enforce against materials including, but not limited to, paints, crayons, colored pencils, glues, adhesives, and putties, if such materials are sold as part of an art, craft, model, or hobby kit. The Commission will enforce the LHAMA requirements against paints or other materials sold separately which are intended to decorate art, craft, model, and hobby items. Adhesives, glues, and putties intended for general repair or construction uses are not subject to LHAMA. However, the Commission will enforce the LHAMA requirements against adhesives, glues, and putties sold separately (not part of a kit) if they are intended for art and craft and model construction uses. This paragraph (b)(8)(iv)(B) applies to products introduced into interstate commerce on or after August 14, 1995.

(C) Commission regulations at §1500.14(b)(8)(i)(C)(7) require that a statement of conformance appear with art materials that have been reviewed in accordance with the Commission standard. The Commission interprets this provision to require a conformance statement regardless of the presence of any chronic hazard warnings.

(D) Nothing in this enforcement statement should be deemed to alter any of the requirements of the Federal Hazardous Substances Act (“FHSA”), such as, but not limited to, the requirement that any hazardous substance intended or packaged in a form suitable for household use must be labeled in accordance with section 2(p) of the FHSA.

APPENDIX A TO §1500.14(b)(8)—GUIDELINES FOR A CERTIFYING ORGANIZATION (NOT MANDATORY)

(a) The term “certifying organization,” as used in this paragraph, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

(b) The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers’ chemists, on its technical and certifying committees.

(c) Representative samples of art materials, labeled as conforming to this section

and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

(d) The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

(e) In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist's decision can be presented to the advisory board of toxicologists for arbitration.

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22934, June 8, 1976; 48 FR 16, Jan. 3, 1983; 53 FR 3018, Feb. 3, 1988; 57 FR 46669, Oct. 9, 1992; 60 FR 8193, Feb. 27, 1995; 61 FR 19829, May 3, 1996; 61 FR 33175, June 26, 1996]

§ 1500.15 Labeling of fire extinguishers.

When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of § 1500.3(c) (1) and (2) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced that meet the definition of highly toxic in § 1500.3(c)(1), the signal word "Danger" and the statement of hazard "Poisonous gases formed when used to extinguish flame or on contact with heat" are required labeling.

(b) When substances are produced that meet the definition of toxic in § 1500.3(c)(2), the signal word "Caution" or "Warning" and the statement of hazard "Dangerous gas formed when used to extinguish flame or on contact with heat" are required labeling.

(c) Regardless of whether paragraph (a) or (b) of this section applies, any substance or mixture of substances labeled for use as a fire extinguisher that, if applied to an electrical fire, would subject the user to the likelihood of electrical shock shall be conspicuously labeled "Caution: Do not use on electrical wires."

(d) The statements specified in paragraphs (a), (b), and (c) of this section shall be in addition to any other that may be required under the act. All such substances or mixtures of substances shall also bear the additional statements "Use in an enclosed place may be fatal" and "Do not enter area until well ventilated and all odor of chemical has disappeared."

§ 1500.17 Banned hazardous substances.

(a) Under the authority of section 2(q)(1)(B) of the act, the Commission declares as banned hazardous substances the following articles because they possess such a degree or nature of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce:

(1) Mixtures that are intended primarily for application to interior masonry walls, floors, etc., as a water repellent treatment and that are "extremely flammable" within the meaning of section 2(1) of the act (repeated in § 1500.3(b)(10)).

(2) Carbon tetrachloride and mixtures containing it (including carbon tetrachloride and mixtures containing it used in fire extinguishers), excluding unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million.

(3) Fireworks devices intended to produce audible effects (including but not limited to cherry bombs, M-80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition; except that this provision shall not apply to such fireworks devices if all of the following conditions are met:

(i) Such fireworks devices are distributed to farmers, ranchers, or growers

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through a wildlife management program administered by the U.S. Department of the Interior (or by equivalent State or local government agencies); and

(ii) Such distribution is in response to a written application describing the wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control are unavailable or inadequate. (See also §1500.14(b)(7); §1500.17(a) (8) and (9); §1500.83(a)(27); §1500.85(a)(2); and part 1507).

(4) Liquid drain cleaners containing 10 percent or more by weight of sodium and/or potassium hydroxide; except that this subparagraph shall not apply to such liquid drain cleaners if packaged in accordance with a standard for special packaging of such articles promulgated under the Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74 (15 U.S.C. 1471-76)).

(5) Products containing soluble cyanide salts, excluding unavoidable manufacturing residues of cyanide salts in other chemicals that under reasonable and foreseeable conditions of use will not result in a concentration of cyanide greater than 25 parts per million.

(6)(i) Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household that:

(A) Is shipped in interstate commerce after December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(B) Is shipped in interstate commerce after December 31, 1972, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(C) [Reserved]

(D) The provisions of paragraph (a)(6)(i) of this section do not apply to artists' paints and related materials.

(ii) Any toy or other article intended for use by children that:

(A) Is shipped in interstate commerce after December 31, 1973, and bears any

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paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(B) Is shipped in interstate commerce after December 31, 1972, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(iii) Since the Commission has issued comprehensive regulations for lead-containing paint and certain consumer products bearing such paint at the 0.06 percent level under the Consumer Product Safety Act (see 16 CFR part 1303), paragraphs (i) and (ii) of §1500.17(a)(6) are revoked as to the subject products manufactured after February 27, 1978.

NOTE: The effective date of paragraphs (a)(6)(i)(A) and (a)(6)(ii)(A) was stayed by an order published in the FEDERAL REGISTER of August 10, 1972 (37 FR 16078).

(7) General-use garments containing asbestos (other than garments having a bona fide application for personal protection against thermal injury and so constructed that the asbestos fibers will not become airborne under reasonably foreseeable conditions of use).

(8) Firecrackers designed to produce audible effects, if the audible effect is produced by a charge of more than 50 milligrams (.772 grains) of pyrotechnic composition (not including firecrackers included as components of a rocket), aerial bombs, and devices that may be confused with candy or other foods, such as "dragon eggs," and "cracker balls" (also known as "ball-type caps"), and including kits and components intended to produce such fireworks except such devices which meet all of the following conditions:

(i) The fireworks devices are distributed to farmers, ranchers, or growers through a wildlife management program administered by the U.S. Department of Interior (or by equivalent State or local governmental agencies); and

(ii) Such distribution is in response to a written application describing the

wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control is unavailable or inadequate. (See also §1500.17(a) (3) and (9)).

(9) All fireworks devices, other than firecrackers, including kits and components intended to produce such fireworks, not otherwise banned under the act, that do not comply with the applicable requirements of part 1507 of this chapter, except fireworks devices which meet all the following conditions:

(i) The fireworks devices are distributed to farmers, ranchers, or growers through a wildlife management program administered by the U.S. Department of the Interior (or by equivalent State or local government agencies); and

(ii) Such distribution is in response to a written application describing the wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control is unavailable or inadequate. (See also §1500.17(a) (3) and (8)).

(10) Self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant manufactured or imported on or after October 7, 1974. (See also §1500.17(a) (3) and (8)).

(11)(i) Reloadable tube aerial shell fireworks devices that use shells larger than 1.75 inches in outer diameter and that are imported on or after October 8, 1991.

(ii) *Findings.* (A) *General.* In order to issue a rule under section 2(q)(1) of the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these findings in the regulation. These findings are discussed below.

(B) *Voluntary standard.* Although a voluntary standard relating to the risk of injury associated with reloadable tube aerial shells has been adopted, it has not been implemented. Thus, the

Commission is not required to make findings covering the likelihood that the voluntary standard would result in elimination or adequate reduction of the risk of injury or that there would be substantial compliance with the voluntary standard.

(C) *Relationship of benefits to costs.* The Commission estimates that the removal of large reloadable shells from the market is likely to virtually eliminate the number of associated injuries, with only a slight offsetting increase in the number of injuries due to the use of substitute Class C fireworks products available to consumers. The estimated net benefits range from essentially zero to close to \$1 million annually. The annual costs of a ban are estimated to be very low. Included are potential costs to foreign manufacturers and U.S. importers from sales losses, production changes, and inventory retrofitting, and slightly reduced market choices for consumers who purchase aerial display fireworks. Costs to each of these sectors are estimated to be slight, and are reduced to the extent that alternative products are perceived as adequate substitutes for large reloadable shells. Thus, the Commission finds that the benefits expected from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered several alternatives to the ban. These included: Design or performance criteria; additional or alternative labeling; inclusion of some reloadable shells 1.75 inches or smaller in the ban; and no action in reliance on the voluntary standard. The Commission determined that a ban of reloadable shells larger than 1.75 inches in outer diameter is the least burdensome alternative that would prevent or adequately reduce the risk of injury.

(1) Regarding design or performance criteria, the Commission considered requirements similar to those stated in the voluntary standard of the American Fireworks Standards Laboratory ("AFSL"). However, such criteria may increase the cost of the product and would not address all factors involved in the incidents. Further, concerns exist about the feasibility of criteria and quality control.

(2) Regarding additional or alternative labeling, the users' perception and experience concerning the amount of time available to get away may lead them to disregard an inconsistent warning. There are no data to suggest that a significant number, if any, incidents would be avoided if large reloadable shells carried more detailed labels or instructions than they currently do. It cannot be concluded that potential benefits would be greater than zero.

(3) The Commission considered including reloadable shells that are 1.75 inches or less in outer diameter and have the "equivalent explosive power" of larger shells. A kinetic energy level of 70 joules was considered to evaluate explosive power. However, any potential benefits are uncertain since the Commission concluded that a clear relation between kinetic energy and injury potential could not be established. Also, costs could be slightly higher.

(4) The Commission also considered imposing no mandatory requirements on large reloadable shells and relying instead on the AFSL voluntary standard. However, it is uncertain whether any net benefits to consumers would result from this alternative, since the level of injury reduction could be near zero if, as is probable, some firms chose not to conform with some or all of the AFSL standard.

(12)(i) *Large multiple-tube devices.* Multiple-tube mine and shell fireworks devices that first enter commerce or are imported on or after March 26, 1997, that have any tube measuring 1.5 inches (3.8 cm) or more in inner diameter, and that have a minimum tip angle less than 60 degrees when tested in accordance with the procedure of § 1507.12 of this part.

(ii) *Findings—(A) General.* In order to issue a rule under the section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these in the regulation. These findings are discussed in paragraphs (a)(12)(ii) (B) through (D) of this section.

(B) *Voluntary standard.* (1) One alternative to the tip-angle requirement that the Commission considered is to

take no mandatory action, and to depend on a voluntary standard. The American Fireworks Safety Laboratory (AFSL) has a standard for mines and shells intended to address the potential tip-over hazard associated with multiple-tube fireworks devices. AFSL's Voluntary Standard for Mines and Shells—Single or Multiple Shot requires that large multiple-tube devices not tip over (except as the result of the last shot) when shot on a 2-inch thick medium-density foam pad. The Commission cannot conclude that AFSL's existing voluntary standard adequately reduces the risk of injury from large devices that tip over while functioning. The Commission's tests using polyurethane foam did not find sufficient agreement between performance on foam and on grass. No other data are available to show that this dynamic test is reliable.

(2) In addition, even if the AFSL standard is effective, the Commission does not believe that compliance with the standard will be adequate. AFSL reports that it has been testing in accordance with its standard since January 1994. However, the results of CPSC's compliance testing indicate that multiple-tube devices still tip over while functioning. In fiscal year 1994, all 24 imported devices the Commission tested, and 1 of 8 domestic devices, tipped over while functioning. In fiscal year 1995, 22 of 27 imported devices and 1 of 5 domestic devices tipped over during Commission testing. The Commission finds that there is unlikely to be substantial compliance with the voluntary standard applicable to multiple-tube devices.

(C) *Relationship of benefits to costs.* The Commission estimates that the 60-degree tip-angle standard will eliminate the unreasonable tip-over risk posed by these devices. This will provide benefits of saving one life about every 3 years, and preventing an unknown number of nonfatal injuries. The annual cost of modifying affected devices is estimated to be between \$1.5 million and \$2.7 million. The Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following

alternatives: a ban of all multiple-tube devices with inner tube diameters 1.5 inches or greater; a dynamic performance standard; additional labeling requirements; and relying on the voluntary standard. Although a ban of all large multiple-tube devices would address the risk of injury, it would be more burdensome than the tip-angle standard. The Commission was unable to develop a satisfactory dynamic standard that would reduce the risk of injury. Neither additional labeling requirements nor reliance on the voluntary standard would adequately reduce the risk of injury. Thus, the Commission finds that a standard requiring large multiple-tube devices to have a minimum tip angle greater than 60 degrees is the least burdensome requirement that would prevent or adequately reduce the risk of injury.

(13)(i) *Candles made with metal-cored wicks.* Candles manufactured or imported on or after October 15, 2003, made with metal-cored candlewicks, unless:

(A) The metal core of each candlewick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candles subject to paragraph (a)(13)(i)(A) of this section are shipped, including each outer container or wrapper in which such candles are distributed to a retail outlet, is labeled “Conforms to 16 CFR 1500.17(a)(13).” For purposes of this paragraph (B), the term “outer container or wrapper” does not include the immediate container in which candle(s) is/are intended to be displayed at retail or during use in the home, unless that container or wrapper is also the only container or wrapper in which the candle(s) is/are shipped to a retailer.

(ii) *Metal-cored candlewicks.* Metal-cored candlewicks manufactured or imported on or after October 15, 2003, unless:

(A) The metal core of each candlewick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candlewicks subject to para-

graph (a)(13)(ii)(A) of this section is shipped, including each outer container or wrapper of a shipment distributed to a retail outlet, is labeled “Conforms to 16 CFR 1500.17(a)(13).” For purposes of this paragraph (B), the term “outer container or wrapper” does not include the immediate container in which candlewick(s) is/are intended to be displayed or sold at retail, unless that container or wrapper is also the only container or wrapper in which the candlewick(s) is/are shipped to a retailer.

(iii) *Findings—(A) General.* To issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include them in the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary Standard.* One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candlewicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore, there is no evidence that the standard has been adopted and implemented by candlewick or candle manufacturers.

(C) *Relationship of Benefits to Costs.* The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no “safe” level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of \$100,000 to \$300,000. On a percentage basis these costs represent only 0.005 to 0.015 percent of the overall value of candle shipments in 2000, which was approximately \$2 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: no action; labeling all

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metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; recordkeeping for shipments of wicks containing 0.06 percent or less lead by weight of the metal and of candles with such wicks; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Recordkeeping for shipments of wicks and of candles was not the least burdensome requirement that would prevent or adequately reduce the risk of illness. Therefore the Commission finds that a ban on candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

(b) [Reserved]

(Secs. 2(f)(1), (A), (B), (g), (q)(1)(B), 3(a), 74 Stat. 372, 374, as amended 80 Stat. 1304-05, 83 Stat. 187-189, 90 Stat. 503 (15 U.S.C. 1261, 1262); sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 371 (e), (f), (g)), sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 27514, Oct. 4, 1973; 38 FR 31520, Nov. 15, 1973; 39 FR 30114, Aug. 21, 1974; 39 FR 42903, Dec. 9, 1974; 41 FR 22935, June 8, 1976; 42 FR 44202, Sept. 1, 1977; 43 FR 12310, Mar. 24, 1978; 48 FR 16, Jan. 3, 1983; 56 FR 37837, Aug. 9, 1991; 61 FR 13095, Mar. 26, 1996; 61 FR 18245, Apr. 25, 1996; 68 FR 19147, Apr. 18, 2003]

§ 1500.18 Banned toys and other banned articles intended for use by children.

(a) *Toys and other articles presenting mechanical hazards.* Under the authority of sections 2(f)(1)(D) and 24 of the act and pursuant to the provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

(1) Any toy rattle containing, either internally or externally, rigid wires, sharp protrusions, or loose small objects that have the potential for caus-

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ing lacerations, puncture wound injury, aspiration, ingestion, or other injury. (But see § 1500.86(a)(1)).

(2) Any toy having noisemaking components or attachments capable of being dislodged by the operating features of the toy or capable of being deliberately removed by a child, which toy has the potential for causing laceration, puncture wound injury, aspiration, ingestion, or other injury.

(3) Any doll, stuffed animal, or other similar toy having internal or external components that have the potential for causing laceration, puncture wound injury, or other similar injury. (But see § 1500.86(a)(2)); (See also §§ 1500.48 and 1500.49).

(4) Lawn darts and other similar sharp-pointed toys usually intended for outdoor use and having the potential for causing puncture wound injury.

(5) [Reserved]

(6) Any article known as a “baby-bouncer” or “walker-jumper” and any other similar article (referred to in this paragraph as “article(s)”), except an infant walker subject to part 1216, which is intended to support very young children while sitting, bouncing, jumping, and/or reclining, and which because of its design has any exposed parts capable of causing amputation, crushing, lacerations, fractures, hematomas, bruises, or other injuries to fingers, toes, or other parts of the anatomy of young children. Included among, but not limited to, the design features of such articles which classify the articles as banned hazardous substances are:

(i) The areas about the point on each side of the article where the frame components are joined together to form an “X” shape capable of producing a scissoring, shearing, or pinching effect.

(ii) Other areas where two or more parts are joined in such a manner as to permit a rotational movement capable of exerting a scissoring, shearing, or pinching effect.

(iii) Exposed coil springs which may expand sufficiently to allow an infant’s finger, toe, or any other part of the anatomy to be inserted, in whole or in

part, and injured by being caught between the coils of the spring or between the spring and another part of the article.

(iv) Holes in plates or tubes which provide the possibility of insertion, in whole or in part, of a finger, toe, or any part of the anatomy that could then be injured by the movement of another part of the article.

(v) Design and construction that permits accidental collapse while in use. (But see §1500.86(a)(4).)

(7) Toys usually known as clacker balls and consisting of two balls of plastic or another material connected by a length of line or cord or similar connector (referred to as "cord" in §1500.86(a)(5)), intended to be operated in a rhythmic manner by an upward and downward motion of the hand so that the two balls will meet forcefully at the top and bottom of two semicircles thus causing a "clacking" sound, which toys present a mechanical hazard because their design or manufacture presents an unreasonable risk of personal injury from fracture, fragmentations, or disassembly of the toy and from propulsion of the toy or its part(s). (But see §1500.86(a)(5).) This does not include products that are constructed so that the connecting members consist of plastic rods integrally molded to the balls and are mounted on a pivot so that movement of the balls is essentially limited to a single plane.

(8) Any pacifier that does not meet the requirements of 16 CFR part 1511 and that is introduced into interstate commerce after February 26, 1978.

(9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. For purposes of this regulation, introduction into interstate commerce is defined as follows: A toy or children's article manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy or children's article manufactured in the United States is introduced into interstate commerce (1) at the time of its first interstate sale, or (2) at the

time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier. Part 1501 defines the term "toy or other article intended for use by children under 3," as used in this regulation, and exempts certain products from banning under this regulation.

(10)-(11) [Reserved]

(12) Any bicycle as defined in §1512.2(a) of this chapter (except a bicycle that is a "track bicycle" or a "one-of-a-kind bicycle" as defined in §1512.2(d) and (e) of this chapter) that is introduced into interstate commerce on or after May 11, 1976, and that does not comply with the requirements of part 1512 of this chapter, except for §§1512.5(c)(3), 1512.9(a), 1512.18(e) and 1512.18(f) which become effective November 13, 1976.

(15) Any rattle (as defined in §1510.2 of this chapter) that is introduced into interstate commerce on or after August 21, 1978, and that does not comply with the requirements of part 1510 of this chapter. For purposes of the regulation, introduction into interstate commerce is defined as follows: A rattle manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A rattle manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate.

(16) (i) Any article known as an "infant cushion" or "infant pillow," and any other similar article, which has all of the following characteristics (But see §1500.86(a)(9)):

(A) Has a flexible fabric covering. The term *fabric* includes those materials covered by the definition of "fabric" in section 2(f) of the Flammable Fabrics Act, 15 U.S.C. 1191(f).

(B) Is loosely filled with a granular material, including but not limited to, polystyrene beads or pellets.

(C) Is easily flattened.

(D) Is capable of conforming to the body or face of an infant.

(E) Is intended or promoted for use by children under one year of age.

(ii) *Findings*—(A) *General*. In order to issue a rule under section 2(q)(1) of the Federal Hazardous Substance Act (FHSA), 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these findings in the regulation. These findings are discussed in paragraphs (a)(16)(ii) (B) through (D) of this section.

(B) *Voluntary standard*. No findings concerning compliance with or adequacy of a voluntary standard are necessary since no voluntary standard addressing infant cushions has been adopted or implemented.

(C) *Relationship of benefits to costs*. The Commission estimates that the removal of infant cushions from the market will result in total annual benefits of approximately five million dollars. The potential costs to businesses are expected to be offset by production of other products, and the potential costs to consumers are likely to be offset by the availability of substitutes for a comparable price.

(D) *Least burdensome requirement*. The Commission considered labeling and a design or performance standard as alternatives to the ban. The Commission does not believe that any form of labeling would have a significant effect in preventing the hazard associated with infant cushions. The Commission also concluded that no feasible standard exists that would address the hazard. Thus, the Commission determined that a ban of infant cushions is the least burdensome alternative that would prevent or adequately reduce the risk of injury.

(17) Any ball intended for children under three years of age that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this paragraph, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

(i) For the purposes of this paragraph, the term “ball” includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or

bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(ii) The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.52, the ball is not removed from the outer container.

(iii) In determining whether such a ball is intended for use by children under three years of age, the criteria specified in 16 CFR 1501.2(b) and the enforcement procedure established by 16 CFR 1501.5 shall apply.

(18)(i) Any bunk bed (as defined in §1513.2(c) of this chapter) that does not comply with the requirements of part 1513 of this chapter.

(ii) *Findings*. In order to issue a rule under Section 3(e) of the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1262(e), classifying a toy or other article intended for use by children as a hazardous substance on the basis that it presents a mechanical hazard (as defined in Section 2(s) of the FHSA), the FHSA requires the Commission to make the following findings and to include these findings in the regulation: Bunk beds present a mechanical hazard; Where a voluntary standard has been adopted and implemented by the affected industry, that compliance with such voluntary standard is not likely to result in the elimination or adequate reduction of the risk of injury, or it is unlikely that there will be substantial compliance with such voluntary standard; The benefits expected from the rule bear a reasonable relationship to its costs; and The rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury for which the rule is being promulgated.

These findings are made in the appendix to Part 1513.

(19)(i) Dive sticks, and other similar articles, that are used in swimming pools or other water environments for such activities as underwater retrieval games or swimming instruction, and which, when placed in the water, submerge and rest at the bottom of the pool. This includes products that are pre-weighted to sink to the bottom and products that are designed to allow the user to adjust the weight. Dive sticks and similar articles that come to rest underwater at an angle greater than 45 degrees from vertical when measured under the test at §1500.86(a)(7) and dive sticks and similar articles that maintain a compressive force of less than 5-lbf under the test at §1500.86(a)(8) are exempt from this banning rule. Articles that have a continuous circular shape, such as dive rings and dive disks are also exempt.

(ii)(A) *Findings.* In order for the Commission to issue a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). These findings are discussed in paragraphs (a)(18)(ii)(B) through (D) of this section.

(B) *Voluntary standard.* No findings concerning compliance with and adequacy of a voluntary standard are necessary because no relevant voluntary standard addressing the risk of injury posed by dive sticks has been adopted and implemented.

(C) *Relationship of benefits to costs.* The Commission estimates the potential benefits of removing hazardous dive sticks from the market to be 2 to 4 cents per dive stick. With the availability of substitutes and the expected low cost of modifying dive sticks to conform to the rule, the Commission anticipates that necessary changes will be minimal. The Commission estimates that the costs of the rule will be no more than 2 to 4 cents per dive stick. Thus, the Commission finds that there is a reasonable relationship between the expected benefits of the rule and its costs.

(D) *Least burdensome requirement.* The Commission considered pursuing vol-

untary recalls, following a voluntary standard, requiring labeling or changing the scope of the rule. A banning rule would be more effective than case-by-case recalls because the impalement hazard affects all dive sticks, not a specific brand or model. Awaiting recalls would allow these hazardous items on the market until the Commission obtained recalls. No applicable voluntary standard exists, and compliance may be low if one did. Although labeling could help reduce the risk of injuries from dive sticks, it would be less effective than a banning rule. It may be difficult for a label to convey the necessary information at the time of use. Modifying the scope so that the rule would only apply to pre-weighted dive sticks would continue to permit hazardous items because the unweighted dive sticks can easily be weighted to stand vertically at the bottom of the water. Thus, the Commission finds that a ban of dive sticks with the hazardous characteristics it has identified is the least burdensome alternative that would adequately reduce the risk of injury.

(b) *Electrically operated toys and other electrical operated children's articles presenting electrical, thermal, and/or certain mechanical hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of electrically operated toys or other electrically operated articles intended for use by children present electrical, thermal, and/or certain mechanical hazards within the meaning of section 2 (r), (s), and/or (t) of the act because in normal use or when subjected to reasonably foreseeable damage or abuse, the design or manufacture may cause personal injury or illness by electric shock and/or presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces, or because of certain mechanical hazards.

(1) Any electrically operated toy or other electrically operated article intended for use by children (as defined in §1505.1(a)(1)) that is introduced into interstate commerce and which does not comply with the requirements of part 1505 of this chapter.

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NOTE: Paragraph (b)(1) was originally promulgated as 21 CFR 191.9a(b)(1) with an effective date of September 3, 1973 (38 FR 6138).

(2) [Reserved]

(c) *Toys and other articles (not electrically operated) presenting electric hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children (not electrically operated) present an electrical hazard within the meaning of section 2(r) of the act.

(1) Any kite 10 inches or greater in any dimension constructed of aluminized polyester film or any kite having a tail or other component consisting of a piece of aluminized polyester film 10 inches or greater in any dimension presents an electrical hazard and is a banned hazardous substance because its design (specifically its size and electrical conductivity) presents a risk of personal injury from electric shock due to its ability to conduct electricity and to become entangled in or otherwise contact high voltage electric power lines.

(2) [Reserved]

(15 U.S.C. 1261 (f)(1)(D), (g)(1)(A), (r); 15 U.S.C. 1262(e)(1); 15 U.S.C. 2079(a))

[38 FR 27012, Sept. 27, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1500.18, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 1500.19 Misbranded toys and other articles intended for use by children.

(a) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes any multi-sided object formed by connecting planes into a generally, spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a

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ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission’s test template shall be no greater than 1.75 inches (44.4 mm.).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children’s toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children’s games, generally as a playing piece or marker. The term “marble” does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Package* or packaging refers to the immediate package in which a product subject to labeling under section 24 of the act is sold, as well as to any outer container or wrapping for that package.

(7) *Descriptive material* means any discrete piece of written material separate from the label of the package that

contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product. A catalog or other marketing material or advertisement that depicts other products in addition to the product it accompanies is not "descriptive material" unless it contains additional information, such as instructions for use of the product it accompanies or lists of accessories exclusively for use with that product, that are designed to focus the purchaser's attention on the product. Descriptive material "accompanies" a product subject to the labeling requirements when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. "Descriptive material" does not include statements that appear on the package of a product subject to the labeling requirements. "Descriptive material" does not include material intended solely for use by children if the package it accompanies contains a separate package insert prominently identified as a warning for parents that contains the required precautionary statements.

(8) *Bin and container for retail display* mean containers in which multiple unpackaged and unlabeled items are held for direct selection by and sale to consumers.

(b) *Misbranded toys and children's articles.* Pursuant to sections 2(p) and 24 of the FHSA, the following articles are misbranded hazardous substances if their packaging, any descriptive material that accompanies them, and, if unpackaged and unlabeled, any bin in which they are held for sale, any container in which they are held for retail display, or any vending machine from which they are dispensed, fails to bear the labeling statements required in paragraphs (b) (1) through (4) and paragraph (f)(3) of this section, or if such labeling statements fail to comply with the prominence and conspicuousness requirements of paragraph (d) of this section.

(1) With the exception of books and other articles made of paper, writing materials such as crayons, chalk, pencils, and pens, modeling clay and similar products, fingerpaints, watercolors, and other paint sets, and any other article identified in 16 CFR 1501.3 (other than balloons), any article that is a toy or game intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:



WARNING:

**CHOKING HAZARD--Small parts
Not for children under 3 yrs.**

(2) Any latex balloon, or toy or game that contains a latex balloon, shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--Children under 8 yrs. can choke or suffocate on uninflated or broken balloons. Adult supervision required.

Keep uninflated balloons from children.
Discard broken balloons at once.

(3)(i) Any small ball intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--This toy is a small ball.
Not for children under 3 yrs.

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--Toy contains a small ball.
Not for children under 3 yrs.

(4)(i) Any marble intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--This toy is a marble.
Not for children under 3 yrs.

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age

that contains a marble shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.**

(c) *Age of intended user.* In determining the ages of the children for which any toy or article subject to this section is intended, the following factors are relevant: the manufacturer's stated intent (such as the age stated on a label) if it is reasonable; the advertising, marketing, and promotion of the article; and whether the article is commonly recognized as being intended for children in this age group. In enforcing this provision, the Commission will follow the procedures set forth in 16 CFR 1501.5.

(d) *Prominence and conspicuousness of labeling statements.* The requirements of 16 CFR 1500.121 relating to the prominence and conspicuousness of precautionary labeling statements for hazardous substances shall apply to any labeling statement required under §1500.19(b) and (f), with the following clarifications and modifications.

(1) All labeling statements required by §1500.19(b) and (f) shall be in the English language. The statements required by paragraph (b) need not appear in the format and layout depicted in paragraph (b). The statements required by 16 CFR 1500.19(b) and (f) shall be blocked together within a square or rectangular area, with or without a border. This means that the statements must appear on at least two lines. The statements shall be separated from all other graphic material by a space no smaller than the minimum allowable height of the type size for other cautionary material (e.g., the phrase "Not for children under 3 yrs.>"). If not separated by that distance, the labeling statements must be surrounded by a border line. Label design,

the use of vignettes, or the proximity of other labeling or lettering shall not obscure or render inconspicuous any labeling statement required under §1500.19(b) and (f). This means that such statements shall appear on a solid background, which need not differ from the background color or any other color on the package label.

(2) The words "WARNING" or "SAFETY WARNING" required by section 24 of the FHSA shall be regarded as signal words.

(3) The statement "CHOKING HAZARD" shall be regarded as a statement of the principal hazard associated with the products subject to this section.

(4) All other remaining statements required by this section shall be regarded as "other cautionary material" as that term is defined in 16 CFR 1500.121(a)(2)(viii).

(5) The principal display panel for a bin, container for retail display, or vending machine shall be the side or surface designed to be most prominently displayed, shown, or presented to, or examined by, prospective purchasers. In the case of bins or containers for retail display, the cautionary material may be placed on a display card of a reasonable size in relationship to the surface area of the bin or container. The area of the display card shall constitute the area of the principal display panel. In the case of vending machines that contain a display card, the cautionary label may be placed either on the display card, on the coinage indicator decal, or on the glass or clear plastic of the machine. If there is no display card inside a vending machine, the size of the principal

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display panel will be calculated in accordance with 16 CFR 1500.121(c) based on the size of the front of the container from which items are dispensed, exclusive of the area of metal attachments, coin inserts, bases, etc. Any other side or surface of such a bin, container for retail sale, or vending machine that bears information, such as price or product description, for examination by purchasers shall be deemed to be a principal display panel, excluding any side or surface with information that only identifies the company that owns or operates a vending machine.

(6) All of the labeling statements required by this section, including those

Area sq. in	0–2	+2–5	+5–10	+10–15	+15–30	+30–100	+100–400	+400
Type Size								
Sig. Wd	3/64"	1/16"	3/32"	7/64"	1/8"	5/32"	1/4"	1/2"
St. Haz	3/64"	3/64"	1/16"	3/32"	3/32"	7/64"	5/32"	1/4"
Oth. Mat	1/32"	3/64"	1/16"	1/16"	5/64"	3/32"	7/64"	5/32"

(8) Labeling required by this section that appears on a bin, container for retail display, or vending machine shall be in reasonable proximity to any pricing or product information contained on the principal display panel, or, if such information is not present, in close proximity to the article that is subject to the labeling requirements.

(9) Descriptive material that accompanies a product subject to the labeling requirements, including accompanying material subject to the alternative allowed by §1500.19(f), shall comply with the requirements of 16 CFR 1500.121(c)(6) relating to literature containing instructions for use which accompanies a hazardous substance. If the descriptive material contains instructions for use, the required precautionary labeling shall be in reasonable proximity to such instructions or directions and shall be placed together within the same general area (see 16 CFR 1500.121(c)(6)).

(10) In the case of any alternative labeling statement permitted under §1500.19(e), the requirements of 16 CFR 1500.121(b)(3) and 1500.121(c)(2)(iii) shall apply to statements or indicators on the principal display panel directing attention to the complete cautionary labeling that appears on another display panel.

classified as “other cautionary material,” must appear on the principal display panel of the product, except as provided for by §1500.19(f). Any signal word shall appear on the same line and in close proximity to the triangle required by section 24 of the act. Multiple messages should be provided with sufficient space between them, when feasible, to prevent them from visually blending together.

(7) All labeling statements required by this section shall comply with the following type size requirements. 16 CFR 1500.121(c)(1) explains how to compute the area of the principal display panel and letter height.

(11) Any triangle required by this section shall be an equilateral triangle. The height of such a triangle shall be equal to or exceed the height of the letters of the signal word “WARNING”. The height of the exclamation point inside the triangle shall be at least half the height of the triangle, and the exclamation point shall be centered vertically in the triangle. The triangle shall be separated from the signal word by a distance at least equal to the space occupied by the first letter of the signal word. In all other respects, triangles with exclamation points shall conform generally to the provisions of 16 CFR 1500.121 relating to signal words.

(e) *Combination of labeling statements.* The labels of products that contain more than one item subject to the requirements of this section may combine information relating to each of the respective hazards, if the resulting condensed statement contains all of the information necessary to describe the hazard presented by each article. However, in the case of a product that contains a balloon and another item subject to the labeling requirements, only the signal word and statement of hazard may be combined.

(f) *Alternative labeling statements for small packages.* Any cautionary statement required by section 1500.19(b) may

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be displayed on a display panel of the package of a product subject to the labeling requirement other than the principal display panel only if:

(1) The package has a principal display panel of 15 square inches or less,

(2) The full labeling statement required by paragraph (b) of this section is displayed in three or more languages

on another display panel of the package of the product, and

(3)(i) In the case of a toy or game subject to §1500.19(b)(1), a small ball subject to §1500.19(b)(3), a marble subject to §1500.19(b)(4), or a toy or game containing such a ball or marble, the principal display panel of the package bears the statement:



SAFETY WARNING

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears, or

(ii) In the case of a balloon subject to §1500.19(b)(2) or a toy or game containing such a balloon, the principal display panel bears the statement:



WARNING--CHOKING HAZARD

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears.

(g) *Alternative for products manufactured outside the United States.* In the case of a product subject to the labeling requirements of §1500.19(b) which is manufactured outside the United States and is shipped directly from the manufacturer to the consumer by United States mail or other delivery service in an immediate package that contains descriptive material, the descriptive material inside the immediate package of the product need not bear the required labeling statement only if the shipping container of the product contains other accompanying material that bears the required statements displayed in a prominent and conspicuous manner. Products shipped from abroad to a U.S. affiliate for shipment to consumers are included within the scope of this exception.

(h) *Preemption.* Section 101(e) of the Child Safety Protection Act of 1994 pro-

hibits any state or political subdivision of a state from enacting or enforcing any requirement relating to cautionary labeling addressing small parts hazards or choking hazards associated with any toy, game, marble, small ball, or balloon intended or suitable for use by children unless the state or local requirement is identical to a requirement established by section 24 of the FHSA or by 16 CFR 1500.19. Section 101(e) allows a state or political subdivision of a state to enforce a non-identical requirement relating to cautionary labeling warning of small parts hazards or choking hazards associated with any toy subject to the provisions of section 24 of FHSA until January 1, 1995, if the non-identical requirement was in effect on October 2, 1993.

[60 FR 10752, Feb. 27, 1995, as amended at 60 FR 41802, Aug. 14, 1995]

§ 1500.20 Labeling requirement for advertising toys and games.

(a) *Scope.* This section applies to catalogue and other printed material

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advertisements which provide a direct means of purchase or order of products requiring cautionary labeling under sections 24(a) and (b) of the FHSA.

(b) *Effective Date.* Under the Consumer Product Safety Improvement Act of 2008, Public Law 110–314, 122 Stat. 3016 (August 14, 2008), (“CPSIA”), the effective date of the CPSIA’s amendment to Section 24 of the FHSA to require cautionary statements in catalogues and other printed materials is February 10, 2009. By this rule, the Commission is providing a grace period of 180 days, or until August 9, 2009, during which catalogues and other printed materials printed prior to February 10, 2009, may be distributed without such cautionary statements. Catalogues and other printed materials that are printed on or after February 10, 2009, must have the required cautionary statements. All catalogues and other printed materials distributed on or after August 9, 2009, must comply with this rule. This rule addresses only catalogues and other printed materials; however, the CPSIA extends the requirements for cautionary statements to Internet advertisements as well. Internet advertisements must comply with Section 24 of the FHSA as amended by the CPSIA no later than December 12, 2008.

(c) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes a multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar other containers. A ball is permanently enclosed if, when tested in ac-

cordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm) in a rigid template $\frac{1}{4}$ inches (6 mm) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission’s test template shall be no greater than 1.75 inches (44.4 mm).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children’s toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of hard material, such as glass, agate, marble, or plastic, that is used in various children’s games, generally as a playing piece or marker. The term “marble” does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Direct means of purchase or order* means any method of purchase that allows the purchaser to order the product without being in the physical presence of the product. Advertising that provides a direct means of purchase or order of a product would include catalogues or other printed advertising material that contain order blanks, telephone numbers or fax numbers for placing orders, and Internet Web sites that enable consumers to purchase a product online or through the use of a telephone number or fax number provided on the Internet Web site.

(d) *Advertising requirements.* Any toy or game that requires a cautionary statement about the choking hazard associated with small parts, balloons, small balls, or marbles must bear that

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cautionary statement in the product's advertising if the advertising provides a direct means to purchase or order the product.

(1) The advertising for any article that is a toy or game intended for use

by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:

FIGURE 1



WARNING:

**CHOKING HAZARD--Small parts
Not for children under 3 yrs.**

(2) The advertising for any latex balloon, or toy or game that contains a

latex balloon, shall bear the following cautionary statement:

FIGURE 2



WARNING:

**CHOKING HAZARD--Children under 8 yrs. can
choke or suffocate on uninflated or broken balloons.
Adult supervision required.**

**Keep uninflated balloons from children.
Discard broken balloons at once.**

(3)(i) The advertising for any small ball intended for children three years

of age or older shall bear the following cautionary statement:

FIGURE 3



WARNING:

**CHOKING HAZARD--This toy is a small ball.
Not for children under 3 yrs.**

(ii) The advertising for any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:

FIGURE 4



WARNING:

**CHOKING HAZARD--Toy contains a small ball.
Not for children under 3 yrs.**

(4)(i) The advertising for any marble or older shall bear the following cautionary statement:

FIGURE 5



WARNING:

**CHOKING HAZARD--This toy is a marble.
Not for children under 3 yrs.**

(ii) The advertising for any toy or game intended for children who are at least three years old but less than eight years of age that contains a marble shall bear the following cautionary statement:

FIGURE 6



WARNING:

**CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.**

(e) *Abbreviated warnings for catalogues and other printed materials.* Abbreviated versions of the required cautionary statements are permitted in each individual product advertisement, provided that the corresponding full cautionary statements appear in the catalogue and a statement referring to the precise location of the full cautionary statements—such as the page number on which the cautionary statements can be found—is located at the bottom of each catalogue page that contains one or more abbreviated cautionary statements. If abbreviated cautionary statements are used:

(1) The full cautionary statements associated with the abbreviated cautionary statements shall appear:

(i) Near the beginning of the catalogue, before any catalogue pages that contain advertisements of products available for purchase, or

(ii) Adjacent to the ordering information or order form in the catalogue.

(2) The full cautionary statements shall be in conspicuous and legible type in contrast by typography, layout or color.

(3) The full cautionary statements shall be clearly numbered according to the following scheme:

Required cautionary statement	Number
16 CFR 1500.19(b)(1) ¹	1
16 CFR 1500.19(b)(2) ²	2
16 CFR 1500.19(b)(3)(i) ³	3
16 CFR 1500.19(b)(3)(ii) ⁴	4
16 CFR 1500.19(b)(4)(i) ⁵	5
16 CFR 1500.19(b)(4)(ii) ⁶	6

¹ See figure 1.

² See Figure 2.

³ See Figure 3.

⁴ See Figure 4.

⁵ See Figure 5.

⁶ See Figure 6.

(4) The abbreviated cautionary statements shall consist of items 1500.20(e)(3)(i) through 1500.20(e)(3)(iv):

(i) A safety alert symbol substantially similar to that shown in figure 7.

FIGURE 7



(ii) The phrase, “CHOKING HAZARD,” written in capital letters.

(iii) Numbers, separated by commas and enclosed within a single set of parentheses, that identify the applicable cautionary statements for the product

being advertised, followed by a period. These numbers shall match the numbers used to identify each full cautionary statement, as specified in 1500.20(e)(2).

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(iv) A single prohibited age range written as either “Not for under 3 yrs” or “Not for under 8 yrs,” based on the most restrictive age range for all required cautionary statements for that product. Thus, if an advertised product requires the cautionary statement specified in 16 CFR 1500.19(b)(2), the prohibited age range in the abbreviated

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cautionary statement shall be “Not for under 8 yrs.”

(v) For example, see Figure 8 for the abbreviated cautionary statement for an advertisement of a product that requires the cautionary statements specified in 16 CFR 1500.19(b)(1) and 16 CFR 1500.19(b)(2).

FIGURE 8

▲ CHOKING HAZARD (1,2). Not for under 8 yrs.

(f) *Alternatives to cautionary statements for individual product advertisements in catalogues and other printed materials.* Multiple identical full or abbreviated cautionary statements may be replaced with a single full cautionary statement under the following circumstances:

(1) If all products available for purchase within a catalogue require the same cautionary statement, that cautionary statement, in full, may appear on the front cover, or equally conspicuous location, of the catalogue in lieu of repeating the cautionary statement within the catalogue, provided that it is communicated to consumers that the cautionary statement applies to all products in the catalogue.

(2) If all products on one catalogue page or on two facing catalogue pages require the same cautionary statement, that cautionary statement, in full, may appear at the top of the page or pages in lieu of repeating the cautionary statement in each product advertisement, provided that it is communicated to consumers that the cautionary statement applies to all products on the catalogue page or pages.

(g) *Prominence and conspicuousness of labeling statements.* The type size of abbreviated cautionary statements shall be reasonably related to the type size of any other printed matter in the product advertisement, and must be in conspicuous and legible type by typography, layout, or color with other

printed matter in the advertisement and separated from other graphic matter.

(h) *Business to Business Catalogue Exception.* The requirements of section 24(c) of the Federal Hazardous Substances Act, as amended by section 105 of the CPSIA, do not apply to catalogues and other printed materials distributed solely between businesses unless the recipient business is one that could be expected to be purchasing the product for the use of children (instead of for resale, e.g.). Examples of businesses that can be expected to be purchasing products for the use of children include day care centers, schools, and churches.

[73 FR 67736, Nov. 17, 2008, as amended at 73 FR 71545, Nov. 25, 2008]

§ 1500.40 Method of testing toxic substances.

Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC’s animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis, including any of the following: existing human and animal data, structure activity relationships, physicochemical properties; and chemical reactivity, or validated *in vitro* or *in silico* testing are recommended to evaluate existing information before *in vivo* tests are considered. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the

number of test animals. The method of testing the toxic substances referred to in §1500.3(c)(1)(ii)(C) and (c)(2)(iii) is as follows:

(a) *Acute dermal toxicity (single exposure)*. In the acute exposures, the agent is held in contact with the skin by means of a sleeve for periods varying up to 24 hours. The sleeve, made of rubber dam or other impervious material, is so constructed that the ends are reinforced with additional strips and should fit snugly around the trunk of the animal. The ends of the sleeve are tucked, permitting the central portion to “balloon” and furnish a reservoir for the dose. The reservoir must have sufficient capacity to contain the dose without pressure. In the following table are given the dimensions of

sleeves and the approximate body surface exposed to the test substance. The sleeves may vary in size to accommodate smaller or larger subjects. In the testing of unctuous materials that adhere readily to the skin, mesh wire screen may be employed instead of the sleeve. The screen is padded and raised approximately 2 centimeters from the exposed skin. In the case of dry powder preparations, the skin and substance are moistened with physiological saline prior to exposure. The sleeve or screen is then slipped over the gauze that holds the dose applied to the skin. In the case of finely divided powders, the measured dose is evenly distributed on cotton gauze which is then secured to the area of exposure.

DIMENSIONS OF SLEEVES FOR ACUTE DERMAL TOXICITY TEST
[Test animal—Rabbits]

Measurements in centimeters		Range of weight of animals (grams)	Average area of exposure (square centimeters)	Average percentage of total body surface
Diameter at ends	Overall length			
7.0	12.5	2,500–3,500	240	10.7

(b) *Preparation of test animal*. The animals are prepared by clipping the skin of the trunk free of hair. Approximately one-half of the animals are further prepared by making epidermal abrasions every 2 or 3 centimeters longitudinally over the area of exposure. The abrasions are sufficiently deep to penetrate the stratum corneum (horny layer of the epidermis) but not to disturb the derma; that is, not to obtain bleeding.

(c) *Procedures for testing*. The sleeve is slipped onto the animal which is then placed in a comfortable but immobilized position in a multiple animal holder. Selected doses of liquids and solutions are introduced under the sleeve. If there is slight leakage from the sleeve, which may occur during the first few hours of exposure, it is collected and reapplied. Dosage levels are adjusted in subsequent exposures (if necessary) to enable a calculation of a dose that would be fatal to 50 percent of the animals. This can be determined from mortality ratios obtained at various doses employed. At the end of 24 hours the sleeves or screens are removed, the volume of unabsorbed ma-

terial (if any) is measured, and the skin reactions are noted. The subjects are cleaned by thorough wiping, observed for gross symptoms of poisoning, and then observed for 2 weeks.

[38 FR 27012, Sept. 27, 1973, as amended at 77 FR 73294, Dec. 10, 2012]

§ 1500.41 Method of testing primary irritant substances.

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC’s animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis or a validated *in vitro* test method is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing

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the dermal corrosivity and primary irritation of substances referred to in §1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. Primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduce under a square patch, such as surgical gauze measuring 1 inch by 1 inch and two single layers thick, 0.5 milliliter (in the case of liquids) or 0.5 gram (in the case of solids and semisolids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material, such as rubberized cloth, for the 24-hour period of exposure. This material aids in maintaining the test patches in position and retards the evaporation of volatile substances. After 24 hours of exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following table:

Skin reaction	Value ¹
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formations (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

¹The "value" recorded for each reading is the average value of the six or more animals subject to the test.

Readings are again made at the end of a total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reac-

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tions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score; for example:

Skin reaction	Exposure time (hours)	Evaluation value
Erythema and eschar formation:		
Intact skin	24	2
Do	72	1
Abraded skin	24	3
Do	72	2
Subtotal		8
Edema formation:		
Intact skin	24	0
Do	72	1
Abraded skin	24	1
Do	72	2
Subtotal		4
Total		12

Thus, the primary irritation score is $12 \div 4 = 3$.

[38 FR 27012, Sept. 27, 1973, as amended at 77 FR 73294, Dec. 10, 2012]

§ 1500.42 Test for eye irritants.

Guidelines for *in vivo* and *in vitro* testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis or a validated *in vitro* test method is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include any of the following: Existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize

pain and distress in ocular safety testing is recommended.

(a)(1) In the method of testing the ocular irritation of a substance referred to in §1500.3(c)(4), six albino rabbits are used for each test substance. Six albino rabbits are used for each test substance. Animal facilities for such procedures shall be so designed and maintained as to exclude sawdust, wood chips, or other extraneous materials that might produce eye irritation. Both eyes of each animal in the test group shall be examined before testing, and only those animals without eye defects or irritation shall be used. The animal is held firmly but gently until quiet. The test material is placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test substance is dropped. The lids are then gently held together for one second and the animal is released. The other eye, remaining untreated, serves as a control. For testing liquids, 0.1 milliliter is used. For solids or pastes, 100 milligrams of the test substance is used, except that for substances in flake, granule, powder, or other particulate form the amount that has a volume of 0.1 milliliter (after compacting as much as possible without crushing or altering the individual particles, such as by tapping the measuring container) shall be used whenever this volume weighs less than 100 milligrams. In such a case, the weight of the 0.1 milliliter test dose should be recorded. The eyes are not washed following instillation of test material except as noted below.

(2) The eyes are examined and the grade of ocular reaction is recorded at 24, 48, and 72 hours. Reading of reactions is facilitated by use of a binocular loupe, hand slit-lamp, or other expert means. After the recording of observations at 24 hours, any or all eyes may be further examined after applying fluorescein. For this optional test, one drop of fluorescein sodium ophthalmic solution U.S.P. or equivalent is dropped directly on the cornea. After flushing out the excess fluorescein with sodium chloride solution U.S.P. or equivalent, injured areas of the cornea appear yellow; this is best visualized in a darkened room under ultraviolet illumination. Any or all eyes

may be washed with sodium chloride solution U.S.P. or equivalent after the 24-hour reading.

(b)(1) An animal shall be considered as exhibiting a positive reaction if the test substance produces at any of the readings ulceration of the cornea (other than a fine stippling), or opacity of the cornea (other than a slight dulling of the normal luster), or inflammation of the iris (other than a slight deepening of the folds (or rugae) or a slight circumcorneal injection of the blood vessels), or if such substance produces in the conjunctivae (excluding the cornea and iris) an obvious swelling with partial eversion of the lids or a diffuse crimson-red with individual vessels not easily discernible.

(2) The test shall be considered positive if four or more of the animals in the test group exhibit a positive reaction. If only one animal exhibits a positive reaction, the test shall be regarded as negative. If two or three animals a positive reaction, the test is repeated using a different group of six animals. The second test shall be considered positive if three or more of the animals exhibit a positive reaction. If only one or two animals in the second test exhibit a positive reaction, the test shall be repeated with a different group of six animals. Should a third test be needed, the substance will be regarded as an irritant if any animal exhibits a positive response.

(c) To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at <http://www.cpsc.gov/library/animaltesting.html> will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation¹ or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.²

[38 FR 27012, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973; 62 FR 46667, Sept. 4, 1997; 77 FR 73294, Dec. 10, 2012]

¹EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712-C-98-195. Washington, DC: U.S. Environmental Protection Agency. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf)

²OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/

Continued

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§ 1500.43 Method of test for flashpoint of volatile flammable materials by Tagliabue open-cup apparatus.

SCOPE

1. (a) This method describes a test procedure for the determination of open-cup flashpoints of volatile flammable materials having flashpoints below 175 °F.

(b) This method, when applied to paints and resin solutions which tend to skin over or which are very viscous, gives less reproducible results than when applied to solvents.

OUTLINE OF METHOD

2. The sample is placed in the cup of a Tag Open Tester, and heated at a slow but constant rate. A small test flame is passed at a uniform rate across the cup at specified intervals. The flashpoint is taken as the lowest temperature at which application of the test flame causes the vapor at the surface of the liquid to flash, that is, ignite but not continue to burn.

APPARATUS

3. The Tag open-cup tester is illustrated in Fig. 1. It consists of the following parts, which must conform to the dimensions shown, and have the additional characteristics as noted:

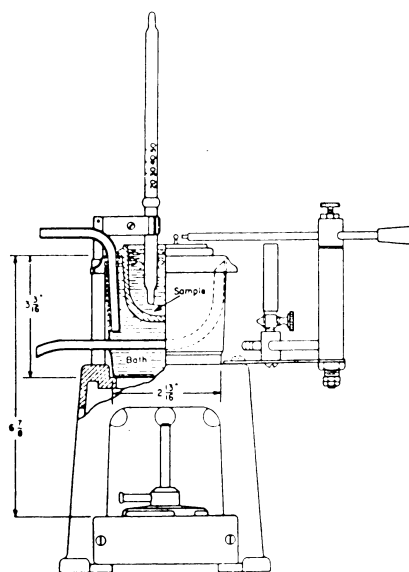


FIGURE 1—Tag open-cup flash tester

(a) *Copper bath*, preferably equipped with a constant level overflow so placed as to maintain the bath liquid level $\frac{1}{8}$ -inch below the rim of the glass cup.

(b) *Thermometer holder*. Support firmly with ringstand and clamp.

(c) *Thermometer*. For flashpoints above 40 °F., use the ASTM Tag Closed Tester Thermometer, range of +20 to +230 °F., in 1 °F. divisions, and conforming to thermometer 9F. of ASTM Standard E 1. For flashpoints from 20 °F. to 40 °F., use ASTM Tag Closed Tester, Low Range, Thermometer 57F. For flashpoints below 20 °F., use ASTM Thermometer 33F. The original Tag Open-Cup (Paper Scale) Thermometer will be a permissible alternate until January 1, 1962. It is calibrated to -20 °F.

(d) *Glass test cup*. Glass test cup (Fig. 2), of molded clear glass, annealed, heat-resistant, and free from surface defects.

Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: <http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf>)

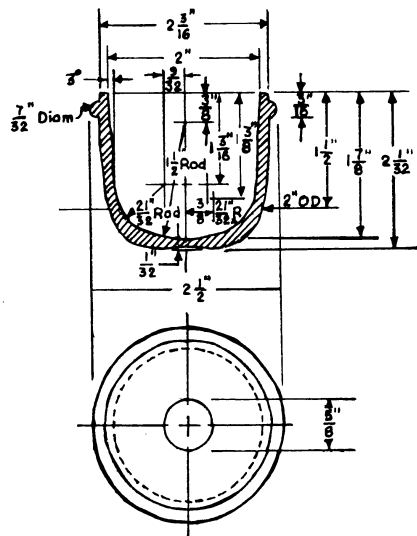


FIGURE 2—Glass test cup

(e) *Leveling device.* Leveling device or guide, for proper adjustment of the liquid level in the cup (Fig. 3). This shall be made of No. 18-gage polished aluminum, with a projection for adjusting the liquid level when the sample is added to exactly $\frac{1}{8}$ -inch below the level of the edge or rim of the cup.

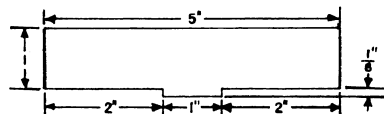


FIGURE 3—Leveling device for adjusting liquid level in test cup

(f) "Micro," or small gas burner of suitable dimensions for heating the bath. A screw clamp may be used to help regulate the gas. A small electric heater may be used.

(g) Ignition taper, which is a small straight, blow-pipe type gas burner. The test flame torch prescribed in the method of test for flash and fire points by Cleveland Open Cup (ASTM designation: D 92) is satisfactory.

(h) Alternative methods for maintaining the ignition taper in a fixed horizontal plane above the liquid may be used, as follows:

(1) Guide wire, $\frac{3}{32}$ -inch in diameter and $3\frac{1}{2}$ inches in length, with a right-angle bend $\frac{1}{2}$ -inch from each end. This wire is placed snugly in holes drilled in the rim of the bath, so that the guide wire is $\frac{5}{8}$ -inch from the center of the cup and resting on the rim of the cup.

(2) Swivel-type taper holder, such as is used in ASTM METHOD D 92. The height and position of the taper are fixed by adjusting

the holder on a suitable ringstand support adjacent to the flash cup.

(i) Draft shield, consisting of two rectangular sheets of noncombustible material, 24 inches \times 28 inches, are fastened together along the 28-inch side, preferably by hinges. A triangular sheet, 24 inches \times 24 inches \times 34 inches is fastened by hinges to one of the lateral sheets (to form a top when shield is open). The interior of the draft shield shall be painted a flat black.

PROCEDURE

4. (a) Place the tester on a solid table free of vibration, in a location free of perceptible draft, and in a dim light.

(b) Run water, brine, or water-glycol solution into the bath to a predetermined level, which will fill the bath to $\frac{1}{8}$ -inch below the top when the cup is in place. An overflow is permissible for water-level control.

(c) Firmly support the thermometer vertically halfway between the center and edge of the cup on a diameter at right angles to the guide wire, or on a diameter passing through the center of the cup and the pivot of the taper. Place so that the bottom of the bulb is $\frac{1}{4}$ -inch from the inner bottom surface of the cup. If the old Tagliabue thermometer is used, immerse to well cover the mercury bulb, but not the wide body of the thermometer.

(d) Fill the glass cup with the sample liquid to a depth just $\frac{1}{8}$ -inch below the edge, as determined by the leveling device.

(e) Place the guide wire or swivel device in position, and set the draft shield around the tester so that the sides from right angles with each other and the tester is well toward the back of the shield.

(f) If a guide wire is used, the taper, when passed, should rest lightly on the wire, with the end of the jet burner just clear of the edge of the guide wire. If the swivel-type holder is used, the horizontal and vertical positions to the jet are so adjusted that the jet passes on the circumference of a circle, having a radius of at least 6 inches, across the center of the cup at right angles to the diameter passing through the thermometer, and in a plane $\frac{1}{8}$ -inch above the upper edge of the cup. The taper should be kept in the "off" position, at one end or the other of the swing, except when the flame is applied.

(g) Light the ignition flame and adjust it to form a flame of spherical form matching in size the $\frac{5}{32}$ -inch sphere on the apparatus.

(h) Adjust heater source under bath so that the temperature of the sample increases at a rate of 2 ± 0.5 °F. per minute. With viscous materials this rate of heating cannot always be obtained.

INITIAL TEST

5. Determine an approximate flashpoint by passing the taper flame across the sample at

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intervals of 2 °F. Each pass must be in one direction only. The time required to pass the ignition flame across the surface of the sample should be 1 second. Remove bubbles from the surface of the sample liquid before starting a determination. Meticulous attention to all details relating to the taper, size of taper flame, and rate of passing the taper is necessary for good results. When determining the flashpoint of viscous liquids and those liquids that tend to form a film of polymer, etc., on the surface, the surface film should be disturbed mechanically each time before the taper flame is passed.

RECORDED TESTS

6. Repeat the procedure by cooling a fresh portion of the sample, the glass cup, the bath solution, and the thermometer at least 20 °F. below the approximate flashpoint. Resume heating, and pass the taper flame across the sample at two intervals of 2 °F. until the flashpoint occurs.

REPORTING DATA

7. The average of not less than three recorded tests, other than the initial test, shall be used in determining the flashpoint and flammability of the substance.

STANDARDIZATION

8. (a) Make determinations in triplicate on the flashpoint of standard paraxylene and of standard isopropyl alcohol which meet the following specifications:

(i) *Specifications for p-xylene, flashpoint check grade. p-xylene shall conform to the following requirements;*

Specific gravity: 15.56 °C./15.56 °C., 0.860 minimum, 0.866 maximum

Boiling range: 2 °C. maximum from start to dry point when tested in accordance with the method of test for distillation of industrial aromatic hydrocarbons (ASTM designation: D 850), or the method of test for distillation range of lacquer solvents and diluents (ASTM) designation D 1078). The range shall include the boiling point of pure *P*-xylene, which is 138.35 °C. (281.03 °F.).

Purity: 95 percent minimum, calculated in accordance with the method of test for determination of purity from freezing points of high-purity compounds (ASTM designation: D 1016), from the experimentally determined freezing point, measured by the method of test for measurement of freezing points of high-purity compounds for evaluation of purity (ASTM designation: D 1015).

(ii) *Specifications for isopropanol, flash point check grade. Isopropanol shall conform to the following requirements:*

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Specific gravity: 0.8175 to 0.8185 at 20 °C./20 °C. as determined by means of a calibrated pycnometer.

Distillation range: Shall entirely distill within a 1.0 °C. range which shall include the temperature 80.4 °C. as determined by ASTM method D 1078.

Average these values for each compound. If the difference between the values for these two compounds is less than 15 °F. (8.5 °C.) or more than 27 °F. (16 °C.), repeat the determinations or obtain fresh standards.

(b) Calculate a correction factor as follows:

$$X = 92 - A$$

$$Y = 71 - B$$

$$\text{Correction} = (X + Y) / 2.$$

Where:

A=Observed flash of *p*-xylene, and

B=Observed flash of isopropyl alcohol.

Apply this correction of all determinations.

Half units in correction shall be discarded.

PRECISION

9. (a) For hydrocarbon solvents having flashpoints between 60 °F. and 110 °F., repeatability is ±2 °F. and the reproducibility is ±5 °F.

(b) If results from two tests differ by more than 10 °F., they shall be considered uncertain and should be checked. This calibration procedure provided in this method will cancel out the effect of barometric pressure if calibration and tests are run at the same pressure. Data supporting the precision are given appendix III of the 1956 Report of Committee D-1 on Paint, Varnish, Lacquers and Related Products, Proceedings, Am. Soc. Testing Mats., Vol. 56 (1956).

NOTE: The test apparatus and procedure described in §1500.43 may be used by manufacturers and labelers of products subject to the Federal Hazardous Substances Act to determine flashpoint temperatures of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

[51 FR 28537, Aug. 8, 1986]

§ 1500.43a Method of test for flashpoint of volatile flammable materials.

(a) *Scope.* (1) This method describes the test procedure which the Commission will use for the determination of the flashpoint of volatile flammable materials, using a Setaflash¹ low-range closed tester, or an apparatus producing equivalent results. The method described in this section is essentially a Setaflash equilibrium procedure

¹Setaflash is a registered trademark of Stanhope-Seta Limited, Surrey, England.

which closely parallels the test method designated ASTM D 3828-81, "Standard Test Methods for Flash Point by Setaflash Closed Tester," published by the American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, Pennsylvania 19103. Manufacturers and labelers of products subject to labeling and other requirements under the Federal Hazardous Substances Act may use other apparatus and/or test methods which produce equivalent results.

(2) At the option of the user, the procedures described in this section may be used to determine the actual flashpoint temperature of a sample or to determine whether a product will or will not flash at a specified temperature (flash/no flash).

(3) If the substance to be tested has a viscosity greater than 150 Stokes at 77 °F (25 °C), see paragraph (n) of this section for modifications to the testing procedure.

(4) If the Commission has reason to believe on the basis of reliable experience or other relevant information or data that the flammability hazard of a substance is greater or less than its flammability classification based on flashpoint temperature determined in accordance with this §1500.43a and that the substance should be reclassified, the Commission will initiate a rule-making proceeding for reclassification of the substance. Product manufacturers and labelers may use reliable experience or other relevant information or data in addition to the flashpoint temperature of a substance as a basis for compliance with any applicable requirements of the Federal Hazardous Substances Act in the absence of a rule issued by the Commission to reclassify the substance.

(b) *Summary of test methods.* (1) Method A—Flash/No Flash Test. A specified volume of sample is introduced by a syringe into the cup of the apparatus that is set and maintained at the specified temperature. After a specific time a test flame is applied and an observation made as to whether or not a flash occurred. Test procedures are set forth in detail in §1500.43a(i).

(2) Method B—Finite (or Actual) Flashpoint. (i) A specified volume of sample is introduced into the cup of

the apparatus that is maintained at the expected flashpoint. After a specified time a test flame is applied and the observation made whether or not a flash occurred.

(ii) The specimen is removed from the cup, the cup cleaned, and the cup temperature adjusted 5 °C (9 °F), lower or higher depending on whether or not a flash occurred previously. A fresh specimen is introduced and tested. This procedure is repeated until the flashpoint is established within 5 °C (9 °F).

(iii) The procedure is then repeated at 1 °C (2 °F) intervals until the flashpoint is determined to the nearest 1 °C (2 °F).

(iv) If improved accuracy is desired the procedure is repeated at 0.5 °C (1 °F). Test procedures are set forth in detail at §1500.43a(j).

(3) The test procedures will be modified, where necessary, to ensure that the results obtained reflect the hazard of the substance under reasonably foreseeable conditions of use. Thus, for example, the material, if a mixture, will normally be tested as it comes from the container, and/or after a period of evaporation. The period of evaporation for a material which is a mixture will normally be the time required for the mixture to evaporate in an open beaker under ambient conditions to 90 percent of its original volume, or a period of four hours, whichever occurs first. However, this period of evaporation will be changed if the results obtained do not represent the hazard of the substance under reasonably foreseeable conditions of use.

(c) *Definition of flashpoint.* The lowest temperature of the sample, corrected to a barometric pressure of 101.3 kPa (760 mm Hg), at which application of a test flame causes the vapor of the sample to ignite under specified conditions of test. The sample is deemed to have flashed when a large flame appears and instantaneously propagates itself over the surface of the sample. Occasionally, particularly near actual flashpoint, the application of the test flame will cause a halo or an enlarged flame; this is not a flash and should be ignored.

(d) *Test apparatus.* The test apparatus is an equilibrium closed-cup tester

with a range up to 100 °C (212 °F). The essential dimensions and requirements are shown in figure 1 and table 3, and are described in §1500.43a(m). Closed-cup flashpoint testers and accessories meeting these requirements are available from commercial suppliers and distributors of laboratory equipment.

(e) *Safety precautions.* The operator must exercise and take appropriate safety precautions during the initial application of the test flame to the sample. Samples containing low-flash material may give an abnormally strong flash when the test flame is first applied.

(f) *Preparation of samples.* (1) Erroneously high flashpoints may be obtained if precautions are not taken to avoid the loss of volatile material. In preliminary tests of materials taken directly from the container, do not open containers unnecessarily and make a transfer unless the sample temperature is at least 10 °C (18 °F) below the expected flashpoint. Do not use samples in leaky containers for this test.

(2) Do not store samples in plastic (polyethylene, polypropylene, etc.) bottles since volatile material may diffuse through the walls of the bottle.

(3) A 2-ml specimen is required for each test. If possible, obtain at least a 50-ml sample from the bulk test site and store in a clean, tightly closed container.

(g) *Preparation of apparatus.* (1) Place the tester on a level, stable surface. Unless tests are made in a draft-free area, surround the tester on three sides with a shield for protection. Do not rely on tests made in a laboratory draft hood or near ventilators.

(2) Read the manufacturer's instructions on the care and servicing of the instrument and for correct operation of its controls.

(h) *Calibration and standardization.* (1) Before initial use determine and plot the relationship between the temperature control dial and the thermometer readings at each major (numbered) dial division as follows:

Turn the temperature control knob² fully counterclockwise ("O" reading).

²If the instrument has two temperature control knobs, set the fine control (center,

Advance the temperature control knob clockwise until the indicator light is illuminated.³ Advance the knob clockwise to the next numbered line. After the thermometer mercury column ceases to advance, record the dial reading and the temperature. Advance the knob clockwise to the next numbered line. After the thermometer mercury column ceases to advance, read the dial reading and the temperature. Repeat this procedure through the full range of the instrument. Plot the dial readings versus the respective temperatures.

(2) Standardize the instrument using a sample of material meeting the specifications in table 1. If the average of two determinations falls within the acceptable limits the instrument is assumed to be operating properly. If the average of the two determinations does not fall within this range, check the manufacturer's operating and maintenance instructions and determine that they are being followed. In particular, be sure that the cup lid assembly makes a vapor-tight seal with the cup, the shutter provides a light-tight seal, and that adequate heat transfer paste surrounds the thermometer bulb and the immersed portion of the barrel.

(i) *Test Method A—for determining Flash/No Flash.* (1) Determine the target flashpoint as follows:

(i) Target flashpoint, °C= $S_c-0.25$ (101.3—A)

(ii) Target flashpoint, °C= $S_c-0.03$ (760—B)

(iii) Target flashpoint, °F= $S_f-0.06$ (760—B)

where:

S_c =specification, or uncorrected target, flashpoint, °C,

S_f =specification, or uncorrected target, flashpoint, °F,

B=ambient barometric pressure, mm Hg,⁴ and

small knob) at its mid-position and allow it to remain there throughout the calibration. The calibration is determined by adjusting the coarse control (large, outer knob) only.

³When using the tester, it will be found that the indicator light may not illuminate and the temperature may not rise until a temperature control dial setting between one and two is reached.

⁴The barometric pressure used in this calculation must be the ambient pressure for

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A=ambient barometer pressure, kPa.⁴

(2) Inspect the inside of the sample cup, lid, and shutter mechanism for cleanliness and freedom from contamination. Use an absorbent paper tissue to wipe clean, if necessary. Put cover in place and lock securely. The filing orifice may be conveniently cleaned with a pipe cleaner.

(3) Set the instrument at the target temperature.

(i) For target temperature below ambient. The instrument power switch is to be in the off position. Fill the refrigerant-charged cooling block with a suitable material.⁵ Raise the lid and shutter assembly, and position the base of the block in the sample cup, being careful not to injure or mar the cup. When the thermometer reads approximately 6 to 10 °C (10 to 20 °F) below the target temperature, remove the cooling block and quickly dry the cup with a paper tissue to remove any moisture. Immediately close the lid and shutter assembly and secure. Prepare to introduce the sample using the syringe, both of which have been precooled to a temperature 5 to 10 °C (10 to 20 °F) below the target temperature.

(A) Caution: Do not cool the sample block below -38 °C, the freezing point of mercury.

(B) Caution: Acetone is extremely flammable. Keep away from heat, sparks, and flames and keep container closed when not actually pouring acetone. Use only in a well-ventilated area. Avoid inhalation and contact with the eyes or skin. Use cloth or leather gloves, goggles or safety shield, and keep dry ice in a canvas bag, especially when cracking.

(ii) For target temperature above ambient. Switch the instrument on and

the laboratory at the time of test. Many aneroid barometers, such as those used at weather stations and airports, are precorrected to give sea-level readings; these must not be used.

⁵If the target or specification temperature is not less than 5 °C (40 °F) crushed ice and water may be used as charging (cooling) fluid. If below 5 °C (40 °F), a suitable charging (cooling) fluid is solid carbon dioxide (dry ice) and acetone. If the refrigerant charged cooling module is unavailable, refer to the manufacturer's instruction manual for alternative methods of cooling.

turn the coarse temperature control knob fully clockwise (full on) causing the indicator light to illuminate.⁶ When the thermometer indicates a temperature about 3 °C (5 °F) below the target (or specification) temperature, reduce the heat input to the sample cup by turning the coarse temperature control knob counter-clockwise to the desired control point (see §1500.43a(i)(1)). When the indicator light slowly cycles on and off read the temperature on the thermometer. If necessary, adjust the fine (center) temperature control knob to obtain the desired test (target) temperature. When the test temperature is reached and the indicator lamp slowly cycles on and off, prepare to introduce the sample.

(4) Charge the syringe with a 2-ml specimen of the sample⁷ to be tested; transfer the syringe to the filling orifice, taking care not to lose any sample; discharge the test specimen into the cup by fully depressing the syringe plunger, remove the syringe.

(5)(i) Set the timer⁸ by rotating its knob clockwise to its stop. Open the gas control valve and light the pilot and test flames. Adjust the test flame with the pinch valve to conform to the size of the 4-mm (5/32-in.) gage.

(ii) After the time signal indicates the specimen is at test temperature⁸, apply the test flame by slowly and uniformly opening the shutter and closing

⁶The target temperature may be attained by originally turning the coarse temperature control knob to the proper setting (see §1500.43a(h)(1) for the temperature desired rather than the maximum setting (full on). The elapsed time to reach the temperature will be greater, except for maximum temperature. However, less attention will be required during the intervening period.

⁷For target or expected temperatures below ambient, both syringe and sample must be precooled to cup temperature (see §1500.43a(i)(3)(i)) before the specimen is taken.

⁸For target temperatures below ambient, do not set the timer. Adjust the test flame and allow the temperature to rise under ambient conditions until the target temperature is reached. Immediately apply the test flame as detailed.

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it completely over a period of approximately 2½ s.⁹ Watch closely for a flash at the cup openings.

(iii) The sample is deemed to have flashed when a large flame appears and instantaneously propagates itself over the surface of the sample (see § 1500.43a(c)).

(6) Record the test results as “flash” or “no flash” and the test temperature.

(7) Turn off the pilot and test flames using the gas control valve. Remove the sample and clean the instrument. It may be necessary to allow the cup temperature to decline to a safe level before cleaning.

(j) *Test Method B—for determining Finite or Actual Flashpoint.* (1) Inspect the inside of the sample cup, lid, and shutter mechanism for cleanliness and freedom from contamination. Use an absorbent paper tissue to wipe clean, if necessary. Put cover in place and lock securely. The filling orifice may be conveniently cleaned with a pipe cleaner.

(2) For expected flashpoints below ambient. (i) The instrument power switch is to be in off position. Fill the refrigerant-charged cooling block with a suitable material.⁵ Raise the lid and shutter assembly, and position the base of the block in the sample cup, being careful not to injure or mar the cup. When the thermometer reaches a temperature 5 to 10 °C (10 to 20 °F) below the expected flashpoint, remove the cooling block and quickly dry the cup with a paper tissue to remove any moisture. Immediately close the lid and shutter assembly and secure. Prepare to introduce the sample using the syringe, both of which have been precooled to a temperature 5 to 10 °C (10 to 20 °F) below the expected temperature (See § 1500.43a(j)(5)).

(ii) Caution: Do not cool the sample block below –38 °C, the freezing point of mercury.

(3) For tests where the expected flashpoint is above ambient. Turn the coarse temperature control knob fully clockwise (full on) causing the indicator light to illuminate. When the thermometer reaches a temperature 3

°C (5 °F) below the estimated flashpoint, turn the coarse temperature knob counter-clockwise to the dial reading representing the estimated flashpoint temperature as shown on the calibration curve (See § 1500.43a(h)(1)). When the indicator light slowly cycles on and off, read the temperature on the thermometer. If necessary, adjust the fine temperature control knob to obtain the exact desired temperature.

(4)(i) Charge the syringe⁷ with a 2 ml specimen of the sample⁷ to be tested; transfer the syringe to the filling orifice, taking care not to lose any sample; discharge the test specimen into the cup by fully depressing the syringe plunger; remove the syringe.

(ii) Set the timer¹⁰ by rotating its knob clockwise to its stop. Open the gas control valve and ignite the pilot and test flames. Adjust the test flame with the pinch valve to conform to the size of the 4-mm (⁵/₃₂-in.) gage.

(iii) After the audible time signal indicates the specimen is at test temperature,¹⁰ apply the test flame by slowly and uniformly opening the shutter and then closing it completely over a period of approximately 2½ s. Watch closely for a flash at the cup opening.

(iv) The sample is deemed to have flashed only if a large flame appears and instantaneously propagates itself over the surface of the sample. (See § 1500.43a(c).)

(v) Turn off the pilot and test flames using the gas control valve. When the cup temperature declines to a safe level, remove the sample and clean the instrument.

(5)(i) If a flash was observed in § 1500.43a(j)(4)(iii) repeat the procedure given in § 1500.43a(j)(2) or (3), and in § 1500.43a(j)(4), testing a new specimen at a temperature 5 °C (9 °F) below that at which the flash was observed.

(ii) If necessary, repeat the procedure in § 1500.43a(j)(5)(i), lowering the temperature 5 °C (9 °F) each time, until no flash is observed.⁹

⁹Never apply the test flame to the specimen more than once. Fresh portions of the sample must be used for each test.

¹⁰For expected flashpoint below ambient, do not set the timing device. Adjust the test flame. Allow the temperature to rise under ambient conditions until the temperature reaches 5 °C (9 °F) below the expected flashpoint. Immediately apply the test flame.

(iii) Proceed to §1500.43a(j)(7).

(6)(i) If no flash was observed in §1500.43a(j)(4)(iii) repeat the procedure given in §1500.43a(j)(2) or (3), and in §1500.43a(j)(4), testing a fresh specimen at a temperature 5 °C (9 °F) above that at which the specimen was tested in §1500.43a(j)(4)(iii).

(ii) If necessary repeat the procedure in §1500.43a(j)(6)(i), above, raising the temperature 5 °C (9 °F) each time until a flash is observed.⁹

(7) Having established a flash within two temperatures 5 °C (9 °F) apart, repeat the procedure at 1 °C (2 °F) intervals from the lower of the two temperatures until a flash is observed.⁹ Record the temperature of the test when this flash occurs as the flashpoint, allowing for any known thermometer correction. Record the barometric pressure.⁴

(8) The flashpoint determined in §1500.43a(j)(7) will be to the nearest 1 °C (2 °F). If improved accuracy is desired (that is, to the nearest 0.5 °C (1 °F)), test a fresh specimen at a temperature 0.5 °C (1 °F) below that at which the flash was observed in §1500.43a(j)(7). If no flash is observed, the temperature recorded in §1500.43a(j)(7), is the flashpoint to the nearest 0.5 °C (1 °F). If a flash is observed at the lower temperature, record this latter temperature as the flashpoint.

(9) Turn off the pilot and test flames using the gas control valve. When the cup temperature declines to a safe level, remove the sample and clean the instrument.

(k) *Calculations.* If it is desired to correct the observed finite flashpoint for the effect of barometric pressure, proceed as follows: Observe and record the ambient barometric pressure⁴ at the time of the test. If the pressure differs from 101.3 kPa (760 mm Hg), correct the flashpoint as follows:

(1) Corrected flashpoint (°C)=C+0.25 (101.3-A)

(2) Corrected flashpoint (°F)=F+0.06 (760-B)

(3) Corrected flashpoint (°C)=C+0.03 (760-B)

Where: F=Observed flashpoint, °F,

C=observed flashpoint, °C,

B=ambient barometric pressure, mm Hg; and

A=ambient barometric pressure, kPa.

(1) *Precision.* The precision of the method as determined by statistical examination of interlaboratory results is as follows:

(1) *Repeatability.* The difference between two test results obtained by the same operator with the same apparatus under constant operating conditions on identical test material, would, in the long run, in the normal and correct operation of the test method, exceed the values shown in table 2 only in 1 case in 20.

(2) *Reproducibility.* The difference between two single and independent results obtained by different operators working in different laboratories on identical test material, would, in the long run, in the normal and correct operation of the test method, exceed the values shown in table 2 only in 1 case in 20.

(m) *Flash Test Apparatus.* (1)(i) Unit consisting of an aluminum alloy or nonrusting metal block of suitable conductivity with a cylindrical depression, or sample cup, over which is fitted a cover. A thermometer is embedded in the block.

(ii) The cover is fitted with an opening slide and a device capable of inserting an ignition flame (diameter 4±0.5 mm) into the well when the slide device shall intersect the plane of the underside of the cover. The cover is also provided with an orifice extending into the sample well for insertion of the test sample and also a suitable clamping device for securing the cover tightly to the metal block. The three openings in the cover shall be within the diameter of the sample well. When the slide is in the open position, the two openings in the slide shall coincide exactly with the two corresponding openings in the cover.

(iii) Electrical heaters are attached to the bottom of the cup in a manner that provides efficient transfer of heat. An electronic heat control is required to hold the equilibrium temperature, in a draft-free area, within 0.1 °C (0.2 °F) for the low-temperature tester. A visual indicator lamp shows when energy is or is not being applied. Energy may be supplied from 120 or 240 V, 50 or 60 Hz main service.

(2)(i) Test flame and pilot flame-regulatable test flame, for dipping into

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the sample cup to try for flash, and a pilot flame, to maintain the test flame, are required. These flames may be fueled by piped gas service. A gage ring 4mm (5/32 in.) in diameter, engraved on the lid near the test flame, is required to ensure uniformity in the size of the test flame.

(ii) Caution: Never recharge the self-contained gas tank at elevated temperature, or with the pilot or test flames lighted, nor in the vicinity of other flames.

(iii) Audible Signal is required. The audible signal is given after 1 min in the case of the low-temperature tester.

(iv) Syringe. 2ml capacity, equipped with a needle suitable for use with the apparatus, adjusted to deliver 2.00±0.05 ml.

(3) Essential dimensions of the test apparatus are set forth in table 3.

(n) *Testing high-viscosity liquids.* (1) High-viscosity materials may be added to the cup by the following procedure:

(i) Back load a 5 or 10-ml syringe with the sample to be tested and extrude 2 ml into the cup. Spread the specimen as evenly as possible over the bottom of the cup.

(ii) If the sample cannot be loaded into a syringe and extruded, other means of adding the sample to the cup may be used such as a spoon. Add approximately 2 ml of material to the spoon and then push the material from the spoon into the cup.

(iii) If the test specimen does not close the sampling port in the cup, seal the cup externally by suitable means.

(2) Using the appropriate procedure, either Method A in §1500.43a(i) or Method B in §1500.43a(j), determine the flashpoint of the specimen which has been added to the tester in accordance with §1500.43a(n)(i), except that the time specified is increased from 1 to 5 minutes for samples at or above ambient temperature.

TABLE 1—CALIBRATION OF TESTER

Material	<i>p</i> -xylene ^A (Caution). ^B
Specific gravity, 15.6/15.6 °C (60/60 °F)	0.850 to 0.866.

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TABLE 1—CALIBRATION OF TESTER—Continued

Boiling range	2 °C maximum including 138.35 °C (281.03 °F).
Freezing point	11.23 °C (52.2 °F) minimum.
Flashpoint °C (acceptable range)	25.6 ±0.5 (78 ±1 Φ).

^A Available as Flash Point Check Fluid (*p*-xylene) from Special Products Div., Phillips Petroleum Co., Drawer 'O,' Borger, Texas 79007.

^B Caution: Handle xylene with care. Avoid inhalation; use only in a well-ventilated area. Avoid prolonged or repeated contact with skin. Keep away from flames and heat, except as necessary for the actual flash point determination.

TABLE 2—REPEATABILITY AND REPRODUCIBILITY

Temperature, °C (°F)	Repeatability, °C (°F)	Reproducibility, °C (°F)
20(68)	0.5(0.9)	1.4(2.6)
70(158)	0.5(0.9)	2.9(5.3)
93(200)	1.3(2.3)	4.9(8.8)
150(300)	2.0(3.6)	7.5(13.5)
200(400)	2.6(4.7)	9.9(17.9)
260(500)	3.3(5.9)	12.4(22.3)

TABLE 3—ESSENTIAL DIMENSIONS OF FLASH TEST APPARATUS^{A B}

Sample Block	
Block diameter	61.5–62.5
Sample well diameter	49.40–49.70
Sample well depth	9.70–10.00
Top of block to center of thermometer hole	16.00–17.00
Diameter of thermometer hole (approx.)	7.0004
Cover	
Large opening length	12.42–12.47
Large opening width	10.13–10.18
Small opening length	5.05–5.10
Small opening width	7.60–7.65
Distance between extreme edges of small openings	48.37–48.32
Filling orifice diameter	4.00–4.50
Bore or filler tube	1.80–1.85
Maximum distance of filler tube from base of well with cover closed (max.)	0.75
Slide	
Large opening length	12.42–12.47
Large opening width	10.13–10.18
Small opening length	5.05–5.10
Small opening width	7.60–7.65
Near edge of large opening to end of slide	12.80–12.85
Extremes of large and small openings	30.40–30.45
Jet	
Length of jet	18.30–18.40
External diameter at end of jet	2.20–2.60
Bore of jet	1.60–1.65
Height of jet center above top surface of cover	11.00–11.20
Jet pivot to center of block with cover closed	12.68–12.72

^A The O-seal or gasket which provides a seal when the cover is shut, should be made of a heat-resistant material capable of withstanding temperatures up to 150 °C for the low-range apparatus.

^B When in position, the thermometer bulb should be surrounded with heat-conducting thermoplastic compound, such as a paste comprised of zinc oxide and mineral oil.

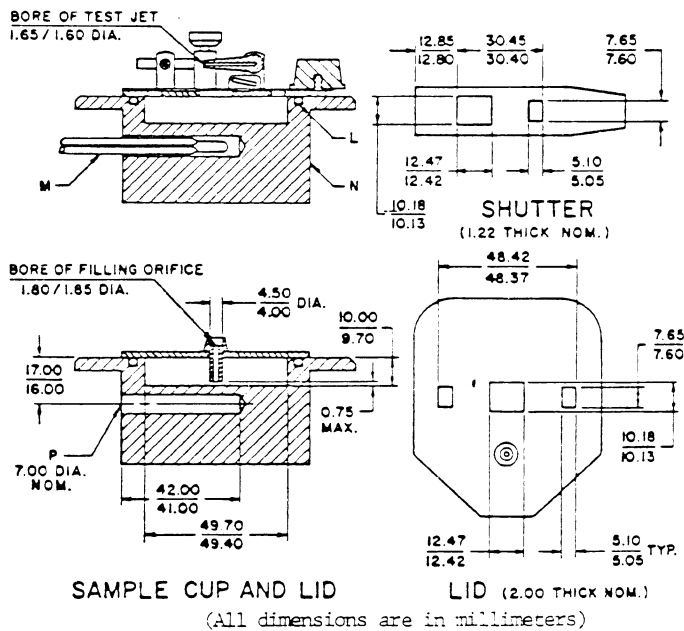
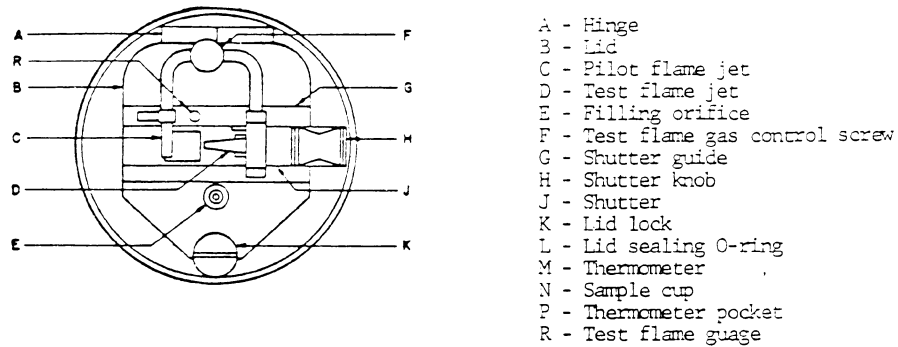


FIGURE 1 - Closed-cup tester

[51 FR 28539, Aug. 8, 1986]

§ 1500.44 Method for determining extremely flammable and flammable solids.

- (a) *Preparation of samples*—(1) *Granules, powders, and pastes.* Pack the sample into a flat, rectangular metal boat with inner dimensions 6 inches long x 1 inch wide x one-fourth inch deep.
- (2) *Rigid and pliable solids.* Measure the dimensions of the sample and sup-

port it by means of metal ringstands, clamps, rings, or other suitable devices as needed, so that the major axis is oriented horizontally and the maximum surface is freely exposed to the atmosphere.

(b) *Procedure.* Place the prepared sample in a draft-free area that can be ventilated and cleared after each test. The temperature of the sample at the

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time of testing shall be between 68 °F. and 86 °F. Hold a burning paraffin candle whose diameter is at least 1 inch, so that the flame is in contact with the surface of the sample at the end of the major axis for 5 seconds or until the sample ignites, whichever is less. Remove the candle. By means of a stopwatch, determine the time of combustion with self-sustained flame. Do not exceed 60 seconds. Extinguish flame with a CO₂ or similar nondestructive type extinguisher. Measure the dimensions of the burnt area and calculate the rate of burning along the major axis of the sample.

§ 1500.45 Method for determining extremely flammable and flammable contents of self-pressurized containers.

(a) *Equipment required.* The test equipment consists of a base 8 inches wide, 2 feet long, marked in 6-inch intervals. A rule 2 feet long and marked in inches is supported horizontally on the side of the base and about 6 inches above it. A paraffin candle 1 inch or more in diameter, and of such height that the top third of the flame is at the height of the horizontal rule, is placed at the zero point in the base.

(b) *Procedure.* The test is conducted in a draft-free area that can be ventilated and cleared after each test. Place the self-pressurized container at a distance of 6 inches from the flame source. Spray for periods of 15 seconds to 20 seconds (one observer noting the extension of the flame and the other operating the container) through the top third of the flame and at a right angle to the flame. The height of the flame should be approximately 2 inches. Take three readings for each test, and average. As a precaution do not spray large quantities in a small, confined space. Free space of previously discharged material.

§ 1500.46 Method for determining flashpoint of extremely flammable contents of self-pressurized containers.

Use the apparatus described in §1500.43a. Use some means such as dry ice in an open container to chill the pressurized container. Chill the container, the flash cup, and the bath solution of the apparatus (brine or glycol

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may be used) to a temperature of about 25 °F below zero. Puncture the chilled container to exhaust the propellant. Transfer the chilled formulation to the test apparatus and test in accordance with the method described in §1500.43a.

[51 FR 28544, Aug. 8, 1986]

§ 1500.48 Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age.

(a) *Objective.* The sharp point test prescribed by paragraph (d) of this section will be used by the Commission in making a preliminary determination that points on toys and other articles intended for use by children under 8 years of age, and such points exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by puncture or laceration under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate points that are identified as presenting a potential risk of puncture or laceration injury to determine the need for individual product regulatory action.

(b) *Scope—(1) General.* The sharp point test of paragraph (d) of this section is applicable to toys or other articles that are introduced into interstate commerce on or after December 22, 1978. The sharp point test shall be applied to any accessible portion of the test sample before and after subjecting the test sample to the use and abuse tests of §§1500.51, 1500.52, and 1500.53 (excluding the bite test-paragraph (c) of each section).

(2) *Exemptions.* (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this §1500.48: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (parts 1508, 1509, and 1512, of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this §1500.48: *Provided*, Each toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp

points. An example of such toys is a toy sewing machine with a needle.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48. An example of such articles is a ball-point pen.

(c) *Accessibility*—(1) *General*. Any point that is accessible either before or after these tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp point test of paragraph (d) of this section.

(2) *Accessible points*. (i) An accessible point for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in figure 2 of this section.

(ii) An accessible point for a toy or article intended for children over 3 years up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe B in figure 2 of this section.

(iii) An accessible point for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either probe A or B, as shown in figure 2 of this section.

(3) *Insertion depth for accessibility*. (i) For any hole, recess, or opening having a minor dimension (The minor dimension of an opening is the diameter of the largest sphere that will pass through the opening.) smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of probe A but less than 7.36 inches (186.9 millimeters), when probe A is used, or a minor dimension larger than the collar diameter of probe B but less than 9.00 inches (228.6 millimeters), when probe B is used, the total insertion depth for ac-

cessibility shall be determined by inserting the appropriate probe with the extension shown in figure 2 in any direction up to two and one-quarter times the minor dimension of the probe, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters), or larger when probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible points*. Points shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample and any gap between the point and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) either before or after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed.

(d) *Sharp point test method*—(1) *Principle of operation*. The principle of operation of the sharp point tester shown in figure 1 of this section is as follows (Detailed engineering drawings for a suggested sharp point tester are available from the Commission's Office of the Secretary.): A rectangular opening measuring 0.040 inch (1.02 millimeters) wide by 0.045 inch (1.15 millimeters) long in the end of the slotted cap establishes two reference dimensions. Depth of penetration of the point being tested determines sharpness. If the point being tested can contact a sensing head that is recessed a distance of 0.015 inch (0.38 millimeter) below the end cap and can move the sensing head a further 0.005 inch (0.12 millimeter) against a 0.5-pound (2.2-newton) force of a return spring, the point shall be identified as

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sharp. A sharp point tester of the general configuration shown in figure 1 of this section or one yielding equivalent results shall identify a sharp point. In conducting tests to determine the presence of sharp points, the Commission will use the sharp point tester shown in figure 1 of this section and the accessibility probes designated as A or B in figure 2 of this section.

(2) *Procedure.* (i) The sample to be tested shall be held in such a manner that it does not move during the test.

(ii) Part of the test sample may need to be removed to allow the sharp point testing device to test a point that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the point in question. The sharp point test shall be performed with the point supported so that its stiffness approximates but is not greater than the point stiffness in the assembled sample.

(iii) Using the general configuration shown in figure 1 of this section, the adjustment and operation of the sharp point tester is as follows: Hold the sharp point tester and loosen the lock ring by rotating it so that it moves towards the indicator lamp assembly a sufficient distance to expose the cali-

bration reference marks on the barrel. Rotate the gaging can clockwise until the indicator lamp lights. Rotate the cap counterclockwise until an equivalent of five divisions (the distance between the short lines on the cap) have passed the calibration reference mark. Lock the gaging cap in this position by rotating the lock ring until it fits firmly against the cap. Insert the point into the gaging slot in all directions in which it was accessible by the criteria of paragraph (c) of this section, and apply a force of 1.00 pound (4.45 newtons). A glowing light identifies the point as sharp.

(iv) The test instruments used by the Commission in its tests for compliance with this regulation shall have gaging slot opening dimensions no greater than 0.040 inch by 0.045 inch and shall have the sensing head recessed a depth of no less than 0.015 inch. The force applied by the Commission when inserting a point into the gaging slot shall be no more than 1.00 pound.

(e) For the purpose of conformance with the technical requirements prescribed by this §1500.48, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

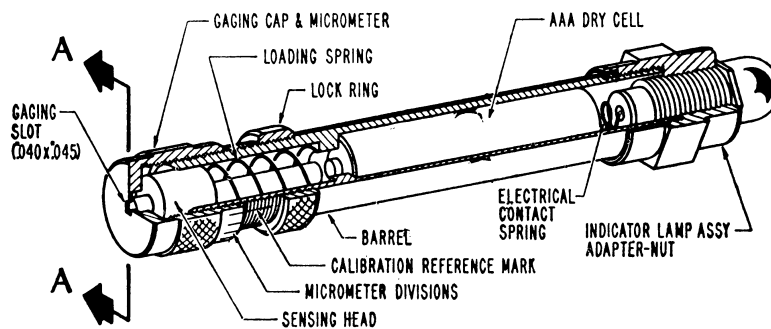
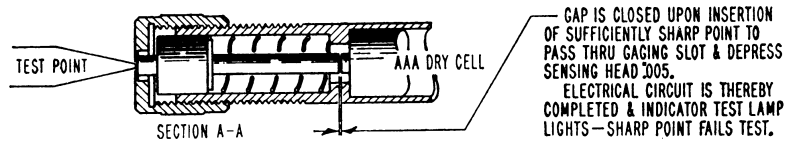
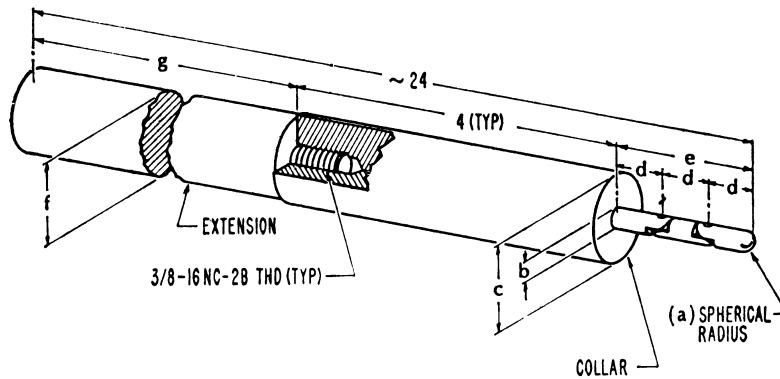


FIG 1—SHARP POINT TESTER



	a	b	c	d	e	f	g
(CHILDREN 0-36 MONTHS INCL)	PROBE A .110	.220	1.020	.577	1.731	1	18 9/32
(" 37-96 " ")	PROBE B .170	.340	1.510	.760	2.280	1 1/2	17 25/32

ALL DIMENSIONS IN INCHES

FIG 2—ACCESSIBILITY PROBES

§ 1500.49 **Technical requirements for determining a sharp metal or glass edge in toys and other articles intended for use by children under 8 years of age.**

(a) *Objective.* The sharp edge test method prescribed by paragraph (d) of this section will be used by the Com-

mission in making a preliminary determination that metal or glass edges on toys and other articles intended for use by children under 8 years of age, and such edges exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by

laceration or avulsion under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate toys and other articles with edges that are identified as presenting a potential risk of laceration or avulsion injury to determine the need for individual product regulation.

(b) *Scope*—(1) *General*. The sharp edge test of paragraph (d) of this section is applicable to toys or other articles containing metal or glass edges that are introduced into interstate commerce after March 26, 1979. Such articles manufactured outside the United States are introduced into interstate commerce when first brought within as U.S. port of entry. Such articles manufactured in the United States are introduced into interstate commerce (a) at the time of first interstate sale, or (b) at the time of first intrastate sale if one or more components and/or raw materials were received interstate, whichever occurs earlier.

(2) *Exemptions*. (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this §1500.49: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (parts 1508, 1509, and 1512 of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any nonfunctional sharp metal or glass edges are exempt from this section: Provided, the toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp metal or glass edges. Examples of these are a pair of toy scissors and toy tool kits.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any non-functional sharp metal or glass edges are exempt from this section. Examples of these are children's ice skates and children's cutlery.

(3) *Definitions*—(i) *Glass*. For the purpose of this regulation the Commission defines glass as a hard, brittle, amorphous substance produced by fusion, usually consisting of mutually dis-

solved silica and silicates that also contain soda and lime.

(ii) *Metal*. For the purpose of this regulation the Commission intends the word metal to include both elemental metals and metal alloys.

(c) *Accessibility*—(1) *General*. Any metal or glass edge that is accessible either before or after the test of §§1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp edge test of paragraph (d) of this section. Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult.

(2) *Accessible edges*. (i) An accessible metal or glass edge for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in Figure 2 of this section.

(ii) An accessible edge for a toy or article intended for children over 3 years and up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as Probe B in Figure 2 of this section.

(iii) An accessible edge for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either Probe A or Probe B, as shown in Figure 2 of this section.

(3) *Insertion depth*. (i) For any hole, recess, or opening having a minor dimension (the minor dimension of an opening is the diameter of the largest sphere that will pass through the opening), smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of Probe A, but less than 7.36 inches (186.9 millimeters),

when Probe A is used, or a minor dimension larger than the collar diameter of Probe B, but less than 9.00 inches (228.6 millimeters), when Probe B is used, the total insertion depth for accessibility shall be determined by inserting the appropriate probe with the extension, shown in Figure 2, in any direction up to $2\frac{1}{4}$ times the minor dimension of the hole, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when Probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters) or larger when Probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible edges.* Metal or glass edges shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample, and any gap between the edge and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) both before and after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed. For example, in a lap joint in which a metal edge is overlapped by a parallel surface, any burr or feather-edge on the side closest to the protecting parallel surface is considered inaccessible if the gap between the edge and the parallel surface is no greater than 0.020 inch (0.50 millimeter). As an additional example, when sheet metal has a hemmed edge a portion of the sheet adjacent to the edge is folded back upon itself, approximately 180 degrees, so that it is roughly parallel to the main sheet. Any burrs or feathering on the inside edge, the side closest to the protecting parallel surface of the main sheet, will be consid-

ered inaccessible if the gap between the inside edge and the parallel surface does not exceed 0.020 inch (0.50 millimeter).

(d) *Sharp edge test method*—(1) *Principle of operation.* The test shall be performed with a sharp edge tester which contains a cylindrical mandrel capable of rotation at a constant velocity. (Engineering drawings for a suitable portable sharp edge test instrument are available from the Commission's Office of the Secretary.) The full circumference of the mandrel shall be wrapped with a single layer of polytetrafluoroethylene (TFE) tape as specified in paragraph (e)(3) of this section. The mandrel shall be applied to the edge to be tested with a normal force of 1.35 pounds (6.00 Newtons) such that the edge contacts the approximate center of the width of the tape as shown in Figure 1 of this section. The mandrel shall be rotated through one complete revolution while maintaining the force against the edge constant. Linear motion of the mandrel along the line of the edge shall be prevented. The edge shall be identified as sharp if it completely cuts through the tape for a length of not less than $\frac{1}{2}$ inch (13 millimeters) at any force up to 1.35 pounds (6.00 Newtons).

(2) *Procedure.* (i) The edge of the sample to be tested shall be held in such a manner that it does not move during the test. If the full mandrel force of 1.35 pounds (6.00 Newtons) causes the edge to bend, a reduced mandrel force may be used.

(ii) Part of the test sample may need to be removed to allow the sharp edge testing device to test an edge that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the edge in question. The sharp edge test shall be performed with the edge supported so that its stiffness approximates but is not greater than the edge stiffness in the assembled sample.

(iii) Conduct of a sharp edge test is as follows: Wrap one layer of polytetrafluoroethylene (TFE) tape, described in paragraph (e)(3) of this section, around the full circumference of the mandrel in an unstretched state. The ends of

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the tape shall be either butted or overlapped not more than 0.10 inch (2.5 millimeters). Apply the mandrel, at the approximate center of the tape, to the edge of the test sample with a force of 1.35 pounds (6.00 Newtons) measured in a direction at right angles to the mandrel axis. The mandrel shall be placed so that its axis is at 90 degrees \pm 5 degrees to the line of a straight test edge or 90 degrees \pm 5 degrees to a tangent at the point of contact with a curved test edge. The point of contact between the test edge and the mandrel shall be in the approximate center of the width of the tape. The axis of the mandrel may be positioned anywhere in a plane which is at right angles to either the line of a straight test edge or to a tangent at the point of contact with a curved test edge. The operator should seek the orientation most likely to cause the edge to cut the tape. Maintain the force against the edge and rotate the mandrel through one complete revolution while preventing any linear motion of the mandrel along the edge. Release the mandrel from the edge and remove the tape without enlarging any cut or causing any score to become a cut. A cut in the tape with a length of not less than $\frac{1}{2}$ inch (13 millimeters) identifies an edge as sharp. (The test instruments used by the Commission in its test for compliance with the regulation will be calibrated to insure that the force with which the mandrel is applied to a test edge does not exceed 1.35 pounds.)

(e) *Specifications for sharp edge test equipment.* The following specifications shall apply to the equipment to be used in the sharp edge test described in paragraph (d) of this section:

(1) The rotation of the mandrel shall produce a constant tangential velocity of 1.00 ± 0.08 inch per second (25.4 \pm 2.0 millimeters per second) during the center 75 percent of its rotation and shall have a smooth start and stop.

(2) The mandrel shall be made of steel. The test surface of the mandrel

shall be free of scratches, nicks, or burrs and shall have a surface roughness no greater than 16 microinches (0.40 micron). The test surface shall have a hardness no less than 40 as measured on the Rockwell "C" scale, as determined pursuant to ASTM E 18-74 entitled "Standard Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials," published July 1974 and which is incorporated by reference in this regulation. (Copies are available from American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.) The diameter of the mandrel shall be 0.375 ± 0.005 inch (9.35 \pm 0.12 millimeters). The mandrel shall be of suitable length to carry out the test.

(3) The tape shall be pressure-sensitive polytetrafluoroethylene (TFE) high temperature electrical insulation tape as described in Military Specification MIL-I-23594B (1971) which is incorporated by reference in this regulation. (Copies are available from Naval Publications and Forms Center, 5801 Tabor Ave., Philadelphia, Pa. 19120.) The thickness of the polytetrafluoroethylene backing shall be between 0.0026 inch (0.066 millimeter) and 0.0035 inch (0.089 millimeter).¹ The adhesive shall be pressure-sensitive silicone polymer with a nominal thickness of 0.003 inch (.08 millimeter). The width of the tape shall not be less than $\frac{1}{4}$ inch (6 millimeters). While conducting sharp edge tests the temperature of the tape shall be maintained between 70 °F (21.1 °C) and 80 °F (26.6 °C).

(f) For the purpose of conformance with the technical requirements prescribed by this §1500.49, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

¹The tape that the Commission will use for the sharp edge test is CHR type "T" manufactured by The Connecticut Hard Rubber Co., New and East Streets, New Haven, Conn. 06509.

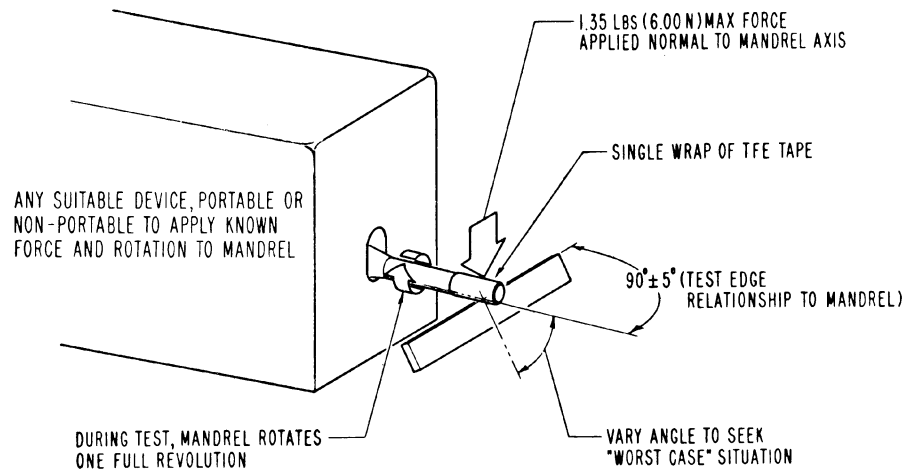


FIG 1-PRINCIPLE OF SHARP EDGE TEST

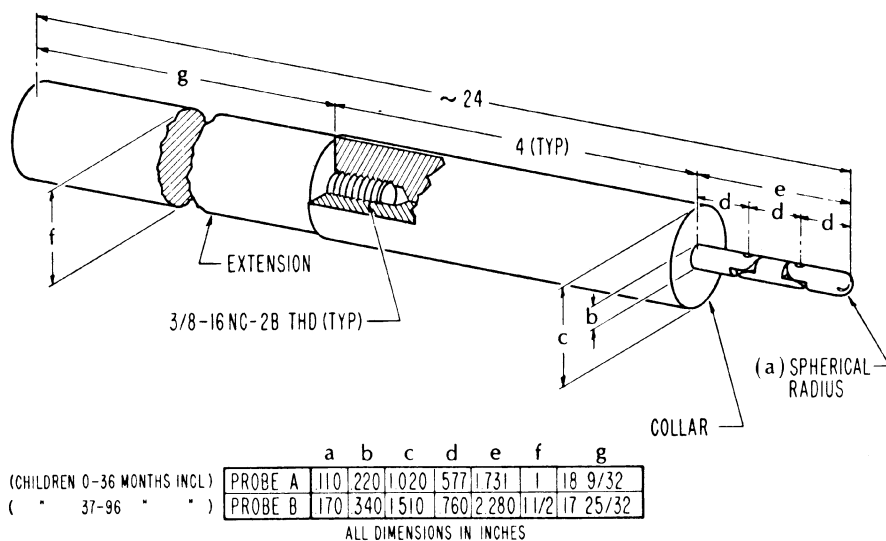


FIG 2-ACCESSIBILITY PROBES

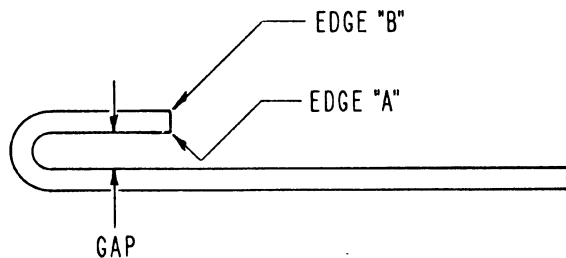


ILLUSTRATION I-HEMMED EDGE

(Secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269))

[43 FR 12645, Mar. 24, 1978, as amended at 43 FR 21324, May 17, 1978]

§ 1500.50 Test methods for simulating use and abuse of toys and other articles intended for use by children.

(a) *Objective.* The objective of §§ 1500.51, 1500.52, and 1500.53 is to describe specific test methods for simulating normal use of toys and other articles intended for use by children as well as the reasonably foreseeable damage or abuse to which the articles may be subjected. The test methods are for use in exposing potential hazards that would result from the normal use or the reasonably foreseeable damage or abuse of such articles intended for children.

(b) *Application—general.* (1)(i) The test methods described in §§ 1500.51, 1500.52 and 1500.53 are to be used in determining what is normal use and reasonably foreseeable damage or abuse when specifically referenced under § 1500.18. Other banning regulations may also reference these use and abuse toy test procedures.

(ii) The test methods described in §§ 1500.51, 1500.52, and 1500.53 have been established for articles intended for the specified age groups of children: 18 months of age or less, over 18 months but not over 36 months of age, and over 36 months but not over 96 months of

age. If an article is marked, labeled, advertised, or otherwise intended for children of ages spanning more than one of these age groups, the article will be subjected to the tests providing the most stringent requirements. If an article is not age-labeled in a clear and conspicuous manner or, based on such factors as marketing practices and the customary patterns of usage of a product by children, is inappropriately age-labeled, and is intended or appropriate for children 96 months of age or less, it will also be subjected to the most stringent test requirements.

(2) For purposes of compliance with the test methods prescribed in §§1500.51, 1500.52, and 1500.53, the English system shall be used. The metric approximations are provided in parentheses for convenience and information only.

(3) Each of the test methods described in §§1500.51, 1500.52, and 1500.53 shall be applied to a previously untested sample except the tension test which shall be conducted with the test sample used in the torque test.

(4) Prior to testing, each sample shall be subjected to a temperature of $73^{\circ}\pm 3^{\circ}$ F. ($23^{\circ}\pm 2^{\circ}$ C.) as a relative humidity of 20–70 percent for a period of at least 4 hours. The toy testing shall commence within five minutes after the toy has been removed from the preconditioning atmosphere.

(5) Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult.

(6) Toys intended to be repeatedly assembled and taken apart shall have the individual pieces as well as the completed article subjected to these test procedures.

(7) In situations where a test procedure may be applied in more than one way to a toy test component, the point (or direction) of force (or torque) application which results in the most severe conditions shall be used.

(c) *Definitions.* As used in this section and in §§1500.51, 1500.52, and 1500.53:

(1) *Toy* means any toy, game, or other article designed, labeled, adver-

tised, or otherwise intended for use by children.

(2) *Mouth toy* means any toy reasonably intended to be placed into or in contact with a child's mouth.

[40 FR 1483, Jan. 7, 1975; 40 FR 16191, Apr. 10, 1975]

§ 1500.51 Test methods for simulating use and abuse of toys and other articles intended for use by children 18 months of age or less.

(a) *Application.* The test methods described in this section shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use by children 18 months of age or less in conjunction with §1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 3.0 pounds ± 0.01 pound (1.4 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* Except as provided in paragraphs (b)(4) (i) and (ii) of this section, the toy shall be dropped 10 times from a height of 4.5 feet ± 0.5 inch (1.37 meters) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop,

¹These documents may be ordered from the General Services Administration, Specifications Unit, Room 6654, 7th and D Streets, S.W., Washington, DC 20407. The price of the specification and amendment is \$1.00.

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the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters), shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section. The base area for toys with permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4)(i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

(c) *Bite test*—(1) *Application.* A toy (or component or any accessible portion thereof) that has an external dimension of 1.25 inches \pm 0.05 inch (3.18 centimeters) or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1.25 inches \pm 0.05 inch (3.18 centimeters), for a penetration of at least 0.25 inch (0.635 centimeter), shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch \pm 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch \pm 0.002 inch (0.05 centimeter), for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of this section.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of \pm 0.5 pound (\pm 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of

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the contact mechanism, and a test load increasing to 25 pounds \pm 0.5 pound (11.35 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 10 pounds \pm 0.5 pound (4.55 kilograms), applied perpendicularly to the major axis of the component at a point 2 inches (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches \pm 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches \pm 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test*—(1) *Application*—(i) *General.* A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components.* Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment*—(i) *Loading device.* The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of \pm 0.2

inch-pound (± 0.23 kilogram-centimeter).

(ii) *Clamp*. The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure*. With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of 2 inch-pounds ± 0.2 inch-pound (2.30 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 2 inch-pounds (2.30 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test*—(1) *Application*—(i) *General*. Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags*. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 10 pounds ± 0.5 pound (4.55 kilograms) of force applied in any direction.

(2) *Test equipment*—(i) *Clamps*. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device*. The loading device is to be a self-indicating gauge or other

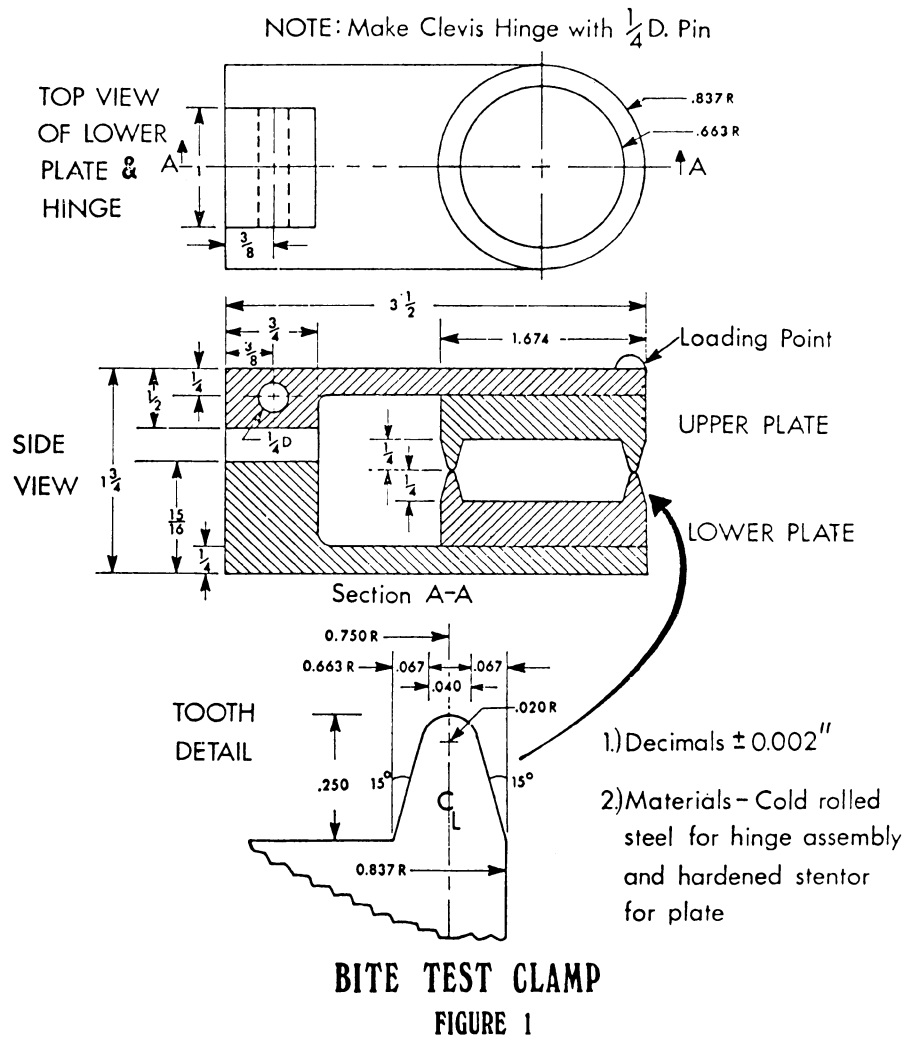
appropriate means having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure*. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 10-pound ± 0.5 pound (4.55-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 10-pound ± 0.5 pound (4.55-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches ± 0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of $\frac{1}{32}$ inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 20 pounds ± 0.5 pound (9.1 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.



[40 FR 1484, Jan. 7, 1975; 40 FR 6210, Feb. 10, 1975; 40 FR 16192, Apr. 10, 1975; 40 FR 17746, Apr. 22, 1975; as amended at 55 FR 52040, Dec. 19, 1990; 56 FR 9, Jan. 2, 1991; 56 FR 558, Jan. 7, 1991]

§ 1500.52 Test methods for simulating use and abuse of toys and other articles intended for use by children over 18 but not over 36 months of age.

(a) *Application.* The test methods described in this section, shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use

by children over 18 but not over 36 months of age in conjunction with § 1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 4.0 pounds ± 0.01 pound (1.8 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* Except as provided in paragraph (b)(4) (i) and (ii) of this section, the toy shall be dropped four times from a height of 3 feet ± 0.5 inch (0.92 meter) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop, the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters) shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section. The base area for toys with permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4) (i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

(c) *Bite test*—(1) *Application.* A toy (or component or any accessible portion thereof) that has an external dimension of 1.25 inches ± 0.05 inch (3.18 centimeters) or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1.25 inches ± 0.05 inches (3.18 centimeters), for a penetration of at least 0.25 inch (0.635 centimeter), shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch ± 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch ± 0.002 inch (0.05 centimeter) for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of § 1500.51.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of the contact mechanism, and a test load increasing to 50 pounds ± 0.5 pound (22.74 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 15 pounds ± 0.5 pound (6.80 kilograms) applied perpendicularly to the major axis of the component at a point 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches ± 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The

¹See footnote 1 to § 1500.51.

component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test*—(1) *Application*—(i) *General*. A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components*. Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment*—(i) *Loading device*. The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of ± 0.2 inch-pound (± 0.23 kilogram-centimeter).

(ii) *Clamp*. The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure*. With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of 3 inch-pounds ± 0.2 inch-pound (3.46 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 3 inch-pounds ± 0.2 inch-pound (3.46 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test*—(1) *Application*—(i) *General*. Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall

be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags*. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pounds ± 0.5 pound (6.80 kilograms) of force applied in any direction.

(2) *Test equipment*—(i) *Clamps*. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device*. The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of ± 0.5 pound (± 255 grams).

(3) *Testing procedure*. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches ± 0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of $\frac{1}{32}$ inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface

is parallel to the surface under test. A direct force of 25 pounds ± 0.5 pound (11.4 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1485, Jan. 7, 1975; 40 FR 6210, Feb. 10, 1975; 40 FR 16192, Apr. 10, 1975; as amended at 56 FR 10, Jan. 2, 1991]

§ 1500.53 Test methods for simulating use and abuse of toys and other articles intended for use by children over 36 but not over 96 months of age.

(a) *Application.* The test methods described in this section shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use by children over 36 but not over 96 months of age in conjunction with § 1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 10.0 pounds ± 0.01 pound (4.6 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* except as provided in paragraph (b)(4) (i) and (ii) of this section, the toy shall be dropped four times from a height of 3 feet ± 0.5 inch (0.92 meter) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop,

the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters) shall be tested for impact in accordance with paragraph (b)(4)(iii) of this subsection. The base area for toys having permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4) (i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

(c) *Bite test*—(1) *Application.* A toy (or component) that is a mouth toy shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch ± 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch ± 0.002 inch (0.5 centimeter) for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of § 1500.51.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of the contract mechanism, and a test load increasing to 100 pounds ± 0.5 pound (45.50 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or

other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 15 pounds ± 0.5 pound (6.80 kilograms) applied perpendicularly to the major axis of the component at a point 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches ± 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test—(1) Application—(i) General.* A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components.* Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment—(i) Loading device.* The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of ± 0.2 inch-pound (± 0.23 kilogram-centimeter).

(ii) *Clamp.* The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure.* With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the

test object or component. A torque of 4 inch-pounds ± 0.2 inch-pound (4.60 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 4 inch-pounds ± 0.2 inch-pound (4.60 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test—(1) Application—(i) General.* Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags.* A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pounds ± 0.5 pound (6.80 kilograms) of force applied in any direction.

(2) *Test equipment—(i) Clamps.* One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device.* The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* With the test sample fastened in a convenient position, and appropriate clamp shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the

test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches \pm 0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of $\frac{1}{32}$ inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of \pm 0.5 pound (\pm 225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 30 pounds \pm 0.5 pound (13.6 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1486, Jan. 7, 1975; 40 FR 16192, Apr. 10, 1975, as amended at 56 FR 10, Jan. 2, 1991]

§ 1500.81 Exemptions for food, drugs, cosmetics, and fuels.

(a) *Food, drugs, and cosmetics*. Substances subject to the Federal Food, Drug, and Cosmetic Act are exempted by section 2(f)(2) of the act; but where a food, drug, or cosmetic offers a substantial risk of injury or illness from any handling or use that is customary or usual it may be regarded as misbranded under the Federal Food, Drug, and Cosmetic Act because its label fails to reveal material facts with respect to consequences that may result from use of the article (21 U.S.C. 321(n)) when its label fails to bear information to alert the householder to this hazard.

(b) *Fuels*. A substance intended to be used as a fuel is exempt from the requirements of the act when in containers that are intended to be or are installed as part of the heating, cooling, or refrigeration system of a house. A portable container used for delivery or temporary or additional storage, and containing a substance that is a hazardous substance as defined in section 2(f) of the act, is not exempt from the labeling prescribed in section 2(p)

of the act, even though it contains a fuel to be used in the heating, cooking, or refrigeration system of a house.

§ 1500.82 Exemption from full labeling and other requirements.

(a) Any person who believes a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full label compliance otherwise applicable under the act, because of the size of the package or because of the minor hazard presented by the substance, or for other good and sufficient reason, may submit to the Commission a request for exemption under section 3(c) of the act, presenting facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health. The Commission shall determine on the basis of the facts submitted and all other available information whether the requested exemption is consistent with adequate protection of the public health and safety. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order published in the FEDERAL REGISTER.

(b) The Commission may on its own initiative determine on the basis of facts available to it that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full labeling compliance otherwise applicable under the act because of the size of the package or because of the minor hazard presented by the substance or for other good and sufficient reason. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

(c) Any person who believes a particular article should be exempted from being classified as a "banned hazardous substance" as defined by section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15)(i)(A)), because its functional purpose requires inclusion of a hazardous substance, it bears labeling giving adequate directions and warnings for safe use, and it is intended for use by children who have attained sufficient maturity, and may reasonably

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be expected, to read and heed such directions and warnings, may submit to the Commission a request for exemption under section 2(q)(1)(B)(i) of the act (repeated in proviso (I) under §1500.3(b)(15(i)), presenting facts in support of his contention. The commission shall determine on the basis of the facts submitted, and all other available information, whether the requested exemption is consistent with the purposes of the act. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

(d) On its own initiative, the Commission may determine on the basis of available facts that a particular banned hazardous substance should be exempted from section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15(i)(A)), because its functional purpose requires inclusion of a hazardous substance, it bears labeling giving adequate directions and warnings for safe use, and it is intended for use by children who have obtained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

§1500.83 Exemptions for small packages, minor hazards, and special circumstances.

(a) The following exemptions are granted for the labeling of hazardous substances under the provisions of §1500.82:

(1) When the sole hazard from a substance in a self-pressurized container is that it generates pressure or when the sole hazard from a substance is that it is flammable or extremely flammable, the name of the component which contributes the hazards need not be stated.

(2) Common matches, including book matches, wooden matches, and so-called “safety” matches are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the product being considered hazardous because of being an “extremely flammable solid” or “flammable solid” as defined in §1500.3(c)(6)(v) and (vi).

(3) Paper items such as newspapers, wrapping papers, toilet and cleansing tissues, and paper writing supplies are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being an “extremely flammable solid” or “flammable solid” as defined in §1500.3(c)(6)(v) and (vi).

(4) Thread, string, twine, rope, cord, and similar materials are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being an “extremely flammable solid” or “flammable solid” as defined in Sec. 1500.3(c)(6)(v) and (vi).

(5) Laboratory chemicals intended only for research or investigational and other laboratory uses (except those in home chemistry sets) are exempt from the requirements of placement provided in §1500.121 if all information required by that section and the act appears with the required prominence on the label panel adjacent to the main panel.

(6) [Reserved]

(7) Rigid or semirigid ballpoint ink cartridges are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), insofar as such requirements would be necessary because the ink contained therein is a “toxic” substance as defined in §1500.3(c)(2)(i), if:

(i) The ballpoint ink cartridge is of such construction that the ink will, under any reasonably foreseeable conditions of manipulation or use, emerge only from the ballpoint end;

(ii) When tested by the method described in §1500.3(c)(2)(i), the ink does not have an LD-50 single oral dose of less than 500 milligrams per kilogram of body weight of the test animal; and

(iii) The cartridge does not have a capacity of more than 2 grams of ink.

(8) Containers of paste shoe waxes, paste auto waxes, and paste furniture and floor waxes containing toluene (also known as toluol), xylene (also known as xylol), petroleum distillates, and/or turpentine in the concentrations described in §1500.14(a)(3) and (5) are exempt from the labeling requirements

of §1500.14(b)(3)(ii) and (5) if the viscosity of such products is sufficiently high so that they will not flow from their opened containers when inverted for 5 minutes at a temperature of 80 °F., and are exempt from bearing a flammability warning statement if the flammability of such waxes is due solely to the presence of solvents that have flashpoints above 80 °F. when tested by the method described in §1500.43.

(9) Porous-tip ink-marking devices are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the labeling requirements of §1500.14(b)(1), (2), and (3)(ii) and (iii) insofar as such requirements would be necessary because the ink contained therein is a toxic substance as defined in §1500.3(c)(2)(i), and/or because the ink contains 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates as defined in §1500.14(a)(3), and/or because the ink contains 10 percent or more by weight of ethylene glycol; provided that:

(i) The porous-tip ink-marking devices are of such construction that:

(A) The ink is held within the device by an absorbent material so that no free liquid is within the device; and

(B) Under any reasonably foreseeable conditions of manipulation and use, including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(ii)(A) The device has a capacity of not more than 10 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(B) The device has a capacity of not more than 12 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 3.0 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than 4 percent methyl alcohol by weight are exempt from the label statement "Cannot be made nonpoisonous" required by §1500.14(b)(4) if:

(i) The total amount of methyl alcohol by weight in the product does not exceed 15 percent; and

(ii) The contents of any container does not exceed 2 fluid ounces.

(11) Packages containing polishing or cleaning products which consist of a carrier of solid particulate or fibrous composition and which contain toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates in the concentrations described in §1500.14(a) (1) and (2) are exempt from the labeling requirements of §1500.14(b)(3)(ii) if such toluene, xylene, or petroleum distillate is fully absorbed by the solid, semisolid, or fibrous carrier and cannot be expressed therefrom with any reasonably foreseeable conditions of manipulation.

(12) Containers of dry ink intended to be used as a liquid ink after the addition of water are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the labeling requirements of §1500.14(b) (1) and (2) insofar as such requirements would be necessary because the dried ink contained therein is a toxic substance as defined in §1500.3(c)(2)(i) and/or because the ink contains 10 percent or more of ethylene glycol as defined in §1500.14(a)(2); provided that:

(i) When tested by the method described in §1500.3(c)(2)(i), the dry ink concentrate does not have an LD-50 (lethal dose, median; lethal for 50 percent or more of test group) single oral dose of less than 1 gram per kilogram of body weight of the test animal.

(ii) The dry ink concentrate enclosed in a single container does not weigh more than 75 milligrams.

(iii) The dry ink concentrate does not contain over 15 percent by weight of ethylene glycol.

(13) Containers of liquid and semi-solid substances such as viscous-type paints, varnishes, lacquers, roof coatings, rubber vulcanizing preparations, floor covering adhesives, glazing compounds, and other viscous products containing toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates in concentrations described in §1500.14(a)(3) are exempt from the labeling requirements of

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§1500.14(b)(3)(ii) insofar as that subdivision applies to such toluene, xylene, or petroleum distillates, provided that the viscosity of the substance or of any liquid that may separate or be present in the container is not less than 100 Saybolt universal seconds at 100 °F.

(14) Customer-owned portable containers that are filled by retail vendors with gasoline, kerosene (kerosine), or other petroleum distillates are exempt from the provision of section 2(p)(1)(A) of the act (which requires that the name and place of business of the manufacturer, distributor, packer, or seller appear on the label of such containers) provided that all the other label statements required by section 2(p)(1) of the act and §1500.14(b)(3) appear on the labels of containers of the substances named in this subparagraph.

(15) Cellulose sponges are exempt from the labeling requirements of section 2(p)(1) of the act and §1500.14(b)(1) insofar as such requirements would be necessary because they contain 10 percent or more of diethylene glycol as defined in §1500.14(a)(1), provided that:

(i) The cellulose sponge does not contain over 15 percent by weight of diethylene glycol; and

(ii) The diethylene glycol content is completely held by the absorbent cellulose material so that no free liquid is within the sponge as marketed.

(16) Containers of substances which include salt (sodium chloride) as a component are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the salt contained therein is present in a quantity sufficient to render the article “toxic” as defined in §1500.3(3)(2)(i), provided that the labels of such containers bear a conspicuous statement that the product contains salt.

(17) The labeling of substances containing 10 percent or more of ferrous oxalate is exempt from the requirement of §1500.129(f) that it bear the word “poison” which would be required for such concentration of a salt of oxalic acid.

(18) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material saturated with a

mixture of drycleaning solvents, are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the “flammable solid” hazard as defined in §1500.3(c)(6)(vi), provided that:

(i) The article is packaged in a sealed foil envelope;

(ii) The total amount of solvent in each package does not exceed 4.5 milliliters; and

(iii) The article will ignite only when in contact with an open flame, and when so ignited, the article burns with a sooty flame.

(19) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material containing methyl alcohol, are exempt from the labeling requirements of §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each package does not exceed 4.5 milliliters of which not more than 25 percent is methyl alcohol; and

(ii) The liquid is completely held by the absorbent materials so that no free liquid is within the packages marketed.

(20) Cigarette lighters containing petroleum distillate fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and §1500.14(b)(3) insofar as such requirements would be necessary because the petroleum distillate contained therein is flammable and because the substance is named in §1500.14(a)(3) as requiring special labeling, provided that:

(i) Such lighters contain not more than 10 cubic centimeters of fuel at the time of sale; and

(ii) Such fuel is contained in a sealed compartment that cannot be opened without the deliberate removal of the flush-set, screw-type refill plug of the lighter.

(21) Containers of dry granular fertilizers and dry granular plant foods are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the fertilizer or plant food contained therein is a toxic substance as defined in §1500.3(c)(2)(i), provided that:

(i) When tested by the method described in §1500.3(c)(2)(i), the product

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has a single dose LD-50 of not less than 3.0 grams per kilogram of body weight of the test animal;

(ii) The label of any such exempt dry granular fertilizers discloses the identity of each of the hazardous ingredients;

(iii) The label bears the name and address of the manufacturer, packer, distributor, or seller; and

(iv) The label bears the statement "Keep out of the reach of children" or its practical equivalent.

(22) Small plastic capsules containing a paste composed of powdered metal solder mixed with a liquid flux are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The capsule holds not more than one-half milliliter of the solder mixture;

(ii) The capsule is sold only as a component of a kit; and

(iii) Adequate caution statements appear on the carton of the kit and on any accompanying labeling which bears directions for use.

(23) Chemistry sets and other science education sets intended primarily for use by juveniles, and replacement containers of chemicals for such sets, are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The immediate container of each chemical that is hazardous as defined in the act and regulations thereunder bears on its main panel the name of such chemical, the appropriate signal word for that chemical, and the additional statement "Read back panel before using" (or "Read side panel before using," if appropriate) and bears on the back (or side) panel of the immediate container the remainder of the appropriate cautionary statement for the specific chemical in the container;

(ii) The experiment manual or other instruction book or booklet accompanying such set bears on the front page thereof, as a preface to any written matter in it (or on the cover, if any there be), the following caution statement within the borders of a rectangle and in the type size specified in §1500.121:

WARNING—This set contains chemicals that may be harmful if misused.

Read cautions on individual containers carefully. Not to be used by children except under adult supervision

; and

(iii) The outer carton of such set bears on the main display panel within the borders of a rectangle, and in the type size specified in §1500.121, the caution statement specified in paragraph (a)(23)(ii) of this section.

(24) Fire extinguishers containing fire extinguishing agents which are stored under pressure or which develop pressure under normal conditions of use are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements apply to the pressure hazard as defined in §1500.3(c)(7)(i), provided that:

(i) If the container is under pressure both during storage and under conditions of use, it shall be designed to withstand a pressure of at least 6 times the charging pressure at 70 °F., except that carbon dioxide extinguishers shall be constructed and tested in accordance with applicable Interstate Commerce Commission specifications; or

(ii) If the container is under pressure only during conditions of use, it shall be designed to withstand a pressure of not less than 5 times the maximum pressure developed under closed nozzle conditions at 70 °F. or 1½ times the maximum pressure developed under closed nozzle conditions at 120 °F., whichever is greater.

(25) Cleaning and spot removing kits intended for use in cleaning carpets, furniture, and other household objects; kits intended for use in coating, painting, antiquing, and similarly processing furniture, furnishings, equipment, sidings, and various other surfaces; and kits intended for use in photographic color processing are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the requirements of §1500.14, provided that:

(i) The immediate container of each hazardous substance in the kit is fully labeled and in conformance with the requirements of the act and regulations thereunder; and

(ii) The carton of the kit bears on the main display panel (or panels) within a

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borderline, and in the type size specified in §1500.121, the caution statement “(Insert proper signal word as specified in paragraph (a)(25)(iii) of this section). This kit contains the following chemicals that may be harmful if misused: (List hazardous chemical components by name.) Read cautions on individual containers carefully. Keep out of the reach of children.”

(iii) If either the word “POISON” or “DANGER” is required on the container of any component of the kit, the same word shall be required to appear as part of the caution statement on the kit carton. If both “POISON” and “DANGER” are required in the labeling of any component or components in the kit, the word “POISON” shall be used. In all other cases the word “WARNING” or “CAUTION” shall be used.

(26) Packages containing articles intended as single-use spot removers and containing methyl alcohol are exempt from the labeling specified in §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each unit does not exceed 1 milliliter, of which not more than 40 percent is methyl alcohol;

(ii) The liquid is contained in a sealed glass ampoule enclosed in a plastic container with a firmly attached absorbent wick at one end through which the liquid from the crushed ampoule must pass, under the contemplated conditions of use; and

(iii) The labeling of each package of the cleaner bears the statement “WARNING—Keep out of the reach of children,” or its practical equivalent, and the name and place of business of the manufacturer, packer, distributor, or seller.

(27) Packaged fireworks assortments intended for retail distribution are exempt from section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The package contains only fireworks devices suitable for use by the public and designed primarily to produce visible effects by combustion, except that small devices designed to produce audible effects may also be included if the audible effect is produced by a charge of not more than 2 grains of pyrotechnic composition;

(ii) Each individual article in the assortment is fully labeled and in conformance with the requirements of the act and regulations thereunder; and

(iii) The outer package bears on the main display panel (or panels), within the borders of a rectangle and in the type size specified in §1500.121, the caution statement “WARNING—This assortment contains items that may be hazardous if misused and should be used only under adult supervision. IMPORTANT—Read cautions on individual items carefully.” (See also §1500.14(b)(7); §1500.17(a) (3), (8) and (9); §1500.85(a)(2); and part 1507).

(28) Packages containing felt pads impregnated with ethylene glycol are exempt from the labeling requirements of §1500.14(b)(1), if:

(i) The total amount of ethylene glycol in each pad does not exceed 1 gram; and

(ii) The liquid is held by the felt pad so that no free ethylene glycol is within the package.

(29) Cigarette lighters containing butane and/or isobutane fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would otherwise be necessary because the fuel therein is extremely flammable and under pressure, provided that:

(i) The lighters contain not more than 12 grams of fuel at the time of sale; and

(ii) The fuel reservoir is designed to withstand a pressure of at least 1½ times the maximum pressure which will be developed in the container at 120 °F.

(30) The outer retail containers of solder kits each consisting of a small tube of flux partially surrounded by a winding of wire-type cadmium-free silver solder are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The metal solder contains no cadmium and is not otherwise hazardous under the provisions of the act;

(ii) The tube of flux in the kit is fully labeled and in conformance with the act and regulations thereunder, and any accompanying literature that bears directions for use also bears all

the information required by section 2(p) of the act; and

(iii) The main panel of the outer container bears in type size specified in §1500.121 the following: (A) The signal word; (B) a statement of principal hazard or hazards; (C) the statement "Keep out of the reach of children," or its practical equivalent; and (D) instructions to read other cautionary instructions on the tube of flux within.

(31) Visual novelty devices consisting of sealed units, each of which unit is a steel and glass cell containing perchloroethylene (among other things), are exempt from the requirements of §1500.121(a) that would otherwise require a portion of the warning statement to appear on the glass face of the device, provided that:

(i) The device contains not more than 105 milliliters of perchloroethylene and contains no other component that contributes substantially to the hazard; and

(ii) The following cautionary statement appears on the device (other than on the bottom) in the type size specified in §1500.121 (c) and (d):

CAUTION—IF BROKEN, RESULTANT VAPORS
MAY BE HARMFUL

Contains perchloroethylene. Do not expose to extreme heat. If broken indoors, open windows and doors until all odor of chemical is gone.

Keep out of the reach of children.

A practical equivalent may be substituted for the statement "Keep out of the reach of children."

(32) Hollow plastic toys containing mineral oil are exempt from the labeling specified in §1500.14(b)(3)(ii), if:

(i) The article contains no other ingredient that would cause it to possess the aspiration hazard specified in §1500.14(b)(3)(ii);

(ii) The article contains not more than 6 fluid ounces of mineral oil;

(iii) The mineral oil has a viscosity of at least 70 Saybolt universal seconds at 100 °F.;

(iv) The mineral oil meets the specifications in the N.F. for light liquid petrolatum; and

(v) The container bears the statement "CAUTION—Contains light liquid petrolatum N.F. Discard if broken or leak develops."

(33) Containers of mineral oil having a capacity of not more than 1 fluid ounce and intended for use in producing a smoke effect for toy trains are exempt from the labeling specified in §1500.14(b)(3), if:

(i) The mineral oil meets the specifications in the N.F. for light liquid petrolatum;

(ii) The mineral oil has a viscosity of at least 130 Saybolt universal seconds at 100 °F.;

(iii) The article contains no other ingredient that contributes to the hazard; and

(iv) The label declares the presence light liquid petrolatum and the name and place of business of the manufacturer, packer, distributor, or seller.

(34) Viscous products containing more than 4 percent by weight of methyl alcohol, such as adhesives, asphalt-base roof and tank coatings, and similar products, are exempt from bearing the special labeling required by §1500.14(b)(4), if:

(i) The product contains not more than 15 percent by weight of methyl alcohol;

(ii) The methyl alcohol does not separate from the other ingredients upon standing or through any foreseeable use or manipulation;

(iii) The viscosity of the product is not less than 7,000 centipoises at 77 °F., unless the product is packaged in a pressurized container and is dispensed as a liquid unsuitable for drinking; and

(iv) The labeling bears the statement "Contains methyl alcohol. Use only in well-ventilated area. Keep out of the reach of children."

(35) Individual detonators or blasting caps are exempt from bearing the statement, "Keep out of the reach of children," or its practical equivalent, if:

(i) Each detonator or cap bears conspicuously in the largest type size practicable the statement, "DANGEROUS—BLASTING CAPS—EXPLOSIVE" or "DANGEROUS—DETONATOR—EXPLOSIVE"; and

(ii) The outer carton and any accompanying printed matter bear appropriate, complete cautionary labeling.

(36) Individual toy rocket propellant devices and separate delay train and/or

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recovery system activation devices intended for use with premanufactured model rocket engines are exempt from bearing the full labeling required by section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the articles are flammable or generate pressure, provided that:

(i) The devices are designed and constructed in accordance with the specifications in §1500.85(a)(8), (9) or (14);

(ii) Each individual device or retail package of devices bears the following:

(A) The statement “WARNING—FLAMMABLE: Read instructions before use”;

(B) The common or usual name of the article;

(C) A statement of the type of engine and use classification;

(D) Instructions for safe disposal; and

(E) Name and place of business of manufacturer or distributor; and

(iii) Each individual rocket engine or retail package of rocket engines distributed to users is accompanied by an instruction sheet bearing complete cautionary labeling and instructions for safe use and handling of the individual rocket engines.

(37) Glues with a cyanoacrylate base in packages containing 3 grams or less are exempt from the requirement of §1500.121(d) that labeling which is permitted to appear elsewhere than on the main label panel must be in type size no smaller than 6 point type, provided that:

(i) The main panel of the immediate container bears both the proper signal word and a statement of the principal hazard or hazards associated with this product, as provided by §1500.121 (a) and (c);

(ii) The main panel of the immediate container also bears an instruction to read carefully additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. The instruction to read additional warnings must comply with the size, placement, conspicuousness, and contrast requirements of §1500.121; and

(iii) The remainder of the cautionary labeling required by the act that is not on the main label panel must appear elsewhere on the label in legible type

and must appear on any outer package, accompanying leaflet, and display card. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed on a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer. That labeling which must appear on any outer package, accompanying leaflet, tag, or other suitable material must comply with the size, placement, contrast, and conspicuousness requirements of §1500.121(d).

(38) Rigid or semi-rigid writing instruments and ink cartridges having a writing point and an ink reservoir are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i) of the regulations) and of regulations issued under section 3(b) of the act (§1500.14(b)(1, 2)) insofar as such requirements would be necessary because the ink contained therein is a “toxic” substance as defined in §1500.3(c)(2)(i) and/or because the ink contains 10 percent or more by weight ethylene glycol or diethylene glycol, if all the following conditions are met:

(i) The writing instrument or cartridge is of such construction that the ink will, under any reasonably foreseeable condition of manipulation and use, emerge only from the writing tip.

(ii) When tested by the method described in §1500.3(c)(2)(i), the ink does not have an LD-50 single oral dose of less than 2.5 grams per kilogram of body weight of the test animal.

(iii) If the ink contains ethylene glycol or diethylene glycol, the amount of such substance, either singly or in combination, does not exceed 1 gram per writing instrument or cartridge.

(iv) The amount of ink in the writing instrument or cartridge does not exceed 3 grams.

[38 FR 27012, Sept. 27, 1973; 42 FR 33026, June 29, 1977, as amended at 43 FR 32745, July 28, 1978; 43 FR 47176, Oct. 13, 1978; 44 FR 42678, July 20, 1979; 46 FR 11513, Feb. 9, 1981; 48 FR 16, Jan. 3, 1983; 68 FR 4699, Jan. 30, 2003; 74 FR 27249, June 9, 2009; 75 FR 49380, Aug. 13, 2010]

§ 1500.85 Exemptions from classification as banned hazardous substances.

(a) The term *banned hazardous substances* as used in section 2(q)(1)(A) of the act shall not apply to the following articles provided that these articles bear labeling giving adequate directions and warnings for safe use:

(1) Chemistry sets and other science education sets intended primarily for juveniles, and replacement components for such sets, when labeled in accordance with § 1500.83(a)(23).

(2) Firecrackers designed to produce audible effects, if the audible effect is produced by a charge of not more than 50 milligrams (.772 grains) of pyrotechnic composition. (See also § 1500.14(b)(7); § 1500.17(a) (3), (8) and (9); and part 1507).

(3) [Reserved]

(4) Educational materials such as art materials, preserved biological specimens, laboratory chemicals, and other articles intended and used for educational purposes.

(5) Liquid fuels containing more than 4 percent by weight of methyl alcohol that are intended and used for operation of miniature engines for model airplanes, boats, cars, etc.

(6) Novelties consisting of a mixture of polyvinyl acetate, U.S. Certified Colors, and not more than 25 percent by weight of acetone, and intended for blowing plastic balloons.

(7) Games containing, as the sole hazardous component, a self-pressurized container of soap solution or similar foam-generating mixture provided that the foam-generating component has no hazards other than being in a self-pressurized container.

(8) Model rocket propellant devices designed for use in light-weight, recoverable, and re-flyable model rockets, provided such devices:

(i) Are designed to be ignited by electrical means.

(ii) Contain no more than 62.5 grams (2.2 ounces) of propellant material and produce less than 80 newton-seconds (17.92 pound seconds) of total impulse with thrust duration not less than 0.050 second.

(iii) Are constructed such that all the chemical ingredients are preloaded into a cylindrical paper or similarly

constructed nonmetallic tube that will not fragment into sharp, hard pieces.

(iv) Are designed so that they will not burst under normal conditions of use, are incapable of spontaneous ignition, and do not contain any type of explosive or pyrotechnic warhead other than a small parachute or recovery-system activation charge.

(9) Separate delay train and/or recovery system activation devices intended for use with premanufactured model rocket engines wherein all of the chemical ingredients are preloaded so the user does not handle any chemical ingredient and are so designed that the main casing or container does not rupture during operation.

(10) Solid fuel pellets intended for use in miniature jet engines for propelling model jet airplanes, speed boats, racing cars, and similar models, provided such solid fuel pellets:

(i) Weigh not more than 11.5 grams each.

(ii) Are coated with a protective resinous film.

(iii) Contain not more than 35 percent potassium dichromate.

(iv) Produce a maximum thrust of not more than 7½ ounces when used as directed.

(v) Burn not longer than 12 seconds each when used as directed.

(11) Fuses intended for igniting fuel pellets exempt under subparagraph (10) of this paragraph.

(12) Kits intended for construction of model rockets and jet propelled model airplanes requiring the use of difluorodichloromethane as a propellant, provided the outer carton bears on the main panel in conspicuous type size the statement "WARNING—Carefully read instructions and cautions before use."

(13) Flammable wire materials intended for electro-mechanical actuation and release devices for model kits described in paragraph (12) of this section, provided each wire does not exceed 15 milligrams in weight.

(14) Model rocket propellant devices (model rocket motors) designed to propel rocket-powered model cars, provided—

(i) Such devices:

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(A) Are designed to be ignited electrically and are intended to be operated from a minimum distance of 15 feet (4.6 m) away;

(B) Contain no more than 4 g. of propellant material and produce no more than 2.5 Newton-seconds of total impulse with a thrust duration not less than 0.050 seconds;

(C) Are constructed such that all the chemical ingredients are pre-loaded into a cylindrical paper or similarly constructed non-metallic tube that will not fragment into sharp, hard pieces;

(D) Are designed so that they will not burst under normal conditions of use, are incapable of spontaneous ignition, and do not contain any type of explosive or pyrotechnic warhead other than a small recovery system activation charge;

(E) Bear labeling, including labeling that the devices are intended for use by persons age 12 and older, and include instructions providing adequate warnings and instructions for safe use; and

(F) Comply with the requirements of 16 CFR 1500.83(a)(36)(ii and iii); and

(ii) The surface vehicles intended for use with such devices:

(A) Are lightweight, weighing no more than 3.0 oz. (85 grams), and constructed mainly of materials such as balsa wood or plastics that will not fragment into sharp, hard pieces;

(B) Are designed to utilize a braking system such as a parachute or shock absorbing stopping mechanism;

(C) Are designed so that they cannot accept propellant devices measuring larger than 0.5" (13 mm) in diameter and 1.75" (44 mm) in length;

(D) Are designed so that the engine mount is permanently attached by the manufacturer to a track or track line that controls the vehicle's direction for the duration of its movement;

(E) Are not designed to carry any type of explosive or pyrotechnic material other than the model rocket motor used for primary propulsion;

(F) Bear labeling and include instructions providing adequate warnings and instructions for safe use; and

(G) Are designed to operate on a track or line that controls the vehicles' direction for the duration of their movement and either cannot operate off the track or line or, if operated off

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the track or line, are unstable and fail to operate in a guided fashion so that they will not strike the operator or bystanders.

(b) [Reserved]

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22935, June 8, 1976; 42 FR 43391, Aug. 29, 1977; 48 FR 16, Jan. 3, 1983; 68 FR 4699, Jan. 30, 2003]

§ 1500.86 Exemptions from classification as a banned toy or other banned article for use by children.

(a) The term *banned hazardous substance* as used in section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15)(i)(A)) of the act shall not apply to the following articles:

(1) Toy rattles described in §1500.18(a)(1) in which the rigid wires, sharp protrusions, or loose small objects are internal and provided that such rattles are constructed so that they will not break or deform to expose or release the contents either in normal use or when subjected to reasonably foreseeable damage or abuse.

(2) Dolls and stuffed animals and other similar toys described in §1500.18(a)(3) in which the components that have the potential for causing laceration, puncture wound injury, or other similar injury are internal, provided such dolls, stuffed animals, and other similar toys are constructed so that they will not break or deform to expose such components either in normal use or when subjected to reasonably foreseeable damage or abuse.

(3) [Reserved]

(4) Any article known as a "baby-bouncer" or "walker-jumper" and any other similar article (referred to in this paragraph as "article(s)"), except an infant walker subject to part 1216 of this chapter, described in §1500.18(a)(6) provided:

(i) The frames are designed and constructed in a manner to prevent injury from any scissoring, shearing, or pinching when the members of the frame or other components rotate about a common axis or fastening point or otherwise move relative to one another; and

(ii) Any coil springs which expand when the article is subjected to a force that will extend the spring to its maximum distance so that a space between successive coils is greater than one-

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eighth inch (0.125 inch) are covered or otherwise designed to prevent injuries; and

(iii) All holes larger than one-eighth inch (0.125 inch) in diameter and slots, cracks, or hinged components in any portion of the article through which a child could insert, in whole or in part a finger, toe, or any other part of the anatomy are guarded or otherwise designed to prevent injuries; and

(iv) The articles are designed and constructed to prevent accidental collapse while in use; and

(v) The articles are designed and constructed in a manner that eliminates from any portion of the article the possibility of presenting a mechanical hazard through pinching, bruising, lacerating, crushing, breaking, amputating, or otherwise injuring portions of the human body when in normal use or when subjected to reasonably foreseeable damage or abuse; and

(vi) Any article which is introduced into interstate commerce after the effective date of this subparagraph is labeled:

(A) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller; and

(B) With a code mark on the article itself and on the package containing the article or on the shipping container, in addition to the invoice(s) or shipping document(s), which code mark will permit future identification by the manufacturer of any given model (the manufacturer shall change the model number whenever the article undergoes a significant structural or design modification); and

(vii) The manufacturer or importer of the article shall make, keep, and maintain for 3 years records of sale, distribution, and results of inspections and tests conducted in accordance with this subparagraph and shall make such records available at all reasonable hours upon request by any officer or employee of the Consumer Product Safety Commission and shall permit such officer or employee to inspect and copy such records, to make such stock inventories as he deems necessary, and to otherwise check the correctness of such records.

(5) Clacker balls described in §1500.18(a)(7) that have been designed, manufactured, assembled, labeled, and tested in accordance with the following requirements, and when tested at the point of production or while in interstate commerce or while held for sale after shipment in interstate commerce do not exceed the failure rate requirements of the table in paragraph (a)(5)(vi) of this section:

(i) The toy shall be so designed and fabricated that:

(A) Each ball: Weighs less than 50 grams; will not shatter, crack, or chip; is free of cracks, flash (ridges due to imperfect molding), and crazing (tiny surface cracks); and is free of rough or sharp edges around any hole where the cord enters or over any surface with which the cord may make contact. Each ball is free of internal voids (holes, cavities, or air bubbles) if the balls are made of materials other than those materials (such as ABS (acrylonitrile butadiene styrene), nylon, and high-impact polystyrene) that are injection-molded and possess high-impact characteristics.

(B) The cord: Is of high tensile strength, synthetic fibers that are braided or woven, having a breaking strength in excess of 445 Newtons (100 pounds); is free of fraying or any other defect that might tend to reduce its strength in use; is not molded in balls made of casting resins which tend to wick up or run up on the outside of the cord; and is affixed to a ball at the center of the horizontal plane of the ball when it is suspended by the cord. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may have a minimum cord breaking strength of less than 445 Newtons (100 pounds), as computed by the following formula:

Adjusted Cord Breaking Strength in Newtons = $0.1382(m_b)(R_p)$, where m_b = mass of a single ball in grams and R_p = pivot length in mm.

(C) When the cord is attached to the ball by means of a knot, the end beneath the knot is chemically fused or otherwise treated to prevent the knot from slipping out or untying in use.

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(ii) The toy shall be tested at the time of production:

(A) By using the sampling procedure described in the table in subdivision (vi) of this subparagraph to determine the number of units to be tested.

(B) By subjecting each ball tested to 10 drops of a 2.25 kg (5-pound) steel impact rod or weight (57-mm (2¼-inch) diameter with a flat head) dropped 1220 mm (48 inches) in a vented steel or aluminum tube (60-mm (2⅜-inch) inside diameter) when the ball is placed on a steel or cast iron mount. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may be tested by dropping the impact weight from a height of less than 1220 mm (48 in.), where the height is computed as follows:

Adjusted drop height in mm= $179 \times 10^{-5} (m_b)$ (R_p^2), where m_b =mass of a single ball in grams and

R_p =pivot length in mm.

Any ball showing any chipping, cracking, or shattering shall be counted as a failure within the meaning of the third column of the table in paragraph (a)(5)(vi) of this section.

(C) By inspecting each ball tested for smoothness of finish on any surface of the ball which may come in contact with the cord during use. A cotton swab shall be rubbed vigorously over each such surface or area of the ball; if any cotton fibers are removed, the ball shall be counted as a failure within the meaning of the fourth column of the table in subdivision (vi) of this paragraph. The toy shall also be checked to ascertain that there is no visibly perceptible "wicking up" or "running up" of the casting resins on the outside of the cord in the vicinity where the ball is attached.

(D) By fully assembling the toy and testing the cord in such a manner as to test both the strength of the cord and the adequacy with which the cord is attached to the ball and any holding device such as a tab or ring included in the assembly. The fully assembled article shall be vertically suspended by one ball and a 445-Newton (100-pound) test applied to the bottom ball. Clacker balls where the mass of each ball is less

than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may be tested with a force of under 445 Newtons (100 pounds). The test force for these clacker balls shall be the same as the cord breaking strength calculated in §1500.86(a)(5)(i)(B). Any breaking, fraying, or unraveling of the cord or any sign of slipping, loosening, or unfastening shall be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section.

(E) By additionally subjecting any ring or other holding device to a 222-Newton (50-pound) test load applied to both cords; the holding device is to be securely fixed horizontally in a suitable clamp in such a manner as to support 50 percent of the area of such holding device and the balls are suspended freely. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may have their holding device tested with a force of less than 222 Newtons (50 pounds). The holding device test force for these clacker balls shall be half of the cord breaking strength calculated in §1500.86(a)(5)(i)(B). Any breaking, cracking, or crazing of the ring or other holding device shall be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section.

(F) By cutting each ball tested in half and then cutting each half perpendicularly to the first cut into three or more pieces of approximately equal thickness. Each portion is to be inspected before and after cutting, and any ball showing any flash, crack, crazing, or internal voids on such inspection is to be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section. Balls that are injection-molded and possess high-impact characteristics (such as injection-molded balls made of ABS, nylon, or high-impact polystyrene) though exempt from the requirements that there be no internal voids, must be tested to determine the presence of any flash, crack or crazing. A transparent ball shall be subjected to

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the same requirements except that it may be visually inspected without cutting.

(iii) The toy shall be fully assembled for use at time of sale, including the proper attachments of balls, cords, knots, loops, or other holding devices.

(iv) The toy shall be labeled:

(A) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller.

(B) To bear on the toy itself and/or the package containing the toy and/or the shipping container, in addition to the invoice(s) and shipping document(s), a code or mark in a form and manner that will permit future identification of any given batch, lot, or shipment by the manufacturer.

(C) To bear a conspicuous warning statement on the main panel of the retail container and display carton and on any accompanying literature: That if cracks develop in a ball or if the cord becomes frayed or loose or unfastened, use of the toy should be discontinued; and if a ring or loop or other holding device is present, the statement "In use, the ring or loop must be placed around the middle finger and the two cords positioned over the forefinger

and held securely between the thumb and forefinger," or words to that effect which will provide adequate instructions and warnings to prevent the holding device from accidentally slipping out of the hand. Such statements shall be printed in sharply contrasting color within a borderline and in letters at least 6 mm (¼ inch) high on the main panel of the container and at least 3 mm (⅛) high on all accompanying literature.

(v) The manufacturer of the toy shall make, keep, and maintain for 3 years records of sale, distribution, and results of inspections and tests conducted in accordance with this subparagraph and shall make such records available upon request at all reasonable hours by any officer or employee of the Consumer Product Safety Commission, and shall permit such officer or employee to inspect and copy such records and to make such inventories of stock as he deems necessary and otherwise to check the correctness of such records.

(vi) The lot size, sample size, and failure rate for testing clacker balls are as follows:

Number of units in batch, shipment, delivery, lot, or retail stock	Number of units in random sample	Failure rate constituting rejection when testing per § 1500.86(a)(5)(ii)(B)	Failure rate constituting rejection when testing per § 1500.86(a)(5)(ii)(C), (D), (E), and (F)
50 or less	8	1	1
51 to 90	13	1	1
91 to 150	20	1	1
151 to 280	32	1	2
281 to 500	50	1	2
501 to 1,200	80	2	4
1,201 to 3,200	125	2	6
3,201 to 10,000	200	3	10
10,001 to 35,000	315	4	16
35,001 to 150,000	500	6	25
150,001 to 500,000	800	8	40
500,001 and over	1,250	11	62

(vii) Applicability of the exemption provided by this paragraph shall be determined through use of the table in paragraph (a)(5)(vi) of this section. A random sample of the number of articles as specified in the second column of the table shall be selected according to the number of articles in a particular batch, shipment, delivery, lot, or retail stock per the first column. A failure rate as shown in either the third or fourth column shall indicate

that the entire batch, shipment, delivery, lot, or retail stock has failed and thus is not exempted under this paragraph from classification as a banned hazardous substance.

(6) [Reserved]

(7) Dive sticks and similar articles described in §1500.18(a)(19) that come to rest at the bottom of a container of water in a position in which the long axis of the article is greater than 45 degrees from vertical when measured in

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accordance with the following test method:

(i) Test equipment.

(A) A container that is filled with tap water to a depth at least 3 inches [76 mm] greater than the longest dimension of the dive stick. The container shall:

(1) Be sufficiently wide to allow the dive stick to lie along the bottom with its long axis in a horizontal position,

(2) Have clear side walls to permit observation of the dive stick under water, and

(3) Be placed on a level surface and have a flat bottom.

(B) A protractor or other suitable angle measurement device that has an indicator for 45 degrees from vertical.

(ii) Testing procedure

(A) If the dive stick is sold such that the consumer is required to attach an additional component(s) to the dive stick, then the product shall be tested both with and without the attachment(s).

(B) From just above the water surface, drop the dive stick into the container.

(C) Let the dive stick sink and come to rest at the bottom of the container. If the dive stick is designed so that the weight can be adjusted by adding water or other substance, adjust the weight so that the dive stick sinks and comes to rest with its long axis positioned as close to vertical as possible.

(D) Align the angle measurement device alongside the dive stick underwater and wait for the dive stick to come to rest if there is any water disturbance. Determine whether the long axis of the dive stick is greater than or less than 45 degrees from vertical.

(8) Dive sticks and similar articles described in §1500.18(a)(19) in which the maximum force measured in the following test method is less than 5-lbf [22N]. The test shall be conducted in the ambient environment of the laboratory and not under water.

(i) Test equipment.

(A) A compression rig that has a force gauge or equivalent device that is calibrated for force measurements within a minimum range of 0 to 5 lbf [0–22 N] and with an accuracy of ±0.1 lbf [±0.44 N] or better. The test rig shall have a system to guide this force appli-

cation in the vertical direction and shall have a means to adjust the rate of load application.

(B) Compression disk—the loading device that is attached to the force gauge shall be a rigid metal disk with a minimum diameter of 1.125 inches [29 mm].

(C) Vise or other clamping device.

(ii) Testing procedure

(A) Position the bottom of the dive stick in the clamping device so that the longest axis of the dive stick is vertical. The bottom end of the dive stick is the end that sinks to the bottom of a pool of water. Secure the bottom of the dive stick in the clamp such that the clamping mechanism covers no more than the bottom ½ inch [13 mm] of the dive stick.

(B) Apply a downward force at a rate of 0.05 in/sec (±0.01 in/sec) [1.3 mm/sec ±0.3 mm/sec] at the top of the dive stick with the compression disk positioned so that the plane of the disk contact surface is perpendicular to the long axis of the dive stick.

(C) Apply the load for a period of 40 seconds or until the maximum recorded force exceeds 5-lbf [22 N].

(D) Record the maximum force that was measured during the test.

(b) [Reserved]

(9) Boston Billow Nursing Pillow and substantially similar nursing pillows that are designed to be used only as a nursing aide for breastfeeding mothers. For example, are tubular in form, C- or crescent-shaped to fit around a nursing mother's waist, round in circumference and filled with granular material.

[38 FR 27012, Sept. 27, 1973, as amended at 53 FR 46839, Nov. 18, 1988; 59 FR 9076, 9077, Feb. 25, 1994; 66 FR 13651, Mar. 7, 2001; 68 FR 70140, Dec. 17, 2003; 73 FR 77495, Dec. 19, 2008; 75 FR 35282, June 21, 2010; 78 FR 66841, Nov. 7, 2013]

§1500.87 Children's products containing lead: inaccessible component parts.

(a) The Consumer Product Safety Improvement Act (CPSIA) provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or

intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm after three years, unless the Commission determines that it is not technologically feasible to have this lower limit.

(b) Section 101 (b)(2) of the CPSIA provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child.

(c) Section 101(b)(2)(B) of the CPSIA directs the Commission to promulgate by August 14, 2009, this interpretative rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible.

(d) The accessibility probes specified for sharp points or edges under the Commission's regulations at 16 CFR 1500.48–1500.49 will be used to assess the accessibility of lead-component parts of a children's product. A lead-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A lead-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For products intended for children that are 18 months of age or less, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of §1500.51(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For products intended for children that are over 18 months but not over 36 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of §1500.52(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For products intended for children that are over 36 months but not over 96 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of §1500.53(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For products intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of §1500.53(c)) intended for children aged 37–96 months will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(i) A children's product that is or contains a lead-containing part which is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child unless the product or part of the product in one dimension is smaller than 5 centimeters.

(j) The intentional disassembly or destruction of products by children older than age 8 years by means or knowledge not generally available to younger children, including use of tools, will not be considered in evaluating products for accessibility of lead-containing components.

[74 FR 39540, Aug. 7, 2009]

§ 1500.88 Exemptions from lead limits under section 101 of the Consumer Product Safety Improvement Act for certain electronic devices.

(a) The Consumer Product Safety Improvement Act (CPSIA) provides for

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specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to meet this lower limit. Section 101(b)(2) of the CPSIA further provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child.

(b) Section 101(b)(4) of the CPSIA provides that if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, the Commission must issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices and establish a compliance schedule unless the Commission determines that full compliance is not technologically feasible within a schedule set by the Commission.

(c) Certain accessible lead-containing component parts in children's electronic devices unable to meet the lead limits set forth in paragraph (a) of this section due to technological infeasibility are granted the exemptions that follow in paragraph (d) of this section below, provided that use of lead is necessary for the proper electronic functioning of the component part and it is not technologically feasible for the component part to meet the lead con-

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tent limits set forth in paragraph (a) of this section.

(d) Exemptions for lead as used in certain electronic components parts in children's electronic devices include:

(1) Lead blended into the glass of cathode ray tubes, electronic components, and fluorescent tubes.

(2) Lead used as an alloying element in steel. The maximum amount of lead shall be less than 0.35% by weight (3,500 ppm).

(3) Lead used in the manufacture of aluminum. The maximum amount of lead shall be less than 0.4% by weight (4,000 ppm).

(4) Lead used in copper-based alloys. The maximum amount of lead shall be less than 4% by weight (40,000 ppm).

(5) Lead used in lead-bronze bearing shells and bushings.

(6) Lead used in compliant pin connector systems.

(7) Lead used in optical and filter glass.

(8) Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring, as well as in print pastes.

(9) Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

(e) Components of electronic devices that are removable or replaceable, such as battery packs and light bulbs that are inaccessible when the product is assembled in functional form or are otherwise granted an exemption, are not subject to the lead limits in paragraph (a) of this section.

(f) Commission staff is directed to re-evaluate and report to the Commission on the technological feasibility of compliance with the lead limits in paragraph (a) of this section for children's electronic devices, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions, no less than every five years after publication of a final rule in the FEDERAL REGISTER on children's electronic devices.

[75 FR 3158, Jan. 20, 2010]

§ 1500.89 Procedures and requirements for determinations regarding lead content of materials or products under section 101(a) of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

(b) The Commission may, either on its own initiative or upon the request of any interested person, make a determination that a material or product does not contain leads levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable.

(c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section.

(d) To request a determination under paragraph (b) of this section, the request must:

(1) Be e-mailed to *cpsc-os@cpsc.gov*, and titled "Section 101 Request for Lead Content Determination." Requests may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address.

(2) Be written in the English language.

(3) Contain the name and address, and e-mail address or telephone number, of the requestor.

(4) Provide documentation including:

(i) A detailed description of the product or material and how it is used by a child;

(ii) Representative data on the lead content of parts of the product or materials used in the production of a product;

(iii) All relevant data or information on manufacturing processes through which lead may be introduced into the material or product;

(iv) An assessment of the likelihood or lack thereof that the manufacturing processes will result in lead contamination of a material or product that ordinarily does not contain lead;

(v) All relevant data or information on the facilities used to manufacture the material or product, and any other materials used in the product;

(vi) An assessment of the likelihood or lack thereof that the use of leaded materials in a facility will result in lead contamination of a material or product that ordinarily does not contain lead;

(vii) Any other information relevant to the potential for lead content of the product or material to exceed the statutory lead limit specified in the request, that is 600 ppm, 300 ppm, or 100 ppm, as applicable;

(viii) Detailed information on the relied upon test methods for measuring lead content of products or materials including the type of equipment used or any other techniques employed and a statement as to why the data is representative of the lead content of such products or materials generally; and

(ix) Any data or information that is unfavorable to the request that is reasonably available to the requestor.

(e) Where a submission fails to meet all of the requirements of paragraph (d) of this section, the Office of the Secretary shall notify the person submitting it, describe the deficiency, and explain that the request may be resubmitted when the deficiency is corrected.

(f) Upon receipt of a complete request for a determination, the Office of Hazard Identification and Reduction

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(EXHR) will assess the request to determine whether the product or material is one that does not contain lead in excess of the limits as provided under paragraph (a) of this section. EXHR will make an initial recommendation within thirty (30) calendar days, to the extent practicable. EXHR may request an extension from the Executive Director of the CPSC, if necessary, to make its initial determination. A complete request is one that does not require additional information from the requestor for EXHR to make an initial recommendation to the Commission.

(g) Where the Office of Hazard Identification and Reduction's (EXHR) initial recommendation is to deny the request for a lead content determination, it will provide, in a staff memorandum to the Commission, submitted to the Commission for ballot vote, the basis for the denial with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are not presented. The Commission, by ballot vote, will render a decision on the staff's recommendation. The ballot vote and the staff memorandum will be posted on the CPSC Web site. Any determination by the Commission to grant a request will be published in the FEDERAL REGISTER for comment. If the Commission concludes that the request shall be denied, the requestor shall be notified in writing of the denial from the Office of the Secretary along with the official ballot results and the EXHR staff's memorandum of recommendation.

(h) Where the Office of Hazard Identification and Reduction's (EXHR) initial recommendation is to grant the request for a lead content determination, it will submit the basis for that recommendation to the Commission in a memorandum to be voted on by ballot, with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are presented. If the notice of proposed rulemaking (NPR) is published, it will invite public comment in the FEDERAL REGISTER. EXHR will review and evaluate any comments and supporting documentation before making its final recommendation to the Commission for final agency action, by staff memorandum submitted to the Commission.

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If the Commission, after review of the staff's final recommendation, determines that a material or product does not and would not exceed the lead content limits, it will decide by ballot vote, on whether to publish a final rule in the FEDERAL REGISTER.

(i) The filing of a request for a determination does not have the effect of staying the effect of any provision or limit under the statutes and regulations enforced by the Commission. Even though a request for a determination has been filed, unless a Commission determination is issued in final form after notice and comment, materials or products subject to the lead limits under section 101 of the CPSIA must be tested in accordance with section 102 of the CPSIA, unless the testing requirement is otherwise stayed by the Commission.

[74 FR 10480, Mar. 11, 2009]

§ 1500.90 Procedures and requirements for exclusions from lead limits under section 101(b) of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

(b) *Exclusion of certain materials or products and inaccessible component parts.* The CPSIA provides the following functional purpose exception from the lead limits stated in section 101(a) of the CPSIA.

(1) *Functional purpose exception*—(i) *In general.* The Commission, on its own initiative or upon petition by an interested party, shall grant an exception to the limit under paragraph (a) of this section for a specific product, class of product, material, or component part if the Commission, after notice and a hearing, determines that:

(A) The product, class of product, material, or component part requires the inclusion of lead because it is not practicable or not technologically feasible to manufacture such product, class of product, material, or component part, as the case may be, in accordance with paragraph (a) of this section by removing the excessive lead or by making the lead inaccessible;

(B) The product, class of product, material, or component part is not likely to be placed in the mouth or ingested, taking into account normal and reasonably foreseeable use and abuse of such product, class of product, material, or component part by a child; and

(C) An exception for the product, class of product, material, or component part will have no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse.

(ii) *Measurement.* For purposes of paragraph (b)(1)(i)(C) of this section, there is no measurable adverse effect on public health or safety if the exception described in paragraph (b)(1)(i) of this section will result in no measurable increase in blood lead levels of a child. The Commission may adopt an alternative method of measurement other than blood lead levels if it determines, after notice and a hearing, that such alternative method is a better scientific method for measuring adverse effect on public health and safety.

(iii) *Procedures for granting exception*—(A) *Burden of proof.* A party seeking an exception under paragraph (b)(1)(i) of this section has the burden of demonstrating that it meets the requirements of such paragraph.

(B) *Grounds for decision.* In the case where a party has petitioned for an exception, in determining whether to grant the exception, the Commission may base its decision solely on the materials presented by the party seeking

the exception and any materials received through notice and a hearing.

(C) *Admissible evidence.* In demonstrating that it meets the requirements of paragraph (b)(1)(i) of this section, a party seeking an exception under such paragraph may rely on any nonproprietary information submitted by any other party seeking such an exception and such information shall be considered part of the record presented by the party that relies on that information.

(D) *Scope of exception.* If an exception is sought for an entire product, the burden is on the petitioning party to demonstrate that the criteria in paragraph (b)(1)(i) of this section are met with respect to every accessible component or accessible material of the product.

(iv) *Limitation on exception.* If the Commission grants an exception for a product, class of product, material, or component part under paragraph (b)(1)(i) of this section, the Commission may, as necessary to protect public health or safety:

(A) Establish a lead limit that such product, class of product, material, or component part may not exceed; or

(B) Place a manufacturing expiration date on such exception or establish a schedule after which the manufacturer of such product, class of product, material, or component part shall be in full compliance with the limit established under paragraph (b)(1)(iv)(A) of this section or the limit set forth under paragraph (a) of this section.

(v) *Application of exception.* An exception under paragraph (b)(1)(i) of this section for a product, class of product, material, or component part shall apply regardless of the date of manufacture unless the Commission expressly provides otherwise.

(vi) *Previously submitted petitions.* A party seeking an exception under this paragraph may rely on materials previously submitted in connection with a petition for exclusion under this section. In such cases, petitioners must notify the Commission of their intent to rely on materials previously submitted. Such reliance does not affect petitioners' obligation to demonstrate that they meet all requirements of this

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paragraph as required by paragraph (b)(1)(iii)(A) of this section.

(2) [Reserved]

[74 FR 10480, Mar. 11, 2009, as amended at 78 FR 41298, July 10, 2013]

§ 1500.91 Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child. Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.

(b) Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, either on its own initiative or upon the request of any interested person, to make a determination that a material or product does not exceed the lead limits as provided under paragraph (a) of this section.

(c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable, does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section if the product or ma-

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terial is changed or altered so that it exceeds the lead content limits.

(d) The following materials do not exceed the lead content limits under section 101(a) of the CPSIA provided that these materials have neither been treated or adulterated with the addition of materials that could result in the addition of lead into the product or material:

(1) Precious gemstones: diamond, ruby, sapphire, emerald.

(2) Semiprecious gemstones and other minerals, provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral based on lead or lead compounds (excluding any mineral that is based on lead or lead compounds including, but not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).

(3) Natural or cultured pearls.

(4) Wood.

(5) Paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard and medium, and coatings on such paper which become part of the substrate.

(6) CMYK process printing inks (excluding spot colors, other inks that are not used in CMYK process, inks that do not become part of the substrate under 16 CFR part 1303, and inks used in after-treatment applications, including screen prints, transfers, decals, or other prints).

(7) Textiles (excluding after-treatment applications, including screen prints, transfers, decals, or other prints) consisting of:

(i) Natural fibers (dyed or undyed) including, but not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco;

(ii) Manufactured fibers (dyed or undyed) including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex.

(8) Other plant-derived and animal-derived materials including, but not

limited to, animal glue, bee's wax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather.

(e) The following metals and alloys do not exceed the lead content limits under section 101(a) of the CPSIA, provided that no lead or lead-containing metal is intentionally added but does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

(1) Surgical steel and other stainless steel within the designations of Unified Numbering System, UNS S13800–S66286, not including the stainless steel designated as 303Pb (UNS S30360).

(2) Precious metals: Gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium, titanium.

[74 FR 43041, Aug. 26, 2009]

§ 1500.121 Labeling requirements; prominence, placement, and conspicuousness.

(a)(1) *Background and scope.* Section 2(p)(1) of the Federal Hazardous Substances Act (FHSA) or “the Act”), 15 U.S.C. 1261(p)(1), requires that hazardous substances bear certain cautionary statements on their labels. These statements include: signal words; affirmative statements of the principal hazard(s) associated with a hazardous substance; the common or usual name, or chemical name, of the hazardous substance; the name and place of business of the manufacturer, packer, distributor, or seller; statements of precautionary measures to follow; instructions, when appropriate, for special handling and storage; the statement “Keep Out of the Reach of Children” or its practical equivalent; and, when appropriate, first-aid instructions. Section 2(p)(2) of the Act specifies that all such statements shall be located prominently on the label of such a substance and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label. This regulation contains the Commission's interpretations and policies for the type size and placement of cautionary material on the labels of hazardous substances and contains other

criteria for such cautionary statements that are acceptable to the Commission as satisfying section 2(p)(2) of the Act. Labels that do not comply with this regulation may be considered misbranded.

(2) *Definitions.* For the purposes of this section:

(i) *Container* means the immediate package from which a hazardous substance may be dispensed and also any article, package or wrapping, such as a tube or cone used for a firework or a wet cell battery casing containing sulfuric acid, which is necessary for the substance to function during actual use.

(ii) *Cautionary material, cautionary labeling, and cautionary labeling required by the Act* mean all items of labeling information required by sections 2(p)(1) of the FHSA (repeated in 16 CFR 1500.3(b)(14)(i) or by the regulations which require additional labeling under section 3(b) of the Act.

(iii) *Display panel* means any surface of the immediate container, and of any outer container or wrapping, which bears labeling.

(iv) *Principal display panel* means the portion(s) of the surface of the immediate container, and of any outer container or wrapping, which bear(s) the labeling designed to be most prominently displayed, shown, presented, or examined under conditions of retail sale. (See paragraph (c)(1) of this section.)

(v) *Type size* means the actual height of the printed image of each upper case or capital letter as it appears on the label of a hazardous substance. (See paragraph (c)(2) of this section.)

(vi) *Signal word* means the appropriate word “DANGER,” “WARNING,” or “CAUTION,” as required by sections 2(p)(1) (C) or (D) of the Act.

(vii) *Statement of principal hazard(s)* means that wording descriptive of the principal or primary hazard(s) associated with a hazardous substance required by section 2(p)(1)(E) of the Act. Some examples of such statements are “HARMFUL OR FATAL IF SWALLOWED,” “VAPOR HARMFUL,” “FLAMMABLE,” and “SKIN AND EYE IRRITANT.”

(viii) *Other cautionary material* means all labeling statements, other than

“signal words” or “statement(s) of principal hazard(s),” required by the Act or by regulations issued under the Act.

(b) *Prominent label placement.* To satisfy the requirement of the Act that cautionary labeling statements shall appear “prominently” on the label of a hazardous substance, all such statements shall be placed on the label as follows:

(1) *Horizontal placement of labeling statements.* Except for the name and place of business of the manufacturer, packer, distributor, or seller, all cautionary material required by the Act shall appear in lines that are generally parallel to any base on which the package rests as it is designed to be displayed for sale or, on display panels other than the principal display panel, in lines generally parallel to all other labeling on that panel. This requirement does not apply to labeling on collapsible tubes, cylindrical containers with a narrow diameter, or F-type containers where both the “front” and “back” of the container are principal display panels. (See paragraph (e) of this section.)

(2) *Principal display panel labeling.* (i) All items of cautionary labeling required by the Act may appear on the principal display panel on the immediate container and, if appropriate, on any other container or wrapper. See paragraph (b)(4) of this section for requirements and exceptions for labeling outer containers and wrappings.

(ii) The signal word, the statement of principal hazard(s), and, if appropriate, instructions to read carefully any cautionary material that may be placed elsewhere on the label shall be blocked together within a square or rectangular area, with or without a border, on the principal display panel on the immediate container and, where required by paragraph (b)(4) of this section, on any outer container or wrapping. All cautionary statements placed on the principal display panel shall be separated on all sides from other printed or graphic matter, with the exception of the declaration of net contents required under the Fair Packaging and Labeling Act, 15 U.S.C. 1453(a) (2) and (3), by a border line or by a space no smaller than the minimum allowable

height of the type size for cautionary material required by the Act (exclusive of signal words and statements of hazard) on the principal display panel.

(iii) Depending on the design of the package or the configuration of the label, or both, a package may have more than one principal display panel. If so, each principal display panel must bear, at a minimum, the signal word, statement of principal hazard or hazards, and, if appropriate, instructions to read carefully any cautionary material that may be placed elsewhere on the label.

(A) Where the principal display panel of the immediate container consists of a lid, cap, or other item which may be separated from the immediate container and discarded, the container shall be deemed to have a second principal display panel elsewhere on the immediate container which must bear, at a minimum, the signal word, statement of principal hazard(s), and instructions, if appropriate, to read any cautionary material which may be placed elsewhere on the label.

(3) *Prominent label placement—other display panel labeling.* All items of cautionary labeling required by the Act which do not appear on the principal display panel shall be placed together on a display panel elsewhere on the container. The name and place of business of the manufacturer, packer, distributor, or seller may appear separately on any display panel. Where cautionary material appears on a display panel other than the principal display panel, the principal display panel shall bear the statement “Read carefully other cautions on the _____ panel,” or its practical equivalent. [A description of the location of the other panel is to be inserted in the blank space.]

(4) *Outer container or wrappings.* All cautionary labeling appearing on the immediate container of a hazardous substance shall also appear on any outer container or wrapping used in the retail display of the substance, in the same manner as required for the immediate container. Those cautionary labeling statements appearing on the immediate container which are clearly legible through any outer container or wrapper used in retail display need not appear on the outer container

or wrapping itself. (See section 2(n)(1) of the Act.)

(5) *Placement of the word "Poison" and the skull and crossbones symbol.* The word "poison" and, when appropriate, the skull and crossbones symbol shall appear on the label of a hazardous substance as follows:

(i) If a hazardous substance is "highly toxic," as defined in §1500.3(c)(i) and section 2(h)(1) of the FHSA, the label must bear the word "poison" in accordance with section 2(p)(1)(H) of the Act, in addition to the signal word "DANGER," and must also bear the skull and crossbones symbol. Some products, under §1500.14(b) of the regulations, may, in addition to any required signal word, be required to bear the word "poison" and the skull and crossbones symbol because of the special hazard associated with their ingredients. In both instances, the word "poison" and the skull and crossbones symbol need not appear on the principal display panel on the container, unless all other cautionary labeling required by the Act appears on the principal display panel. The word "poison" and the skull and crossbones symbol, when required, must appear either together with other cautionary labeling on a display panel other than the principal display panel or together with the signal word and statement(s) of principal hazard on the principal display panel.

(ii) Where, pursuant to a regulation issued under section 3(b) of the Act, the label of a hazardous substance requires the word "poison" instead of a signal word, the word, "POISON" shall appear in capital letters on the principal display panel, together with the statement(s) of the principal hazard. Certain substances for which the word "poison" is required instead of any signal word are listed in §1500.129.

(c) *Conspicuousness—type size and style.* To satisfy the requirement that cautionary labeling statements under the Act be conspicuous and legible, such statements shall conform to the following requirements:

(1) *Area of principal display panel.* The area of the principal display panel is the area of the side or surface of the immediate container, or of the side or surface of any outer container or wrapping, that bears the labeling designed

to be most prominently displayed, shown, presented, or examined under conditions of retail sale. This area is not limited to the portion of the surface covered with labeling; rather, it includes the entire surface. Flanges at the tops and bottoms of cans, conical shoulders of cans, handles, and shoulders and necks of bottles and jars are excluded in measuring the area. For the purposes of determining the proper type size for cautionary labeling, the area of the principal display panel (or other panel bearing cautionary labeling, under paragraph (c)(2)(ii) of this section) is to be computed as follows:

(i) In the case of a rectangular package, where one entire side is the principal display panel, the product of the height times the width of that side shall be the area of the principal display panel.

(ii) In the case of a cylindrical or nearly cylindrical container or tube on which the principal display panel appears on the side, the area of the principal display panel shall be 40 percent of the product of the height of the container times its circumference.

(iii) In the case of any other shape of container, the area of the principal display panel shall be 40 percent of the total surface of the container, excluding those areas, such as flanges at tops and bottoms, specified in paragraph (c)(1) above. However, if such a container presents an obvious principal display panel (such as an oval or hourglass shaped area on the side of a container for dishwashing detergent), the area to be measured shall be the entire area of the obvious principal display panel.

(2) *Type-size requirements.* (i) The term *type size* refers to the height of the actual printed image of each upper case or capital letter as it appears on the label. The size of cautionary labeling shall be reasonably related to the type size of any other printing appearing on the same panel, but in any case must meet the minimum size requirements in table 1.

(ii) When an item of labeling is required to be in a specified type size, all upper case, or capital, letters must be at least equal in height to the required type size, and all other letters must be the same style as the upper case or

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capital letters. Unless otherwise specified in the regulations (examples appear at §§1500.14(b)(6), 1512.19, 1508.9, and part 1505), the type size of all cautionary statements appearing on any

display panel shall comply with the specifications in table 1 when the area of the display panel is measured by the method in paragraph (c)(1) above:

TABLE 1

Area of principal display panel in square inches	0–2	>2–5	>5–10	>10–15	>15–30	>30
Type size in inches*						
Signal word**	3/64	1/16	3/32	7/64	1/8	5/32
Statement of hazard	3/64	3/64	1/16	3/32	3/32	7/64
Other cautionary material***	1/32	3/64	1/16	1/16	5/64	3/32

> means “greater than.”
 * minimum height of printed image of capital or upper case letters.
 ** including the word “poison” when required instead of a signal word by Section 3(b) of the Act (§ 1500.129).
 *** size of lettering for other cautionary material is based on the area of the display panel on which such cautionary material appears.

(iii) If all of the required cautionary labeling does not appear on the principal display panel, the statement to “Read carefully other cautions on the _____ panel,” or its practical equivalent, must appear in, as a minimum, the same type size as that required in table 1 for the other cautionary material which appears elsewhere on the label of a hazardous substance. The size of the cautionary labeling that does not appear on the principal display panel is determined by the area of the panel on which it does appear.

(3) *Type style—proportion.* The ratio of the height of a capital or uppercase letter to its width shall be such that the height of the letter is no more than 3 times its width.

(4) *Signal word and statements of hazard—capital letters.* The signal word, the word “poison” if required instead of a signal word (see §1500.129), and the statement of principal hazard or hazards shall be in capital letters.

(5) *Multiple statement of hazard—type size and style.* All statements of principal hazard or hazards on a label shall appear in the same size and style of type, and shall appear in the same color or have the same degree of boldness.

(6) *Accompanying literature containing directions for use.* Where literature accompanying the package of a hazardous substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling.

(i) All such cautionary labeling shall be in reasonable proximity to any di-

rection for use and shall be placed together within the same general area.

(ii) The type size of such cautionary labeling shall be reasonably related to the type size of any other printed matter in the accompanying literature and must be in conspicuous and legible type by typography, layout, or color with other printed matter on the label. The signal word and statement of principal hazard or hazards shall appear in capital letters.

(d) *Conspicuousness—contrast.* To satisfy the requirement that cautionary labeling statements appear in conspicuous and legible type which is in contrast by typography, layout, or color with the other printed matter on the label, such statements shall conform to the following requirements:

(1) *Color.* Where color is the primary method used to achieve appropriate contrast, the color of any cautionary labeling statement shall be in sharp contrast with the color of the background upon which such a statement appears. Examples of combinations of colors which may not satisfy the requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(2) *Interference with conspicuousness—labeling design, vignettes, or other printed material.* For cautionary information appearing on panels other than the principal display panel, the label design, the use of vignettes, or the proximity of other labeling or lettering

shall not be such that any cautionary labeling statement is obscured or rendered inconspicuous.

(e) *Collapsible metal tubes.* Collapsible metal tubes containing hazardous substances shall be labeled so that all cautionary labeling required by the Act appears as close to the dispensing end of the container as possible. The placement and conspicuousness of these statements shall conform to the provisions of paragraphs (b), (c), and (d) of this section.

(f) *Unpackaged hazardous substances.* Where practicable, unpackaged hazardous substances intended, or distributed in a form suitable, for use in or around a household or by children shall be labeled so that all items of information required by the Act appear upon the article itself. In instances where this is impracticable (for example, because of the size or nature of the article), the required cautionary labeling must be displayed by means of a tag or other suitable material that is no less than five square inches in area and is securely affixed to the article so that the labeling will remain attached throughout conditions of merchandising and distribution to the ultimate consumer. The placement and conspicuousness of all cautionary labeling appearing on such a tag or material, or on an unpackaged article, shall conform to the provisions of paragraphs (b), (c), and (d) of this section. For the purposes of determining the proper type size to use on a tag or other material, the area of one side of the tag or other material shall be the area of the principal display panel.

(g) *Exemptions.* All requirements of the Act are satisfied by compliance with this §1500.121. However, exemptions can be granted under section 3(c) of the Act and §1500.83, or under the provisions of another statute should this section be incorporated in regulations under another statute. Section 1500.82 contains the requirements for exemption requests under the Federal Hazardous Substances Act.

(h) *Effective date.* The provisions of this rule apply to hazardous substances bearing labels printed after December 30, 1985. Labels printed prior to the effective date of this rule may be applied until not later than December 28, 1987.

This rule applies to all hazardous substances to which labels are applied after December 28, 1987.

[49 FR 50383, Dec. 28, 1984]

§ 1500.122 Deceptive use of disclaimers.

A hazardous substance shall not be deemed to have met the requirements of section 2(p) (1) and (2) of the act (repeated in §1500.3(b)(14) (i) and (ii)) if there appears in or on the label (or in any accompanying literature; words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the act; for example, the statement "Harmless" or "Safe around pets" on a toxic or irritant substance.

§ 1500.123 Condensation of label information.

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p)(1) (E) and (F) of the act (repeated in §1500.3(b)(14)(i) (E) and (F)). When the statement of precautionary measures in effect provides instruction for first-aid treatment, the statement of the precautionary measures will satisfy the requirements of section 2(p)(1) (F) and (G) of the act (repeated in §1500.3(b)(14)(i) (F) and (G)).

§ 1500.125 Labeling requirements for accompanying literature.

When any accompanying literature includes or bears any directions for use (by printed word, picture, design, or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act (repeated in §1500.3(b)(14)).

§ 1500.126 Substances determined to be "special hazards."

Whenever the Commission determines that for a particular hazardous substance intended or packaged in a form suitable for use in the household or by children, the requirements of section 2(p) of the act (repeated in

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§1500.3(b)(14)) are not adequate for the protection of the public health and safety because of some special hazard, the Commission, by an appropriate order in the FEDERAL REGISTER, shall specify such reasonable variations or additional label requirements that it finds are necessary for the protection of the public health and safety. Such order shall specify a date that is not less than 90 days after the order is published (unless emergency conditions stated in the order specify an earlier date) after which any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children that fails to bear a label in accordance with such order shall be deemed to be a misbranded hazardous substance.

§ 1500.127 Substances with multiple hazards.

(a) Any article that presents more than one type of hazard (for example, if the article is both toxic and flammable) must be labeled with: An affirmative statement of each such hazard; the precautionary measures describing the action to be followed or avoided for each such hazard; instructions, when necessary or appropriate, for first-aid treatment of persons suffering from the ill effects that may result from each such hazard; instructions for handling and storage of articles that require special care in handling and storage because of more than one type of hazard presented by the article; and the common or usual name (or the chemical name if there is no common or usual name) for each hazardous component present in the article.

(b) Label information referring to the possibility of one hazard may be combined with parallel information concerning any additional hazards presented by the article if the resulting condensed statement contains all of the information needed for dealing with each type of hazard presented by the article.

[38 FR 27012, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973]

§ 1500.128 Label comment.

The Commission will offer informal comment on any proposed label and ac-

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companying literature involving a hazardous substance if furnished with:

(a) Complete labeling or proposed labeling, which may be in draft form.

(b) Complete quantitative formula.

(c) Adequate clinical pharmacological, toxicological, physical, and chemical data applicable to the possible hazard of the substance.

(d) Any other information available that would facilitate preparation of a suitable label, such as complaints of injuries resulting from the product's use or other evidence that would furnish human-experience data.

§ 1500.129 Substances named in the Federal Caustic Poison Act.

The Commission finds that for those substances covered by the Federal Caustic Poison Act (44 Stat. 1406), the requirements of section 2(p)(1) of the Federal Hazardous Substances Act (repeated in §1500.3(b)(14)(i)) are not adequate for the protection of the public health. Labeling for those substances, in the concentrations listed in the Federal Caustic Poison Act, were required to bear the signal word "poison." The Commission concludes that the lack of the designation "poison" would indicate to the consumer a lesser hazard and that such would not be in the interest of the public health. Under the authority granted in section 3(b) of the act, the Commission therefore finds that for the following substances, and at the following concentrations, the word "poison" is necessary instead of any signal word:

(a) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid (HCl) in a concentration of 10 percent or more.

(b) Sulfuric acid and any preparation containing free or chemically unneutralized sulfuric acid (H₂SO₄) in a concentration of 10 percent or more.

(c) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO₃) in a concentration of 5 percent or more.

(d) Carboic acid (C₆H₅OH), also known as phenol, and any preparation containing carboic acid in a concentration of 5 percent or more.

(e) Oxalic acid and any preparation containing free or chemically

unneutralized oxalic acid ($H_2 C_2 O_4$) in a concentration of 10 percent or more.

(f) Any salt of oxalic acid and any preparation containing any such salt in a concentration of 10 percent or more.

(g) Acetic acid or any preparation containing free or chemically unneutralized acetic acid ($HC_2 H_2 O_2$) in a concentration of 20 percent or more.

(h) Hypochlorous acid, either free or combined, and any preparation containing the same in a concentration that will yield 10 percent or more by weight of available chlorine.

(i) Potassium hydroxide and any preparation containing free or chemically unneutralized potassium hydroxide (KOH), including caustic potash and vienna paste (vienna caustic), in a concentration of 10 percent or more.

(j) Sodium hydroxide and any preparation containing free or chemically unneutralized sodium hydroxide (NaOH), including caustic soda and lye in a concentration of 10 percent or more.

(k) Silver nitrate, sometimes known as lunar caustic, and any preparation containing silver nitrate ($AgNO_3$) in a concentration of 5 percent or more.

(l) Ammonia water and any preparation containing free or chemically uncombined ammonia (NH_3), including ammonium hydroxide and "hartshorn," in a concentration of 5 percent or more.

§ 1500.130 Self-pressurized containers: labeling.

(a) Self-pressurized containers that fail to bear a warning statement adequate for the protection of the public health and safety may be misbranded under the act, except as otherwise provided pursuant to section 3 of the act.

(b) The following warning statement will be considered as meeting the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) if the only hazard associated with an article is that the contents are under pressure:

WARNING—CONTENTS UNDER PRESSURE

Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120 °F. Keep out of the reach of children.

The word "CAUTION" may be substituted for the word "WARNING". A

practical equivalent may be substituted for the statement "Keep out of the reach of children."

(c) That portion of the warning statement set forth in paragraph (b) of this section in capital letters should be printed on the main (front) panel of the container in capital letters of the type size specified in §1500.121(c). The balance of the cautionary statements may appear together on another panel if the front panel also bears a statement such as "Read carefully other cautions on _____ panel."

(d) If an article has additional hazards, such as skin or eye irritancy, toxicity, or flammability, appropriate additional front and rear panel precautionary labeling is required.

§ 1500.133 Extremely flammable contact adhesives; labeling.

(a) Extremely flammable contact adhesives, also known as contact bonding cements, when distributed in containers intended or suitable for household use may be misbranded under the act if the containers fail to bear a warning statement adequate for the protection of the public health and safety.

(b) The following warning statement is considered as the minimum cautionary labeling adequate to meet the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) with respect to containers of more than one-half pint of contact adhesive and similar liquid or semiliquid articles having a flashpoint at or below 20 °F. as determined by the method in §1500.43, when the only hazard foreseeable is that caused by the extreme flammability of the mixture:

DANGER

EXTREMELY FLAMMABLE

VAPORS MAY CAUSE FLASH FIRE

Vapors may ignite explosively.

Prevent buildup of vapors—open all windows and doors—use only with cross-ventilation.

Keep away from heat, sparks, and open flame.

Do not smoke, extinguish all flames and pilot lights, and turn off stoves, heaters, electric motors, and other sources of ignition during use and until all vapors are gone.

Close container after use.

Keep out of the reach of children.

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(c) The words that are in capital letters in the warning statement set forth in paragraph (b) of this section should be printed on the main (front) panel or panels of the container in capital letters of the type size specified in §1500.121(c). The balance of the cautionary information may appear together on another panel provided the front panel bears a statement such as "Read carefully other cautions on _____ panel," the blank being filled in with the identification of the specific label panel bearing the balance of the cautionary labeling. It is recommended that a borderline be used in conjunction with the cautionary labeling.

(d) If an article has additional hazards, or contains ingredients listed in §1500.14 as requiring special labeling, appropriate additional front and rear panel precautionary labeling is required.

(e) Since the Commission has issued a regulation banning under the Consumer Product Safety Act extremely flammable contact adhesives covered by this labeling regulation (sec. 16 CFR part 1302), paragraphs (a), (b), (c) and (d) of this section are revoked as to the subject products after June 13, 1978.

[38 FR 27012, Sept. 27, 1973, as amended at 42 FR 63742, Dec. 19, 1977]

§ 1500.134 Policy on first aid labeling for saline emesis.

(a) This section states the Consumer Product Safety Commission's policy concerning first aid instructions for the use of a salt solution to induce vomiting (saline emesis) in the event of ingestion of hazardous substances.

(b) In many cases where hazardous substances are ingested, the recommended first aid instructions for inducing vomiting have contained a statement that this should be accomplished by drinking a solution of salt (sodium chloride) in warm water. At one time, this direction was considered medically acceptable. However, the Commission has obtained information showing that the instruction to perform saline emesis is no longer appropriate. This is because the use of salt to induce vomiting can cause severe hypernatremia (salt poisoning) with potentially toxic effects, particularly in children 5 years old or younger, the

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age group most often involved in accidental poisonings. In view of the availability of safer and more effective emetics such as ipecac syrup, the Commission no longer recommends a direction to perform saline emesis as a first aid direction for inducing vomiting.

(c) The Commission believes that, for products for which directions for saline emesis have been given in the past, ipecac syrup, U.S.P., is the most appropriate emetic, unless a particular contraindication exists in connection with any particular hazardous substance.

(d) The Commission wishes to emphasize that this policy does not require that any specific first aid instruction or wording be used. Where appropriate, the label may include directions (1) that the victim immediately contact a doctor or poison control center and/or (2) that vomiting be induced using methods other than salt. It is, of course, the manufacturer's responsibility to insure that the label provides enough information in addition to first aid instructions to fulfill all other labeling required by statute or regulation.

(Sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[43 FR 33704, Aug. 1, 1978]

§ 1500.135 Summary of guidelines for determining chronic toxicity.

A substance may be toxic due to a risk of a chronic hazard. (A regulatory definition of "toxic" that pertains to chronic toxicity may be found at 16 CFR 1500.3(c)(2).) The following discussions are intended to help clarify the complex issues involved in assessing risk from substances that may potentially cause chronic hazards and, where possible, to describe conditions under which substances should be considered toxic due to a risk of the specified chronic hazards. The guidelines are not intended to be a static classification system, but should be considered along with available data and with expert judgment. They are not mandatory. Rather, the guidelines are intended as an aid to manufacturers in determining whether a product subject to the FHSA presents a chronic hazard. All default assumptions contained in the guidelines on hazard and risk determination

are subject to replacement when alternatives which are supported by appropriate data become available. The following are brief summaries of more extensive discussions contained in the guidelines. Thus, the guidelines should be consulted in conjunction with these summaries. Copies of the guidelines may be obtained from the Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207. (In addition to the chronic hazards discussed below, issues relating to the chronic hazard of sensitization are discussed in 16 CFR 1500.3(c)(5).)

(a) *Carcinogenicity*. Substances are toxic by reason of their potential carcinogenicity in humans when they are known or probable human carcinogenic substances as defined below. Substances that are possible human carcinogenic substances or for which there is no evidence of carcinogenic effect under the following categories lack sufficient evidence to be considered toxic by virtue of their potential carcinogenicity.

(1) *Known Human carcinogenic Substances* (“sufficient evidence” in humans). Substances are toxic by reason of their carcinogenicity when they meet the “sufficient evidence” criteria of carcinogenicity from studies in humans, which require that a causal relationship between exposure to an agent and cancer be established. This category is similar to the Environmental Protection Agency’s (EPA) Group A, the International Agency for Research on Cancer’s (IARC) Group 1, or the American National Standards Institute’s (ANSI) Category 1. A causal relationship is established if one or more epidemiological investigations that meet the following criteria show an association between cancer and exposure to the agent.

(i) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(ii) All possible confounding factors which could account for the observed association can be ruled out with reasonable confidence.

(iii) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(2) *Probable Human Carcinogenic Substances*. Substances are also toxic by reason of their probable carcinogenicity when they meet the “limited evidence” criteria of carcinogenicity in humans or the “sufficient evidence” criteria of carcinogenicity in animals described below. This category is similar to EPA’s Group B, IARC’s Group 2, or ANSI’s Categories 2 and 3. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. For example, such evidence would result when there was an identified mechanism of action for a chemical that causes cancer in animals that has been shown not to apply to the human situation. It is reasonable, for practical purposes, to regard an agent for which there is “sufficient” evidence of carcinogenicity in animals as if it presented a carcinogenic risk to humans.

(i) *“Limited evidence” of carcinogenicity in humans*. The evidence is considered limited for establishing a causal relationship between exposure to the agent and cancer when a causal interpretation is credible, but chance, bias, or other confounding factors could not be ruled out with reasonable confidence.

(ii) *“Sufficient evidence” of carcinogenicity in animals*. Sufficient evidence of carcinogenicity requires that the substance has been tested in well-designed and -conducted studies (e.g., as conducted by National Toxicology Program (NTP), or consistent with the Office of Science Technology Assessment and Policy (OSTP) guidelines) and has been found to elicit a statistically significant ($p < 0.05$) exposure-related increase in the incidence of malignant tumors, combined malignant and benign tumors, or benign tumors if there is an indication of the ability of such benign tumors to progress to malignancy:

(A) In one or both sexes of multiple species, strains, or sites of independent origin; or experiments using different routes of administration or dose levels; or

(B) To an unusual degree in a single experiment (one species/strain/sex) with regard to unusual tumor type, unusual tumor site, or early age at onset of the tumor.

The presence of positive effects in short-term tests, dose-response effects data, or structure-activity relationship are considered additional evidence.

(3) *Possible Human Carcinogenic Substance* (“limited evidence” animal carcinogen). In the absence of “sufficient” or “limited” human data, agents with “limited” evidence of carcinogenicity from animal studies fall into this category. Such substances, and those that do not fall into any other group, are not considered “toxic.” This does not imply that the substances are or are not carcinogens, only that the evidence is too uncertain to provide for a determination. This category is similar to EPA’s Group C, IARC’s Group 3, or ANSI’s category 4.

(b) *Neurotoxicity*. Substances are toxic by reason of their potential neurotoxicity in humans when they meet the “sufficient evidence” or “limited evidence” criteria of neurotoxicity in humans, or when they meet the “sufficient evidence” criteria of neurotoxicity in animals.

(1) *Known Neurotoxic Substances* (“sufficient evidence in humans”). Substances are toxic by reason of their neurotoxicity and are considered “known neurotoxic substances” when they meet the “sufficient evidence” criteria of neurotoxicity derived from studies in humans which require that a causal association between exposure to an agent and neurotoxicity be established with a reasonable degree of certainty. Substances in this category meet the definition of “neurotoxic” as stated above. “Sufficient evidence,” derived from human studies, for a causal association between exposure to a chemical and neurotoxicity is considered to exist if the studies meet the following criteria.

(i) A consistent pattern of neurological dysfunction is observed.

(ii) The adverse effects/lesions account for the neurobehavioral dysfunction with reasonable certainty.

(iii) All identifiable bias and confounding factors are reasonably discounted after consideration.

(iv) The association has been shown unlikely to be due to chance, based on statistical analysis.

(2) *Probable Neurotoxic Substances*. Substances are also toxic by reason of

their probable neurotoxicity when they meet the “limited evidence” criteria of neurotoxicity in humans, or the “sufficient evidence” criteria derived from animal studies. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. Such evidence would result, for example, when there was an identified mechanism of action for a chemical that causes neurotoxicity in animals that has been shown not to apply to the human situation.

(i) *“Limited evidence” of neurotoxicity in humans*. The evidence derived from human studies is considered limited for neurotoxicity when the evidence is less than convincing, i.e., one of the criteria of “sufficient evidence” of neurotoxicity for establishing a causal association between exposure to the agent and neurotoxicity is not met, leaving some uncertainties in establishing a causal association.

(ii) *“Sufficient evidence” of neurotoxicity in animals*. Sufficient evidence of neurotoxicity derived from animal studies for a causal association between exposure to a chemical and neurotoxicity requires that:

(A) The substance has been tested in well-designed and -conducted studies (e.g., NTP’s neurobehavioral battery, or conforming to EPA’s neurotoxicity test guidelines); and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) increase in any neurotoxic effect in one or both sexes of multiple species, strains, or experiments using different routes of administration and dose-levels.

(3) *Possible Neurotoxic Substances*. “Possible neurotoxic substances” are the substances which meet the “limited evidence” criteria of neurotoxicity evidence derived from animal studies in the absence of human data, or in the presence of inadequate human data, or data which do not fall into any other group. Substances in this category are not considered “toxic.”

(c) *Developmental and Reproductive Toxicity—(1) Definitions of “Sufficient” and “Limited” Evidence*. The following definitions apply to all categories stated below.

(i) "Sufficient evidence" from human studies for a causal association between human exposure and the subsequent occurrence of developmental or reproductive toxicity is considered to exist if the studies meet the following criteria:

(A) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(B) All possible confounding factors which could account for the observed association can be ruled out with reasonable confidence.

(C) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(ii) "Limited evidence" from human studies exists when the human epidemiology meets all but one of the criteria for "sufficient evidence"; i.e., the statistical evidence is borderline as opposed to clear-cut, there is a source of bias, or there are confounding factors that have not been and cannot be accounted for.

(iii) "Sufficient evidence" from animal studies exists when

(A) Obtained from a good quality animal study; and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) treatment-related increase in multiple endpoints in a single species/strain, or in the incidence of a single endpoint at multiple dose levels or with multiple routes of administration in a single species/strain, or increase in the incidence of a single endpoint in multiple species/strains/ experiments.

(iv) "Limited evidence" from animal studies exists when:

(A) Obtained from a good quality study and there is a statistically significant ($p < 0.05$) treatment-related increase in the incidence of a single endpoint in a single species/strain/experiment at a single dose level administered through only one route and such evidence otherwise does not meet the criteria for "sufficient evidence"; or

(B) The evidence is derived from studies which can be interpreted to show positive effects but have some qualitative or quantitative limitations with respect to experimental procedures (e.g., doses, exposure, follow-up, number of animals/group, reporting of

the data, etc.) which would prevent classification of the evidence in the group of "sufficient evidence."

(2) *Developmental Toxicants*. Substances are toxic by reason of their potential developmental or reproductive toxicity when they meet the "sufficient evidence" or "limited evidence" criteria of developmental or reproductive toxicity in humans, or when they meet the "sufficient evidence" criteria of developmental or reproductive toxicity in animals. The Food and Drug Administration (FDA) and the European Economic Community (EEC) have developed categories for teratogens but not other developmental toxicants. The teratogen guidelines limit the information only to structural birth defects and do not include other hazards of developmental toxicity such as embryonal death, fetal death, or functional deficiencies which are also important in assessing the overall toxicity of a substance when administered during pregnancy. Recently, EPA has proposed a system for classifying developmental toxicity. The Occupational Safety and Health Administration (OSHA) has not yet developed any classification for developmental toxicity. The commission has established the following categories for determination of developmental toxicity according to the available evidence.

(i) *Known Human Developmental Toxicant* ("sufficient evidence in humans"). A substance is considered a "known human developmental toxicant" if there is "sufficient" human evidence to establish a causal association between human exposure and the subsequent occurrence of developmental toxicity manifested by death of the conceptus (embryo or fetus), or structural or functional birth defects. This category (Human Developmental Toxicant) is comparable to category 1 of the EEC and categories D and X of FDA, except that these guidelines are limited to teratogens. This category is also comparable to the category "definitive evidence for human developmental toxicity" proposed by EPA.

(ii) *Probable Human Developmental Toxicant*. A substance is considered a "probable human developmental toxicant" if there is "limited" human evidence or "sufficient" animal evidence

to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. This group (Probable Human Developmental Toxicant) is comparable to the category “adequate evidence for human developmental toxicity” proposed by EPA. This category is also comparable to category 2 of the EEC and category A1 of FDA, except that these guidelines are limited to teratogens.

(iii) *Possible Human Developmental Toxicant*. A substance is considered a “possible human developmental toxicant” if there is “limited” animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. EEC, FDA, and EPA have not developed a category comparable to this group. The Commission believes that data from well planned animal studies are important to consider even though they may provide only limited evidence of developmental toxicity.

(3) *Male Reproductive Toxicants*. Male reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies.

(i) *Known Human Male Reproductive Toxicant*. A substance is considered a “known human male reproductive toxicant” if there is “sufficient” human evidence to establish a causal association between human exposure and the adverse effects on male reproductive main endpoints which are mating ability, fertility, and prenatal and postnatal development of the conceptus. This category is comparable to the one termed “Known Positive” in the EPA guidelines on male reproductive risk assessment.

(ii) *Probable Human Male Reproductive Toxicant*. A substance is considered a “probable human male reproductive toxicant” if there is “limited” human evidence or “sufficient” animal evidence to establish a causal association between human exposure and the adverse effects on male reproductive main endpoints. This category is comparable to the one termed “Probable

Positive” in the EPA guidelines on male reproductive risk assessment. However, the EPA category is based only on sufficient animal evidence. CPSC believes that limited human evidence is also sufficient for a chemical to be placed in this category.

(iii) *Possible Human Male Reproductive Toxicant*. A substance is considered a “possible human male reproductive toxicant” if there is limited animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on male reproductive main endpoints. This category is comparable to the one termed “Possible Positive A” in the EPA guidelines on male reproductive risk assessment. EPA proposes to use either limited human or limited animal evidence data to classify a toxicant as a “Possible Positive A” toxicant. As described above, CPSC would elevate limited human evidence to the category “Probable Human Male Reproductive Toxicant.”

(4) *Female Reproductive Toxicants*. Female reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies. EPA has proposed guidelines for assessing female reproductive risk but has not yet proposed a specific system for categorization of female reproductive toxicants.

(i) *Known Human Female Reproductive Toxicant*. A substance is considered a “known human female reproductive toxicant” if there is “sufficient” human evidence to establish a causal association between human exposure and adverse effects on female reproductive function such as mating ability, fertility, and prenatal and postnatal development of the conceptus.

(ii) *Probable Human Female Reproductive Toxicant*. A substance is considered a “probable human female reproductive toxicant” if there is “limited” human evidence or “sufficient” animal evidence to establish a causal association between human exposure and adverse effects on female reproductive function.

(iii) *Possible Human Female Reproductive Toxicant.* A substance is considered a "possible human female reproductive toxicant" if there is "limited" animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on female reproductive function.

(d) *Other Subjects Related to the Determination that a Substance is Toxic.* Under the FHSA, for a toxic substance to be considered hazardous, it must not only have the potential to be hazardous but there must also be the potential that persons are exposed to the substance, that the substance can enter the body, and that there is a significant risk of an adverse health effect associated with the customary handling and use of the substance. Under these guidelines, existence of an adverse health effect means that such exposure is above the "acceptable daily intake" ("ADI"). The ADI is based on the risks posed by the substance, and whether they are acceptable under the FHSA. This section addresses those issues by providing guidelines concerning assessment of exposure, assessment of bioavailability, determination of acceptable risks and the ADI to children and adults, and assessment of risk.

(1) *Assessment of Exposure.* An exposure assessment may comprise a single exposure scenario or a distribution of exposures. Reasonably foreseeable use, as well as accidental exposure, should be taken into consideration when designing exposure studies. The following guidelines should be used in the assessment of exposure.

(i) *Inhalation.* Inhalation studies to assess exposure should be reliable studies using direct monitoring of populations, predictions of exposure through modeling, or surrogate data.

(A) *Direct Monitoring.* Populations to be monitored should be selected randomly to be representative of the general population, unless the exposure of a particular subset population is the desired goal of the assessment. The monitoring technique should be appropriate for the health effect of interest.

(B) *Modeling.* Predictions of exposure to a chemical using mathematical

models can be based on physical and chemical principles, such as mass balance principles. Mass balance models should consider the source strength of the product of interest, housing characteristics, and ambient conditions likely to be encountered by the studied population.

(C) *Surrogate Data.* Surrogate data should only be used when data concerning the chemical of interest are sparse or unavailable and when there is a reasonable assurance that the surrogate data will accurately represent the chemical of interest.

(ii) *Oral Ingestion.* Oral ingestion studies may involve direct monitoring of sources of chemicals as well as laboratory simulations. The estimation of exposure from ingestion of chemicals present in consumer products is predicted based upon estimates of use of the product and absorption of the chemical from the gastrointestinal tract. The following criteria should be established for laboratory simulations to estimate exposure:

(A) A simulant or range of simulants should be carefully selected to mimic the possible range of conditions which occur in humans, such as full and empty stomachs, or various saliva compositions at different times of the day.

(B) The mechanical action to which a product is submitted must be chosen to represent some range of realistic conditions to which a human may subject the product.

(iii) *Dermal Exposure.* (A) Dermal exposure involves estimating the amount of substance contacting the skin. This may involve experiments measuring the amount of material leached from a product contacting a liquid layer which interfaces with the skin, or the amount of substance which migrates from a product (in solid or liquid form) which is in contact with the skin.

(B) Parameters to be considered include: Surface area of the skin contacted, duration of contact, frequency of contact, and thickness of a liquid interfacial layer.

(2) *Assessment of Bioavailability.* (i) The need to consider bioavailability in estimating the risk from use of a product containing a toxic substance only arises when it is anticipated that the

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absorption characteristics of a substance to which there is human exposure will differ from those characteristics for the substance tested in the studies used to define the dose-response relationship.

(ii) In determining the need to assess bioavailability, the factors to be examined include:

(A) The physical or chemical form of the substance,

(B) The route of exposure (inhalation, ingestion, or through the skin),

(C) The presence of other constituents in the product which interfere with or alter absorption of the toxic substance, and

(D) Dose.

(3) *Assessment of Risk.* This section on quantitative risk assessment applies to estimates of risk for substances that are toxic by reason of their carcinogenicity.

(i) Generally, the study leading to the highest risk should be used in the risk assessment; however, other factors may influence the choice of study.

(ii) Risk should be based on the maximum likelihood estimate from a multistage model (such as Global83 or later version) unless the maximum likelihood estimate is not linear at low dose, in which case the 95% upper confidence limit on risk should be used.

(iii) For systemic carcinogens, if estimates of human risk are made based on animal data, a factor derived from dividing the assumed human weight (70 kg) by the average animal weight during the study and taking that to the $\frac{1}{3}$ power should be used. There is the possibility that this factor may be changed, using the $\frac{1}{4}$ power instead of the $\frac{1}{3}$ power, as part of a unified Federal regulatory approach. If such an approach is adopted, it will apply here.

(iv) When dose is expressed as parts per million, and the carcinogen acts at the site of contact, humans and animals exposed to the same amount for the same proportion of lifetime should be assumed to be equally sensitive.

(v) If no experimental study having the same route of exposure as that anticipated for human use of a substance is available, a study by another route of exposure may be used. Pharmacokinetic methods may be used if sufficient data are available.

(vi) When exposure scenarios are different from those used in the underlying study upon which estimates of risk are based, proportionality should be applied. If pharmacokinetic methods are used to adjust for risks at high versus low exposure levels, level-time measures should not be combined without taking the non-linearity into account.

(4) *Acceptable Risks*—(i) *ADI for Carcinogens.* The maximum acceptable daily intake (“ADI”) is that exposure of a toxic (by virtue of its carcinogenicity) substance that is estimated to lead to a lifetime excess risk of one in a million. Exposure refers to the anticipated exposure from normal lifetime use of the product, including use as a child as well as use as an adult.

(ii) *ADI for Neurotoxicological and Developmental/Reproductive Agents.* Due to the difficulties in using a numerical risk assessment method to determine risk for neurotoxicological or developmental/reproductive toxicants, the Commission is using a safety factor approach, as explained below.

(A) *Human Data.* If the hazard is ascertained from human data, a safety factor of ten will be applied to the lowest No Observed Effect Level (“NOEL”) seen among the relevant studies. If no NOEL can be determined, a safety factor of 100 will be applied to the Lowest Observed Effect Level (“LOEL”). Both the NOEL and LOEL are defined in terms of daily dose level.

(B) *Animal Data.* If the hazard is ascertained from animal data, a safety factor of one hundred will be applied to the lowest NOEL. If no NOEL can be determined, a safety factor of one thousand will be applied to the lowest LOEL. Both the NOEL and LOEL are defined in terms of daily dose level.

[57 FR 46665, Oct. 9, 1992]

§ 1500.210 Responsibility.

The provisions of these regulations (16 CFR subchapter C of chapter II) with respect to the doing of any act shall be applicable also to the causing of such act to be done.

§ 1500.211 Guaranty.

In the case of the giving of a guaranty or undertaking referred to in section 5(b)(2) of the act, each person signing such guaranty or undertaking, or causing it to be signed, shall be considered to have given it. Each person causing a guaranty or undertaking to be false is chargeable with violations of section 4(d) of the act.

§ 1500.212 Definition of guaranty; suggested forms.

(a) A guaranty or undertaking referred to in section 5(b)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment of delivery; or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered, or caused to be shipped or delivered, by the person who gives the guaranty of undertaking.

(b) The following are suggested forms of guaranty or undertaking referred to in section 5(b)(2) of the act.

(1) *Limited form for use on invoice or bill of sale.*

(Name of person giving the guaranty or undertaking)
 hereby guarantees that no article listed herein is misbranded within the meaning of the Federal Hazardous Substances Act.
 (Signature and post-office address of person giving the guaranty or undertaking)

(2) *General and continuing forms.*

The article comprising each shipment or other delivery hereafter made by _____

(Name of person giving the guaranty or undertaking)

to, or on the order of _____

(Name and post-office address of person to whom the guaranty or undertaking is given)

is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not misbranded within the meaning of the Federal Hazardous Substances Act.

(Signature and post-office address of person giving the guaranty or undertaking)

(c) The application of a guaranty or undertaking referred to in section 5(b)(2) of the act to any shipment or

other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes misbranded within the meaning of the act.

§ 1500.213 Presentation of views under section 7 of the act.

(a) Presentation of views under section 7 of the act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 5(b)(2) of the act applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, reasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 7 of the act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Consumer Product Safety Commission that issued the notice.

§ 1500.214 Examinations and investigations; samples.

When any officer or employee of the Commission collects a sample of a hazardous substance for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Commission indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory not organized with a legislative body. Only samples so designated by an officer or employee of the Commission shall be considered to be official samples:

(a) For the purpose of determining whether or not a sample is collected for

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analysis, the term “analysis” includes examinations and tests.

(b) The owner of a hazardous substance of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

§ 1500.230 Guidance for lead (Pb) in consumer products.

(a) *Summary.* (1) The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in consumer products.¹ The Commission identifies the major factors that it considers when evaluating products that contain lead, and informs the public of its experience with products that have exposed children to potentially hazardous amounts of lead.

(2) To reduce the risk of hazardous exposure to lead, the Commission requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children.

(b) *Hazard.* Young children are most commonly exposed to lead in consumer products from the direct mouthing of objects, or from handling such objects and subsequent hand-to-mouth activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of the product. The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the

body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided. The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood as a threshold level of concern with respect to lead poisoning. To avoid exceeding that level, young children should not chronically ingest more than 15 micrograms of lead per day from consumer products.

(c) *Guidance.* (1) Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), household products that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are “hazardous substances.” A household product that is not intended for children but which creates such a risk of injury because it contains lead requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children which contains a hazardous amount of lead that is accessible for children to ingest is a banned hazardous substance. 15 U.S.C. 1261(q)(1)(B). In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: the total amount of lead contained in a product, the bio-availability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.

(2) Paint and similar surface coatings containing lead have historically been the most commonly-recognized sources of lead poisoning among the products within the Commission’s jurisdiction. The Commission has, by regulation, banned paint and other similar surface coatings that contain more than 0.06% lead (“lead-containing paint”), toys and other articles intended for use by children that bear lead-containing paint, and furniture articles for consumer use that bear lead-containing paint. 16 CFR Part 1303. In recent

¹This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

years, however, the Commission staff has identified a number of disparate products—some intended for use by children and others simply used in or around the household or in recreation—that presented a risk of lead poisoning from sources other than paint. These products included vinyl miniblinds, crayons, figurines used as game pieces, and children's jewelry.

(3) In several of these cases, the staff's determination that the products presented a risk of lead poisoning resulted in recalls or in the replacement of those products with substitutes, in addition to an agreement to discontinue the use of lead in future production. The Commission believes that, had the manufacturers of these lead-containing products acted with prudence and foresight before introducing the products into commerce, they would not have used lead at all. This in turn would have eliminated both the risk to young children and the costs and other consequences associated with the corrective actions.

(4) The Commission urges manufacturers to eliminate lead in consumer products to avoid similar occurrences in the future. However, to avoid the possibility of a Commission enforcement action, a manufacturer who believes it necessary to use lead in a consumer product should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a "hazardous substance." If the product is a hazardous substance and is also a children's product, it is banned. If it is a hazardous household substance but is not intended for use by children, it requires precautionary labeling. This same type of analysis also should be performed on materials substituted for lead.

(5) The Commission also notes that, under the FHSA, any firm that purchases a product for resale is responsible for determining whether that product contains lead and, if so, whether it is a "hazardous substance." The Commission, therefore, recommends that, prior to the acquisition or distribution of such products, importers, distributors, and retailers obtain information and data, such as analyses of chemical composition or accessibility,

relevant to this determination from manufacturers, or have such evaluations conducted themselves.

[63 FR 70649, Dec. 22, 1998]

§ 1500.231 Guidance for hazardous liquid chemicals in children's products.

(a) *Summary.* The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from exposure to hazardous chemicals found in liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, keychains, liquid timers, and mazes.¹ The Commission identifies the major factors that it considers when evaluating liquid-filled children's products that contain hazardous chemicals, and informs the public of its experience with exposure to these hazardous chemicals to children. To reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, methylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children's products. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

(b) *Hazard.* During reasonably foreseeable handling or use of liquid-filled children's products, hazardous chemicals may become accessible to young children in a manner that places children at risk. Young children are exposed to the chemicals from directly mouthing them or from handling such objects and subsequent hand-to-mouth or hand-to-eye activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of

¹This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

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the product. The adverse health effects of these chemicals to children include chemical poisoning from ingestion of the chemicals, pneumonia from aspiration of the chemicals into the lungs, and skin and eye irritation from exposure to the chemicals. The chemicals may also be combustible.

(c) *Guidance.* (1) Under the Federal Hazardous Substances Act (FHSA), products that are toxic or irritants and that may cause substantial injury or illness under reasonably foreseeable conditions of handling or use, including reasonably foreseeable ingestion by children, are "hazardous substances." 15 U.S.C. 1261(f)(1). A product that is not intended for children, but that creates a risk of substantial injury or illness because it contains hazardous chemicals, requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children that contains an accessible and harmful amount of a hazardous chemical is banned. 15 U.S.C. 1261(q)(1)(A). In evaluating the potential hazard associated with children's products that contain hazardous chemicals, the Commission's staff considers certain factors on a case-by-case basis, including: the total amount of the hazardous chemical in a product, the accessibility of the hazardous chemicals to children, the risk presented by that accessibility, the age and foreseeable behavior of the children exposed to the product, and the marketing, patterns of use, and life cycle of the product.

(2) The Commission's staff has identified a number of liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, maze toys, liquid timers, and keychains, that contain hazardous chemicals. In several of these cases, the staff determined that these products violated the FHSA because they presented a risk of chemical poisoning and/or chemical pneumonia from aspiration. This determination resulted in recalls or in the replacement of those products with substitutes, as well as in agreements with the manufacturers to discontinue the use of hazardous chemicals in liquid-filled children's products in future production. The Commission believes that these haz-

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ardous substances pose a risk to young children and, consequently, manufacturers should not have included them in the product design or manufacturing process.

(3) Therefore, the Commission considers the use of hazardous chemicals in children's products such as those described above to be ill-advised and encourages manufacturers to avoid using them in such products. Further, the Commission recommends that, before purchasing such products for resale, importers, distributors, and retailers obtain assurances from the manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

[63 FR 70648, Dec. 22, 1998]

§ 1500.232 Statement on animal testing policy.

(a) *Summary.* (1) The U.S. Consumer Product Safety Commission issues this statement of policy on animal testing and alternatives to animal testing of hazardous substances regulated under the Federal Hazardous Substances Act (FHSA). The FHSA requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazard(s) that the products may present. Among the hazards addressed by the FHSA are toxicity, corrosivity, sensitization, and irritation.

(2) In order to determine the appropriate cautionary labeling, it is necessary to have objective criteria by which the existence of each hazard can be determined. Hazards such as toxicity, tissue corrosiveness, eye irritancy, and skin irritancy result from the biological response of living tissue and organs to the presence of the hazardous substance. One means of characterizing these hazards is to use animal testing as a proxy for the human reaction. In fact, the FHSA defines the hazard category of "highly toxic" in terms of animal toxicity when groups of 10 or more rats are exposed to specified amounts of the substance. The Commission's regulations under the FHSA concerning toxicity and irritancy allow the use of animal tests to determine the presence of the hazard when human data or existing animal data are not available.

(3) Neither the FHSA nor the Commission's regulations requires animal testing. The FHSA and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. If animal testing is conducted, Commission policy supports limiting such tests to a minimum number of animals and advocates measures that eliminate or reduce the pain or discomfort to animals that can be associated with such tests. The Commission has prepared this statement of policy with respect to animal testing to encourage the manufacturers subject to the FHSA to follow a similar policy.

(4) In making the appropriate hazard determinations, manufacturers of products subject to the FHSA should use existing alternatives to animal testing whenever possible. These include: prior human experience (*e.g.*, published case studies), *in vitro* or *in silico* test methods that have been approved by the Commission, literature sources containing the results of prior animal testing or limited human tests (*e.g.*, clinical trials, dermal patch testing), and expert opinion (*e.g.*, hazard assessment, structure-activity analysis). If a manufacturer or other entity performs a hazard test for FHSA labeling purposes that has not been previously approved by the Commission, CPSC staff will consider the data on a case-by-case basis and, upon review, determine whether to post the test method on the animal testing Web site. The Commission recommends resorting to animal testing only when the other information sources have been exhausted. At this time, the Commission recommends use of the most humane procedures with the fewest animals possible to achieve reliable results. Recommended procedures are summarized in the following statement and can be accessed on the Commission's Web page at: <http://www.cpsc.gov/library/animaltesting.html>. If a manufacturer or other entity performs a hazard test for FHSA labeling purposes that has not been previously approved by the Commission (*e.g.*, an ICCVAM-recommended test method or one of the tests described in the current version of the FHSA), CPSC staff will consider the data on a case-by-case basis and,

upon review, determine whether to post the test method on the animal testing Web site.

(b) *Statement of policy on animal testing.* (1) Neither the FHSA nor the Commission's regulations requires animal testing. Reliable human experience always takes precedence over results from animal data. In the cases where animal tests are conducted, the Commission prefers test methods that reduce stress and suffering in test animals and that use fewer animals while maintaining scientific integrity. To this end, the Commission reviews recommendations on alternative test methods developed by the scientific and regulatory communities. Current descriptions of test method recommendations approved by or known to the Commission can be accessed via the Internet at: <http://www.cpsc.gov/library/animaltesting.html>. The Commission strongly supports the use of scientifically sound alternatives to animal testing. The following parts of this section outline some of these alternatives. Testing laboratories and other interested persons requiring assistance interpreting the results obtained when a substance is tested in accordance with the methods described here, or in following the testing strategies outlined in the section, should refer to the Commission's animal testing Web page at: <http://www.cpsc.gov/library/animaltesting.html>.

(i) *Acute toxicity.* The traditional FHSA animal test for acute toxicity determines the median lethal dose (LD50) or lethal concentration (LC50), the dose or concentration that is expected to kill half the test animals. Procedures for determining the median LD50/LC50 are described in section 2(h)(1) of the Act and supplemented in §1500.3(c)(1) and (2) and the test method outlined in §1500.40. The Commission recommends *in vitro* alternatives over *in vivo* LD50/LC50 tests, or using modifications of the traditional LD50/LC50 test during toxicity testing that reduce the number of animals tested whenever possible. Data from *in vitro* or *in silico* test methods that have not been approved by the Commission may be submitted to the Commission for consideration of their acceptability. Commission-approved testing alternatives are

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identified on the Web site at: <http://www.cpsc.gov/library/animaltesting.html> and include:

(A) *In vitro* and *in vivo* test methods that have been scientifically validated and approved for use in toxicity testing by the Commission;

(B) Valid *in vitro* methods to estimate a starting dose for an acute *in vivo* test;

(C) A sequential version of the traditional LD50/LC50 tests described in § 1500.3(c)(1) and (2) and the test method described in § 1500.40, in which dose groups are run successively rather than simultaneously;

(D) A limit-dose test where the LD50/LC50 is determined as a point estimate, which can still be used to categorize a hazard, although it gives no information on hazard dose-response. In the limit test, animals (10 rats) each receive a single dose of product at 5g per kilogram of body weight. If not more than one animal dies in 14 days, the product is considered to have an LD50 of greater than 5g/kg, and thus, deemed to be nontoxic. Only if two or more animals die is a second group of 10 rats tested (at a lower dose). This procedure reduces the number of animals tested from the 80 to 100 animals involved in a full LD50 test to, typically, 10 to 20 rats per product. This reduction in the number of animals tested is justified because an exact LD50 is not required by either the FHSA or the regulations. The FHSA requires only a categorical determination that the toxicity is greater than 5g/kg, between 50 mg/kg and 5g/kg, or less than 50 mg/kg.

(ii) *Dermal irritation/corrosivity*. An acceptable *in vitro* test method or weight-of-evidence analysis is recommended before *in vivo* dermal irritation testing is considered to determine appropriate cautionary labeling. The weight-of-evidence analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test results (valid tests are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), the substance's dermal toxicity, evidence of corrosivity/irritation of one or more structurally related substances or mixtures of such substances, data demonstrating low or high pH (≤ 2 or ≥ 11.5) of the substance, and any other relevant physico-

chemical properties that indicate the substance might be a dermal corrosive or irritant. If there is any indication from this analysis that the substance is either corrosive or irritating to the skin, the substance should be labeled appropriately. If the substance is not corrosive *in vitro*, but no data exist regarding its irritation potential, human patch testing should be considered. If *in vitro* data are unavailable, human patch testing is not an option, and there are insufficient data to determine the weight-of-evidence, a tiered *in vivo* animal test is recommended.

(A) In a tiered *in vivo* dermal study, a single rabbit is tested initially. If the outcome is positive for corrosivity, testing is stopped, and the substance is labeled appropriately. If the substance is not corrosive, two more rabbits should be patch-tested to complete the assessment of skin irritation potential.

(B) If a tiered test is not feasible, the Commission recommends the test method described in § 1500.41. Note that in any *in vivo* dermal irritation test method, the Commission recommends using a semioclusive patch to cover the animal's test site and eliminating the use of stocks for restraint during the exposure period, thereby allowing the animal free mobility and access to food and water.

(iii) *Ocular irritation*. A weight-of-evidence analysis is recommended to evaluate existing information before any *in vivo* ocular irritation testing is considered. This analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test data (identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), the substance's dermal corrosivity/irritation (primary skin irritants and corrosives are also usually eye irritants and therefore do not need to be tested in the eye), evidence of ocular irritation of one or more structurally related substances or mixtures of such substances, data demonstrating high acidity or alkalinity of the substance, and any other relevant physicochemical properties that indicate the substance might be a dermal corrosive or irritant or ocular irritant.

(A) When the weight-of-evidence is insufficient to determine a substance's ocular irritation, a Commission-approved *in vitro* or *in silico* assay for ocular irritancy should be run to assess eye irritation potential and determine labeling. Examples of Commission-validated *in vitro* assays are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>). If no valid *in vitro* test exists, the test strategy for determining dermal corrosion/irritation outlined in paragraph (b)(1)(ii)(B) of this section can be followed to determine ocular irritation.

(B) If the dermal test strategy outlined in section paragraph (b)(1)(ii)(B) of this section leads to a conclusion of not corrosive, a tiered *in vivo* ocular irritation test should be performed, in which a single rabbit is exposed to the substance initially. If the outcome of this initial test is positive, testing is stopped, and the substance is labeled an eye irritant. If the outcome of this initial test is negative, one to two more rabbits are tested for ocular irritation, and the outcome of this test will determine the label. If a tiered test is not feasible, the Commission recommends the test method described in §1500.42.

(C) When any ocular irritancy testing on animals is conducted, including the method described in §1500.42, the Commission recommends a threefold plan to reduce animal suffering: The use of preemptive pain management, including topical anesthetics and systemic analgesics that eliminate or reduce suffering that may occur as a result of the application process or from the test substance itself (an example of a typical preemptive pain treatment is two applications of tetracaine ophthalmic anesthetic, 10–15 minutes apart, prior to instilling the test material to the eye); post-treatment with systemic analgesics for pain relief; and implementation of humane endpoints, including scheduled observations, monitoring, and recording of clinical signs of distress and pain, and recording the nature, severity, and progression of eye injuries. The specific techniques that have been approved by the Commission can be found at: <http://www.cpsc.gov/library/animaltesting.html>.

(iv) *Dermal sensitization*. An acceptable *in vitro* test method (examples of valid *in vitro* tests are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), or weight-of-evidence analysis is recommended before *in vivo* animal sensitization testing is considered to determine appropriate cautionary labeling. The weight-of-evidence analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test results, and any relevant physicochemical properties that indicate the substance might be a dermal sensitizer. If there is any indication from this analysis that the substance is sensitizing to the skin, the substance should be labeled appropriately.

(2) [Reserved]

[77 FR 73288, Dec. 10, 2012]

IMPORTS

§ 1500.265 Imports; definitions.

For the purposes of the regulations prescribed under section 14 of the act:

(a) The term *owner or consignee* means the person who has the rights of a consignee under the provisions of the Tariff Act of 1930 (secs. 483, 484, 485, 46 Stat. 721 as amended; 19 U.S.C. 1483, 1484, 1485).

(b) The term *area office director* means the director of the area office of the Consumer Product Safety Commission having jurisdiction over the port of entry through which a hazardous substance is imported or offered for import, or such officer of the area office as he may designate to act in his behalf in administering and enforcing the provisions of section 14 of the act.

§ 1500.266 Notice of sampling.

When a sample of a hazardous substance offered for import has been requested by the director of the area office, the collector of customs having jurisdiction over the hazardous substance shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon

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receipt of the notice, the owner or consignee shall hold such hazardous substance and not distribute it until further notice from the area office director or the collector of customs of the results of the examination of the sample.

§ 1500.267 Payment for samples.

The Consumer Product Safety Commission will pay for all import samples that are found to be in compliance with the requirements of the act. Billing for reimbursement should be made by the owner or consignee to the Commission area office headquarters in the territory of which the shipment was offered for import. Payment for samples will not be made if the hazardous substance is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance.

§ 1500.268 Hearing.

(a) If it appears that the hazardous substance may be subject to refusal of admission, the area office director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the hazardous substance, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the hazardous substance into compliance with the act, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the area office director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1500.269 Application for authorization.

Application for authorization to relabel or perform other action to

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bring the hazardous substance into compliance with the act may be filed only by the owner or consignee and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1500.270 Granting of authorization.

(a) When authorization contemplated by § 1500.269 is granted, the area office director shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) That the operations are to be carried out under the supervision of an officer of the Consumer Product Safety Commission or the Bureau of Customs, as the case may be;

(3) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(4) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the area office director may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the area office director.

(d) If ownership of a hazardous substance covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 1500.271 Bonds.

(a) The bonds required under section 14(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part

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thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the hazardous substance into compliance with the act in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the area office director is in full agreement with the action.

§ 1500.272 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

The cost of supervising the relabeling or other action necessary in connection with an import of a hazardous substance that fails to comply with the act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 14(b) of the act. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station as provided by law.

(c) Services of the supervising officer, to be calculated at the rate of a GS 11, step 1 employee, except that such services performed by a customs officer and subject to the provisions of the Act of February 13, 1911, as amended (sec. 5, 36 Stat. 901 as amended; 19 U.S.C. 267), shall be calculated as provided in that Act.

(d) Services of the analyst, to be calculated at the rate of a GS 12, step 1 employee (which shall include the use of the chemical laboratories and equipment of the Consumer Product Safety Commission).

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

[38 FR 27012, Sept. 27, 1973, as amended at 57 FR 28605, June 26, 1992]

PART 1501—METHOD FOR IDENTIFYING TOYS AND OTHER ARTICLES INTENDED FOR USE BY CHILDREN UNDER 3 YEARS OF AGE WHICH PRESENT CHOKING, ASPIRATION, OR INGESTION HAZARDS BECAUSE OF SMALL PARTS

Sec.

1501.1 Purpose.

1501.2 Scope.

1501.3 Exemptions.

1501.4 Size requirements and test procedure.

1501.5 Enforcement procedure.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), and 10; 74 Stat. 372, 374, 375 as amended; 80 Stat. 1304-05, 83 Stat. 187-89 (15 U.S.C. 1261, 1262, 1269).

SOURCE: 44 FR 34903, June 15, 1979, unless otherwise noted.

§ 1501.1 Purpose.

Section 1500.18(a)(9) of this chapter classifies as a banned hazardous substance any toy or other article intended for use by children under 3 years of age that presents a choking, aspiration, or ingestion hazard because of small parts. This part 1501 describes certain articles that are subject to § 1500.18(a)(9); lists certain articles that are specifically exempted; and provides a test method for determining whether an article is hazardous to children under 3 because it, or one of its components that can be detached or broken off during normal or reasonable foreseeable use, is too small.

§ 1501.2 Scope.

(a) This regulation (§ 1500.18(a)(9) and the criteria described in § 1501.4 below) applies to all toys and other articles intended for use by children under 3 years (36 months) of age that are introduced into interstate commerce after

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the effective date. Such articles include, but are not limited to: squeeze toys; teething rings; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures; preschool toys, games and puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy cars, trucks, and other vehicles intended for use by children under 3. In addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.

(b) In determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant: the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.

(c) This regulation does not apply to toys or articles which are solely intended for use by children 3 years of age or older. In addition, it does not apply to all articles to which children under 3 years of age might have access simply because of presence in a household. Certain articles which are specifically exempted from this regulation are listed in § 1501.3 below.

§ 1501.3 Exemptions.

The following articles are exempt from this regulation (§§ 1500.18(a)(9) and 1501.4 below):

- (a) Balloons;
- (b) Books and other articles made of paper;

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(c) Writing materials such as crayons, chalk, pencils, and pens;

(d) Children's clothing and accessories, such as shoe lace holders and buttons;

(e) Grooming, feeding, and hygiene products, such as diaper pins and clips, barrettes, toothbrushes, drinking glasses, dishes and eating utensils;

(f) Phonograph records;

(g) Modeling clay and similar products;

(h) Fingerpaints, watercolors, and other paint sets;

(i) Rattles (as defined at 16 CFR 1510.2); and

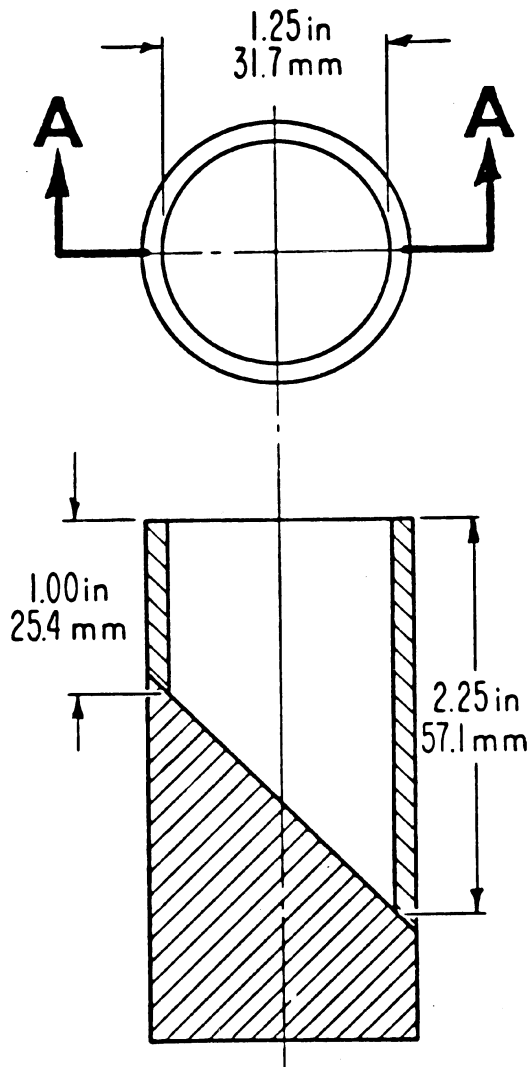
(j) Pacifiers (as defined at 16 CFR 1511.2(a)).

§ 1501.4 Size requirements and test procedure.

(a) No toy or other children's article subject to § 1500.18(a)(9) and to this part 1501 shall be small enough to fit entirely within a cylinder with the dimensions shown in Figure 1, when tested in accordance with the procedure in paragraph (b) of this section. In testing to ensure compliance with this regulation, the dimensions of the Commission's test cylinder will be no greater than those shown in Figure 1. (In addition, for compliance purposes, the English dimensions shall be used. The metric approximations are included only for convenience.)

(b)(1) Place the article, without compressing it, into the cylinder. If the article fits entirely within the cylinder, in any orientation, it fails to comply with the test procedure. (Test any detached components of the article the same way.)

(2) If the article does not fit entirely within the cylinder, subject it to the appropriate "use and abuse" tests of 16 CFR 1500.51 and 1500.52 (excluding the bite tests of §§ 1500.51(c) and 1500.52(c)). Any components or pieces (excluding paper, fabric, yarn, fuzz, elastic, and string) which have become detached from the article as a result of the use and abuse testing shall be placed into the cylinder, one at a time. If any such components or pieces fit entirely within the cylinder, in any orientation and without being compressed, the article fails to comply with the test procedure.



Section A-A

FIG I-SMALL PARTS CYLINDER

§ 1501.5 Enforcement procedure.

The Commission will enforce this regulation, unless it determines that

an emergency situation exists, only in accordance with Chapter 2, Guide 2.05—Letter of Advice/Notices of Noncompliance of the CPSC Enforcement Policy

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and Procedural Guides, issued in January 1990 and available from the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207. Under the procedure described in this chapter, firms must be informed by letter that they or their products may be the subject of enforcement action and must be provided ten days within which to submit evidence and arguments that the products are not violative or are not covered by the regulation, prior to the initiation of enforcement action by the Commission or by its delegated staff member. The function of approving such enforcement actions is currently delegated by the Commission to the Assistant Executive Director for Compliance and Enforcement (copies of the existing delegation documents are also available from the CPSC's Office of the Secretary).

[56 FR 46986, Sept. 17, 1991]

**PART 1502—PROCEDURES FOR
FORMAL EVIDENTIARY PUBLIC
HEARING**

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- 1502.30 Prehearing conference procedure.
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- 1502.36 Official transcript.
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Subpart F—Administrative Record

- 1502.38 Administrative record of a hearing.
- 1502.39 Examination of record.

Subpart G—Initial and Final Decision

- 1502.40 Initial decision.
- 1502.41 Appeal from or review of initial decision.
- 1502.42 Decision by Commission on appeal or review of initial decision.
- 1502.43 Reconsideration and stay of Commission's action.

Subpart H—Judicial Review

- 1502.44 Review by the courts.
- 1502.45 Copies of petitions for judicial review.

AUTHORITY: 15 U.S.C. 1261(q)(1)(B), 1262(a), 1262(e), 1269(a); 15 U.S.C. 1474(a); 21 U.S.C. 371(e)–(g).

SOURCE: 56 FR 9278, Mar. 6, 1991, unless otherwise noted.

Subpart A—General Provisions

§ 1502.1 Scope.

The procedures in this part apply when—

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(a) A person has a right to an opportunity for a hearing under sections 2(q)(1)(B) or 3(a) of the Federal Hazardous Substances Act (“FHSA”) and 701(e) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (15 U.S.C. 1261(q)(1)(B) and 1262(a), and 21 U.S.C. 371(e));

(b) The Commission elects to hold a hearing under section 3(e)(1) of the FHSA or section 5 of the Poison Prevention Packaging Act (“PPPA”) and section 701(e) of the FDCA (15 U.S.C. 1262(e)(1) and 1474(a), and 21 U.S.C. 371(e)); or

(c) The Commission concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before it in such a proceeding.

§ 1502.2 Computation of time periods.

Whenever a time period for taking action is specified by these procedures, by the presiding officer, or by the Commission, Saturdays, Sundays, and Federal holidays are included in computing time. However, if the last day for taking such action falls on a Saturday, Sunday, or Federal holiday, the action shall be timely if taken on or before the next Federal Government business day.

§ 1502.3 Confidential information.

Whenever any participant desires or is required to submit information in any proceeding under this part 1502, and the participant believes that such information consists of trade secret or other confidential business or financial information that should not be disclosed publicly, the participant may, instead of submitting such information, file a motion for a protective order containing a general description of the information desired to be withheld, together with a detailed argument supporting the claim that the information should be held in confidence.

§ 1502.4 Office of the Secretary.

(a) The mailing address of the Commission’s Office of the Secretary is: Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

(b) The address for delivery to the Office of the Secretary is: Office of the Secretary, Room 502, 4330 East West Highway, Bethesda, Maryland 20816.

(c) The telephone number of the Office of the Secretary is (301)504-0800.

[56 FR 9278, Mar. 6, 1991, as amended at 62 FR 46667, Sept. 4, 1997]

Subpart B—Initiation of Proceedings

§ 1502.5 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) The FEDERAL REGISTER notice promulgating the final regulation will describe how to submit objections and requests for hearing.

(b) On or before the 30th day after the date of publication of a final regulation in the FEDERAL REGISTER, a person may file written objections, with or without a request for a hearing, with the Commission. The 30-day period may not be extended, except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission or for other good cause shown, if consideration of the additional information will not delay review of the objection and request for hearing.

§ 1502.6 Filing objections and requests for a hearing on a regulation.

(a) Objections and requests for a hearing under §1502.5(a) must be filed with the Office of the Secretary and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in §1502.5(b).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision(s) of the regulation to which that objection is directed.

(4) Each objection on which a hearing is requested specifically requests a hearing. Failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed description of the basis for the objection and the factual information or analysis in support thereof. Failure to include a description and analysis for an objection constitutes a waiver of the right

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to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under §1502.8, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, unless the document is—

(A) A CPSC document that is routinely publicly available; or

(B) A recognized medical or scientific textbook or journal in the public domain.

(ii) A summary of the non-documentary testimony to be presented by any witnesses relied upon must be submitted.

(b) If an objection or request for a public hearing fails to meet the requirements of this section the Office of the General Counsel shall notify the Office of the Secretary of the deficiency. The Office of the Secretary shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in §1502.5(b).

(c) If another person objects to a regulation issued in response to a petition, the petitioner may submit a written reply to the Office of the Secretary on or before the 15th day after the last day for filing objections.

§ 1502.7 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under the FHSA or the PPPA and section 701(e) of the Federal Food, Drug, and Cosmetic Act, the Commission shall publish a notice in the FEDERAL REGISTER specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue

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delay, the notice required by this section may be combined with the notices described in §§1502.10 and 1502.13.

§ 1502.8 Ruling on objections and requests for hearing.

(a) As soon as practicable, the Commission will review all objections and requests for hearing filed under §1502.6 and determine—

(1) Whether the regulation should be modified or revoked under §1502.9; and

(2) Whether a hearing has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commission concludes that the data and information submitted, even though accurate, are insufficient to justify the factual determination urged.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commission concludes that the Commission's action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal.

(5) The action requested is not inconsistent with any provision in the FHSA or any regulation in 16 CFR subchapter C explaining or particularizing the requirements of the FHSA.

(6) The requirements in other applicable regulations, and in the notice promulgating the final regulation or

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the notice of opportunity for hearing are met.

(c) In making the determinations specified in paragraph (a) of this section, the Commission may issue an appropriate order on the determinations without further notice or opportunity for comment from interested parties. However, the Commission, at its option, may use the procedure specified in 16 CFR part 1052 or any other applicable public procedure available to it.

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commission concludes that summary decision against the person requesting a hearing should be considered, the Commission may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing.

§ 1502.9 Modification or revocation of regulation or order.

If, upon review of an objection or request for hearing, the Commission determines that the regulation should be modified or revoked, the Commission will promptly take such action by notice in the FEDERAL REGISTER. Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 1502.5 and 1502.6, but no further issue may be taken with other provisions in the regulation. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 1502.10 Denial of hearing in whole or in part.

(a) If the Commission determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published in the FEDERAL REGISTER.

(b) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 1502.13, and will specify the objections and requests for hearing that have been granted and denied.

(c) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(d) The notice will confirm, modify, or stay the effective date of the regulation involved.

(e) The record of the administrative proceeding relating to denial in whole or in part of a public hearing on an objection or request for hearing consists of the following:

- (1) The entire rulemaking record;
- (2) The objections and requests for hearing filed by the Office of the Secretary; and
- (3) The notice denying a formal evidentiary public hearing.

(f) The record specified in paragraph (e) of this section is the exclusive record for the Commission's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commission's decision denying a hearing, unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration or a petition for stay of the Commission's action. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commission with a petition to modify the final regulation.

(g) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the FEDERAL REGISTER.

(1) Before requesting a court for a stay of the Commission's action pending judicial review, a person shall first submit a petition to the Commission for a stay of action.

(2) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the FEDERAL REGISTER. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue,

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regardless whether a hearing has been granted on other objections and issues.

§ 1502.11 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 1502.5(a) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in § 1502.6(a)(4).

(b) If a person waives the right to a hearing, the Commission will rule upon the person's objections under §§ 1502.8 through 1502.10. As a matter of discretion, the Commission may also order a hearing on the matter.

(c) If the Commission rules adversely on a person's objection, the person may petition for judicial review in a U.S. court of appeals under the appropriate statute.

(1) The record for judicial review is the record designated in § 1502.10(e).

(2) The time for filing a petition for judicial review begins on the date of publication of the Commission's ruling on the objections in the FEDERAL REGISTER.

§ 1502.12 Request for alternative form of hearing.

(a) A person with a right to request a formal hearing may waive that right and request a hearing before the Commission under 16 CFR part 1052.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commission;

(2) Must be submitted by the person in the form of a petition before publication of a notice of hearing under § 1502.13 or a denial of hearing under § 1502.10; and

(3) Must be—

(i) In lieu of a request for a formal hearing under § 1502.5; or,

(ii) If submitted with or after a request for formal hearing, accompanied by a waiver of the right to a formal hearing, conditioned on the request for the alternative form of hearing. Upon acceptance by the Commission, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing, unless the Commission determines otherwise.

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(c) When more than one person requests and justifies a formal hearing under these procedures, an alternative form of hearing may be used only if all the persons concur and waive their right to request a formal hearing.

(d) The Commission will determine whether an alternative form of hearing should be used after considering the requests submitted and the appropriateness of the alternative hearing for the issues raised in the objections. The Commission's determination is binding unless, for good cause, the Commission subsequently determines otherwise.

(e) If the Commission determines that an alternative form of hearing will be used, the Commission will publish a notice in the FEDERAL REGISTER setting forth the following information:

(1) A description of the regulation that is the subject of the hearing.

(2) A statement specifying any part of the regulation that has been stayed by operation of law or in the Commission's discretion.

(3) The time, date, and place of the hearing, or a statement that such information will be contained in a later notice.

(4) The parties to the hearing.

(5) The issues at the hearing. The statement of issues determines the scope of the hearing.

§ 1502.13 Notice of hearing; stay of action.

(a) If the Commission determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commission will publish a notice setting forth the following:

(1) A description of the regulation that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commission's discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 1502.10.

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(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 1502.16.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 1502.16(a).

(9) The time within which participants should submit written information and views under § 1502.25(b). Additional copies of material already submitted under § 1502.25 need not be included with any later submissions.

(10) The contents of the portions of the administrative record relevant to the issues at the hearing. Except for trade secrets or other confidential information, the disclosure of which is prohibited by statute, the portions listed will be placed on public display in the Office of the Secretary before the notice is published.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commission of a decision by the presiding officer to revise the issues to include an issue on which the Commission has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

§ 1502.14 Effective date of a regulation when no objections are filed.

(a) If no objections are filed and no hearing is requested on a regulation under § 1502.5, the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commission shall publish a confirmation of the effective date of the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

Subpart C—Appearance and Participation

§ 1502.15 Appearance.

(a) A person who has filed a notice of participation under § 1502.16 may appear in person or by counsel or other representative in any hearing and, subject to § 1502.27, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the requirements regarding conduct in § 1502.28.

§ 1502.16 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 1502.13, a person desiring to participate in a hearing is to file with the Office of the Secretary a notice of participation in the following form:

(Date) _____
Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD. Mailing address: Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

Notice of Participation

(Title of Regulation) _____
Docket No. _____
Please enter the participation of:
(Name) _____
(Street address) _____
(City, State, and Zip Code) _____

(Telephone number) _____
Service on the above will be accepted by:
(Name) _____
(City, State, and Zip Code) _____

(Telephone number) _____

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of § 1502.25 of these procedures.)
(Signed) _____

(b) Any amendment to a notice of participation should be filed with the Office of the Secretary and served on all participants.

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(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for non-participation in the hearing or for failure to comply with any requirement of this subpart, e.g., disclosure of information as required by §1502.25 or the prehearing order issued under §1502.30. Any person whose participation is stricken may petition the Commission for interlocutory review of that decision.

[56 FR 9278, Mar. 6, 1991, as amended at 62 FR 46667, Sept. 4, 1997]

§ 1502.17 Advice on public participation in hearings.

(a) All inquiries from the public about scheduling, location, and general procedures should be addressed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or telephone (301) 504-0800.

(b) Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the presiding officer.

(c) Under no circumstances will the Office of the General Counsel of CPSC directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the staff. Other members of the office, ordinarily including the General Counsel, are designated to advise the Commission on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the Office of the General Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commission to respond to inquiries from other participants in the hearing; such participants may be urging views contrary to those of the staff involved or to what may ultimately be the final conclusions of the Commis-

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sion. Accordingly, members of the Office of the General Counsel, other than the attorneys responsible for representing the staff, will not answer questions about the hearing from any participant or potential participant.

(d) Participants in a hearing may communicate with the attorneys responsible for representing the staff, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Office of the Secretary.

(e) Separation of functions and *ex parte* communications will be handled as follows.

(1) An interested person may meet or correspond with any CPSC representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing on the matter. The provisions of 16 CFR part 1012 apply to such meetings.

(2) Upon publication of a notice announcing a formal evidentiary public hearing, the following rules concerning separation of functions apply:

(i) The CPSC staff members responsible for preparing evidence and participating in the hearing in the matter are, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the staff at the hearing and in any pleading or oral argument before the Commission. These representatives of the staff may not participate or advise in any decision except as witnesses or counsel in public proceedings. Except as provided herein, there shall be no other communication between representatives of the staff and representatives of the various Commissioners' offices concerning the matter prior to the decision of the Commission. The Commission may, however, designate other representatives of the staff to advise the Commission. The designation will be in writing and filed with the Office

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of the Secretary no later than the time specified in paragraph (f)(2) of this section for the application of separation of functions. All employees of the CPSC other than representatives of the involved staff (except for those specifically designated otherwise) may be called upon to advise and participate with the offices of the Commissioners in their functions relating to the hearing and the final decision.

(ii) The General Counsel of CPSC shall designate members of the Office of the General Counsel to advise and participate with the staff in its functions in the hearing and shall designate other members of the Office of the General Counsel to advise the offices of the Commissioners in their functions related to the hearing and the final decision. The members of the Office of the General Counsel designated to advise the staff may not participate or advise in any decision of the Commission except as counsel in public proceedings. The designation shall be in the form of a memorandum filed with the Office of the Secretary and made a part of the administrative record in the proceeding. There may be no other communication between those members of the Office of the General Counsel designated to advise the offices of the Commissioners and any other person in the Office of the General Counsel or in the involved staff with respect to the matter prior to the decision of the Commission. The General Counsel may assign different attorneys to advise either the staff or the offices of the Commissioners at any stage of the proceedings. The General Counsel will ordinarily advise and participate with the offices of the Commissioners in their functions relating to the hearing and the final decision.

(iii) The Commissioners are responsible for the agency review and final decision of the matter, with the advice and participation of anyone in CPSC other than representatives of the responsible staff and those members of the Office of the General Counsel designated to assist in the staff functions in the hearing.

(iv) Between the date that separation of functions applies and the date of the Commission's decision on the matter, communication concerning the matter

involved in the hearing will be restricted as follows:

(A) No person outside CPSC may have an *ex parte* communication with the presiding officer or any person representing the offices of the Commissioners concerning the matter in the hearing. Neither the presiding officer nor any person representing the offices of the Commissioners may have any *ex parte* communications with a person outside CPSC concerning the matter in the hearing. All communications are to be public communications, as witness or counsel under the applicable procedures.

(B) A participant in the hearing may submit a written communication concerning a proposal for settlement to the presiding officer with a request that it be transmitted to the Commission. These communications are to be in the form of pleadings, served on all other participants, and filed with the Office of the Secretary like any other pleading.

(C) A written communication contrary to this section must be immediately served on all other participants and filed with the Office of the Secretary by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Office of the Secretary. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Office of the Secretary.

(D) The making of a communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute,

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result in a decision adverse to the person knowingly making or causing the making of such a communication.

[56 FR 9278, Mar. 6, 1991, as amended at 62 FR 46667, Sept. 4, 1997]

Subpart D—Presiding Officer

§ 1502.18 Presiding officer.

The presiding officer in a hearing will be an administrative law judge qualified under 5 U.S.C. 3105.

§ 1502.19 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 1502.20 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 1502.30(b) and to rule on the need for oral testimony and cross-examination under § 1502.26(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike or limit their testimony if they fail to respond fully to proper questions;

(h) Admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 1502.31;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any procedure in this subpart if the presiding officer determines that no party will be prejudiced, the ends of justice

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will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 1502.16(e) or exclude any person from the hearing under § 1502.28, or take other reasonable disciplinary action; and

(o) Take any other action required for the fair, expeditious, and orderly conduct of the hearing.

§ 1502.21 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 1502.35(b).

(b) A presiding officer who is aware of grounds for disqualification, whether or not raised by a participant, shall withdraw from the proceeding.

§ 1502.22 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commission will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 1502.23 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Office of the Secretary. Two copies shall be filed. To determine compliance with filing deadlines in a hearing, a submission is considered filed on the day of filing with or mailing to the Office of the Secretary. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants.

(c) Service is accomplished by mailing a submission to the address shown

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in the notice of participation or by personal delivery.

(d) All submissions are to be accompanied by a certificate of service or by a statement that service is not required, stating the reason therefor.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §1502.3.

§ 1502.24 Petition to participate *in forma pauperis*.

(a) A participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden may submit to the Commission a petition to participate *in forma pauperis*.

(b) The petition will be captioned: "Request to Participate *In Forma Pauperis*, Docket No. _____." Filing and service requirements for the petition are described in paragraph (c) of this section, whether or not the petition is granted; The petition must demonstrate that either:

(1) The participant is indigent and a strong public interest justifies participation, or

(2) The participant's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commission may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Office of the Secretary. The Office of the Secretary will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 1502.25 Disclosure of data and information to be relied on by the participants.

(a) Before the notice of hearing is published under §1502.13, the Assistant General Counsel for Regulatory Affairs shall submit the following to the Office of the Secretary:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not required to be submitted.

(2) All other documentary data and information relied upon.

(3) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the Assistant General Counsel intends to introduce.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the Office of the Secretary all data and information specified in paragraph (a) (2) and (3) of this section and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete, and any documents in the participants' files containing factual information, whether favorable or unfavorable to the regulation issued by the Commission, which relates to the issues involved in the hearing.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material in the supplement was not reasonably known or available when the submission was made, that the relevance of the material contained in the supplement could not reasonably have been foreseen, or that admission of the material in the supplement is necessary for a fair determination of the issues involved in the hearing.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

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§ 1502.26 Purpose; oral and written testimony; burden of proof.

(a) The objective of a formal evidentiary hearing is the fair determination of relevant facts consistent with the right of all interested persons to participate and the public interest in promptly settling controversial matters affecting the public health and welfare.

(b) Accordingly, the evidence at a hearing is to be developed to the maximum extent through written submissions, including written direct testimony, which may be in narrative or in question-and-answer form.

(1) Direct testimony will be submitted in writing, except on a showing that written direct testimony is insufficient for a full and true disclosure of relevant facts and that the participant will be prejudiced if unable to present oral direct testimony. If the proceeding involves particular issues, each party may determine whether, and the extent to which, each wishes to present direct testimony orally or in writing.

(2) Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.

(3) Witnesses shall give testimony under oath.

(c) A participant who proposes to substitute a new provision for a provision objected to has the burden of proof in relation to the new provision.

§ 1502.27 Participation of nonparties.

(a) A nonparty participant may—

(1) Attend all conferences (including the prehearing conference), oral proceedings, and arguments;

(2) Submit written testimony and documentary evidence for inclusion in the record;

(3) File written objections, briefs, and other pleadings; and

(4) Present oral argument.

(b) A nonparty participant may not—

(1) Submit written interrogatories; or

(2) Conduct cross-examination.

(c) A person whose petition is the subject of the hearing has the same right as a party.

(d) A nonparty participant will be permitted additional rights if the presiding officer concludes that the participant's interests would not be adequately protected otherwise or that broader participation is required for a full and true disclosure of the facts, but the rights of a nonparty participant may not exceed the rights of a party.

§ 1502.28 Conduct at oral hearings or conferences.

All participants in a hearing will conduct themselves with dignity and observe judicial standards of practice and ethics. They may not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. Representatives of parties shall, to the extent possible, restrain clients from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing shall constitute grounds for immediate exclusion from the proceeding by the presiding officer.

§ 1502.29 Time and place of prehearing conference.

A prehearing conference will commence at the date, time, and place announced in the notice of hearing, or in a later notice, or as specified by the presiding officer in a notice modifying a prior notice. At the prehearing conference, insofar as practicable at that time, the presiding officer will establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination, if leave to conduct oral examination is granted on any issue.

§ 1502.30 Prehearing conference procedure.

(a) Participants in a hearing are to appear at the prehearing conference

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prepared to discuss and resolve all matters specified in paragraph (b) of this section.

(1) To expedite the hearing, participants are encouraged to prepare in advance for the prehearing conference. Participants should cooperate with each other, and should request information and begin preparation of testimony at the earliest possible time. Failure of a participant to appear at the prehearing conference or to raise matters that reasonably could be anticipated and resolved at that time will not delay the progress of the hearing and constitutes a waiver of the rights of the participant regarding such matters as objections to the agreements reached, actions taken, or rulings issued by the presiding officer at or as a result of the prehearing conference and may be grounds for striking the participation under §1502.16.

(2) Participants shall bring to the prehearing conference the following specific information, which will be filed with the Office of the Secretary under §1502.23:

(i) Any additional information desired to supplement the submission filed under §1502.25; the supplement may be filed if approved under §1502.25.

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, with a full curriculum vitae for each. Additional witnesses may be identified later, with the approval of the presiding officer, on a showing that the witness was not reasonably available at the time of the prehearing conference, that the relevance of the witness's views could not reasonably have been foreseen at that time, or for other good cause shown, as where a previously identified witness is unforeseeably unable to testify.

(iii) All prior written statements, including articles and any written statement signed or adopted, or a recording or transcription of an oral statement made, by persons identified as witnesses if—

(A) The statement is available without making a request to the witness;

(B) The statement relates to the subject matter of the witness's testimony; and

(C) The statement either was made before the time the person agreed to

become a witness or has been made publicly available by the person.

(b) The presiding officer will conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement to be considered at the hearing. The presiding officer may hold conferences off the record in an effort to reach agreement on disputed factual questions, subject to the *ex parte* limitations in §1502.17(f).

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider, but is not limited to, the following techniques.

(i) Submission of narrative statements of position on factual issues in controversy.

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports.

(iii) Exchange of written interrogatories directed to particular witnesses.

(iv) Written requests for the production of additional documentation, data, or other relevant information.

(v) Submission of written questions to be asked by the presiding officer of a specific witness.

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting information submitted under §1502.25 into evidence.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order

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reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 1502.31 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, allow additional time to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy

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and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant submitting or opposing a motion for summary decision may obtain interlocutory review by the Commission of a summary decision of the presiding officer.

§ 1502.32 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth in this subpart and in the prehearing order.

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding comprise the administrative record of the hearing, and will be promptly placed on public display in the Office of the Secretary, except as ordered by the presiding officer.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 1502.25.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 1502.25.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of these procedures.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commission, without taking oral exception at the hearing. Upon review, the Commission may reopen the hearing to permit the evidence to be admitted if the Commission determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the progress of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating only to trade secrets and privileged or confidential commercial or financial information. Participation in closed proceedings will be limited to the witness, the witness's counsel, and Federal Government employees.

§ 1502.33 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of CPSC as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 1502.34 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument shall refrain from disclosing specific details of written and oral testimony and documents relating to trade secrets and privileged or confidential commercial or financial information, except as specifically authorized in a protective order issued by the presiding officer.

§ 1502.35 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 1502.13(b), 1502.16(e), 1502.31(f), and 1502.37(d) authorizing interlocutory appeals, rulings of the presiding officer may not be appealed to the Commission before the Commission's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commission if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commission, a participant may file a brief with the Commission only if such is specifically authorized by the presiding officer or the Commission, and, if such authorization is granted, within the period the Commission directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commission directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commission. The oral argument will be transcribed. If briefs are authorized, oral argument will be

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heard only at the discretion of the Commission.

§ 1502.36 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the Office of the Secretary upon receipt.

(c) Copies of the transcript may be obtained by application to the official reporter and payment of costs thereof.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 1502.37 Motions.

(a) Except for a motion made in the course of an oral hearing before the presiding officer, a motion on any matter relating to the proceeding shall be filed under § 1502.23 and must include a draft order.

(b) A response may be filed within 10 days of service of a motion. The time may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commission for interlocutory review.

Subpart F—Administrative Record

§ 1502.38 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed with the Office of the Secretary under §§ 1502.5 and 1502.6;

(3) The notice of hearing published under § 1502.13;

(4) All notices of participation filed under § 1502.16;

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(5) All FEDERAL REGISTER notices pertinent to the proceeding;

(6) All submissions filed under § 1502.24, e.g., the submissions required by § 1502.25, all other documentary evidence and written testimony, pleadings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 1502.30;

(8) All documents relating to any motion for summary decision under § 1502.31;

(9) All documents of which official notice is taken under § 1502.33;

(10) All pleadings filed under § 1502.34;

(11) All documents relating to any interlocutory appeal under § 1502.35;

(12) All transcripts prepared under § 1502.36; and

(13) Any other document relating to the hearing and filed with the Office of the Secretary by the presiding officer or any participant.

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 1502.34(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 1502.39 Examination of record.

Except as provided in § 1502.3, documents in the record will be publicly available. Documents available for examination or copying will be placed on public display in the Office of the Secretary promptly upon receipt in that office.

Subpart G—Initial and Final Decision

§ 1502.40 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as practicable after the filing of briefs and oral argument.

(b) The initial decision shall contain—

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(1) Findings of fact based upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation supported by substantial evidence of record and based upon the findings of fact and conclusions of law (unless the initial decision is to not issue a regulation);

(6) An effective date for the regulation (if any), together with an explanation of why the effective date is appropriate; and

(7) The periods of time for filing exceptions to the initial decision with the Office of the Secretary and for filing replies to such exceptions, in accordance with §1502.41(a)–(c).

(c) The initial decision must refrain from disclosing specific details of trade secrets and privileged or confidential commercial or financial information, except as specifically authorized in a protective order issued by the presiding officer.

(d) The initial decision is to be filed with the Office of the Secretary and served upon all participants. Once the initial decision is filed with the Office of the Secretary, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Office of the Secretary will be decided by the Commission.

(e) The initial decision becomes the final decision of the Commission by operation of law unless a participant files exceptions with the Office of the Secretary under §1502.41(a) or the Commission files a notice of review under §1502.41(f).

(f) Notice that an initial decision has become the decision of the Commission without appeal to or review by the Commission will be published in the FEDERAL REGISTER. The Commission also may publish the decision when it is of widespread interest.

§ 1502.41 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commission by filing exceptions with the Office of the Secretary, and serving them on the other participants within the period specified in the initial decision. The period for appeal to the Commission may not exceed 30 days, unless extended by the Commission under paragraph (d) of this section.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commission may be requested in the exceptions.

(c) Any reply to the exceptions shall be filed and served within the period specified in the initial decision. The period may not exceed 30 days after the end of the period (including any extensions) for filing exceptions, unless extended by the Commission under paragraph (d) of this section.

(d) The Commission may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) If the Commission decides to hear oral argument, the participants will be informed of the date, time, and place of the argument, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commission may file with the Office of the Secretary, and serve on the participants, a notice of the Commission's determination to review the initial decision. The Commission may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

§ 1502.42 Decision by Commission on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commission has all the powers given to the presiding officer with respect to the initial decision. On the Commission's own initiative or on motion, the Commission

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may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues at the public hearing is the same as the scope of the issues on appeal at the public hearing unless the Commission specifies otherwise.

(c) As soon as possible after the filing of briefs and the presentation of any oral argument, the Commission will issue a final decision in the proceeding, which meets the requirements established in § 1502.40 (b) and (c).

(d) The Commission may adopt the initial decision as the final decision.

(e) Notice of the Commission's decision will be published in the FEDERAL REGISTER. The Commission may also publish the decision when it is of widespread interest.

§ 1502.43 Reconsideration and stay of Commission's action.

Following notice or publication of the final decision, a participant may petition the Commission for reconsideration of any part or all of the decision or may petition for a stay of the decision.

Subpart H—Judicial Review

§ 1502.44 Review by the courts.

(a) The Commission's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of the Commission's action pending judicial review, a participant shall first submit a petition for a stay of action under § 1502.43.

(b) Under 28 U.S.C. 2112(a), CPSC will request consolidation of all petitions related to a particular matter.

§ 1502.45 Copies of petitions for judicial review.

The General Counsel of CPSC has been designated by the Commission as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Secretary of the Commission.

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PART 1505—REQUIREMENTS FOR ELECTRICALLY OPERATED TOYS OR OTHER ELECTRICALLY OPERATED ARTICLES INTENDED FOR USE BY CHILDREN

Subpart A—Regulations

Sec.

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1505.50 Stalled motor testing.

1505.51 Hot surfaces.

AUTHORITY: 15 U.S.C. 1261–1262, 2079.

SOURCE: 38 FR 27032, Sept. 27, 1973, unless otherwise noted.

Subpart A—Regulations

§ 1505.1 Definitions.

(a) The following definitions apply to this part 1505:

(1) The term “electrically operated toy or other electrically operated article intended for use by children” means any toy, game, or other article designed, labeled, advertised, or otherwise intended for use by children which is intended to be powered by electrical current from nominal 120 volt (110–125 v.) branch circuits. Such articles are referred to in this part in various contexts as “toy” or “electrically operated toy.” If the package (including packing materials) of the toy or other article is intended to be used with the product, it is considered to be part of the toy or other article. This definition does not include components which are powered by circuits of 30 volts r.m.s. (42.4 volts peak) or less, articles designed primarily for use by adults which may be used incidentally by children, or video games.

(2) The term *video games* means video game hardware systems, which are games that both produce a dynamic video image, either on a viewing screen that is part of the video game or,

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through connecting cables, on a television set, and have some way to control the movement of at least some portion of the video image.

[38 FR 27032, Sept. 27, 1973, as amended at 58 FR 40335, July 28, 1993]

§ 1505.2 Scope of part.

This part sets forth the requirements whereby electrically operated toys and other electrically operated articles intended for use by children (as defined in §1505.1(a)(1)) are not banned toys or banned articles under §1500.18(b)(1) of this chapter.

§ 1505.3 Labeling.

(a) *General.* Electrically operated toys, and the instruction sheets and outer packaging thereof, shall be labeled in accordance with the requirements of this section and any other applicable requirements of the Federal Hazardous Substances Act and regulations promulgated thereunder. All labeling shall be prominently and conspicuously displayed under customary conditions of purchase, storage, and use. All required information shall be readily visible, noticeable, clear, and, except where coding is permitted, shall be in legible English (other languages may also be included as appropriate). Such factors governing labeling as location, type size, and contrast against background may be based on necessary condensations to provide a reasonable display.

(b) *Specific items.* (1) The toy shall be marked in accordance with the provisions of paragraph (d) of this section to indicate:

(i) The electrical ratings required by paragraph (c) of this section.

(ii) Any precautionary statements required by paragraph (e) of this section.

(iii) The date (month and year) of manufacture (or appropriate codes). As an alternative to putting this information on the toy itself, it may be included in the instructions provided with the toy (see paragraph (b)(3) of this section).

(2) The shelf pack or package of the toy shall be labeled in accordance with the provisions of paragraph (d) of this section to indicate:

(i) The date (month and year) of manufacture (or appropriate codes).

(ii) The electrical ratings required by paragraph (c) of this section.

(iii) Any precautionary statements required by paragraph (e) of this section.

(3) Each toy shall be provided with adequate instructions that are easily understood by children of those ages for which the toy is intended. The instructions shall describe the applicable installation, assembly, use, cleaning, maintenance (including lubrication), and other functions as appropriate. Applicable precautions shall be included as well as the information required by paragraphs (b) (1) and (2) of this section, except that the date of manufacture information described in paragraph (b)(1)(iii) of this section need not be included in the instructions provided with the toy if it is placed on the toy itself. The instructions shall also contain a statement addressed to parents recommending that the toy be periodically examined for potential hazards and that any potentially hazardous parts be repaired or replaced.

(4) If a toy is produced or assembled at more than one establishment, the toy and its shelf pack or package shall have a distinctive mark (which may be in code) identifying the toy as the product of a particular establishment.

(c) *Rating.* (1) A toy shall be marked to indicate its rating in volts and also in amperes and/or watts.

(2) If a toy utilizes a single motor as its only electric energy consuming component, the electrical rating may be marked on a motor nameplate and need not be marked elsewhere on the toy if the nameplate is readily visible after the motor has been installed in the toy.

(3) A toy shall be rated for alternating current only, direct current only, or both alternating and direct current.

(4) The alternating current rating shall include the frequency or frequency range requirement, if necessary because of a special component.

(d) *Markings.* (1) The markings required on the toy by paragraph (b) of this section shall be of a permanent nature, such as paint-stenciled, die-stamped, molded, or indelibly stamped. The markings shall not be permanently obliterated by spillage of any material

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intended for use with the toy and shall not be readily removable by cleaning with ordinary household cleaning substances. All markings on the toy and labeling of the shelf pack or package required by paragraph (b) of this section shall contrast sharply with the background (whether by color, projection, or indentation) and shall be readily visible and legible. Such markings and labeling shall appear in lettering of a height not less than that specified in paragraph (d)(2) of this section, except that those words shown in capital letters in paragraph (e) of this section shall appear in capital lettering of a height not less than twice that specified in paragraph (d)(2) of this section.

(2) Minimum lettering heights shall be as follows:

SURFACE AREA DISPLAY MARKING, MINIMUM HEIGHT OF LETTERING	
Square inches	Inches
Under 5	1/16
5 or more and under 25	1/8
25 or more and under 100	3/16
100 or more and under 400	1/4
400 or more	1/2

(e) *Precautionary statements*—(1) *General*. Electrically operated toys shall bear the statement: “CAUTION—ELECTRIC TOY.” The instruction booklet or sheet accompanying such toys shall bear on the front page thereof (in the type size specified in §1500.121), as a preface to any written matter contained therein, and the shelf pack or package of such toys shall bear in the upper right hand quarter of the principal display panel, the statement: “CAUTION—ELECTRIC TOY: Not recommended for children under _____ years of age. As with all electric products, precautions should be observed during handling and use to prevent electric shock.” The blank in the preceding statement shall be filled in by the manufacturer, but in no instance shall the manufacturer indicate that the article is recommended for children under 8 years of age if it contains a heating element. In the case of other electrically operated products which may not be considered to be “toys” but are intended for use by children, the term “ELECTRICALLY OPERATED

PRODUCT” may be substituted for the term “ELECTRIC TOY.”

(2) *Thermal hazards*. (i) Toys having Type C or Type D surfaces (described in §1505.6(g)(2)) which reach temperatures greater than those shown in paragraph (e)(2)(ii) of this section shall be defined as hot and shall be marked where readily noticeable when the hot surface is in view with the statement: “HOT—Do Not Touch.” When the marking is on other than the hot surface, the word “HOT” shall be followed by appropriate descriptive words such as “Molten Material,” “Sole Plate,” or “Heating Element,” and the statement “Do Not Touch.” An alternative statement for a surface intended to be handheld as a functional part of the toy shall be “HOT _____ Handle Carefully,” the blank being filled in by the manufacturer with a description of the potential hazard such as “Curler” or “Cooking Surface.”

(ii) Surfaces requiring precautionary statements of thermal hazards are those exceeding the following temperatures when measured by the test described in §1505.6(g)(4):

Surface type (see § 1505.6 (g)(2))	Thermal inertia type ¹	Temperature	
		Degrees C.	Degrees F.
C	1	65	149
C	2	75	167
C	3	85	185
C	4	95	203
D	1	55	131
D	2	70	158
D	3	80	176
D	4	90	194

¹Thermal inertia types are defined in terms of lambda as follows:
 Type 1: Greater than 0.0045 (e.g., most metals).
 Type 2: More than 0.0005 but not more than 0.0045 (e.g., glass).
 Type 3: More than 0.0001 but not more than 0.0005 (e.g., most plastics).
 Type 4: 0.0001 or less (e.g., future polymeric materials).
 The thermal inertia of a material can be obtained by multiplying the thermal conductivity (cal./cm./sec./degrees C.) by the density (gm./cm.³) by the specific heat (cal./gm./degrees C.)

(3) *Lamp hazards*—(i) *Replaceable incandescent lamps*. A toy with one or more replaceable incandescent lamps, having a potential difference of more than 30 volts r.m.s. (42.4 volts peak) between any of its electrodes or lampholder contacts and any other part or ground, shall be marked inside the lamp compartment where readily noticeable during lamp replacement with the statement: “WARNING—Do

not use light bulbs larger than _____ watts”, the blank being filled in by the manufacturer with a number specifying the wattage rating of the lamp. Such toys shall bear the statement: “WARNING—Shock Hazard. Pull plug before changing light bulb” on the outside of the lamp compartment where it will be readily noticed before gaining access to the lamp compartment.

(ii) *Nonreplacement incandescent lamps.* A toy which utilizes one or more nonreplaceable incandescent lamps (other than pilot or indicator lamps) shall be marked where clearly visible with the statement: “SEALED UNIT—Do not attempt to change light bulb” or equivalent.

(4) *Water.* If not suitable for immersion in water, a toy cooking appliance (such as a corn popper, skillet, or candy-maker) or other article which may conceivably be immersed in water shall be marked with the statement: “DANGER—To prevent electric shock, do not immerse in water; wipe clean with damp cloth” or equivalent.

[38 FR 27032, Sept. 27, 1973, as amended at 42 FR 34280, July 5, 1977; 42 FR 43392, Aug. 29, 1977]

§ 1505.4 Manufacturing requirements.

(a) *General.* (1) Only materials safe and suitable for the particular use for which the electrically operated toy is intended shall be employed.

(2) Toys shall be produced in accordance with detailed material specifications, production specifications, and quality assurance programs. Quality assurance programs shall be established and maintained by each manufacturer to assure compliance with all requirements of this part.

(3) The manufacturer or importer shall keep and maintain for 3 years after production or importation of each lot of toys (i) the material and production specifications and the description of the quality assurance program required by paragraph (a)(2) of this section, (ii) the results of all inspections and tests conducted, and (iii) records of sale and distribution. These records shall be made available upon request at reasonable times to any officer or employee of the Consumer Product Safety Commission. The manufacturer or importer shall permit such officer or em-

ployee to inspect and copy such records, to make such inventories of stock as he deems necessary, and to otherwise verify the accuracy of such records.

(4) Toys shall be constructed and finished with a high degree of uniformity and as fine a grade of workmanship as is practicable in a well-equipped manufacturing establishment. Each component of a toy shall comply with the requirements set forth in this part.

(b) [Reserved]

(c) *Protective coatings.* Iron and steel parts shall be suitably protected against corrosion if the lack of a protective coating would likely produce a hazardous condition in normal use or when the toy is subjected to reasonably foreseeable damage or abuse.

(d) *Mechanical assembly—(1) General.* A toy shall be designed and constructed to have the strength and rigidity necessary to withstand reasonably foreseeable damage and abuse without producing or increasing a shock, fire, or other accident hazard. An increase in hazards may be due to total or partial structural collapse of the toy resulting in a reduction of critical spacings, loosening or displacement of one or more components, or other serious defects.

(2) *Mounting.* Each switch, lampholder, motor, automatic control, transformer, and similar component shall be securely mounted and shall be prevented from turning, unless the turning of such component is part of the design of the toy and produces no additional hazard such as reduced spacings below acceptable levels or stress on the connection. Friction between tight-fitting surfaces shall not be considered sufficient for preventing the turning of components. The proper use of a suitable lockwasher or a keyed and notched insert plus a suitable lockwasher for single-hole mountings shall be acceptable. Each toy shall be designed and constructed so that vibrations occurring during normal operation and after reasonably foreseeable damage or abuse will not affect it adversely. Brush caps shall be tightly threaded or otherwise designed to prevent loosening.

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(3) *Structural integrity.* Heating elements shall be supported in a substantial and reliable manner and shall be structurally prevented from making contacts inside or outside of the toy which may produce shock hazards. The current-carrying component(s) of the heating element shall be enclosed, and the enclosure shall be designed or insulated to prevent the development of a shock or fire hazard that may result from element failure. A toy operating with a gas or liquid under pressure, such as an electrically operated steam engine, shall be tested with respect to its explosion hazard and shall be provided with a pressure relief device that will discharge in the safest possible direction; that is, avoiding direct human contact and avoiding the wetting of electrical contacts.

(e) *Insulating material.* (1) Material to be used for mounting uninsulated live electrical elements shall be generally accepted as suitable for the specific application, particularly with regard to electrical insulation (voltage breakdown) and good aging characteristics (no significant change in insulating characteristics over the expected lifetime of the toy).

(2) Material used to insulate a heating element from neighboring parts shall be suitable for the purpose. If plain asbestos in a glass braid is used to so insulate the heating element, it shall be tightly packed and totally enclosed by the braid, and the overall thickness, including the braid, shall not be less than one-sixteenth inch. Hard fiber may be used for electrically insulating bushings, washers, separators, and barriers, but is not sufficient as the sole support of uninsulated live metal parts.

(f) *Enclosures*—(1) *General.* Each toy shall have an enclosure constructed of protective material suitable for the particular application, for the express purpose of housing all electrical parts that may present a fire, shock, or other accident hazard under any conditions of normal use or reasonably foreseeable damage or abuse. Enclosures shall meet the performance requirements prescribed by § 1505.6(b).

(2) *Accessibility.* An enclosure containing a wire, splice, brush cap, connection, electrical component, or

uninsulated live part or parts at a potential of more than 30 volts r.m.s. (42.4 volts peak) to any other part or to ground:

(i) Shall be sealed by welding, riveting, adhesive bonding, and/or by special screws or other fasteners not removable with a common household tool (screwdriver, pliers, or other similar household tool) used as intended; and

(ii) Shall have no opening permitting entry of a 0.010-inch-diameter music wire that could contact a live part. Cross-notch-head screws, spring clips, bent tabs, and similar fasteners shall not be considered suitable sealing devices for enclosures since they are easy to remove with common household tools. Bent tabs shall be acceptable if, due to metal thickness or other factors, they successfully resist forceful attempts to dislodge them with ordinary tools.

(3) *Nonapplication.* The requirements of this paragraph are not applicable to an insulating husk enclosure or equivalent that covers the electrodes of a replaceable incandescent lamp and its lampholder contacts. The primary function of an enclosure containing a lamp shall be to protect it from breakage during normal use or reasonably foreseeable damage or abuse.

(g) *Spacings.* The distance, through air or across the surface of an insulator, between uninsulated live metal parts and a metallic enclosure and between uninsulated live metal parts and all other metal parts shall be suitable for the specific application as determined by the dielectric strength requirements prescribed by § 1505.6(e)(2). Electrical insulating linings on barriers shall be held securely in place.

(h) *Special safety features*—(1) *Moving parts.* If the normal use of a toy involves accident hazards, suitable protection shall be provided for the reduction of such hazards to an acceptable minimum. For example, rotors, pulleys, belting, gearing, and other moving parts shall be enclosed or guarded to prevent accidental contact during normal use or when subjected to reasonably foreseeable damage or abuse. Such enclosure or guard shall not contain openings that permit entrance of a ¼-inch-diameter rod and present a hazardous condition.

(2) *Switch marking.* Any toy having one or more moving parts which perform an inherent function of the toy and which may cause personal injury shall have a switch that can deenergize the toy by a simple movement to a plainly marked "OFF" position. Momentary contact switches which are normally in the "OFF" position need not be so marked.

(3) *Electrically operated sewing machines.* Electrically operated toy sewing machines shall be designed and constructed to eliminate the possibility of a child's finger(s) being pierced by a needle. For the purpose of this paragraph, a clearance of not more than five thirty-seconds of an inch below the point of the needle when in its uppermost position or below the presser foot, if provided, shall be considered satisfactory.

(4) *Pressure relief valves.* A pressurized enclosure shall have an automatic pressure relief device and shall be capable of withstanding hydrostatic pressure equal to at least five times the relief pressure.

(5) *Containers for heated materials.* Containers intended for holding molten compounds and hot liquids shall be designed and constructed to minimize accidental spillage. A pot or pan having a lip and one or more properly located pouring spouts and an adequately thermally insulated handle may provide satisfactory protection. Containers intended solely for baking need not be designed and constructed to minimize accidental spillage. Containers shall be of such material and construction that they will not deform or melt when subjected to the maximum operating temperature occurring during normal use or after reasonably foreseeable damage or abuse.

(6) *Water.* Electrically operated toys (such as toy irons) shall not be designed or manufactured to be used with water except for toy steam engines or other devices in which the electrical components are separate from the water reservoir and are completely contained in a sealed chamber. Toys requiring occasional or repeated cleaning with a wet cloth shall be constructed to prevent seepage of water into any electrically active area that may produce a hazardous condition.

§ 1505.5 Electrical design and construction.

(a) *Switches.* (1) Switches and other control devices of electrically operated toys shall be suitable for the application and shall have a rating not less than that of the load they control (see § 1505.6(e)(5)(ii) regarding electrical switch overload). A switch that controls a replaceable incandescent lamp, electrode, or lampholder contact which is at a potential of more than 30 volts r.m.s. (42.4 volts peak) to any other part or to ground shall open both sides of the circuit and shall have a marked "OFF" position. A switch that may reasonably be expected to be subjected to temperatures higher than 50 °C. (122 °F.) shall be constructed of materials which are suitable for use at such temperatures.

(2) Switches shall be located and protected so that they are not subject to mechanical damage that would produce a hazard in normal use or from reasonably foreseeable damage or abuse (see § 1505.6(b)).

(b) *Lamps.* (1) A replaceable incandescent lamp having a voltage of more than 30 volts r.m.s. (42.4 volts peak) between any of its electrodes or lampholder contacts and any other part or ground shall be in an enclosure that has at least one door or cover permitting access to the lamp. Such door(s) or cover(s) of the enclosure shall be so designed and constructed that they cannot be opened manually or with a flat bladed screwdriver or pliers.

(2) With all access doors and covers closed, the lamp enclosure shall have no opening that will permit entry of a straight rod 6 inches long and one-fourth inch in diameter if such entry would present an electrical hazard. The lamp shall be located no less than one-half inch from any ¼-inch-diameter opening in the enclosure.

(3) A toy having one or more lampholders shall be designed and constructed so that no live parts other than the contacts of the lampholders are exposed to contact by persons removing or replacing lamps. The shells of all lampholders for incandescent lamps shall be at the same potential.

(4) If the potential between the contacts of a lampholder for a replaceable

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incandescent lamp and any other part or ground is greater than 30 volts r.m.s. (42.4 volts peak), the contacts shall be located in an insulating husk or equivalent.

(c) *Transformers.* Transformers that are integral parts of toys shall be of the 2-coil insulated type.

(d) *Automatic controls.* Automatic controls for temperature regulations shall have the necessary capacity and reliability for their particular application.

(e) *Power supply connections (cords and plugs).* (1) A toy shall be provided with a suitable means for attachment to the power supply circuit.

(2) A toy requiring a power cord shall have a flexible cord that is permanently attached to the toy.

(3) The perimeter of the face of the attachment-plug cap shall be not less than five-sixteenths of an inch from any point on either blade of the plug.

(4) The body of the attachment-plug cap shall decrease in cross section from the face but shall have an expansion of the body, after a suitable distance from the face, sufficient to provide an effective finger grip.

(5) A flexible electrical power cord provided on a toy shall be type SP-2 (as defined in the "National Electrical Code," Chapter 4, article 400, pages 230-241 (1978)¹, or its equivalent, or a heavier general-use type, and shall be not less than 5 feet nor more than 10 feet in length when measured as the overall length of the attached cord outside the enclosure of the toy, including fittings,

¹NFPA No. 70-1978, 1978 edition of National Electrical Code, Article 400, "Flexible Cords and Cables," pages 70-230 through 70-240, published by the National Fire Protection Association, which is incorporated by reference. Copies of this document are available from the National Fire Protection Administration, 60 Batterymarch Park, Quincy, Massachusetts 02269. This document is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

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up to the face of the attachment-plug cap. However, hand-held educational or hobby-type products intended for heating such as woodburning tools, shall use one of the type cords designated below, in accordance with the weight of the product without the cord:

WEIGHT OF APPLIANCE (WITHOUT CORD) AND CORD TYPE

½ lb. (0.227 kg) and lighter: SP-1, SPT-1, HPD. Heavier than ½ lb. (0.227 kg): SP-2, SPT-2, SV, SVO, SVT, SVTO, HPD, HPN, SJ, SJO, SJT, SJTO.

(6) A flexible cord and plug shall have a current-carrying capacity of not less than the ampere rating of the toy, and the conductor of the cord shall have a cross sectional area no less than No. 18 AWG (American wire gauge).

(7) Cords on toys which are intended to come in direct contact with water or other liquids during use shall be of a jacketed type. Cords on toys with which water or other liquids are to be indirectly used (such as for cooling a mold) shall be plastic covered.

(8) Transformers in which the primary coil connects directly to the branch circuit outlet shall not be subject to the requirements of paragraphs (e) (2), (4), and (5) of this section.

(f) *Bushings.* (1) At the point where a power supply cord passes through an opening in a wall, barrier, or the overall enclosure of a toy, a suitable and substantial bushing, insulating bushing, or equivalent shall be reliably secured in place and shall have smooth surfaces and well-rounded edges against which the cord may bear.

(2) If a cord hole is in wood, porcelain, phenolic composition, or other suitable insulating material, the surface of the hole is acceptable without a bushing if the edges of the hole are smooth and well-rounded. Where a separate insulating bushing is required, a bushing made of ceramic material or a suitable molded composition is acceptable if its edges are smooth and well-rounded.

(3) In no instance shall a separate bushing of wood, rubber, or any of the hot-molded shellac-and-tar compositions be considered acceptable.

(g) *Wiring.* (1) The internal wiring of a toy shall consist of suitable insulated conductors having adequate mechanical strength, dielectric properties, and

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electrical capacity for the particular application.

(2) Wireways shall be smooth and entirely free of sharp edges, burrs, fins, and moving parts that may abrade conductor insulation. Each splice and connection shall be mechanically secure, shall provide adequate and reliable electrical contact, and shall be provided with insulation at least equivalent to that of the wire involved unless adequate spacing between the splice and all other metal parts is permanently assured.

(3) A wire connector for making a splice in a toy shall be a type that is applied by a tool and for which the application force of the tool is independent of the force applied by the operator.

(4) Soldered connections shall be made mechanically secure before soldering.

(5) Current-carrying parts shall be made of silver, copper, a copper alloy, or other electrically conductive material suitable for the particular application.

(h) *Strain relief.* (1) A means of strain relief shall be provided to prevent mechanical stress on a flexible cord from being transmitted to terminals, splices, or interior wiring.

(2) If suitable auxiliary insulation is provided under a clamp for mechanical protection, clamps of any material are acceptable for use on Type SP-2 (as defined in the "National Electrical Code," chapter 4, article 400, pages 184-194 (1971)²) or equivalent rubber-insu-

²NFPA No. 70-1971, 1971 edition of National Electrical Code, Article 400, "Flexible Cords and Cables," pages 70-184 through 70-194, published by the National Fire Protection Association, which is incorporated by reference. Copies of this document are available from the National Fire Protection Association, 60 Batterymarch Park, Quincy, Massachusetts 02269. This document is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as they exist in the edition which has been approved by the Director of the

lated cord. For heavier types of thermoplastic-insulated cord, clamps may be without auxiliary insulation unless the clamp may damage the cord insulation.

(3) A flexible cord shall be prevented from being pushed into the toy through the cord-entry hole if such displacement would result in a hazardous condition.

(4) A knot in the cord shall not be considered an acceptable means of strain relief, but a knot associated with a loop around a smooth, fixed structural component shall be considered acceptable.

(i) *Additional requirements.* Except for the electrodes of a replaceable incandescent lamp and its lampholder contacts, a potential of more than 30 volts r.m.s. (42.4 volts peak) shall not exist between any exposed live part in a toy and any other part or ground.

(Sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[38 FR 27032, Sept. 27, 1973, as amended at 43 FR 45552, Oct. 3, 1978; 46 FR 63251, Dec. 31, 1981]

§ 1505.6 Performance.

(a) *General.* Electrically operated toys and components thereof shall be tested by the appropriate methods described in this section and shall pass the tests in such a manner as to provide the necessary assurance that normal use and reasonably foreseeable damage or abuse will not produce a hazard or a potentially hazardous condition. The toy shall be capable of passing all applicable tests with any door, cover, handle, operable part, or accessory placed in any normal position. A toy shall not present a fire, casualty, or shock hazard when operated continuously for 6 hours under conditions of normal use and reasonably foreseeable damage or abuse, including the most hazardous position in which the toy can be left.

(b) *Enclosures.* For the purposes of this section, the term *enclosure* means any surface or surrounding structure which prevents access to a real or potential hazard. An enclosure shall withstand impact, compression, and pressure tests (see paragraphs (b)(1),

Federal Register and which has been filed with the Office of the Federal Register.

(2), and (3) of this section) without developing any openings above those specified, reduction of electrical spacings below those specified, or other fire, casualty, or shock hazards, including the loosening or displacement of components but excluding breakage of a lamp. After completion of each test, the toy shall comply with the requirements of the dielectric strength test described in paragraph (e)(2) of this section and, upon visual examination, shall not evidence the development of any hazards. Rupture of a fuse shall be considered a test failure.

(1) *Impact test.* A toy weighing 10 pounds or less shall be dropped four times from a height of 3 feet onto a 2½ inch thick concrete slab covered with 0.125 inch nominal thickness vinyl tile. The impact area shall be at least 3 square feet. The test shall be conducted while the toy is energized and operating and with all dead metal of the toy that may be energized connected together electrically and grounded through a 3-ampere plug fuse. The toy shall be dropped in random orientation. After each drop the test sample shall be allowed to come to rest and examined and evaluated before continuing.

(2) *Compression test.* Any area on the surface of the enclosure that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subjected to a direct force of 20 pounds for 1 minute. The force shall be applied over a period of 5 seconds through the axis of a ½-inch-diameter metal rod having a flat end with the edge rounded to a radius of one thirty-seconds of an inch to eliminate sharp edges. The axis of the rod shall be perpendicular to the surface being tested. During the test the toy shall rest on a flat, hard surface in any test-convenient position.

(3) *Pressure test.* If any portion of the top of a toy has a flat surface measuring 24 square inches or more and a minor dimension of at least 3 inches, that surface shall be subjected to a direct vertical pressure increasing to 50 pounds over a period of 5 seconds and maintained for 1 minute. The force shall be applied through a steel ball 2 inches in diameter. During the test the

toy shall be in an upright position on a flat, horizontal solid surface.

(c) *Handles and knobs*—(1) *General.* For the purposes of tests in this paragraph, the parts of a lifting handle on a toy that are within seven-sixteenths of an inch of the surface to which the handle is attached, or the parts of a lifting knob that are within one-fourth inch of the surface to which the knob is attached, are considered to be for support purposes, and the remainder of the handle or knob is considered to be generally functional in nature. A handle or knob shall withstand crushing and lifting tests (see paragraphs (c)(2) and (3) of this section) without fracture of the handle or knob, development of an opening that may pinch the hand, or breakage of the means used to fasten the handle or knob in place.

(2) *Crushing test.* The functional portion of a handle or knob shall be subjected to a crushign force increasing to 20 pounds over a period of 5 seconds and maintained for 1 minute. The force shall be applied through two flat and parallel hardwood blocks, each at least 2½ inches thick and each having dimensions slightly exceeding those of the handle or knob being tested. The crushing force between the blocks shall be exerted in any direction perpendicular to the major axis of the handle or knob.

(3) *Lifting test.* The support portion of a handle or knob shall be subjected to a force equal to four times the weight of the object it is intended to support. The direction of the lifting force shall be as intended by the design of the toy and shall be applied through a ½-inch-wide strap through or around a handle or by fingers or the equivalent on a knob. The force shall be applied over a period of 5 seconds through the center of gravity of the toy and maintained for 1 minute.

(d) *Stability.* A toy shall not overturn while resting in an upright position on a flat surface inclined 15° from horizontal. No spillage of molten material or hot liquids from containers shall occur while the toy is operating in this position under normal conditions of use. During this test, casters, if any, shall be in the position most likely to

result in tipping, but shall not be artificially held in one position to prevent a natural rotation to another position.

(e) *Electrical*—(1) *Power input*. The actual current flow in a toy without a heating element shall not exceed 110 percent of the rated value, and shall not exceed 5.5 amperes, at rated voltage. The power input to a toy with a heating element shall not exceed 105 percent of the rated value at rated voltage. The power input rating of a toy employing one or more incandescent lamps as the only power-consuming components shall be considered to be the total rated wattage of such lamps. The rated voltage shall be considered to be the mean value of a marked voltage range.

(2) *Dielectric strength*. (i) A toy shall be capable of withstanding without breakdown for 1 minute a 60-cycle-per-second (60 Hertz) essentially sinusoidal potential of 1,000 volts applied between live parts and any dead metal parts.

(ii) If a toy employs a low-voltage secondary winding (either in the form of a conventional transformer or as an insulated coil of a motor), the toy shall also be capable of withstanding without breakdown for 1 minute a sinusoidal test potential applied between the high-voltage and low-voltage windings. The test potential shall be applied at the rated frequency of the toy and shall have a value of 1,000 volts plus twice the rated voltage of the high-voltage winding. The test potential shall be supplied from a suitable capacity-testing transformer, the output voltage of which can be regulated. The waveform of the test voltage shall approximate a sine wave as closely as possible.

(iii) The applied test potential shall be increased rapidly and uniformly from zero until the required test value is reached and shall be held at that value for 1 minute. Unless otherwise specified, the toy shall be at the maximum operating temperature reached in normal use prior to conducting the tests.

(iv) The dielectric strength requirements of this subparagraph may also be determined by subjecting the toy to a 60-cycle-per-second (60 Hertz) essentially sinusoidal potential of 1,200 volts for 1 second. If the dielectric strength

is determined by this method, the toy need not be in a heated condition.

(3) *Leakage current and repeated dielectric withstand tests*. (i) Both before and after being conditioned, a toy intended to operate from a source exceeding 42.4 volts peak shall:

(A) Not have a leakage current exceeding 0.5 milliampere, except that during the interval beginning 5 seconds and terminating 10 minutes after the toy is first energized, the leakage current of toys with heating elements other than lamps shall not exceed 2.5 milliamperes; and

(B) Comply with the requirements of a repeated dielectric withstand test both with and without preheating.

(ii) All accessible parts of a toy shall be tested for leakage current. If an insulating material is used for the enclosure or part of the enclosure, the leakage current shall be measured using a metal foil with an area not exceeding 10 by 20 centimeters in contact with accessible surfaces of such insulating material. Where the accessible surface of insulating material is less than 10 by 20 centimeters, the metal foil shall be the same size as the surface. The metal foil shall be so applied that it will not affect the temperature of the toy. The accessible parts shall be tested individually, collectively, and from one part to another.

(iii) Following the initial leakage current test, the toy shall be cooled down or heated up to 32 °C. (90 °F.). The toy shall then be conditioned for 48 hours in air at a temperature of 32° ±2 °C. (89.6° ±3.6 °F.) and with a relative humidity of 90–95 percent. The specified relative humidity shall be maintained inside a closed compartment in which a saturated solution of potassium sulphate is kept in a suitable container. Leakage current measurements shall be made, as specified in paragraph (e)(3)(ii) of this section and before the toy is energized, while the toy is in the humidity compartment.

(iv) With the connections intended for the source of supply connected thereto and then connected to the ungrounded side of a power supply circuit having a voltage equal to 110 percent of the rated voltage of the toy, the

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leakage current through a noninductive 1,500-ohm resistor connected between the grounded side of the supply circuit and each dead metal part (accessible and inaccessible) shall, when stable, be measured in accordance with the test provisions established in ANSI Standard C 101.1–1971, “American National Standard for Leakage Current for Appliances,” approved November 17, 1970, which is incorporated by reference. Copies of this document are available from American National Standards Institute, 1430 Broadway, New York, New York 10018. This document is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. This incorporation by reference was approved by the Director of the Federal Register. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

(v) For a toy whose outer enclosure consists wholly or partly of insulating material, the term *dead metal part* means metal foil tightly wrapped around the exterior of the enclosure in a manner that covers, but does not enter into, any enclosure openings.

(4) *Motor operation.* (i) A motor provided as part of a toy shall be capable of driving its maximum normal load in the toy without introducing any potentially hazardous condition. The performance of the toy shall be considered unacceptable if, during the test, temperatures in excess of those specified in §1505.7 for Type D surfaces are attained on any accessible surface. The performance of the toy shall also be considered unacceptable if the rise in temperature during the test causes melting, scorching, embrittlement, or other evidence of thermal damage to the insulating material used to prevent exposure of live metal parts.

(ii) A motor-operated toy shall be tested with the motor stalled if the construction of the toy is such that any person can touch moving parts associated with the motor from outside

the toy. The performance of the toy shall be considered unacceptable if, during the test, temperatures higher than those specified in §1505.8 are attained or if temperatures higher than those specified for Type C surfaces in §1505.7 are attained on any accessible surface of the motor. (See also §1505.50.)

(5) *Overload*—(i) *Motor.* A motor-control switch that is a part of a toy shall be horsepower-rated to cover the load or shall be capable of performing acceptably when subjected to an overload test consisting of 50 cycles of operation by making and breaking the stalled-rotor current of the toy at maximum rated voltage. There shall be no electrical or mechanical failure nor any visible burning or pitting of the switch contacts as a result of this test.

(ii) *Switch.* To determine if a motor-control switch is capable of performing acceptably when subjected to overload conditions, the toy shall be connected to a grounded supply circuit of rated frequency and maximum rated voltage with the rotor of the motor locked into position. During the test, exposed dead metal parts of the toy shall be connected to ground through a 3-ampere plug fuse such that any single pole, current-rupturing device will be located in the ungrounded conductor of the supply circuit. If the toy is intended for use on direct current, or on direct current as well as alternating current, the exposed dead metal parts of the toy shall be so connected as to be positive with respect to a single pole, current-rupturing device. The switch shall be operated at a rate of not more than 10 cycles per minute. The performance of the toy shall be considered unacceptable if the fuse in the grounding connection is blown during the test.

(f) *Hydrokinetic*—(1) *General.* Electrically operated toy steam engines shall be capable of performing acceptably when subjected to the tests described in this paragraph.

(2) *Preliminary test.* The ultimate strength of the boiler assembly shall first be determined by applying a hydrostatic pressure to the boiler with all openings blocked (the pressure-relief valve, steam exhausts, and any whistle or other accessory shall be removed

and the resulting openings sealed); however, a water or other type of gage shall be left in place. The hydrostatic pressure shall be applied slowly and the ultimate value which is attained shall be recorded.

(3) *Pressure-relief test.* A pressure gage shall be connected to the boiler assembly which shall then be operated normally. The pressure at which the pressure-relief valve functions shall be noted while the engine is shut off (if a shutoff valve is provided) and with the whistle, if any, turned off. The test shall be discontinued and shall be considered a failure if the observed pressure exceeds one-fifth the value attained in the preliminary test described in paragraph (f)(2) of this section.

(4) *Operating pressure test.* If the boiler is still intact and no failure has occurred, the pressure-relief valve shall then be rendered inoperable and all other valves (such as a whistle and exhaust from the assembly) shall be tightly closed. Operations shall be continued until the pressure becomes constant. This test shall be discontinued and shall be considered a failure if the observed pressure exceeds one-third the value attained in the preliminary test described in paragraph (f)(2) of this section. During this test, all valves, gaskets, joints, and similar components shall be sufficiently tightened to prevent leakage. Rupture of the boiler or of any other fittings supplied with the engine shall be considered a failure.

(5) *Hydrostatic test.* If there has been no failure, two previous untested toys shall withstand for 1 minute a hydrostatic pressure of 5 times the pressure at which the safety valve operated or 3 times the constant pressure observed with the pressure-relief valve inoperable, whichever is greater. During this test, all openings shall be blocked (the pressure-relief valve, steam exhaust from the assembly, and any whistle or other outlet); however, a water or other type of gage shall remain in place. Rupture of the boiler or of a gage shall be considered a failure.

(g) *Thermal*—(1) *General.* The normal operation of a toy includes performance in normal use and after being subjected to reasonably foreseeable damage or abuse likely to produce the

highest temperatures or, in the case of motor-operated toys, the load that most closely approximates the severest conditions of normal use or reasonably foreseeable damage or abuse.

(2) *Classification.* Parts or surfaces of a toy are classified according to their use or function as follows (for the purposes of paragraph (g)(2) (v), (vi), and (vii) of this section, accessibility shall be defined as the ability to reach a heated surface with a ¼-inch-diameter rod 3 inches long as described in §1505.51(a)):

(i) *Type A.* A part or surface of a toy (such as a handle) likely to be grasped by the hand or fingers for the purpose of carrying the toy or lifting a separable lid.

(ii) *Type B.* A part or surface of a toy that is (a) part of a handle, knob, or similar component, as in Type A (described in paragraph (g)(2)(i) of this section), but which is not normally grasped or contacted by the hand or fingers for carrying (including parts of a handle within 7/16 inch of the surface to which the handle is attached and parts of a finger knob within ¼ inch of the surface to which the knob is attached, if the remainder of the knob is large enough to be grasped), or (b) a handle, knob, or part that may be touched but which need not be grasped for carrying the toy or lifting a lid, door, or cover (e.g., support part of a handle or knob).

(iii) *Type C.* A part or surface of a toy that can be touched by casual contact or that can be touched without employing the aid of a common household tool (screwdriver, pliers, or other similar household tool) and that is either (a) a surface that performs an intended heating function (e.g., the soleplate of a flat-iron, a cooking surface, or a heating element surface), or (b) a material heated by the element and intended to be used as the product of the toy, excluding pans, dishes, or other containers used to hold the material to be cooked or baked if a common utensil or other device is supplied with the toy and specific instructions are established for using such a device to remove the container from the heated area. (See also §1505.51(b))

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(iv) *Type C marked.* A Type C surface which has been marked with a precautionary statement of thermal hazards in accordance with §1505.3(e)(2). (See also §1505.51(b))

(v) *Type D.* An accessible part or surface of a toy other than Types A, B, C or E (see paragraph (g)(2) (i), (ii), (iii) and (vii) of this paragraph).

(vi) *Type D marked.* A Type D surface which has been marked with a precautionary statement of thermal hazards in accordance with §1505.3(e)(2).

(vii) *Type E.* A heated surface in an oven or other article that is inaccessible or protected by an electrical-thermal safety interlock. Such interlocks shall prohibit the operation of a heating device whenever such surfaces are accessible and shall not allow accessibility to such surfaces until the temperatures of those surfaces have been reduced to levels below those established for Type D surfaces (paragraph (g)(2)(v) of this section).

(3) *Requirements.* When tested under the conditions described in paragraph (g)(4) of this section, a toy shall not attain a temperature at any point sufficiently high to constitute a fire hazard or to adversely affect any materials employed and shall not show a maximum temperature higher than those established by §§1505.7 and 1505.8. These maximum surface temperature requirements are not applicable to educational-or hobby-type products such as lead-casting sets and wood-burning tools which are appropriately labeled on the shelf pack or package as being intended only for children over 12 years of age provided that the maximum surface temperature of any such toy does not exceed that reasonably required to accomplish the intended technical effect. Such toys shall be provided with specific instructions and the warning statements required by and in accordance with §1505.3 (d) and (e), and shall be appropriately identified as educational or hobby-type products.

(4) *Test conditions—(i) General.* Tests shall be conducted while the toy is connected to a circuit of 60-cycle-per-second (60 Hertz) current using the materials supplied with the toy or using materials otherwise intended to be used with the toy. Following such tests, the toy shall be energized for a 6-hour pe-

riod to determine that no hazardous conditions would result from unattended use of the toy.

(ii) *Temperature.* Normally, tests shall be performed at an ambient (room) temperature of 25 °C. (77 °F.); however, a test may be conducted at any ambient temperature within the range of 21° to 30 °C. (69.8° to 86 °F.).

(iii) *Voltage.* The toy shall be tested at the voltage indicated in the manufacturer's rating or at 120 volts, whichever is greater.

(5) *Temperature measurements—(i) General.* Temperatures shall be measured by means of instruments utilizing thermocouples of No. 30 AWG (American Wire Gage) wire (either copper and constantan or iron and constantan) and potentiometer-type instruments that are accurate and are calibrated in accordance with current good laboratory practices. The thermocouple wire shall conform with the requirements for "special" thermocouples as listed in the table of limits of error of thermocouples (Table VIII) in ANSI Standard C 96.1–1964, "American Standard for Temperature Measurement Thermocouples," approved June 9, 1964, which is incorporated by reference. Copies of this document are available from American National Standards Institute, 1430 Broadway, New York, New York 10018. This standard is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. This incorporation by reference was approved by the Director of the Office of the Federal Register. These materials are incorporated as they exist in the edition which has been approved by the Director of the Federal Register and which has been filed with the Office of the Federal Register.

(ii) *Test procedures.* The thermocouple junction and adjacent thermocouple lead wire shall be securely held in good thermal contact with the surface of the material whose temperature is being measured. In most cases, good thermal contact will result from securely taping or cementing the thermocouple in

place. If a metal surface is involved, brazing or soldering the thermocouple to the metal may be necessary. The surface temperatures of a toy shall be measured with the toy operating in any unattended condition (e.g., with and without opening and closing doors or covers) for a sufficient period of time to allow temperatures to become constant, or, in the case of a toy with a thermostatically controlled heating element, for a sufficient period of time to determine the maximum surface temperature attained. A temperature shall be considered to be constant when three successive readings taken at 15-minute intervals indicate no change.

(iii) *Heating devices.* Toy ovens, casting toys, popcorn and candy makers, and other toys requiring the insertion of any materials or substances shall be additionally tested by feeding crumpled strips of newspaper and tissue paper into or onto the toy in place of the intended materials or substances. The test strips shall be conditioned for at least 48 hours in air at a temperature of 25° ±4 °C. (77° ±7 °F.) and a relative humidity of 50 percent ±5 percent. The test strips shall be 2 inches wide by 8 inches long before crumpling. The crumpled paper shall occupy not more than 25 percent of the accessible volume. The performance of the toy shall be considered unacceptable if flaming occurs within a 60-minute period following the attainment of normal operating temperatures. If a light bulb is used for heating purposes, the test shall be conducted using the largest wattage bulb that can be easily inserted into the socket.

(h) *Strain-relief test.* (1) The strain-relief means provided on the flexible power cord of a toy shall be capable of withstanding a direct pull of 35 pounds applied to the cord for 2 minutes without displacement of the strain-relief unit or a deformation of the anchoring surface that would produce a stress which would result in a potentially hazardous condition. A 35-pound weight shall be attached to the cord and supported by the toy in such a manner that the strain-relief means is stressed from any angle that the construction of the toy permits. The test shall be conducted with the electrical connection within the toy disconnected.

(2) The initial 2-minute test shall be conducted with the force vector parallel to the longitudinal axis of the cord and perpendicular to the anchoring surface of the strain-relief unit. Each test at other angles of stress shall be conducted for periods of 1 minute. The strain-relief means is not acceptable if, at the point of disconnection of the cord, there is any movement of the cord to indicate that stress would have resulted on the connections.

(3) Except for toys weighing more than 10 pounds, the strain-relief unit and its support base shall be designed and constructed in such a manner that no indication of stress would result which would produce a hazard when the cord is held firmly in place 3 feet from the strain-relief unit and the toy is dropped the 3 feet at any angle.

[38 FR 27032, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973, as amended at 43 FR 26428 June 20, 1978; 46 FR 63251, Dec. 31, 1981; 51 FR 34199, Sept. 26, 1986]

§ 1505.7 Maximum acceptable surface temperatures.

The maximum acceptable surface temperatures for electrically operated toys shall be as follows:

Surface type (as described—in § 1505.6 (g)(2))	Thermal inertia type ¹	Temperatures	
		°C.	°F.
A	1	50	122
A	2	55	131
A	3	60	140
B	1	55	131
B	2	65	149
B	3	75	167
C (unmarked)	1	65	149
C (unmarked)	2	75	167
C (unmarked)	3	85	185
C (unmarked)	4	95	203
C marked	1	70	158
C marked	2	90	194
C marked	3	110	230
C marked	4	130	266
D (unmarked)	1	55	131
D (unmarked)	2	70	158
D (unmarked)	3	80	176
D (unmarked)	4	90	194
D marked	1	60	140
D marked	2	75	167
D marked	3	100	212
D marked	4	125	257
E	(²)	(³)	(³)

¹ Thermal inertia types are defined in terms of lambda as follows:
 Type 1: Greater than 0.0045 (e.g., most metals).
 Type 2: More than 0.0005 but not more than 0.0045 (e.g., glass).
 Type 3: More than 0.0001 but not more than 0.0005 (e.g., most plastics).
 Type 4: 0.0001 or less (e.g., future polymeric materials).

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The thermal inertia of a material can be obtained by multiplying the thermal conductivity (cal./cm./sec./degrees C.) by the density (gm./cm.³) by the specific heat (cal./gm./degrees C.).

² All types.
³ No limit.

§ 1505.8 Maximum acceptable material temperatures.

The maximum acceptable material temperatures for electrically operated toys shall be as follows (Classes 105, 130, A, and B are from “Motors and Generators,” Standard MG-1-1967¹ published by the National Electrical Manufacturers Association):

Material	Degrees C.	Degrees F.
Capacitors	(¹)	(¹)
Class 105 insulation on windings or relays, solenoids, etc.:		
Thermocouple method ²	90	194
Resistance method	110	230
Class 130 insulation system	110	230
Insulation:		
Varnished-cloth insulation	85	185
Fiber used as electrical insulation	90	194

	Class A	Class B	Class A	Class B
Insulation on coil windings of a.c. motors (not including universal motors) and on vibrator coils:				
In open motors and on vibrator coils—thermocouple or resistance method ²	100	120	212	248
In totally enclosed motors—thermocouple or resistance method ²	105	125	221	257
Insulation on coil windings of d.c. motors and of universal motors:				
In open motors:				
Thermocouple method ²	90	110	194	230
Resistance method	100	120	212	248
In totally enclosed motors:				
Thermocouple method ²	95	115	203	239
Resistance method	105	125	221	257
Phenolic composition ³		150	302
Rubber- or thermoplastic-insulated wires and cords ³		60	140
Sealing compound		(⁴)	(⁵)
Supporting surface while the toy is operating normally		90	194
Wood and other similar combustible material		90	194

¹ If the capacitor has no marked temperature limit, the maximum acceptable temperature will be assumed to be 65 °C. (149 °F.) for an electrolytic type and 90 °C. (194 °F.) for other than an electrolytic type.
² The temperature indicated refers to the hottest spot on the outside surface of the coil measured by the thermocouple method.
³ The limitations on rubber- and thermoplastic-insulated wires and cords and on phenolic composition do not apply if the insulation or the phenolic has been investigated and found to have special heat-resistant properties, or if the insulation meets the thermal requirements.
⁴ 40 less than melting point.
⁵ 104 less than melting point.

Subpart B—Policies and Interpretations

§ 1505.50 Stalled motor testing.

(a) § 1505.6(e)(4)(ii) requires that a motor-operated toy be tested with the motor stalled if the construction of the toy is such that any person can touch moving parts associated with the motor from outside the toy. The performance of the toy shall be considered unacceptable if, during the test, temperatures higher than those specified

in § 1505.8 are attained or if temperatures higher than those specified for Type C surfaces in § 1505.7 are attained on any accessible surface of the motor.

(b) To determine if a moving part associated with the motor can be touched from outside the toy, the Commission staff will use a ¼-inch diameter rod, as referenced in § 1505.4(h)(1). If the rod, when inserted into openings in the toy, can touch any moving part associated with the motor, the toy will be tested with the motor stalled.

¹Copies may be obtained from: National Electrical Manufacturers Association, 155 East 44th Street, New York, NY 10017.

(c) The requirement that temperatures higher than those specified in §1505.8 not be attained applies to those internal components which are described in §1505.8. Additionally, temperatures of accessible surfaces shall not exceed those specified for Type C surfaces in §1505.7.

(Secs. 2(q)(1)(A), 2(r), 3(e), 10(a), 74 Stat. 372, 378, 80 Stat. 1303-1304, 83 Stat. 187-189 (15 U.S.C. 1261, 1262, 1269); sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[43 FR 26428, June 20, 1978]

§ 1505.51 Hot surfaces.

(a) *Test probe.* Section 1505.6(g)(2) defines accessibility, for certain paragraphs, as the ability to reach a heated surface with a ¼-inch-diameter rod 3 inches long. To test for accessibility using this test probe, it shall be inserted no more than 3 inches into any opening in the toy. Unless the probe contacts a surface within 3 inches of the plane of the toy's opening, that surface is not accessible.

(b) *Accessibility of Type C and C-marked surfaces.* Under §1505.6(g)(2) (iii) and (iv), touching by casual contact or without employing the aid of a common household tool shall be determined by use of the accessibility test probe described in §§1505.6(g)(2) and 1505.51(a).

[51 FR 34199, Sept. 26, 1986]

PART 1507—FIREWORKS DEVICES

- Sec.
 1507.1 Scope.
 1507.2 Prohibited chemicals.
 1507.3 Fuses.
 1507.4 Bases.
 1507.5 Pyrotechnic leakage.
 1507.6 Burnout and blowout.
 1507.7 Handles and spikes.
 1507.8 Wheel devices.
 1507.9 Toy smoke devices and flitter devices.
 1507.10 Rockets with sticks.
 1507.11 Party poppers.
 1507.12 Multiple-tube fireworks devices.

AUTHORITY: 15 U.S.C. 1261-1262, 2079(d); 21 U.S.C. 371(e).

SOURCE: 41 FR 22935, June 8, 1976, unless otherwise noted.

CROSS REFERENCE: See also 1500.14(b)(7); 1500.17(a) (3), (8) and (9); 1500.83(a)(27) and 1500.85(a)(2).

§ 1507.1 Scope.

This part 1507 prescribes requirements for those fireworks devices (other than firecrackers) not otherwise banned under the act. Any fireworks device (other than firecrackers) which fails to conform to applicable requirements is a banned hazardous substance and is prohibited from the channels of interstate commerce. Any fireworks device not otherwise banned under the act shall not be a banned hazardous substance by virtue of the fact that there are no applicable requirements prescribed herein.

§ 1507.2 Prohibited chemicals.

Fireworks devices shall not contain any of the following chemicals:

(a) Arsenic sulfide, arsenates, or arsenites.

(b) Boron.

(c) Chlorates, except:

(1) In colored smoke mixtures in which an equal or greater amount of sodium bicarbonate is included.

(2) In caps and party poppers.

(3) In those small items (such as ground spinners) wherein the total powder content does not exceed 4 grams of which not greater than 15 percent (or 600 milligrams) is potassium, sodium, or barium chlorate.

(d) Gallates or gallic acid.

(e) Magnesium (magnesium/aluminum alloys, called magnalium, are permitted).

(f) Mercury salts.

(g) Phosphorus (red or white). Except that red phosphorus is permissible in caps and party poppers.

(h) Picrates or picric acid.

(i) Thiocyanates.

(j) Titanium, except in particle size greater than 100-mesh.

(k) Zirconium.

§ 1507.3 Fuses.

(a) Fireworks devices that require a fuse shall:

(1) Utilize only a fuse that has been treated or coated in such manner as to reduce the possibility of side ignition. Devices such as ground spinners that require a restricted orifice for proper thrust and contain less than 6 grams of pyrotechnic composition are exempted from §1507.3(a)(1).

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(2) Utilize only a fuse which will burn at least 3 seconds but not more than 9 seconds before ignition of the device.

(b) The fuse shall be securely attached so that it will support either the weight of the fireworks device plus 8 ounces of dead weight or double the weight of the device, whether is less, without separation from the fireworks device.

[41 FR 22935, June 8, 1976, as amended at 61 FR 67200, Dec. 20, 1996; 61 FR 67200, Dec. 20, 1996]

§ 1507.4 Bases.

The base or bottom of fireworks devices that are operated in a standing upright position shall have the minimum horizontal dimensions or the diameter of the base equal to at least one-third of the height of the device including any base or cap affixed thereto.

§ 1507.5 Pyrotechnic leakage.

The pyrotechnic chamber in fireworks devices shall be sealed in a manner that prevents leakage of the pyrotechnic composition during shipping, handling, and normal operation.

§ 1507.6 Burnout and blowout.

The pyrotechnic chamber in fireworks devices shall be constructed in a manner to allow functioning in a normal manner without burnout or blowout.

§ 1507.7 Handles and spikes.

(a) Fireworks devices which are intended to be hand-held and are so labeled shall incorporate a handle at least 4 inches in length (see §1500.14(b)(7)). Handles shall remain firmly attached during transportation, handling and full operation of the device, or shall consist of an integral section of the device at least four inches below the pyrotechnic chamber.

(b) Spikes provided with fireworks devices shall protrude at least 2 inches from the base of the device and shall have a blunt tip not less than 1/8-inch in diameter of 1/8-inch square.

§ 1507.8 Wheel devices.

Drivers in fireworks devices commonly known as "wheels" shall be securely attached to the device so that

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they will not come loose in transportation, handling, and normal operation. Wheel devices intended to operate in a fixed location shall be designed in such a manner that the axle remains attached to the device during normal operation.

§ 1507.9 Toy smoke devices and flitter devices.

(a) Toy smoke devices shall be so constructed that they will neither burst nor produce external flame (excluding the fuse and firstfire upon ignition) during normal operation.

(b) Toy smoke devices and flitter devices shall not be of such color and configuration so as to be confused with banned fireworks such as M-80 salutes, silver salutes, or cherry bombs.

(c) Toy smoke devices shall not incorporate plastic as an exterior material if the pyrotechnic composition comes in direct contact with the plastic.

§ 1507.10 Rockets with sticks.

Rockets with sticks (including sky-rockets and bottle rockets) shall utilize a straight and rigid stick to provide a direct and stable flight. Such sticks shall remain straight and rigid and attached to the driver so as to prevent the stick from being damaged or detached during transportation, handling, and normal operation.

§ 1507.11 Party poppers.

Party poppers (also known by other names such as "Champagne Party Poppers," and "Party Surprise Poppers,") shall not contain more than 0.25 grains of pyrotechnic composition. Such devices may contain soft paper or cloth inserts provided any such inserts do not ignite during normal operation.

§ 1507.12 Multiple-tube fireworks devices.

(a) *Application.* Multiple-tube mine and shell fireworks devices with any tube measuring 1.5 inches (3.8 cm) or more in inside diameter and subject to §1500.17(a)(12) of this part shall not tip over when subjected to the tip-angle test described in this section.

(b) *Testing procedure.* The device shall be placed on a smooth surface that can

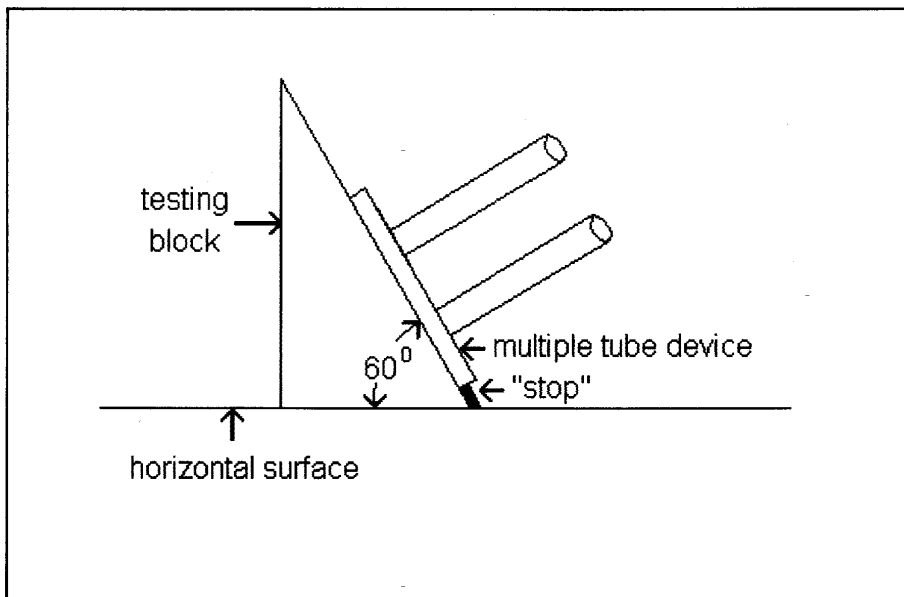
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be inclined at 60 degrees from the horizontal, as shown in Figure 1 of this section. The height and width of the inclined plane (not including the portion of the plane below the mechanical stop) shall be at least 1 inch (2.54 cm) greater than the largest dimension of the base of the device to be tested. The test shall be conducted on a smooth, hard surface that is horizontal as measured by a spirit level or equivalent instrument. The mechanical stop

on the inclined plane shall be $\frac{1}{16}$ inches (1.6 mm) in height and perpendicular to the inclined plane. The stop shall be positioned parallel to the bottom edge of the inclined plane and so that no portion of the device to be tested or its base touches the horizontal surface. The device shall not tip over when the plane is inclined at 60-degrees from the horizontal. The procedure shall be repeated for each edge of the device.

FIGURE 1 TO § 1507.12



Side view of an apparatus or testing block for testing compliance with the proposed 60-degree tilt angle standard.

[61 FR 13096, Mar. 26, 1996]

FIGURE 2 TO PART 1508—HEADFORM PROBE

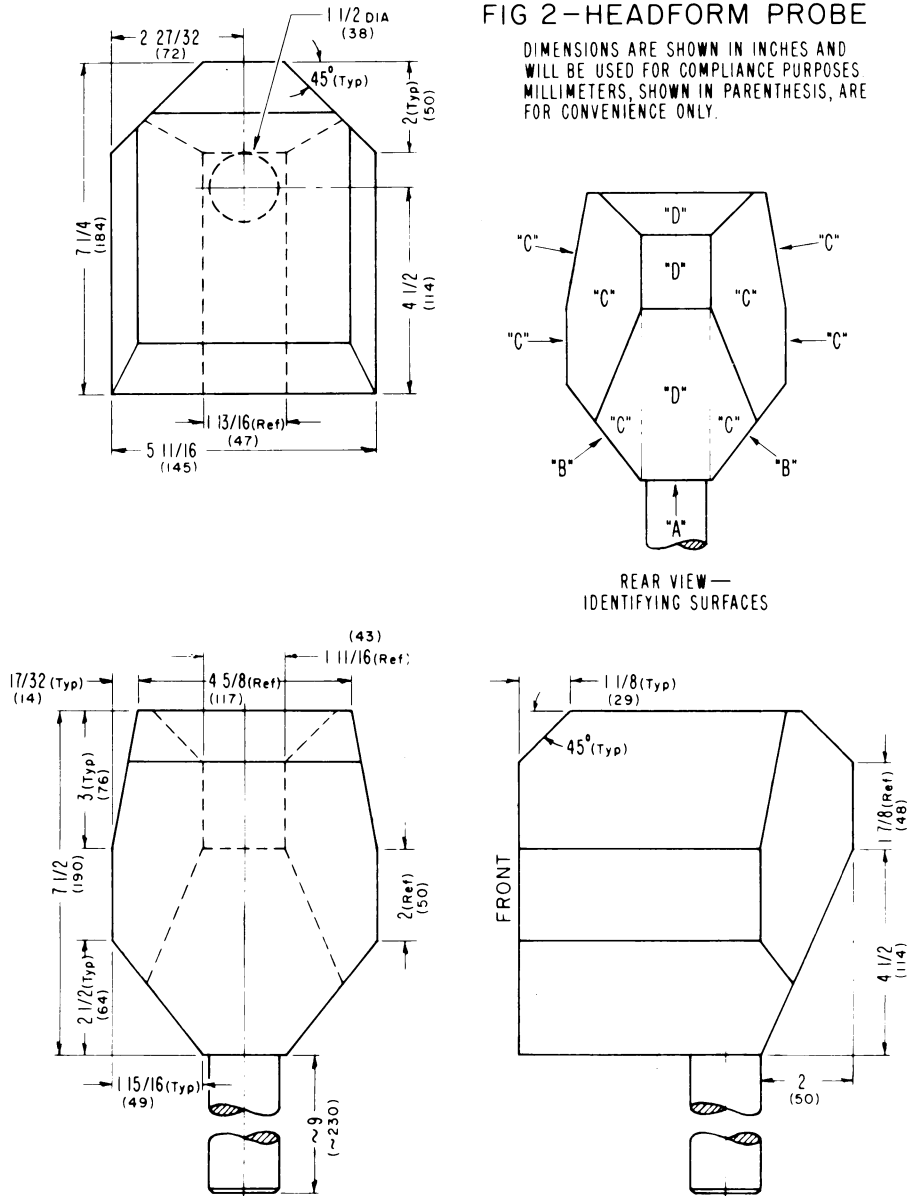
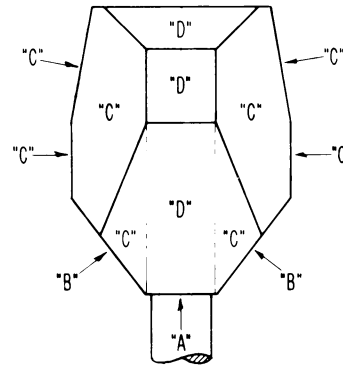


FIG 2—HEADFORM PROBE

DIMENSIONS ARE SHOWN IN INCHES AND WILL BE USED FOR COMPLIANCE PURPOSES. MILLIMETERS, SHOWN IN PARENTHESIS, ARE FOR CONVENIENCE ONLY.



[47 FR 47544, Oct. 27, 1982]

FIGURE 3 TO PART 1508

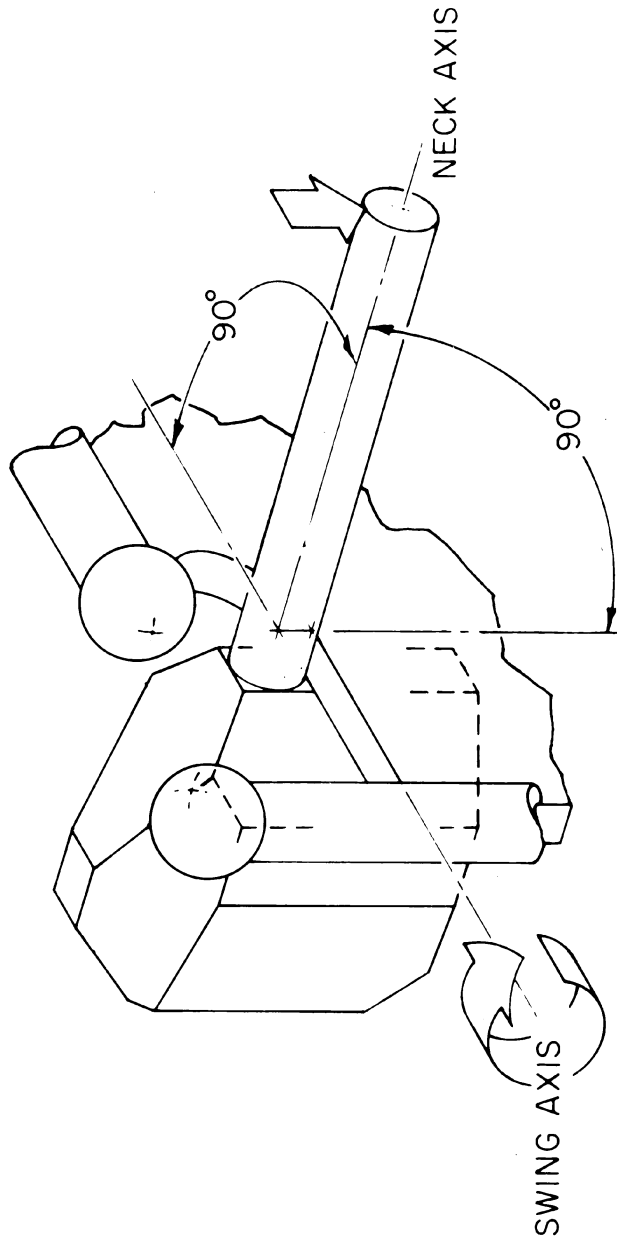


FIG 3

PART 1510—REQUIREMENTS FOR RATTLES

Sec.

1510.1 Scope and purpose of part 1510.

1510.2 Definition.

1510.3 Requirements.

1510.4 Test procedure.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 64 Stat. 372, 374, 375, as amended 80 Stat. 1304–05, 83 Stat. 187–89 (15 U.S.C. 1261, 1262); sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)).

SOURCE: 43 FR 22002, May 23, 1978, unless otherwise noted.

§ 1510.1 Scope and purpose of part 1510.

This part 1510 sets forth the requirement whereby rattles (as defined in § 1510.2) are not banned articles under § 1500.18(a)(15) of this chapter. The purpose of these requirements is to ensure that certain infant rattles which may cause choking and/or suffocation because their design or construction permits them to enter into an infant's mouth and become lodged in the throat are eliminated from interstate commerce.

§ 1510.2 Definition.

For the purposes of this part 1510, a rattle is an infant's toy, intended to be hand held, usually containing pellets or other small objects and which produces sounds when shaken. Examples of products which may have similar noisemaking characteristics but which are excluded from the scope of this definition are: dolls, stuffed animals, crib exercisers, crib mobiles, pull toys, shoe lace holders, bells which are not part of

the noisemaking component of a rattle, plastic keys or other figures on loops or chains which produce sound by striking together, games, puzzles and musical instruments such as tambourines, castanets, and maracas.

§ 1510.3 Requirements.

No portion of a rattle, when tested in accordance with the procedure of § 1510.4 below, shall be capable of entering and penetrating to the full depth of a cavity in a test fixture with dimensions shown in figure 1. (In determining these dimensions for compliance purposes, the English measurements shall be used. Metric equivalents are included for convenience.) Rattles shall meet this requirement both before and after performing the use and abuse tests of § 1500.51 of this chapter (excluding the bite and flexure tests of paragraphs (c) and (d)).

§ 1510.4 Test procedure.

Place the test fixture shown in Figure 1 on a horizontal plane surface. Under its own weight and in a non-compressed state apply any portion of the test sample in the most adverse orientation to the opening in the test fixture. Repeat this procedure after performing the use and abuse tests of § 1500.51 (excluding the bite and flexure tests of paragraphs (c) and (d) of this section). In testing to ensure compliance with this regulation, the measurements of the opening of the Commission's test fixture will be no greater than those shown in Figure 1 and the depth of the fixture used will be no less than that shown in Figure 1.

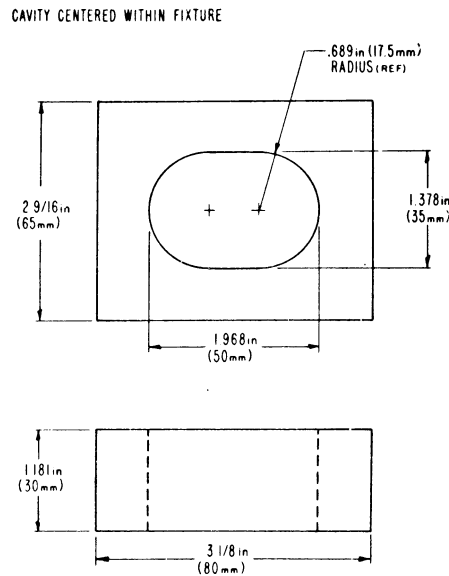


FIG 1—RATTLE TEST FIXTURE

PART 1511—REQUIREMENTS FOR PACIFIERS

- Sec.
- 1511.1 Scope of part 1511.
- 1511.2 Definitions.
- 1511.3 Guard or shield requirements.
- 1511.4 Protrusions.
- 1511.5 Structural integrity tests.
- 1511.6 Ribbons, strings, cords, or other attachments.
- 1511.7 Labeling.
- 1511.8 Metric references.

FIGURE 1 TO PART 1511—PACIFIER TEST FIXTURE

FIGURE 2 TO PART 1511—SMALL PARTS GAGE

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended 80 Stat. 1304-05, 83 Stat. 187-89; 15 U.S.C. 1261, 1262.

SOURCE: 42 FR 33279, June 30, 1977, unless otherwise noted.

§ 1511.1 Scope of part 1511.

This part 1511 sets forth the requirements whereby pacifiers (as defined in § 1511.2(a)) are not banned articles under § 1500.18(a)(8) of this chapter.

§ 1511.2 Definitions.

(a) A *pacifier* is an article consisting of a nipple that is intended for a young child to suck upon, but is not designed to facilitate a baby's obtaining fluid, and usually includes a guard or shield and a handle or ring.

(b) *Guard or shield* means the structure located at the base of the nipple used to prevent the pacifier from being completely drawn into the child's mouth.

(c) *Handle or ring* means the structure usually located adjacent to the guard or shield used for holding or grasping the pacifier. A hinged handle or ring is one that is free to pivot about an axis parallel to the plane of the guard or shield.

§ 1511.3 Guard or shield requirements.

(a) *Performance requirements.* Place the pacifier in the opening of the fixture illustrated in Figure 1(a) of this part so that the nipple of the pacifier is centered in the opening and protrudes through the back of the fixture as shown in Figure 1(b). For pacifiers with

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non-circular guards or shields, align the major axis of the guard or shield with the major axis of the opening in the fixture. Apply a tensile force to the pacifier nipple in the direction shown. The force shall be applied gradually attaining but not exceeding 2.0 pounds (8.9 newtons) within a period of 5 seconds and maintained at 2.0 pounds for an additional 10 seconds. Any pacifier which can be completely drawn through an opening with dimensions no greater than those of Figure 1(a) by such a force shall fail the test in this part.

(b) *Ventilation holes.* The pacifier guard or shield shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier guard or shield.

§ 1511.4 Protrusions.

(a) *Protrusions limitation.* No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16mm) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) *Protrusion test.* Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be applied to any protrusion from the guard or shield with a force gradually attaining but not exceeding 2.0 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple.

§ 1511.5 Structural integrity tests.

(a) *Nipple.* Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force to the pacifier nipple in any possible direction. The force shall be applied gradually, attaining but not exceeding 10.0 pounds (44.5 newtons) with-

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in a period of 5 seconds and maintained at 10.0 pounds for an additional 10 seconds.

(b) *Handle or ring.* Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force shall be applied gradually attaining but not exceeding 10.0 pounds (44.5 newtons) within a period of 5 seconds and maintained at 10.0 pounds for an additional 10 seconds.

(c) *Heat cycle deterioration.* After the testing prescribed in paragraphs (a) and (b) of this section, all pacifiers shall be subject to the following: submerge the pacifier in boiling water for 5 minutes and then remove the pacifier and allow it to cool for 5 minutes in room temperature air, 60° to 80 °F. (16° to 27 °C). After the cooling period, re-submerge the pacifier in the boiling water for 5 minutes. The process shall be repeated for a total of 6 boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and section 1511.3.

(d) *Small parts.* Any components or fragments which are released as a result of the tests specified in paragraphs (a), (b) and (c) of this section shall be placed in the truncated cylinder shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

§ 1511.6 Ribbons, strings, cords, or other attachments.

A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, twine, leather, yarn or similar attachments.

§ 1511.7 Labeling.

(a) As required by paragraphs (b) and (c) of this section, pacifiers shall be labeled with the statement: "Warning—Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on

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any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

§ 1511.8 Metric references.

For purposes of compliance with the test procedure prescribed by this § 500.46, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

FIGURE 1 TO PART 1511—PACIFIER TEST FIXTURE

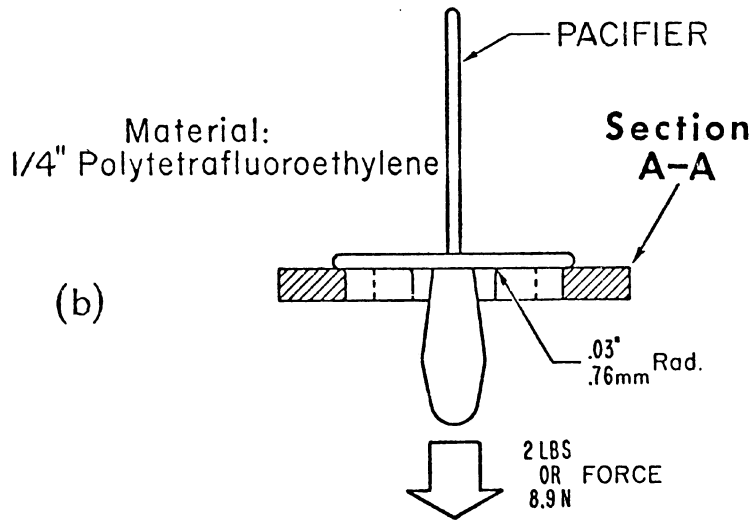
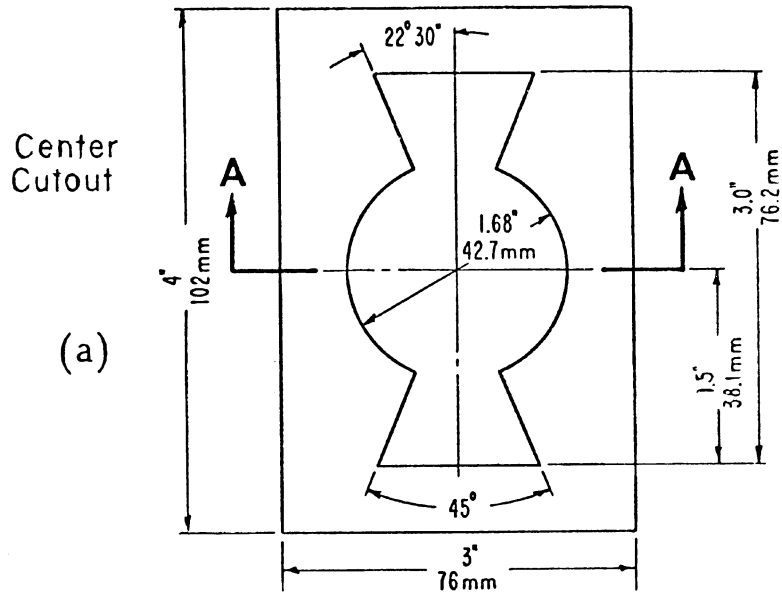
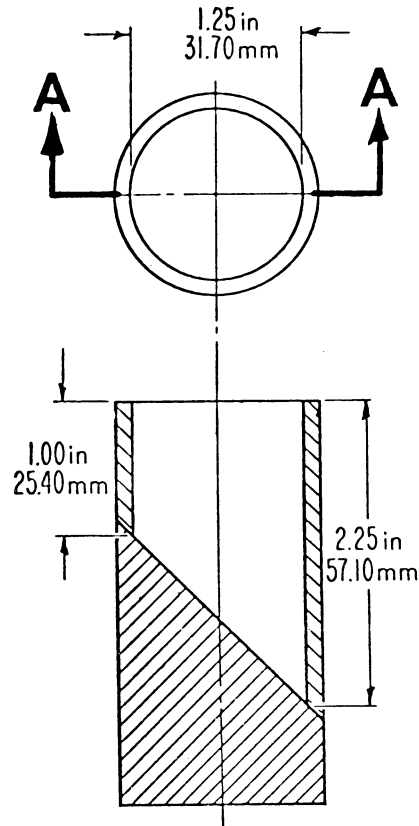


FIG I-PACIFIER TEST FIXTURE

FIGURE 2 TO PART 1511—SMALL PARTS GAGE



Section A-A

FIG 2-SMALL PARTS GAGE

PART 1512—REQUIREMENTS FOR BICYCLES

Subpart A—Regulations

- Sec.
- 1512.1 Scope.
- 1512.2 Definitions.
- 1512.3 Requirements in general.
- 1512.4 Mechanical requirements.
- 1512.5 Requirements for braking system.
- 1512.6 Requirements for steering system.
- 1512.7 Requirements for pedals.
- 1512.8 Requirements for drive chain.
- 1512.9 Requirements for protective guards.

- 1512.10 Requirements for tires.
- 1512.11 Requirements for wheels.
- 1512.12 Requirements for wheel hubs.
- 1512.13 Requirements for front fork.
- 1512.14 Requirements for fork and frame assembly.
- 1512.15 Requirements for seat.
- 1512.16 Requirements for reflectors.
- 1512.17 Other requirements.
- 1512.18 Tests and test procedures.
- 1512.19 Instructions and labeling.
- 1512.20 Separability.

Subpart B—Policies and Interpretations [Reserved]

§ 1512.1

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FIGURE 1 TO PART 1512—BICYCLE FRONT FORK CANTILEVER BENDING TEST RIG

FIGURES 2 AND 3 TO PART 1512—HANDLEBAR STEM LOADING AND ENTRANCE 8 OBSERVATION ANGLES

FIGURE 5 TO PART 1512—TYPICAL HANDBRAKE ACTUATOR SHOWING GRIP DIMENSION

FIGURES 6 AND 7 TO PART 1512—TOE CLEARANCE AND CHAIN GUARD REQUIREMENTS

FIGURE 8 TO PART 1512—REFLECTORIZED BICYCLE WHEEL RIM ABRASION TEST DEVICE

TABLE 1 TO PART 1512—MINIMUM CANDLEPOWER PER INCIDENT FOOT-CANDLE FOR CLEAR REFLECTOR¹

TABLE 2 TO PART 1512—MINIMUM CANDLEPOWER PER INCIDENT FOOT-CANDLE FOR CLEAR REFLECTOR¹

TABLE 3 TO PART 1512—MINIMUM ACCEPTABLE VALUES FOR THE QUANTITY A DEFINED IN THE RETROREFLECTIVE TIRE AND RIM TEST PROCEDURE

TABLE 4 TO PART 1512—RELATIVE ENERGY DISTRIBUTION OF SOURCES

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended, 80 Stat. 1304–05, 83 Stat. 187–89 (15 U.S.C. 1261, 1262); Pub. L. 107–319, 116 Stat. 2776.

SOURCE: 43 FR 60034, Dec. 22, 1978, unless otherwise noted.

Subpart A—Regulations

§ 1512.1 Scope.

This part sets forth the requirements for a bicycle as defined in § 1512.2(a) (except a bicycle that is a “track bicycle” or a “one-of-a-kind bicycle” as defined in § 1512.2 (d) and (e)) which is not a banned article under § 1500.18(a)(12) of this chapter.

§ 1512.2 Definitions.

For the purposes of this part:

(a) Bicycle means:

(1) A two-wheeled vehicle having a rear drive wheel that is solely human-powered;

(2) A two- or three-wheeled vehicle with fully operable pedals and an electric motor of less than 750 watts (1 h.p.), whose maximum speed on a paved level surface, when powered solely by such a motor while ridden by an operator who weighs 170 pounds, is less than 20 mph.

(b) *Sidewalk bicycle* means a bicycle with a seat height of no more than 635 mm (25.0 in); the seat height is measured with the seat adjusted to its high-

est position. Recumbent bicycles are not included in this definition.

(c) *Seat height* means the dimension from the point on the seat surface intersected by the seat post center line (or the center of the seating area if no seat post exists) and the ground plane, as measured with the wheels aligned and in a plane normal to the ground plane.

(d) *Track bicycle* means a bicycle designed and intended for sale as a competitive velodrome machine having no brake levers or calipers, single crank-to-wheel ratio, and no free-wheeling feature between the rear wheel and the crank.

(e) *One-of-a-kind bicycle* means a bicycle that is uniquely constructed to the order of an individual consumer other than by assembly of stock or production parts.

(f) *Normal riding position* means that the rider is seated on the bicycle with both feet on the pedals and both hands on the handlegrips (and in a position that allows operation of handbrake levers if so equipped); the seat and handlebars may be adjusted to positions judged by the rider to be comfortable.

(g) *Recumbent bicycle* means a bicycle in which the rider sits in a reclined position with the feet extended forward to the pedals.

[43 FR 60034, Dec. 22, 1978, as amended at 68 FR 7073, Feb. 12, 2003; 76 FR 27888, May 13, 2011]

§ 1512.3 Requirements in general.

Any bicycle subject to the regulations in this part shall meet the requirements of this part in the condition to which it is offered for sale to consumers; any bicycle offered for sale to consumers in disassembled or partially assembled condition shall meet these requirements after assembly according to the manufacturer's instructions. For the purpose of compliance with this part, where the metric and English units are not equal due to the conversion process the less stringent requirement will prevail.

§ 1512.4 Mechanical requirements.

(a) *Assembly*. Bicycles shall be manufactured such that mechanical skills required of the consumer for assembly shall not exceed those possessed by an

adult of normal intelligence and ability.

(b) *Sharp edges.* There shall be no unfinished sheared metal edges or other sharp parts on assembled bicycles that are, or may be, exposed to hands or legs; sheared metal edges that are not rolled shall be finished so as to remove any feathering of edges, or any burrs or spurs caused during the shearing process.

(c) *Integrity.* There shall be no visible fracture of the frame or of any steering, wheel, pedal, crank, or brake system component resulting from testing in accordance with: The handbrake loading and performance test, §1512.18(d); the foot brake force and performance test, §1512.18(e); and the road test, §1512.18(p) (or the sidewalk bicycle proof test, §1512.18(q)).

(d) *Attachment hardware.* All screws, bolts, or nuts used to attach or secure components shall not fracture, loosen, or otherwise fail their intended function during the tests required in this part. All threaded hardware shall be of sufficient quality to allow adjustments and maintenance. Recommended quality thread form is specified in Handbook H28, "Screw Thread Standards for Federal Service,"¹ issued by the National Bureau of Standards, Department of Commerce; recommended mechanical properties are specified in ISO Recommendation R898, "Mechanical Properties of Fasteners," and in ISO Recommendations 68, 262, and 263, "General Purpose Screw Threads."²

(e)-(f) [Reserved]

(g) *Excluded area.* There shall be no protrusions located within the area bounded by (1) a line 89 mm (3½ in) to the rear of and parallel to the handlebar stem; (2) a line tangent to the front tip of the seat and intersecting the seat mast at the top rear stay; (3) the top surface of the top tube; and (4) a line connecting the front of the seat (when adjusted to its highest position) to the junction where the handlebar is attached to the handlebar stem. The top tube on a female bicycle model shall be

the seat mast and the down tube or tubes that are nearest the rider in the normal riding position. Control cables no greater than 6.4 mm (¼ in) in diameter and cable clamps made from material not thicker than 4.8 mm (¾ in) may be attached to the top tube.

(h) [Reserved]

(i) *Control cable ends.* Ends of all accessible control cables shall be provided with protective caps or otherwise treated to prevent unraveling. Protective caps shall be tested in accordance with the protective cap and end-mounted devices test, §1512.18(c), and shall withstand a pull of 8.9 N (2.0 lbf).

(j) *Control cable abrasion.* Control cables shall not abrade over fixed parts and shall enter and exit cable sheaths in a direction in line with the sheath entrance and exit so as to prevent abrading.

[43 FR 60034, Dec. 22, 1978, as amended at 76 FR 27888, May 13, 2011]

§ 1512.5 Requirements for braking system.

(a) *Braking system.* Bicycles shall be equipped with front- and rear-wheel brakes or rear-wheel brakes only.

(b) *Handbrakes.* Handbrakes shall be tested at least ten times by applying a force sufficient to cause the handlebar to contact the handlebar, or a maximum of 445 N (100 lbf), in accordance with the loading test, §1512.18(d)(2), and shall be rocked back and forth with the weight of a 68.1 kg (150 lb) rider on the seat with the same handbrake force applied in accordance with the rocking test, §1512.18(d)(2)(iii); there shall be no visible fractures, failures, movement of clamps, or misalignment of brake components.

(1) *Stopping distance.* A bicycle equipped with only handbrakes shall be tested for stopping distance by a rider of at least 68.1 kg (150 lb) weight in accordance with the performance test, §1512.18(d)(2) (v) and (vi), and shall have a stopping distance of no greater than 4.57 m (15 ft) from the actual test speed as determined by the equivalent ground speed specified in §1512.18(d)(2)(vi).

(2) *Hand lever access.* Hand lever mechanisms shall be located on the handlebars in a position that is readily

¹Copies may be obtained from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

²Copies may be obtained from: American National Standards Institute, 1430 Broadway, New York, New York 10018.

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accessible to the rider when in a normal riding position.

(3) *Grip dimension.* The grip dimension (maximum outside dimension between the brake hand lever and the handlebars in the plane containing the centerlines of the handgrip and the hand brake lever) shall not exceed 89 mm (3½ in) at any point between the pivot point of the lever and lever midpoint; the grip dimension for sidewalk bicycles shall not exceed 76 mm (3 in). The grip dimension may increase toward the open end of the lever but shall not increase by more than 12.7 mm (½ in) except for the last 12.7 mm (½ in) of the lever. (See figure 5 of this part 1512.)

(4) *Attachment.* Brake assemblies shall be securely attached to the frame by means of fasteners with locking devices such as a lock washer, locknut, or equivalent and shall not loosen during the rocking test, §1512.18(d)-(2)(iii). The cable anchor bolt shall not cut any of the cable strands.

(5) *Operating force.* A force of less than 44.5 N (10 lbf) shall cause the brake pads to contact the braking surface of the wheel when applied to the handlebar at a point 25 mm (1.0 in) from the open end of the handlebar.

(6) *Pad and pad holders.* Caliper brake pad shall be replaceable and adjustable to engage the braking surface without contacting the tire or spokes and the pad holders shall be securely attached to the caliper assembly. The brake pad material shall be retained in its holder without movement when the bicycle is loaded with a rider of at least 68.1 kg (150 lb) weight and is rocked forward and backward as specified in the rocking test, §1512.18(d)(2)(iii).

(7) [Reserved]

(8) *Hand lever location.* The rear brake shall be actuated by a control located on the right handlebar and the front brake shall be actuated by a control located on the left handlebar. The left-hand/right-hand locations may be reversed in accordance with an individual customer order. If a single hand lever is used to actuate both front and rear brakes, it shall meet all applicable requirements for hand levers and shall be located on either the right or left handlebar in accordance with the customer's preference.

(9) *Hand lever extensions.* Bicycles equipped with hand lever extensions shall be tested with the extension levers in place and the hand lever extensions shall also be considered to be hand levers.

(c) *Footbrakes.* All footbrakes shall be tested in accordance with the force test, §1512.18(e)(2), and the measured braking force shall not be less than 178 N (40 lbf) for an applied pedal force of 310 N (70 lbf).

(1) *Stopping distance.* Bicycles equipped with footbrakes (except sidewalk bicycles) shall be tested in accordance with the performance test, §1512.18(e)(3), by a rider of at least 68.1 kg (150 lb) weight and shall have a stopping distance of no greater than 4.57 m (15 ft) from an actual test speed of at least 16 km/h (10 mph). If the bicycle has a footbrake only and the equivalent groundspeed of the bicycle is in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute),³ the stopping distance shall be 4.57 m (15 ft) from an actual test speed of 24 km/h (15 mph) or greater.

(2) *Operating force.* Footbrakes shall be actuated by a force applied to the pedal in a direction opposite to that of the drive force, except where brakes are separate from the drive pedals and the applied force is in the same direction as the drive force.

(3) *Crank differential.* The differential between the drive and brake positions of the crank shall be not more than 60° with the crank held against each position under a torque of no less than 13.6 N-m (10 ft-lb).

(4) *Independent operation.* The brake mechanism shall function independently of any drive-gear positions or adjustments.

(d) *Footbrakes and handbrakes in combination.* Bicycles equipped with footbrakes and handbrakes shall meet all the requirements for footbrakes in §1512.5(c), including the tests specified. In addition, if the equivalent ground speed of the bicycle is 24 km/h (15 mph) or greater (in its highest gear ratio at

³This is proportional to a gear development greater than 6.67 m (21.9 ft) in the bicycle's highest gear ratio. Gear development is the distance the bicycle travels in meters, in one crank revolution.

a pedal crank rate of 60 revolutions per minute),³ the actual test speed specified in §1512.18(e)(3) shall be increased to 24 km/h (15 mph) and both braking systems may be actuated to achieve the required stopping distance of 4.57 m (15 ft).

(e) *Sidewalk bicycles.* (1) Sidewalk bicycles shall not have handbrakes only.

(2) Sidewalk bicycles with a seat height of 560 mm (22 in) or greater (with seat height adjusted to its lowest position) shall be equipped with a footbrake meeting all the footbrake requirements of §1512.5(c), including the specified tests except that the braking force transmitted to the rear wheel shall be in accordance with the sidewalk bicycle footbrake force tests, §1512.18(f).

(3) Sidewalk bicycles with a seat height less than 560 mm (22 in) (with seat height adjusted to its lowest position) and not equipped with a brake shall not have a freewheel feature. Such sidewalk bicycles equipped with a footbrake shall be tested for brake force in accordance with the sidewalk bicycle footbrake force test, §1512.18(f). Such sidewalk bicycles not equipped with brakes shall be identified with a permanent label clearly visible from a distance of 3.1 m (10 ft) in daylight conditions and promotional display material and shipping cartons shall prominently display the words "No Brakes."

§ 1512.6 Requirements for steering system.

(a) *Handlebar stem insertion mark.* Quill-type handlebar stems shall contain a permanent ring or mark which clearly indicates the minimum insertion depth of the handlebar stem into the fork assembly. The insertion mark shall not affect the structural integrity of the stem and shall not be less than 2½ times the stem diameter from the lowest point of the stem. The stem strength shall be maintained for at least a length of one shaft diameter below the mark.

(b) *Handlebar stem strength.* The handlebar stem shall be tested for strength in accordance with the handlebar stem test, §1512.18(g), and shall withstand a force of 2000 N (450 lbf) for bicycles and 1000 N (225 lbf) for sidewalk bicycles.

(c) *Handlebar.* Handlebars shall allow comfortable and safe control of the bicycle. Handlebar ends shall be symmetrically located with respect to the longitudinal axis of the bicycle and no more than 406 mm (16 in) above the seat surface when the seat is in its lowest position and the handlebar ends are in their highest position. This requirement does not apply to recumbent bicycles.

(d) *Handlebar ends.* The ends of the handlebars shall be capped or otherwise covered. Handgrips, end plugs, control shifters, or other end-mounted devices shall be secure against a removal force of no less than 66.8 N (15 lbf) in accordance with the protective cap and end-mounted devices test, §1512.18(c).

(e) *Handlebar and clamps.* The handlebar and clamps shall be tested in accordance with the handlebar test, §1512.18(h). Directions for assembly of the bicycle required in the instruction manual by §1512.19(a)(2) shall include an explicit warning about the danger of damaging the stem-to-fork assembly and the risk of injury to the rider that can result from overtightening the stem bolt or other clamping device. The directions for assembly shall also contain a simple, clear, and precise statement of the procedure to be followed to avoid damaging the stem-to-fork assembly when tightening the stem bolt or other clamping device.

[43 FR 60034, Dec. 22, 1978, as amended at 76 FR 27888, May 13, 2011]

§ 1512.7 Requirements for pedals.

(a) *Construction.* Pedals shall have right-hand/left-hand symmetry. The tread surface shall be present on both top and bottom surfaces of the pedal except that if the pedal has a definite preferred position, the tread surface need only be on the surface presented to the rider's foot.

(b) *Toe clips.* Pedals intended to be used only with toe clips shall have toe clips securely attached to them and need not have tread surfaces. Pedals designed for optional use of toe clips shall have tread surfaces.

(c) *Pedal reflectors.* Pedals for bicycles other than sidewalk bicycles shall have reflectors in accordance with §1512.16(e). Pedals for sidewalk bicycles are not required to have reflectors.

§ 1512.8**§ 1512.8 Requirements for drive chain.**

The drive chain shall operate over the sprockets without catching or binding. The tensile strength of the drive chain shall be no less than 8010 N (1,800 lbf) or 6230 N (1,400 lbf) for sidewalk bicycles.

§ 1512.9 Requirements for protective guards.

(a) *Chain guard.* Bicycles having a single front sprocket and a single rear sprocket shall have a chain guard that shall cover the top strand of the chain and at least 90° of the perimeter where the drive chain contacts the drive sprocket as shown in figure 7. The chain guard shall extend rearward to a point at least 8 cm (3.2 in.) forward of the centerline of the rear axle. The minimum width of the top area of the chain guard shall be twice the width of the chain in that portion forward of the rear wheel rim. The rear part of the top area may be tapered. The minimum width at the rear of the guard shall be one-half the chain width. Such chain guard shall prevent a rod of 9.4 mm ($\frac{3}{8}$ in.) diameter and 76 mm (3.0 in.) length from entrapment between the upper junction of the chain and the sprocket when introduced from the chain side of the bicycle in any direction within 45° from a line normal to the sprocket.

(b) *Derailleur guard.* Derailleurs shall be guarded to prevent the drive chain from interfering with or stopping the rotation of the wheel through improper adjustments or damage.

§ 1512.10 Requirements for tires.

The manufacturer's recommended inflation pressure shall be molded into or onto the sidewall of the tire in lettering no less than 3.2 mm ($\frac{1}{8}$ in.) in height. The statement of recommended inflation pressure shall be in the English language utilizing Arabic numerals. (The following language is suggested to indicate recommended inflation pressure: "Inflate to ___ PSI.") After inflation to 110 percent of the recommended inflation pressure, the tire shall remain intact on the rim, including while being tested under a load of 2,000 N (450 lbf) in accordance with the rim test, § 1512.18(j). Tubular sew-up tires, nonpneumatic tires, and non-

molded wired-on tires are exempt from this section.

§ 1512.11 Requirements for wheels.

(a) *Spokes.* There shall be no missing spokes.

(b) *Alignment.* The wheel assembly shall be aligned such that no less than 1.6 mm ($\frac{1}{16}$ in.) clearance exists between the tire and fork or any frame member when the wheel is rotated to any position.

(c) *Rims.* Rims shall retain the spokes and tire when side-loaded with 2000 N (450 lbf) and tested in accordance with the rim test, § 1512.18(j). Sidewalk bicycles need not meet this requirement.

§ 1512.12 Requirements for wheel hubs.

All bicycles (other than sidewalk bicycles) shall meet the following requirements:

(a) *Locking devices.* Wheels shall be secured to the bicycle frame with a positive lock device. Locking devices on threaded axles shall be tightened to the manufacturer's specifications.

(1) *Rear wheels.* There shall be no relative motion between the axle and the frame when a force of 1,780 N (400 lbf) is applied symmetrically to the axle for a period of 30 seconds in the direction of wheel removal.

(2) *Front wheels.* Locking devices, except quick-release devices, shall withstand application of a torque in the direction of removal of 17 N-m (12.5 ft-lb).

(b) *Quick-release devices.* Lever-operated, quick-release devices shall be adjustable to allow setting the lever position for tightness. Quick-release levers shall be clearly visible to the rider and shall indicate whether the levers are in a locked or unlocked position. Quick-release clamp action shall emboss the frame or fork when locked, except on fiber reinforced plastics.

(c) *Front hubs.* Front hubs not equipped with lever-operated quick-release devices shall have a positive retention feature that shall be tested in accordance with the front hub retention test, § 1512.18(j)(3), to assure that when the locking devices are released the wheel will not separate from the fork.

[43 FR 60034, Dec. 22, 1978, as amended at 76 FR 27888, May 13, 2011]

§ 1512.13 Requirements for front fork.

The front fork shall be tested for strength by application of at least 39.5 J (350 in-lb) of energy in accordance with the fork test, §1512.18(k)(1), without visible evidence of fracture. Sidewalk bicycles need not meet this requirement.

§ 1512.14 Requirements for fork and frame assembly.

The fork and frame assembly shall be tested for strength by application of a load of 890 N (200 lbf) or at least 39.5 J (350 in-lb) of energy, whichever results in the greater force, in accordance with the frame test, §1512.18(k)(2), without visible evidence of fracture or frame deformation that significantly limits the steering angle over which the wheel can be turned. Sidewalk bicycles are exempt from this section.

§ 1512.15 Requirements for seat.

(a) *Seat limitations.* No part of the seat, seat supports, or accessories attached to the seat shall be more than 125 mm (5.0 in) above the top of the seat surface at the point where the seat surface is intersected by the seat post axis. This requirement does not apply to recumbent bicycles.

(b) *Seat post.* The seat post shall contain a permanent mark or ring that clearly indicates the minimum insertion depth (maximum seat-height adjustment); the mark shall not affect the structural integrity of the seat post. This mark shall be located no less than two seat-post diameters from the lowest point on the post shaft, and the post strength shall be maintained for at least a length of one shaft diameter below the mark. This requirement does not apply to bicycles with integrated seat masts, however, a permanent mark or other means to clearly indicate that the seat or seat posts is safely installed shall be provided.

(c) *Adjustment clamps.* The seat adjustment clamps shall be capable of securing the seat in any position to which it can be adjusted and preventing movement of the seat in any direction under normal conditions of use. Following the road test, §1512.18(p) (or the sidewalk bicycle proof test, §1512.18(q), as applicable), the seat clamps shall be tested in accordance

with the seat adjustment clamps and load test, §1512.18(l).

[43 FR 60034, Dec. 22, 1978, as amended at 76 FR 27888, May 13, 2011]

§ 1512.16 Requirements for reflectors.

Bicycles shall be equipped with reflective devices to permit recognition and identification under illumination from motor vehicle headlamps. The use of reflector combinations off the center plane of the bicycle (defined in §1512.18(m)(2)) is acceptable if each reflector meets the requirements of this section and of §1512.18 (m) and (n) and the combination of reflectors has a clear field of view of $\pm 10^\circ$ vertically and $\pm 50^\circ$ horizontally. Sidewalk bicycles are not required to have reflectors.

(a) *Front, rear, and pedal reflectors.* There shall be an essentially colorless front-facing reflector, essentially colorless or amber pedal reflectors, and a red rear-facing reflector.

(b) *Side reflectors.* There shall be retroreflective tire sidewalls or, alternatively, reflectors mounted on the spokes of each wheel, or, for non-caliper rim brake bicycles, retroreflective wheel rims. The center of spoke-mounted reflectors shall be within 76 mm (3.0 in.) of the inside of the rim. Side reflective devices shall be visible on each side of the wheel.

(c) *Front reflector.* The reflector or mount shall not contact the ground plane when the bicycle is resting on that plane in any orientation. The optical axis of the reflector shall be directed forward within 5° of the horizontal-vertical alignment of the bicycle when the wheels are tracking in a straight line, as defined in §1512.18(m)(2). The reflectors and/or mounts shall incorporate a distinct, preferred assembly method that shall insure that the reflector meets the optical requirements of this paragraph (c) when the reflector is attached to the bicycle. The front reflector shall be tested in accordance with the reflector mount and alignment test, §1512.18(m).

(d) *Rear reflector.* The reflector or mount shall not contact the ground plane when the bicycle is resting on that plane in any orientation. The reflector shall be mounted such that it is to the rear of the seat mast with the top of the reflector at least 76 mm (3.0

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in) below the point on the seat surface that is intersected by the line of the seat post. The optical axis of the reflector shall be directed rearward within 5° of the horizontal-vertical alignment of the bicycle when the wheels are traveling in a straight line, as defined in §1512.18(m)(2). The reflectors and/or mounts shall incorporate a distinct, preferred assembly method that shall insure that the reflector meets the optical requirements of this paragraph (d) when the reflector is attached to the bicycle. The rear reflector shall be tested in accordance with the reflector mount and alignment test, §1512.18(m).

(e) *Pedal reflectors.* Each pedal shall have reflectors located on the front and rear surfaces of the pedal. The reflector elements may be either integral with the construction of the pedal or mechanically attached, but shall be sufficiently recessed from the edge of the pedal, or of the reflector housing, to prevent contact of the reflector element with a flat surface placed in contact with the edge of the pedal.

(f) *Side reflectors.* Reflectors affixed to the wheel spokes shall be mounted either flat on the spokes or within the spoke cage such that the angle between the optical axis and the normal to the plane of the wheel shall not exceed the angle of the spokes with the plane of the wheel. The reflectors shall not interfere with any wheel adjustments. The side-mounted reflector devices shall be essentially colorless or amber on the front wheel and essentially colorless or red on the rear wheel.

(g) *Reflector tests.* The pedal, front-mount, rear-mount, and side-mount reflectors shall be tested in accordance with the reflector test, §1512.18(n), to assure the reflectance values over the angles given in tables 1 and 2.

(h) *Retroreflective tire sidewalls.* When retroreflective tire sidewalls are used in lieu of spoke-mounted reflectors, the reflecting material shall meet the following requirements:

(1) The retroreflective material shall form a continuous circle on the sidewall.

(2) The retroreflective material shall adhere to the tire such that after the tire has been subjected to a temperature of 50° ±3 °C (122° ±5.4 °F) for 30 minutes, the retroreflective material can-

not be peeled or scraped away without removal of tire material.

(3) The retroreflective material shall be as resistant to abrasion as is the adjacent sidewall material so that when retroreflective material is removed from the inflated tire by abrasion with a wet, steel bristle brush, tire material will be removed along with the retroreflective material.

(4) The retroreflective material shall be tested for performance in accordance with the retroreflective tire test, §1512.18(o), to assure the reflectance properties over the angles given in table 3. When a portion of the retroreflective material is selected (and the remainder is masked as specified in §1512.18(o)(2)(i)), the selected portion shall not contact the ground plane when the assembled bicycle is resting on that plane in any orientation.

(i) *Retroreflective rims.* When retroreflective rims are used in lieu of spoke-mounted reflectors or retroreflective tire sidewalls, the reflecting material shall meet the following requirements:

(1) The retroreflective material shall form a continuous circle on the rim.

(2) If the retroreflective material is applied to the rim in the form of a self-adhesive tape, the following requirement must be met: Use a sharp knife, razor blade, or similar instrument to carefully release an end of the tape material sufficient to be grasped between the thumb and finger. Grasp the freed tape end and gradually pull in a direction 90° to the plane of the rim. The tape material must break before additional separation (peeling) from the rim is observed.

(3) After the retroreflective material is abraded in accordance with the abrasion test for retroreflective rims at §1512.18(r), the rim must then be tested for performance in accordance with the retroreflective tire and rim test at §1512.18(o), to assure the reflectance properties over the angles given in table 3.

[43 FR 60034, Dec. 22, 1978, as amended at 45 FR 82627, 82628, Dec. 16, 1980]

§ 1512.17 Other requirements.

(a) *Road test.* Bicycles, other than sidewalk bicycles, shall be ridden at

least 6.4 km (4.0 mi.) by a rider weighing at least 68.1kg (150 lb.) and travel five times over a 30.5 m (100 ft.) cleared course in accordance with the road test, §1512.18(p), and shall exhibit stable handling, turning, and steering characteristics without difficulty of operation. There shall be no system or component failure of the structure, brakes, or tires, and there shall be no loosening or misalignment of the seat, handlebars, controls, or reflectors during or resulting from this test.

(b) *Sidewalk bicycle proof test.* Sidewalk bicycles shall be dropped a distance of at least 300 mm (1.0 ft.) three times onto a paved surface with weights attached in accordance with the sidewalk bicycle proof test, §1512.18(q). There shall be no fracture of wheels, frame, seat, handlebars, or fork during or resulting from this test.

(c) *Ground clearance.* With the pedal horizontal and the pedal crank in its lowest position and any training wheels removed, it shall be possible to tilt the bicycle at least 25° from the vertical without the pedal or any other part (other than tires) contacting the ground plane.

(d) *Toe clearance.* Bicycles not equipped with positive foot-retaining devices (such as toe clips) shall have at least 89 mm (3½ in) clearance between the pedal and the front tire or fender (when turned to any position). The clearance shall be measured forward and parallel to the longitudinal axis of the bicycle from the center of either pedal to the arc swept by the tire or fender, whichever results in the least clearance. (See figure 6 of this part 1512.)

§ 1512.18 Tests and test procedures.

(a) *Sharp edge test.* [Reserved]

(b) [Reserved]

(c) *Protective cap and end-mounted devices test.* (Ref. §1512.4(i), §1512.6(d).) Any device suitable for exerting a removal force of at least 67 N (15 lbf) for protective caps and 8.9 N (2.0 lbf) for end caps at any point and in any direction may be used. All protective caps and end-mounted handlebar devices shall be tested to determine that they cannot be removed by application of the specified forces.

(d) *Handbrake loading and performance test.* (Ref. §1512.5(b)).

(1) *Apparatus.* A spring scale or other suitable device for measuring the specified forces on the handbrake levers and a dry, clean, level, paved surface of adequate length.

(2) *Procedure.* The loading test, §1512.18(d)(2)(i), and the rocking test, §1512.18(d)(2)(iii), shall be performed before the performance test, §1512.18(d)(2)(v), is performed and no adjustments shall be made between these tests.

(i) *Loading test procedure.* The hand levers shall be actuated with a force applied at a point no more than 25 mm (1.0 in) from the open end of the lever. If the hand lever contacts the handlebar (bottoms) before a force of 445 N (100 lbf) is reached, the loading may be stopped at that point, otherwise the loading shall be increased to at least 445 N (100 lbf).⁴ Application of the loading force shall be repeated for a total of 10 times and all brake components shall be inspected.

(ii) *Loading test criteria.* There shall be no visible fractures, failures, misalignments, and clearances not in compliance with applicable parts of §1512.5.

(iii) *Rocking test procedure.* A weight of at least 68.1 kg (150 lb) shall be placed on the seat; the force required for the hand levers to contact the handlebars or 445 N (100 lbf), as determined in §1512.18(d)(2), shall be applied to the hand levers;⁴ and the bicycle shall be rocked forward and backward over a dry, clean, level, paved surface at least six times and for a distance of at least 76 mm (3 in) in each direction.

(iv) *Rocking test criteria.* There shall be no loosening of the brake pads, pad holders, or cable and hand-lever securing devices or any other functional brake component.

(v) *Performance test procedure.* The following test conditions, unless otherwise specified in this part 1512, shall be followed:

(A) The bicycle shall be ridden over a dry, clean, smooth paved test course

⁴For hand lever extensions, the loading shall be continued until a force of 445 N (100 lbf) is reached or the hand lever extension is in the same plane as the upper surface of the handlebars or the extension lever contacts the handlebars.

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free from protruding aggregate. The test course shall provide a coefficient of friction of less than 1.0 and shall have a slope of less than 1 percent.

(B) The wind velocity shall be less than 11 km/h (7 mph).

(C) Only the brake system under test shall be actuated.

(D) The bicycle shall attain the specified ground speed while the rider is in the normal riding position.

(E) The rider shall remain in the normal riding position throughout the test.

(F) The bicycle must be moving in a straight line at the start of brake application.

(G) Corrections for velocity at the initiation of braking may be made. The corrected braking distance shall be computed as follow:

$$S_c = (V_s / V_m)^2 S_m$$

where:

S_c = Corrected braking distance,

V_s = Specified test velocity,

V_m = Measured test velocity,

S_m = Measured braking distance.

The test run is invalid if at the commencement of the test, the measured test speed of the bicycle is not less than nor greater than the test speed required by this part 1512 by 1.5 km/h (0.9 mph).

(H) Four test runs are required. The stopping distance shall be determined by averaging the results of the four test runs.

(I) The stopping distances specified are based on a rider weight of at least 68.1 kg (150 lb) and a maximum rider and weight combination of 91 kg (200 lb). Greater stopping distances are allowable for heavier riders and test equipment weights at the rate of 0.30 m per 4.5 kg (1.0 ft per 10 lb).

(J) A test run is invalid if front-wheel lockup occurs.

(vi) *Performance test criteria.* The stopping force applied to the hand lever at a point no closer than 25 mm (1.0 in) from the open end shall not exceed 178 N (40 lbf). Bicycles with an equivalent ground speed in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute)³ shall stop from an actual test

speed of 24 km/h (15 mph) or greater within a distance of 4.57 m (15 ft); when the equivalent ground speed is less than 24 km/h (15 mph) under the same conditions, the bicycle shall stop from an actual test speed of 16 km/h (10 mph) or greater within a distance of 4.57 m (15 ft).

(e) *Footbrake force and performance test.* (Ref. §1512.5(c) (1) and (2)):

(1) *Apparatus.* Suitable devices for exerting and measuring the required forces and a dry, clean, level, paved surface of adequate length.

(2) *Force test.* The braking force shall be measured as the wheel is rotated in a direction of forward motion, and the braking force is measured in a direction tangential to the tire during a steady pull after the wheel completes one-half revolution but before the wheel completes one revolution. The brake shall be capable of producing a linearly proportional brake force for a gradually applied pedal force from 89 N to 310 N (20 to 70 lbf) and shall not be less than 178 N (40 lbf) for an applied pedal force of 310 N (70 lbf). All data points must fall within plus or minus 20 percent of the brake force, based on the measured brake load using the least square method of obtaining the best straight line curve.

(3) *Performance test.* The procedure of §1512.18(d)(2)(v) shall be followed to test the footbrake performance. The stopping distance shall be less than 4.57 m (15 ft) from an actual test speed of 16 km/h (10 mph). In addition, if the equivalent ground speed of the bicycle is in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute),³ the stopping distance shall be 4.57 m (15 ft) from an actual test speed of 24 km/h (15 mph) or greater.

NOTE: No allowance shall be made for rider weight. See §1512.5(d) for additional requirements for bicycles with both handbrakes and footbrakes.

(f) *Sidewalk bicycle footbrake force test.* For sidewalk bicycles, the footbrake force test is the same as for bicycles except; the brake force transmitted to the rear wheel shall continually increase as the pedal force is increased from 44.5 N to 225 N (10 to 50 lbf). The ratio of applied pedal force to braking

³See footnote 3 to §1512.5.

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force shall not be greater than two-to-one.

(g) *Handlebar stem test.* (Ref. §1512.6(b)):

(1) *Procedure.* The handlebar stem shall be tested for strength by applying a force of 2000 N (450 lbf), in a forward direction, for bicycles, or 1000 N (225 lbf) for sidewalk bicycles, at a point in line with the handlebar attachment point and at an angle of 45° from the stem centerline (See fig. 2).

(2) *Criteria.* No visible fractures shall result from this test.

(h) *Handlebar test.* (Ref. §1512.6(e)):

(1) *Stem-to-fork clamp test*—(i) *Procedure.* The handlebar and handlebar stem shall be assembled to the bicycle in accordance with the manufacturer's instructions. The handlebar-fork assembly shall be subjected to a torque applied about the axis of the stem, and shall then be disassembled and examined for signs of structural damage including cracking, splitting, stripping of threads, bearing damage, and bulging of the stem and fork structures. The handlebar and handlebar stem components shall be inspected for visible signs of galling, gouging, and scoring not due to normal assembly and disassembly operations.

(ii) *Criteria.* There shall be no visible movement between the stem and fork when a torque of 47+3, -0 N-m (35+2, -0 ft=lb) for bicycles and 20+3, -0 N-m (15+2, -0 ft=lb) for sidewalk bicycles is applied to the handlebar about the stem-to-fork axis. There shall be no visible signs of damage to the stem-to-fork assembly or any component part thereof.

(2) *Handlebar strength and clamp test*—

(i) *Procedure.* The stem shall be in place on the bicycle or in an equivalent test fixture and secured according to manufacturer's instructions. A load shall be applied equally to each handlebar end in a direction to cause the greatest torque about the handlebar-to-stem clamp; deflection shall be measured along the line of applied force.

(ii) *Criteria.* The handlebars shall support a force of no less than 445 N (100 lbf) or absorb no less than 22.6 J (200 in-lb) of energy through a maximum deflection of no more than 76 mm (3.0 in.); the handlebar clamp shall prevent rotational movement of the handlebars

relative to the clamp, and there shall be no visible fractures.

(i) *Pedal slip test.* [Reserved]

(j) *Rim test.* (Ref. §§1512.10 and 1512.11(c)):

(1) *Procedure.* Only one wheel need be tested if the front and rear wheel are of identical construction. The wheel to be tested shall be removed from the bicycle and be supported circumferentially around the tire sidewall. A load of 2000 N (450 lbf) shall be applied to the axle and normal to the plane of the wheel for at least 30 seconds. If the wheel hub is offset, the load shall be applied in the direction of the offset.

(2) *Criteria.* The wheel and tire assembly shall be inspected for compliance with the requirements of §1512.11(a) and shall be remounted on the bicycle according to the manufacturer's instructions and shall turn freely without roughness and shall comply with the requirement of §1512.11(b).

(3) *Front hub retention test.* (Ref. §1512.12(c)).

(i) *Procedures.* Front hub locking devices shall be released. When threaded nuts and axles are used, the nuts shall be open at least 360° from a finger tight condition. A separation force of at least 111 N (25 lb) shall be applied to the hub on a line along the slots in the fork ends.

(ii) *Criteria.* The front hub shall not separate from the fork; fenders, mudguards, struts, and brakes shall not be allowed to restrain the separation.

(k) *Fork and frame test.* (Ref. §§1512.13 and 1512.14):

(1) *Fork test*—(i) *Procedure.* With the fork stem supported in a 76 mm (3.0 in) vee block and secured by the method illustrated in figure 1 of this part 1512, a load shall be applied at the axle attachment in a direction perpendicular to the centerline of the stem and against the direction of the rake. Load and deflection readings shall be recorded and plotted at the point of loading.

(ii) *Criteria.* Energy of at least 39.5 J (350 in-lb) shall be absorbed with a deflection in the direction of the force of no more than 64 mm (2½ in.).

(2) *Fork and frame assembly test*—(i) *Procedure.* The fork, or one identical to that tested in accordance with the fork test, §1512.18(k)(1), shall be replaced on

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the bicycle in accordance with the manufacturer's instructions; and a load of 890 N (200 lbf), or an energy of at least 39.5 J (350 in-lb), whichever results in the greater force, shall be applied to the fork at the axle attachment point against the direction of the rake in line with the rear wheel axle. The test load shall be counteracted by a force applied at the location of the rear axle during this test.

(ii) *Criteria.* There shall be no visible evidence of fracture and no deformation of frame that significantly limits the steering angle over which the front wheel can be turned.

(1) *Seat adjustment clamps and load test.* (Ref. § 1512.15(c)).

(1) *Procedure.* A force of at least 668 N (150 lbf) shall be applied vertically downward (334 N (75 lbf) for sidewalk bicycles) to a point within 25 mm (1.0 in.) from either the front or rear of the seat, whichever produces the greatest torque on the seat clamp. After removal of this force, a force of 222 N (50 lbf) shall then be applied horizontally (111 N (25 lbf) for sidewalk bicycles) to a point within 25 mm (1.0 in.) from either the front or rear of the seat, whichever produces the greatest torque on the clamp.

(2) *Criteria.* No movement of the seat with respect to the seat post, or of the seat post with respect to the bicycle frame, shall have resulted from application of the forces specified.

(m) *Reflector mount and alignment test.* (Ref. § 1512.16 (c) and (d)):

(1) *Procedure.* A force of 89 N (20 lbf) shall be applied to the reflector mount in at least three directions selected as most likely to affect its alignment. At least one of those directions shall be selected to represent a force that would be expected in lifting the bicycle by grasping the reflector.

(2) *Criteria.* (i) *During test:* The optical axis of the reflector shall remain parallel within 15° to the line or intersection of the ground plane and the center plane of the bicycle defined as a plane containing both wheels and the centerlines of the down tube and seat mast.

(ii) *Post test:* The optical axis of the reflector shall remain parallel within 5° to the line or intersection of the ground plane and the center plane of

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the bicycle defined as a plane containing both wheels and the centerlines of the down tube and seat mast.

(n) *Reflector test.* (Ref. § 1512.16(g)):

(1) *Conditioning.* The following conditioning in the order given shall be performed prior to testing for performance.

(i) *Warpage conditioning.* The reflector shall be held in a preheated oven for at least one hour at 50° ± 5 °C (122 ± 5.4 °F). A pedal reflector may be conditioned integrally with its pedal.

(ii) *Mechanical impact conditioning.* The reflector shall be mounted faceup in a manner similar to the way in which it is mounted on the bicycle. A 13 mm (½ in.) diameter polished steel ball shall be dropped normal to the center of the face of the reflector from a height of 0.76 m (30 in.). The ball may be guided by a tube with holes, but not restricted in free fall. Pedal reflectors are exempt from this impact conditioning.

(iii) *Moisture conditioning.* The reflector shall be submerged in tap water in a suitable container. The container shall be pressurized in 17.2 kN/m² (2.5 psi) (equivalent to 1.7 m (5¾ ft.)) of water for 15 minutes and then released.

(2) *Reflector performance test.* (i) Arrangements for the reflector performance test shall be as shown in figure 3 and the distance *D* between the light source and the reflector shall be 30.5 m (100 ft.). The source of illumination shall be a lamp with a 51 mm (2.0 in.) effective diameter and a filament operating at 2,856 ± 10 percent color temperature. The observation point shall be collocated (as close as practicable) with the source of illumination. The reflector shall be mounted with the center of the reflector at the center of rotation and at the same horizontal level as the source of illumination. Photometric measurements shall be made at the observation angles and entrance angles given in tables 1 and 2.

(ii) The observation angle is the angle formed by a line from the point of observation to the center of the reflector with a second line from the center of the reflector to the source of illumination. The entrance angle is the angle between the optical axis of the reflector and a line from the center of

the reflector to the source of illumination. The entrance angle shall be designated left, right, up, and down in accordance with the position of the source of illumination with respect to the axis of the reflector as viewed from behind the reflector when the plane of the observation angle is vertical and the receiver is above the source.

(iii) Photometric measurements shall be made either visually or photoelectrically. With either method, the light reflected to the observation point shall be determined. Also, the illumination on the reflector from the source shall be measured.

(iv) For visual measurements a comparison lamp, emitting light similar in spectral quality to the reflector, shall be located adjacent to the reflector (at an angle not to exceed $\frac{1}{2}^\circ$) and arranged so that the candlepower can be varied from 0.01 to 0.25 to make the intensity duplicate that of the reflector under test. The candlepower of the source of the illumination of the reflector under test shall be known or determined for this test. Means shall be provided to change the intensity of the source of illumination without changing the filament color temperature. The comparison lamp shall be designed to avoid reflection from the source of illumination back in the direction of the observer. It shall be of such size and so diffused that when viewed by the observer (through a $2\frac{1}{2}\times$ reducing monocular), the candlepower can be readily compared and adjusted to that of the reflector. The observer shall have at least 10 minutes of dark adaptation before making observations. For photoelectric measurements, the opening to the photocell shall not be more than $\frac{1}{2}$ inch vertical by 1 inch horizontal.

(v) Reflectors that mount on the bicycle in a fixed rotational position with respect to the bicycle, or the bicycle component on which they are mounted (such as pedals or spokes), shall be tested with a single orientation. Reflectors that do not mount on the bicycle in a fixed rotational position with respect to the bicycle shall be rotated about their axis through 360° to find the minimum candlepower per footcandle for each test point. If the measurement falls below the minimum

requirement at any test point, the reflector shall be rotated $\pm 5^\circ$ about its axis from the angle where the minimum occurs, and the maximum candlepower per footcandle within this angle shall be the measured value.

(vi) Should uncolored reflections from the front surface interfere with photometric readings at any test point the lowest reading and location within 1° above, below, right, and left of the test point shall meet the minimum requirement for the test point.

(vii) A recommended coordinate system for definition of color is the "Internationale de l'Eclairage (CIE 1931)" system. In the coordinate system and when illuminated by the source defined in table 4 of this part 1512, a reflector will be considered to be red if its color falls within the region bounded by the red spectrum locus and the lines $y = 0.980 - x$ and $y = 0.335$; a reflector will be considered to be amber if its color falls within the region bounded by the yellow spectrum locus and the lines $y = 0.382$, $y = 0.790 - 0.667x$, and $y = x - 0.120$.

(o) Reflective tire and rim test (Ref. § 1512.16(h) and (i)):

(1) *Apparatus.* Arrangements for the reflective intensity measurement shall be as shown in figure 3 of this part 1512. A light projector (having a maximum effective lens diameter of $D/500$, where D is the distance from the source to the retroreflective surface being measured) capable of projecting light of uniform intensity shall be used to illuminate the sample. The light falling on the sample shall have a color temperature of $2856^\circ\text{K} + 10\%$ (equivalent to a tungsten filament lamp operated at a color temperature of $2856^\circ\text{K} + 10\%$ having approximately the relative energy distribution given in table 4 of this part 1512). The light reflected from the test surface shall be measured with a photoelectric receiver, the response of which has been corrected for the spectral sensitivity of the average photopic human eye. The dimensions of the active area of the receiver shall be such that no point on the perimeter of the receiver is more than $D/100$ from its center (where d is the distance from the receiver to the retroreflective surface). Wheels used for the measurement of retroreflective tires or rims shall

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have all exposed metallic surfaces, including spokes, masked in flat black so that when measured these surfaces indicate no appreciable reflectance. The tire shall be mounted and fully inflated. Distances shall be measured from the plane of the wheel and the center of the hub. For the tests, the distance D between the projector and the center of the wheel and distance d between the center of the wheel and the receiver shall each be at least 15 m (50 ft.).

(2) *Procedure*—(i) *Masking*. The reflecting strip to be tested shall be within two concentric circles, the larger of which is no more than 0.02 m (0.79 in.) greater in radius than the smaller. While additional reflecting material is permitted outside such boundaries, such additional material shall not be counted in determining the average width of the reflecting strip and shall be masked off with opaque, matte black tape in testing the reflecting material.

(ii) *Orientation*. Every position of the reflecting strip on the rim or the mounted and fully inflated tire to be tested shall be oriented so that the normal to this portion is within 40° of parallel to the axis of rotation of the wheel.

(iii) *Measurement*. Measure the distance d from the receiver to the center of the wheel and the minimum distance r from the axis of rotation of the wheel to the unmasked portion of the reflective strip. Measure the illumination incident on the reflective strip at uniform intervals of no more than 45° around the wheel, with the receiver oriented in the direction of the incident radiation. The average of such readings will be the mean illumination of the sample E . If any one of such readings differs by more than 10 percent from the mean illumination, then a more uniform source must be obtained. Measure the illumination of the receiver due to reflection from the retroreflective surface for each entrance angle and each observation angle given in table 3 of this part 1512. The entrance angle and the observation angle shall be in the same plane. A negative entrance angle (figure 3 of this part 1512) is specified when the entrance angle is small because the loca-

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tion of the receiver with respect to the direction of illumination becomes important for distinguishing between ordinary mirror-like reflection and retroreflection. The illumination incident on the test surface and the receiver shall be measured in the same units on a linear scale. Compute the ratio A for each combination of entrance angle and observation angle listed in table 3 as follows:

$$A = [(E_r / E_s)(d^2 / r)]$$

Where:

A = Ratio in meters,

E_r = Illumination incident upon the receiver,

E_s = Illumination incident upon a plane perpendicular to the incident ray at the specimen position (see instructions above in this paragraph (o)(2)(iii) for averaging), measured in the same units as E_r ,

d = The distance in meters from the receiver to the center of the wheel,

r = The minimum radius in meters of the boundary circles of the retroreflective strip.

The minimum value of A shall be that listed in table 3 of this part 1512 for each combination of entrance angle and observation angle. The plane containing the entrance angle and the plane containing the observation angle shall coincide. In table 3, a positive entrance angle corresponds to the case in which the line of sight to the receiver lies between the line of incidence and the optic axis of the reflector, and a negative entrance angle corresponds to the case in which the line of incidence lies between the line of sight of the receiver and optic axis of the reflector.

(iv) *Criteria*. The ratio A as defined in § 1512.18(o)(2)(iii) shall not be less than:

$$A = 4\text{Cos}^2\theta/[1+(\Phi/0.225)^{3/2}]$$

where A is ratio in meters, θ is the entrance angle in degrees, and Φ is the observation angle in degrees. The criterion applies only for entrance angles from 0° to 40° and observation angles from 0.2° to 1.5°, and performance is not specified beyond this range. The values of A in table 3 are obtained from the above formula by rounding up to two significant figures. Except in cases in which the performance of the reflector is seriously questionable, a reflector with A at least the value given in table

3 at each of the six combinations of entrance and observation angles will be considered to satisfy this criteria.

(p) *Road test.* (Ref. §§ 1512.15(c) and 1512.17(a)):

(1) *Procedure.* The bicycle shall be ridden at least 6.4 km (4.0 mi.) by a rider weighing at least 68.1 kg (150 lb.) with the tires inflated to maximum recommended pressure. Travel shall include riding the bicycle five times over a 30 m (100 ft.) course of wooden cleats fastened to a paved surface. The cleats shall be a full 25 mm (1.0 in.) high by 51 mm (2.0 in.) wide lumber with a 12 mm by 12 mm (½ in. by ½ in.) chamfer of 45° on the corners contacting the tires. The cleats shall be spaced every 1.8 m (6.0 ft.) over the 30 m (100 ft.) course. The bicycle shall be ridden over the cleated course at a speed of at least 24 km/hr (15 mph) with the rider firmly seated.

(2) *Criteria.* The bicycle shall exhibit stable handling, turning, and steering characteristics without difficulty of operation. There shall be no system or component failure of the structure, brakes, or tires and there shall be no loosening or misalignment of the seat, handlebars, controls, or reflectors.

(q) *Sidewalk bicycle proof test.* (Ref. §§ 1512.15(c) and 1512.17(b)):

(1) *Procedure.* The bicycle shall be loaded with weights of 13.6 kg (30 lb.) on the seat surface and 4.5 kg (10 lb.) attached to the end of each handle grip for a total load of 22.7 kg (50 lb.). The bicycle shall be lifted a distance of 0.3 m (1.0 ft.) and dropped (while maintaining an upright position) three times onto a paved surface. Following this and with weight removed, it shall be allowed to fall in any configuration and attitude from an upright position to the paved surface three times on each side.

(r) *Abrasion test for retroreflective rims.* (Ref. § 1512.16(i)):

(1) This test consists of a steel wire cup brush rotating at a constant velocity of 60 rpm that is applied at a force of 2 N (0.45 lbf) to the retroreflective material on one side of a bicycle wheel rim. The rim is rotated about the axle at a linear velocity of 0.23 m/sec (9 in./sec). The test is complete when the wheel has completed 1000 revolutions.

(2) *Apparatus.* Figure 8 of this part 1512 illustrates the following test fixture arrangement that is suitable to perform this abrasion test:

(i) *Test fixture.* The test fixture contains a clamp to hold the axle of a bicycle wheel so that the wheel can rotate freely about the axle. The axis of rotation is capable of being inclined from the vertical to bring that portion of the side of the wheel rim containing the retroreflective material into a horizontal plane as it passes beneath the abrading brush. A drive mechanism to rotate the bicycle wheel contains a means to adjust the rotational velocity to obtain the specified linear velocity measured at a point on the wheel rim on the axis of the abrading brush.

(ii) *Abrader.* The abrader is a cup brush meeting the specification in paragraph (r)(3)(v) of this section. It is mounted in a chuck attached to a motor that rotates about a vertical axis at the specified rotational velocity. A means is provided to apply the rotating cup brush at the specified force against the retroreflective material on the bicycle wheel rim. The axis of the abrading brush is positioned on the mid point in the width of the retroreflective material. The force is produced by deadweights applied to a pan on the axis of the counterbalanced motor/brush assembly.

(3) *Specifications.* (i) The linear velocity of the reflective band on wheel rim shall be 0.23 m/sec (9 in./sec) measured at a point on the axis of the abrading brush.

(ii) The rotational velocity of the abrading brush shall be 60 rpm.

(iii) The force normal to the plane of the retroreflective material at which the abrading brush is to be applied shall be 2 N (0.45 lbf).

(iv) The bicycle wheel shall make 1000 complete revolutions per test.

(v) The abrader shall be a cup brush having bristles that are 0.005 in. (approx. 0.13mm) diameter low carbon steel wire; an outside diameter of 0.5 inch (approx. .13mm); a wire bristle length of 0.25 inch (approx. 6.4mm); and

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a cup diameter of 0.405 inch (approx. 10.29mm).⁶

(vi) The abrasion test shall be conducted at an ambient temperature of between 16 °C (60 °F) and 27 °C (80 °F).

(4) *Procedure.* (i) The retroreflective bicycle rim to be tested shall be an unused sample free from grit, grime and grease. Prior to beginning the test, remove, according to instructions supplied with the bicycle, any protective coating or material used to prevent damage in shipping.

(ii) Test the wheel in a suitable test fixture, according to the specifications in paragraph (r)(3) of this section.

(iii) Clamp the wheel by its axle in the test fixture and align the axis of rotation so that the portion of the reflective material below the axis of the abrading brush is horizontal.

(iv) Shape the cup brush by hand to the specified 0.5 (approx. 13mm) diameter. Any stray wire bristles projecting more than $\frac{1}{32}$ in. (approx. 1 mm) beyond the tip of the bulk of the bristles should be clipped off. Adjust the position of the brush so that its axis is centered over the mid-point in the width of the retroreflective material.

(v) Adjust the rotational velocity of the bicycle wheel to obtain a linear velocity of 0.23 m/sec (9 in./sec) measured at the mid-point in the width of the retroreflective material. Adjust the force to obtain a force normal to the surface under the brush of 2 N (0.45 lbf).

(vi) Apply the abrading brush to the retroreflective material on the wheel rim, and continue the test for 1000 complete revolutions of the bicycle wheel.

[43 FR 60034, Dec. 22, 1978, as amended at 45 FR 82628, Dec. 16, 1980; 46 FR 3204, Jan. 14, 1981; 68 FR 52691, Sept. 5, 2003; 76 FR 27888, May 13, 2011]

§ 1512.19 Instructions and labeling.

A bicycle shall have an instruction manual attached to its frame or included with the packaged unit.

(a) The instruction manual shall include at least the following:

⁶For compliance testing the Commission will use a brush meeting this description distributed by Dremel Manufacturing Company, Racine, Wisconsin as Dremel Part No. 442. This brush is manufactured by Weiler Brush Company as No. 26074, MC-10 Wire.

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(1) Operations and safety instructions describing operation of the brakes and gears, cautions concerning wet weather and night-time operation, and a guide for safe on-and-off road operation.

(2) Assembly instructions for accomplishing complete and proper assembly.

(3) Maintenance instructions for proper maintenance of brakes, control cables, bearing adjustments, wheel adjustments, lubrication, reflectors, tires and handlebar and seat adjustments; should the manufacturer determine that such maintenance is beyond the capability of the consumer, specifics regarding locations where such maintenance service can be obtained shall be included.

(b) A bicycle less than fully assembled and fully adjusted shall have clearly displayed on any promotional display material and on the outside surface of the shipping carton the following: (1) A list of tools necessary to properly accomplish assembly and adjustment, (2) a drawing illustrating the minimum leg-length dimension of a rider and a method of measurement of this dimension.

(c) The minimum leg-length dimension shall be readily understandable and shall be based on allowing no less than one inch of clearance between (1) the top tube of the bicycle and the ground plane and (2) the crotch measurement of the rider. A girl's style frame shall be specified in the same way using a corresponding boys' model as a basis.

(d) [Reserved]

(e) Every bicycle subject to the requirements of this part 1512 shall bear a marking or label that is securely affixed on or to the frame of the bicycle in such a manner that the marking or label cannot be removed without being defaced or destroyed. The marking or label shall identify the name of the manufacturer or private labeler and shall also bear some form of marking from which the manufacturer can identify the month and year of manufacture or from which the private labeler can identify the manufacturer and the month and year of manufacture. For purposes of this paragraph, the term *manufacture* means the completion by the manufacturer of a bicycle of those construction or assembly operations

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that are performed by the manufacturer before the bicycle is shipped from the manufacturer's place of production for sale to distributors, retailers, or consumers.

[43 FR 60034, Dec. 22, 1978, as amended at 60 FR 62990, Dec. 8, 1995]

§ 1512.20 Separability.

If any section or portion thereof of this part 1512 or its application to any person or circumstance is held invalid, the remainder of the section(s) and its (their) application to other persons or circumstances is not thereby affected.

Subpart B—Policies and Interpretations [Reserved]

FIGURE 1 TO PART 1512—BICYCLE FRONT FORK CANTILEVER BENDING TEST RIG

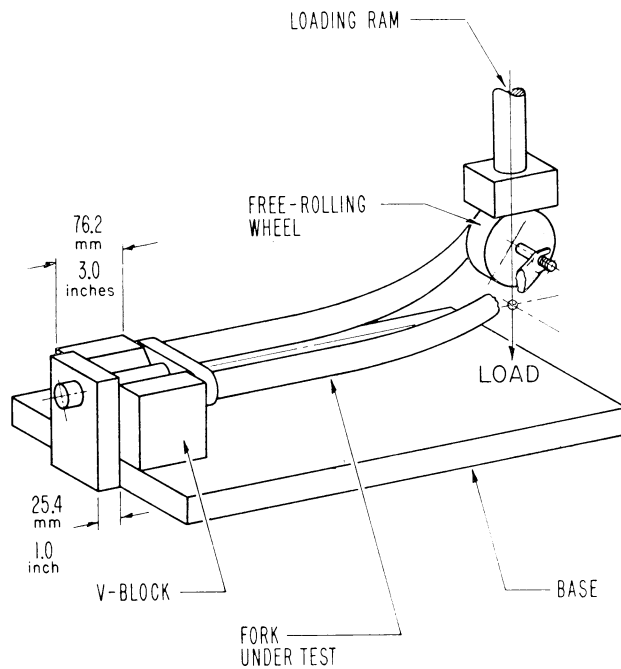


FIG 1-BICYCLE FRONT FORK CANTILEVER BENDING TEST RIG

FIGURES 2 AND 3 TO PART 1512—HANDLEBAR STEM LOADING AND ENTRANCE 8 OBSERVATION ANGLES

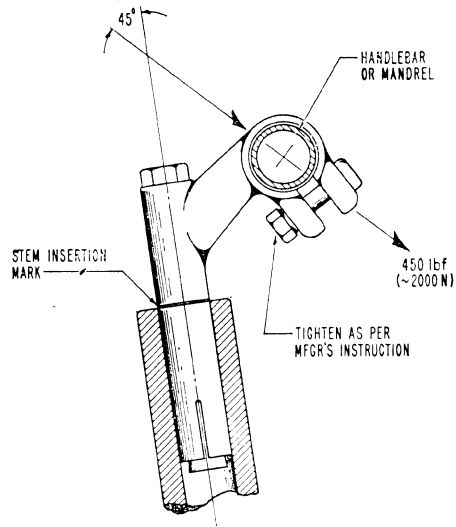
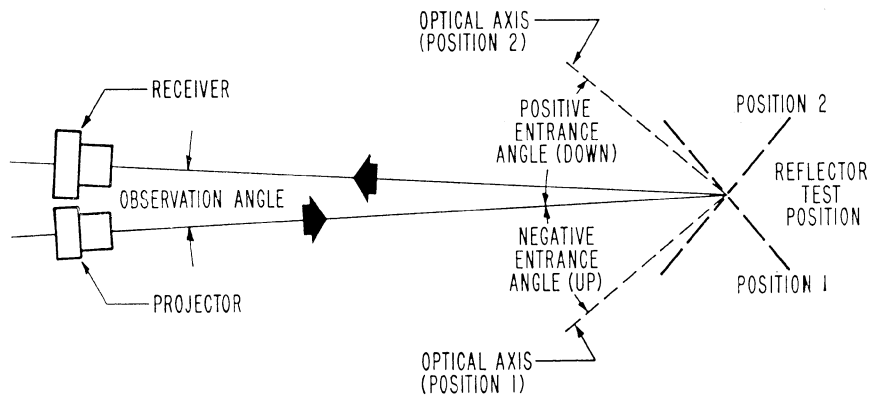


FIG 2—HANDLEBAR STEM LOADING



Side View

FIG 3—ENTRANCE & OBSERVATION ANGLES
[FIG 4 - REVOKED]

FIGURE 5 TO PART 1512—TYPICAL HANDBRAKE ACTUATOR SHOWING GRIP DIMENSION

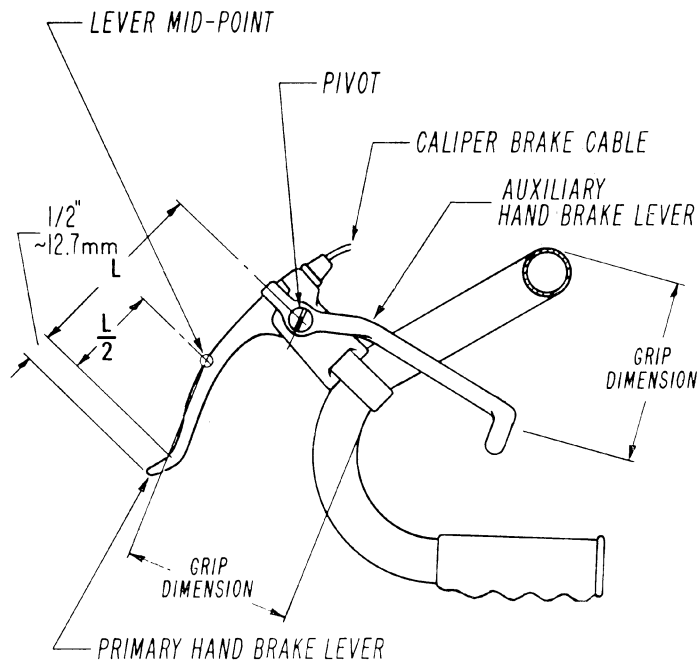
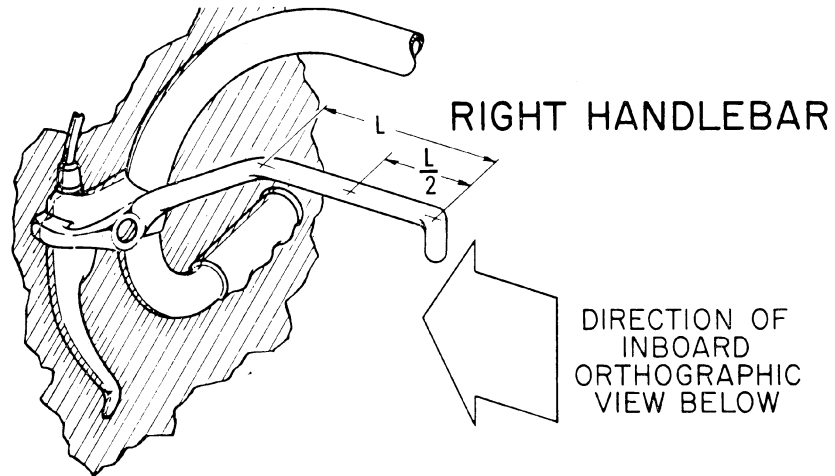


FIG. 5-TYPICAL HANDBRAKE ACTUATOR SHOWING GRIP DIMENSION

FIGURES 6 AND 7 TO PART 1512—TOE CLEARANCE AND CHAIN GUARD REQUIREMENTS

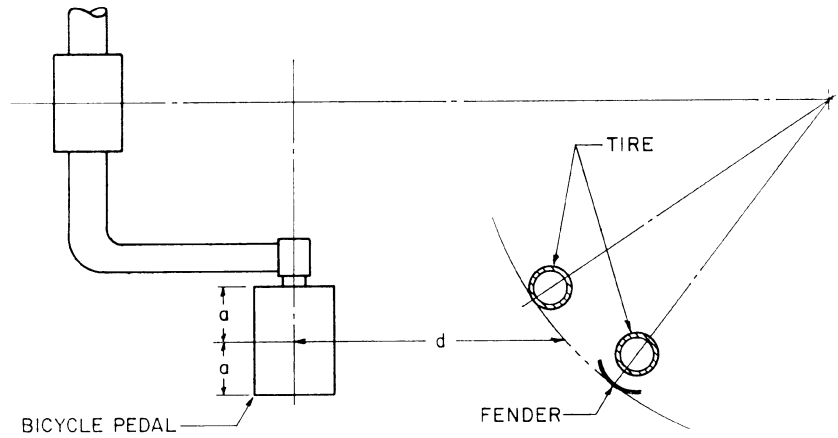


FIG 6 -TOE CLEARANCE

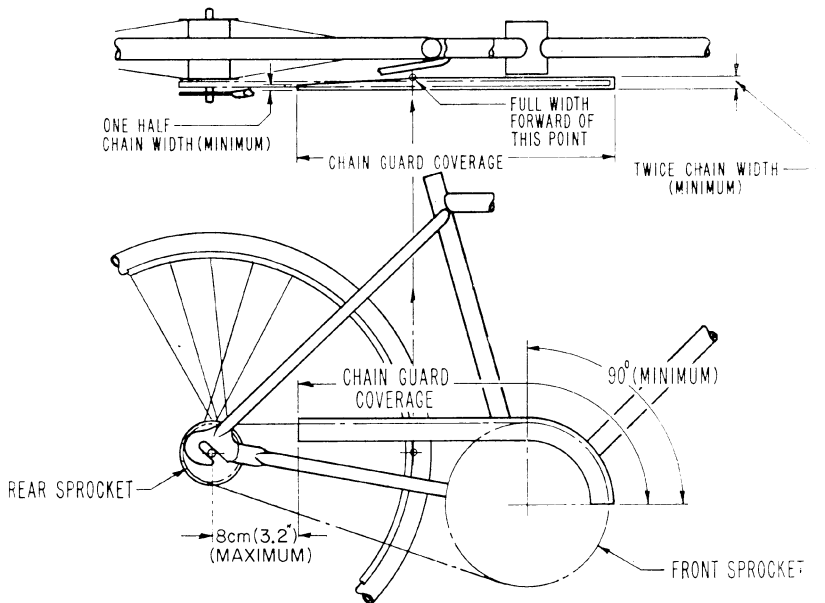


FIG 7 -CHAIN GUARD REQUIREMENTS

FIGURE 8 TO PART 1512—REFLECTORIZED BICYCLE WHEEL RIM ABRASION TEST DEVICE

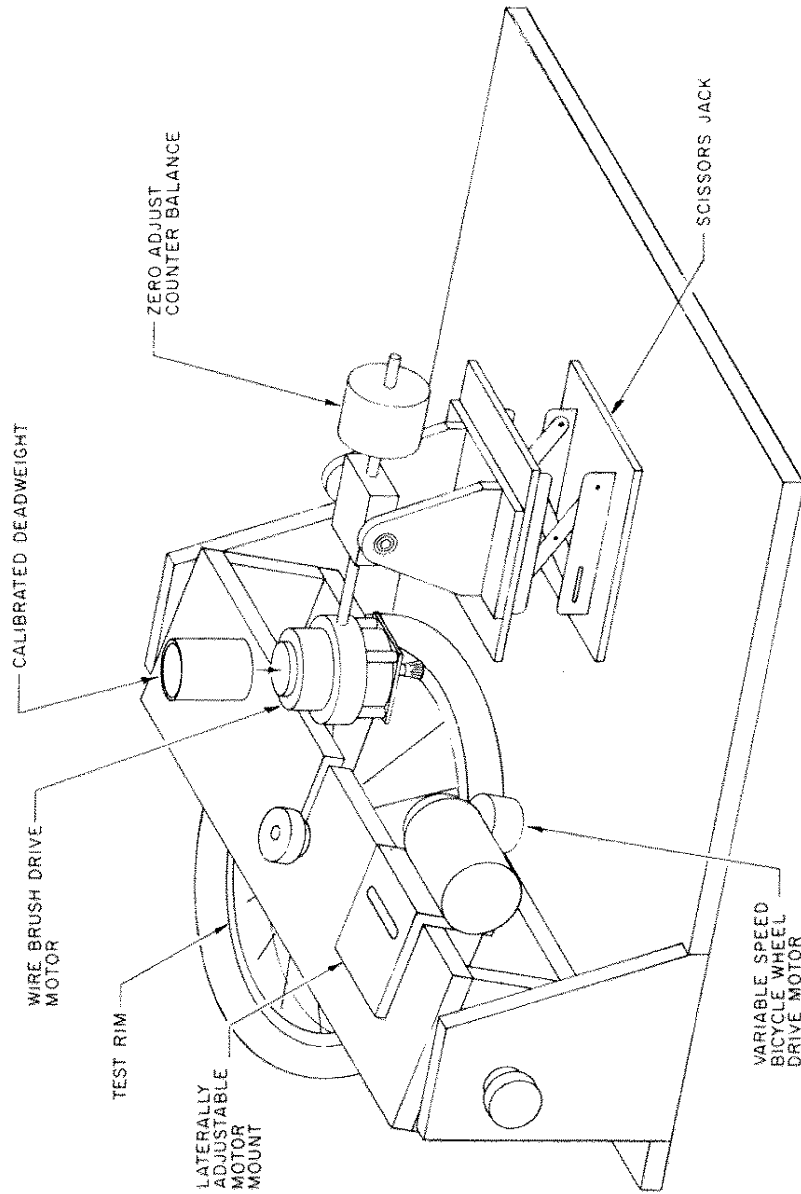


FIG 8--REFLECTORIZED BICYCLE WHEEL RIM ABRASION TEST DEVICE

Pt. 1512, Table 1

TABLE 1 TO PART 1512—MINIMUM CANDLEPOWER PER INCIDENT FOOT-CANDLE FOR CLEAR REFLECTOR¹

Observation angle	Front, rear, and side reflectors; entrance angle in degrees			Pedal reflectors; entrance angle in degrees		
	0	10 up/down	20 left/right	0	10 up/down	20 left/right
0.2	27.0	18.0	9.0	7.5	6.0	3.0
0.3				6.0	4.8	2.4
1.5	.28	.20	.12	.28	.20	.12

¹ Amber values shall be 5/8 × clear values. Red values shall be 1/4 clear values.

TABLE 2 TO PART 1512—MINIMUM CANDLEPOWER PER INCIDENT FOOT-CANDLE FOR CLEAR REFLECTOR¹

Observation angle	Front, rear, and side reflectors; entrance angle in degrees		
	30 left/right	40 left/right	50 left/right
0.2	8.0	7.0	6.0
1.5	.12	.12	.12

¹ Amber values shall be 5/8 × clear values. Red values shall be 1/4 × clear values.

TABLE 3 TO PART 1512—MINIMUM ACCEPTABLE VALUES FOR THE QUANTITY A DEFINED IN THE RETROREFLECTIVE TIRE AND RIM TEST PROCEDURE

Observation angle (degrees)	Entrance angle (degrees)	Minimum acceptable value of A	
		Meters	Feet
0.2	−4	2.2	7.25
.2	20	1.9	6.27
.2	40	1.3	4.29
1.5	−4	.22	.73
1.5	20	.19	.63
1.5	40	.13	.43

[43 FR 60034, Dec. 22, 1978, as amended at 45 FR 82631, Dec. 16, 1980; 46 FR 3204, Jan. 14, 1981]

TABLE 4 TO PART 1512—RELATIVE ENERGY DISTRIBUTION OF SOURCES

Wave length (nanometers)	Relative energy
380	9.79
390	12.09
400	14.71
410	17.68
420	21.00
430	24.67
440	28.70
450	33.09
460	37.82
470	42.87
480	48.25

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Wave length (nanometers)	Relative energy
490	53.91
500	59.86
510	66.06
520	72.50
530	79.13
540	85.95
550	92.91
560	100.00
570	107.18
580	114.44
590	121.73
600	129.04
610	136.34
620	143.62
630	150.83
640	157.98
650	165.03
660	171.96
670	178.77
680	185.43
690	191.93
700	198.26
710	204.41
720	210.36
730	216.12
740	221.66
750	227.00
760	232.11

PART 1513—REQUIREMENTS FOR BUNK BEDS

Sec.

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- 1513.3 Requirements.
- 1513.4 Test methods.
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APPENDIX TO PART 1513—FINDINGS UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT

AUTHORITY: 15 U.S.C. 1261(f)(1)(D), 1261(s), 1262(e)(1), 1262(f)–(i).

SOURCE: 64 FR 71907, Dec. 22, 1999, unless otherwise noted.

§ 1513.1 Scope, application, and effective date.

(a) *Scope, basis, and purpose.* This part 1513 prescribes requirements for bunk beds to reduce or eliminate the risk that children will die or be injured from being trapped between the upper

bunk and the wall or in openings below guardrails or in other structures in the bed. Bunk beds meeting these requirements are exempted from 16 CFR 1500.18(a)(18).

(b) *Application and effective date.* This part applies to all bunk beds, except those manufactured only for institutional use, that are manufactured in the United States, or imported, on or after June 19, 2000. (Facilities intended for use by children under age 6 are not considered to be institutions.) Bunk beds, as described in this section, that are not intended for use by children are subject to the requirements in 16 CFR part 1213, and not to 16 CFR 1500.18(a)(18). However, the provisions of 16 CFR 1213 are substantively identical to the requirements in this part 1513.

§ 1513.2 Definitions.

As used in this part 1513:

Bed. See *Bunk bed.*

Bed end structure means an upright unit at the head and foot of the bed to which the side rails attach.

Bunk bed means a bed in which the underside of any foundation is over 30 inches (760 mm) from the floor.

Foundation means the base or support on which a mattress rests.

Guardrail means a rail or guard on a side of the upper bunk to prevent a sleeping occupant from falling or rolling out.

§ 1513.3 Requirements.

(a) *Guardrails.* (1) Any bunk bed shall provide at least two guardrails, at least one on each side of the bed, for each bed having the underside of its foundation more than 30 inches (760 mm) from the floor.

(2) One guardrail shall be continuous between each of the bed's end structures. "Continuous" means that any gap between the guardrail and end structure shall not exceed 0.22 inches (5.6 mm) (so as to not cause a finger entrapment hazard for a child).

(3) The other guardrail may terminate before reaching the bed's end structures, providing there is no more than 15 inches (380 mm) between either end of the guardrail and the nearest bed end structure.

(4) For bunk beds designed to have a ladder attached to one side of the bed, the continuous guardrail shall be on the other side of the bed.

(5) Guardrails shall be attached so that they cannot be removed without either intentionally releasing a fastening device or applying forces sequentially in different directions.

(6) The upper edge of the guardrails shall be no less than 5 inches (130 mm) above the top surface of the mattress when a mattress of the maximum thickness specified by the manufacturer's instructions is on the bed. This requirement does not prohibit a wall-side guardrail that terminates in a quarter-circle bend and attaches to the side rail of the upper bunk foundation.

(7) With no mattress on the bed, there shall be no openings in the structure between the lower edge of the uppermost member of the guardrail and the underside of the upper bunk's foundation that would permit passage of the wedge block shown in Figure 1 of this part when tested in accordance with the procedure at § 1513.4(a).

(b) *Bed end structures.* (1) The upper edge of the upper bunk end structures shall be at least 5 inches (130 mm) above the top surface of the mattress for at least 50 percent of the distance between the two posts at the head and foot of the upper bunk when a mattress and foundation of the maximum thickness specified by the manufacturer's instructions is on the bed.

(2) With no mattress on the bed, there shall be no openings in the rigid end structures above the foundation of the upper bunk that will permit the free passage of the wedge block shown in Figure 1 when tested in accordance with the procedure at § 1513.4(b).

(3) When tested in accordance with § 1513.4(c), there shall be no openings in the end structures between the underside of the foundation of the upper bunk and upper side of the foundation of the lower bunk that will permit the free passage of the wedge block shown in Figure 1, unless the openings are also large enough to permit the free passage of a 9-inch (230-mm) diameter rigid sphere.

(4) All portions of the boundary of any opening required by §§ 1513.4(c)(1) and (2) to be probed by the wedge block

§ 1513.4

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of Figure 1, and that permits free passage of a 9-inch diameter sphere, must conform to the neck entrapment requirements of § 1513.4(c)(3).

§ 1513.4 Test methods.

(a) *Guardrails* (see § 1513.3(a)(6)). With no mattress on the bed, place the wedge block shown in Figure 1, tapered side first, into each opening in the rigid bed structure below the lower edge of the uppermost member of the guardrail and above the underside of the upper bunk's foundation. Orient the block so that it is most likely to pass through the opening (e.g., the major axis of the block parallel to the major axis of the opening) ("most adverse orientation"). Then, gradually apply a 33-lbf (147-N) force in a direction perpendicular to the plane of the large end of the block. Sustain the force for 1 minute.

(b) *Upper bunk end structure* (see § 1513.3(b)(2)). Without a mattress or foundation on the upper bunk, place the wedge block shown in Figure 1 into any opening, tapered side first, and in the most adverse orientation. Determine if the wedge block can pass freely through the opening.

(c) *Lower bunk end structure* (see § 1513.3(b)(3)). (1) Without a mattress or foundation on the lower bunk, place the wedge block shown in Figure 1, tapered side first, into each opening in the lower bunk end structure in the most adverse orientation. Determine whether the wedge block can pass freely through the opening. If the wedge block passes freely through the opening, determine whether a 9-inch (230-mm) diameter rigid sphere can pass freely through the opening.

(2) With the manufacturer's recommended maximum thickness mattress and foundation in place, repeat the test in paragraph (c)(1) of this section.

(3) All portions of the boundary of any opening that is required to be probed by the wedge block of Figure 1 by paragraphs (c)(1) and (c)(2) of this section, and that permits free passage of a 9-inch diameter sphere, must satisfy the requirements of paragraphs

(c)(3)(i) and (c)(3)(ii) of this section addressing neck entrapment:

(i) Insert the "A" section of the test template shown in Figure 2 of this part into the portion of the boundary to be tested, with the plane of the template in the plane of the opening and with the centerline of the top of the template (as shown in Figure 2) aligned parallel to the centerline of the opening, until motion is stopped by contact between the test template and the boundaries of the opening (see Figure 3 of this part). By visual inspection, determine if there is simultaneous contact between the boundary of the opening and both sides of the "A" section of the template. If simultaneous contact occurs, mark the contact points on the boundary of the opening and conduct the additional test described in paragraph (c)(3)(ii) of this section.

(ii) To check the potential for neck entrapment, place the neck portion of the "B" section of the template into the opening, with its plane perpendicular to both the plane of the opening and the centerline of the opening (see Figure 4 of this part). If the neck portion of the "B" section of the template can completely enter the opening (passes 0.75 inch or more beyond the points previously contacted by the "A" section of the template), the opening is considered to present a neck entrapment hazard and fails the test, unless its lower boundary slopes downward at 45° or more for the whole distance from the narrowest part of the opening the neck can reach to the part of the opening that will freely pass a 9-inch diameter sphere.

§ 1513.5 Marking and labeling.

(a) There shall be a permanent label or marking on each bed stating the name and address (city, state, and zip code) of the manufacturer, distributor, or retailer; the model number; and the month and year of manufacture.

(b) The following warning label shall be permanently attached to the inside of an upper bunk bed end structure in a location that cannot be covered by the bedding but that may be covered by the placement of a pillow.

<p>△ WARNING</p>
<p>To help prevent serious or fatal injuries from entrapment or falls:</p> <ul style="list-style-type: none"> • Never allow a child under 6 years on upper bunk • Use only a mattress that is ___ inches long and ___ inches wide on upper bunk • Ensure thickness of mattress and foundation combined does not exceed ___ inches and that mattress surface is at least 5 inches below upper edge of guardrails <p style="text-align: center;">DO NOT REMOVE THIS LABEL</p>

§ 1513.6 Instructions.

Instructions shall accompany each bunk bed set, and shall include the following information.

(a) *Size of mattress and foundation.* The length and width of the intended mattress and foundation shall be clearly stated, either numerically or in conventional terms such as twin size, twin extra-long, etc. In addition, the maximum thickness of the mattress and foundation required for compliance with § 1513.3 (a)(5) and (b)(1) of this part shall be stated.

(b) *Safety warnings.* The instructions shall provide the following safety warnings:

(1) Do not allow children under 6 years of age to use the upper bunk.

(2) Use guardrails on both sides of the upper bunk.

(3) Prohibit horseplay on or under beds.

(4) Prohibit more than one person on upper bunk.

(5) Use ladder for entering or leaving upper bunk.

(6) If the bunk bed will be placed next to a wall, the guardrail that runs the full length of the bed should be placed against the wall to prevent entrapment between the bed and the wall. (This applies only to bunk beds without two full-length guardrails.)

FIGURE 1 TO PART 1513—WEDGE BLOCK FOR TESTS IN § 1513.4 (a), (b), AND (c)

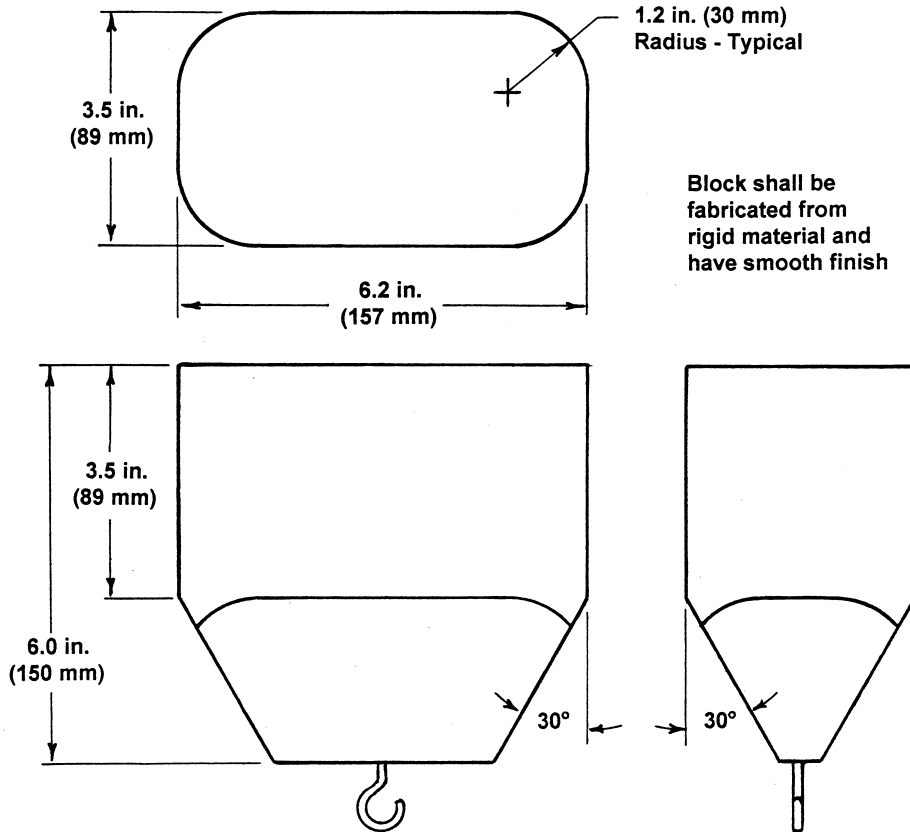
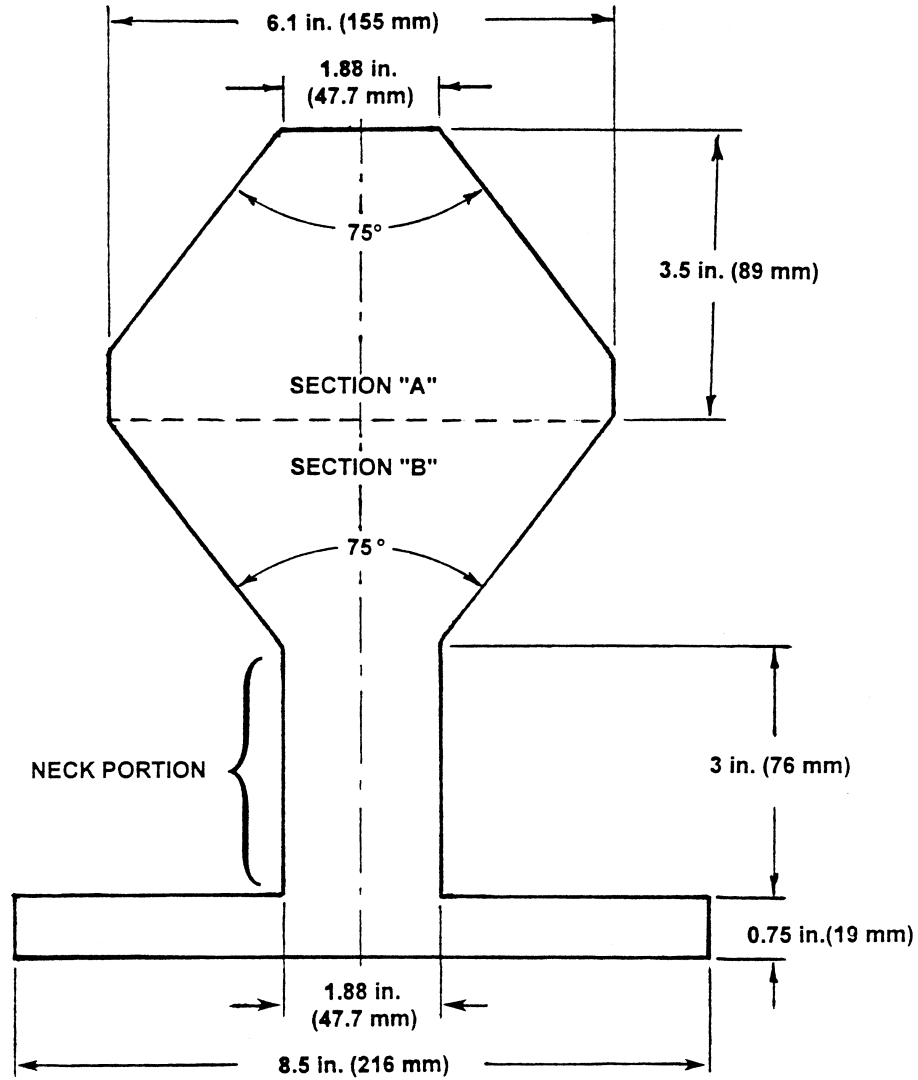


Figure 1 to Part 1513 - Wedge Block for Tests in § 1513.4(a), (b) and (c)

FIGURE 2 TO PART 1513—TEST PROBE FOR NECK ENTRAPMENT



NOTE – Probe to be constructed from any rigid material 0.75 in. (19 mm) thick

Fig. 2 – Test Probe for Neck Entrapment

FIGURE 3 TO PART 1513—MOTION OF TEST PROBE ARRESTED BY SIMULTANEOUS CONTACT WITH BOTH SIDES OF "A" SECTION OF PROBE AND BOUNDARIES OF OPENING

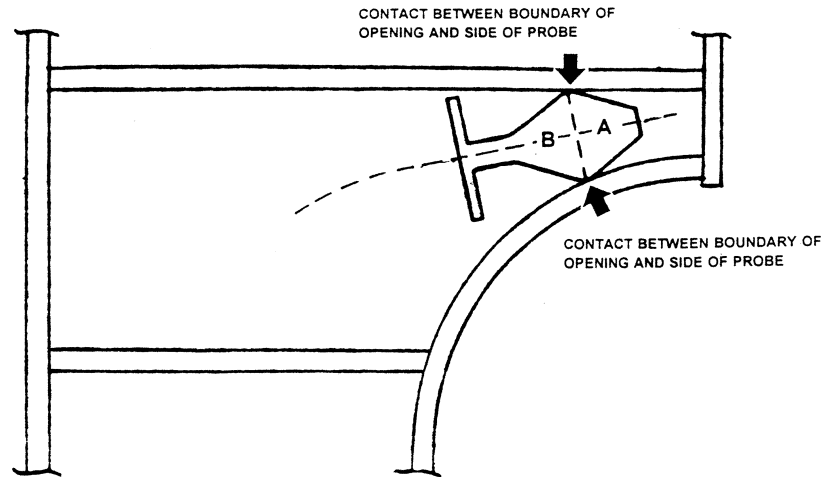


Fig. 3 – Motion of Test Probe Arrested by Simultaneous Contact With Both Sides of "A" Section of Probe and Boundaries of Opening

FIGURE 4 TO PART 1513—NECK PORTION OF “B” SECTION OF PROBE ENTERS COMPLETELY INTO OPENING

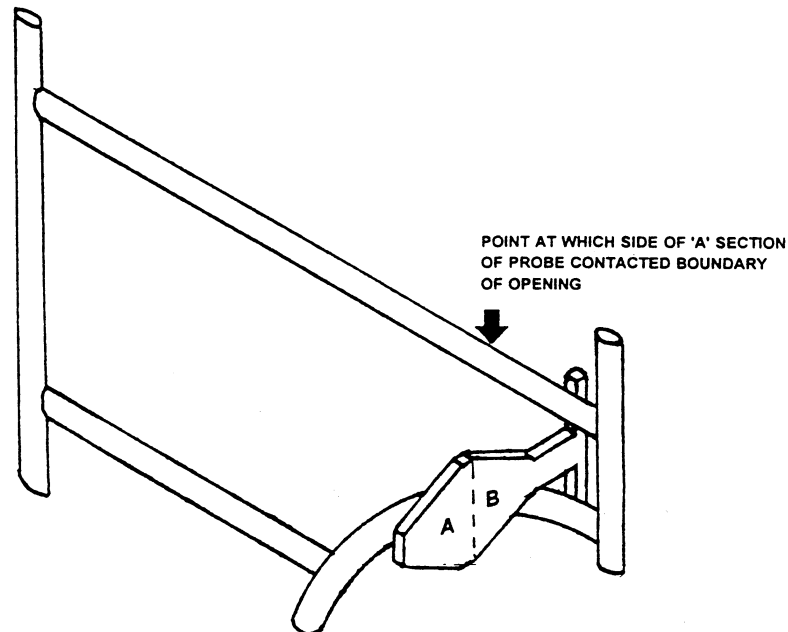


Fig 4 – Neck Portion of “B” Section of Probe Enters Completely into Opening

APPENDIX TO PART 1513—FINDINGS UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT

The Federal Hazardous Substances Act (FHSA) requires that the Commission, in order to issue part 1513, make the following findings and include them in the rule. 15 U.S.C. 1261(s), 1262(i). Because of this, the facts and determinations in these findings apply as of the date the rule was issued, December 22, 1999.

A. *Bunk beds present a mechanical hazard.* Section 2(s) of the FHSA states that an “article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness * * * (3 from * * * surfaces, edges, openings, or closures * * * , or (9) because of

any other aspect of the articles design or manufacture.” 15 U.S.C. 1261(s).

2. For a recent 9.6-year period, the CPSC received reports of 57 deaths of children under age 15 who died when they were trapped between the upper bunk of a bunk bed and the wall or when they were trapped in openings in the bed’s structure. Over 96% of those who died in entrapment incidents were age 3 or younger. On average, averting these deaths is expected to produce a benefit to society with a present value of about \$175 to \$350 for each bed that otherwise would not have complied with one or more of the rule’s requirements.

3. This increased safety will be achieved in three main ways. First, all bunk beds will be required to have a guardrail on both sides of the bed. If the bed is placed against a wall, the guardrail on that side is expected to prevent a child from being entrapped between the bed and the wall. The guardrail on the

wall side of the bed must extend continuously from one end to the other. Second, the end structures of the bed must be constructed so that, if an opening in the end structure is large enough so a child can slip his or her body through it, it must be large enough that the child's head also can pass through. Third, this area must also be constructed so that a child cannot insert his or her head into an opening and move to another part of the opening where the head cannot be pulled out and the neck can become entrapped.

4. For the reasons discussed in paragraph C of this appendix, the benefits of the changes to bunk beds caused by this rule will have a reasonable relationship to the changes' costs. The rule addresses a risk of death, and applies primarily to a vulnerable population, children under age 3. The life-saving features required by the rule are cost-effective and can be implemented without adversely affecting the performance and availability of the product. The effective date provides enough time so that production of bunk beds that do not already comply with the standard can easily be changed so that the beds comply. Accordingly, the Commission finds that there is an unreasonable risk of entrapment injury associated with bunk beds that do not comply with part 1513.

B. *Where a voluntary standard has been adopted and implemented by the affected industry, that compliance with such voluntary standard is not likely to result in the elimination or adequate reduction of the risk of injury, or it is unlikely that there will be substantial compliance with such voluntary standard.*

1. *Adequacy of the voluntary standard.* In this instance, there is a voluntary standard addressing the risk of entrapment in bunk beds. However, the rule goes beyond the provisions of the voluntary standard. First, it eliminates the voluntary standard's option to have an opening of up to 15 inches at each end of the wall-side guardrail. Second, it requires more of the lower bunk end structures to have entrapment protection. The voluntary standard protects against entrapment only within the 9-inch space immediately above the upper surface of the lower bunk's mattress. The mandatory standard extends this area of protection upward to the level of the underside of the upper bunk foundation. Both of these provisions, which are in the rule but not in the voluntary standard, address fatalities and, as noted in this paragraph (a)(18), have benefits that bear a reasonable relationship to their costs.

Therefore, the Commission finds that compliance with the voluntary standard is not likely to result in the elimination or adequate reduction of the risk of entrapment injury or death.

2. *Substantial compliance.* i. The FHSA does not define "substantial compliance." The March 3, 1999 Notice of Proposed Rulemaking

summarized an interpretation of "substantial compliance" that the Office of General Counsel provided to the Commission. 64 FR 10245, 10248–49 (March 3, 1999). The Commission specifically invited public comment on that interpretation from "all persons who would be affected by such an interpretation." Id. at 10249. The Commission received more than 20 comments on the interpretation.

ii. Having now considered all the evidence that the staff has presented, the comments from the public, and the legal advice from the Office of General Counsel, the Commission concludes that there is not "substantial compliance" with the ASTM voluntary standard for bunk beds within the meaning of the Consumer Product Safety Act and the Federal Hazardous Substances Act. See, e.g., 15 U.S.C. 2058(f)(3)(D)(ii); 15 U.S.C. 1262(i)(2)(A)(ii). However, the Commission does not adopt a general interpretation of "substantial compliance" focusing on whether the level of compliance with a voluntary standard could be improved under a mandatory standard. Rather, the grounds for the Commission's decision focus on the specific facts of this rulemaking and are stated below.

iii. The legislative history regarding the meaning of "substantial compliance" indicates that the Commission should consider whether compliance is sufficient to eliminate or adequately reduce the risk of injury in a timely fashion and that, generally, compliance should be measured in terms of the number of complying products, rather than the number of manufacturers who are in compliance. E.g., Senate Report No. 97–102, p. 14 (May 15, 1981); House Report No. 97–158, p. 11 (June 19, 1981); H. Conf. Rep. No. 97–208, 97th Cong., 1st Sess. 871, reprinted in 1981 U.S. Code Cong. & Admin. News 1010, 1233.

iv. Given this Congressional guidance, the Commission believes it appropriate to examine the number of conforming products as the starting point for analysis. However, the Commission does not believe that there is any single percentage of conforming products that can be used in all cases to define "substantial compliance." Instead, the percentage must be viewed in the context of the hazard the product presents. Thus, the Commission must examine what constitutes substantial compliance with a voluntary standard in light of its obligation to safeguard the American consumer.

v. There are certain factors the agency considers before it initiates regulatory action, such as the severity of the potential injury, whether there is a vulnerable population at risk, and the risk of injury. See 16 CFR 1009.8. These and other factors also appropriately inform the Commission's decision regarding whether a certain level of conformance with a voluntary standard is

substantial. In the light of these factors, industry's compliance rate with the voluntary standard for bunk beds is not substantial.

vi. In this case, the Commission deals with the most severe risk—death—to one of the most vulnerable segments of our population—infants and young children. While the risk of death is not high, it exists whenever a young child is in a residence with a nonconforming bunk bed.

vii. Additionally, some products, such as hairdryers without shock protection devices, require some intervening action (dropping the hair dryer into water) to create the hazard. By contrast, deaths in bunk beds occur during the intended use of the product—a child rolling over in bed or climbing in or out of it—without any intervening action.

viii. The Commission must also consider that bunk beds have a very long product life, frequently being passed on to several families before being discarded. Thus, a number of children may be exposed to a bed during its useful life. Every noncomplying bed that poses an entrapment hazard presents the potential risk of death to any young child in the house. It is a risk that is hard for a parent to protect against, as children find their way onto these beds even if they are not put to sleep in them.

ix. Bunk beds are products that can be made relatively easily by very small companies, or even by a single individual. The Office of Compliance believes smaller entities will always present a compliance problem, because new manufacturers can enter the marketplace relatively easily and need little expertise to make a wooden bunk bed. The evidence seems to support the view that there will always be an irreducible number of new, smaller bunk bed manufacturers who will not follow the voluntary standard.

x. What constitutes substantial compliance is also a function of what point in time the issue is examined. In 1989, the Commission denied a petition for a mandatory bunk bed rule. At that time, industry was predicting that by April of 1989, 90% of all beds being manufactured would comply with the voluntary guidelines. But that was in the context of years of steadily increasing conformance and the hope that conformance would continue to grow and that deaths and near-misses would begin to decline. But the conformance level never grew beyond the projection for 1989 and deaths and near-misses have not dropped.

xi. Even with the existing compliance rate, the Commission is contemplating the prospect of perhaps 50,000 nonconforming beds a year (or more) entering the marketplace, with many beds remaining in use for perhaps 20 years or longer. Under these circumstances, a 10% rate of noncompliance is too high.

xii. It is now clear that the bunk bed voluntary standard has not achieved an ade-

quate reduction of the unreasonable risk of death to infants and children in a timely fashion, and it is unlikely to do so. Accordingly, the Commission finds that substantial compliance with the voluntary standard for bunk beds is unlikely.

xiii. Products that present some or all of the following factors might not be held to as strict a substantial compliance analysis. Those which:

- Rarely or never cause death;
- Cause only less severe injuries;
- Do not cause deaths or injuries principally to a vulnerable segment of the population;
- Are not intended for children and which have no special attraction for children;
- Have a relatively short life span;
- Are made by a few stable manufacturers or which can only be made by specialized manufacturers needing a significant manufacturing investment to produce the product;
- Are covered by a voluntary standard which continues to capture an increasing amount of noncomplying products; or
- Require some additional intervening action to be hazardous.

xiv. And, in analyzing some other product, there could be other factors that would have to be taken into consideration in determining what level of compliance is adequate to protect the public. The tolerance for nonconformance levels has to bear some relationship to the magnitude and manageability of the hazard addressed.

xv. The Commission emphasizes that its decision is not based on the argument that a mandatory rule provides more powerful enforcement tools. If this were sufficient rationale, mandatory rules could always displace voluntary standards, and this clearly was not Congress's intent. But, with a mandatory standard, the necessity of complying with a mandatory federal regulation will be understandable to small manufacturers. State and local governments will have no doubt about their ability to help us in our efforts to locate these manufacturers.

C. The benefits expected from the rule bear a reasonable relationship to its costs.

1. *Bunk beds that do not comply with ASTM's requirements for guardrails.* The cost of providing a second guardrail for bunk beds that do not have one is expected to be from \$15-40 per otherwise noncomplying bed. If, as expected, the standard prevents virtually all of the deaths it addresses, the present value of the benefits of this modification are estimated to be from \$175-350 per otherwise noncomplying bed. Thus, the benefit of this provision is about 4-23 times its cost.

2. *Bunk beds that comply with ASTM's requirements for guardrails.* The voluntary standard allows up to a 15-inch gap in the coverage of the guardrail on the wall side of the upper bunk. Additional entrapment deaths are addressed by requiring that the

wall-side guardrail be continuous from one end of the bed to the other. The estimated present value of the benefits of this requirement will be \$2.40 to \$3.50 per otherwise non-complying bed. The Commission estimates that the materials cost to extend one guardrail an additional 30 inches (760 mm) will be less than the present value of the benefits of making the change. Further, the costs of any design changes can be amortized over the number of bunk beds produced after the design change is made. Thus, any design costs are nominal.

3. *Lower bunk end structures.* The Commission is aware of a death, involving entrapment in the end structures of the lower bunk, occurring in a scenario not currently addressed by the voluntary standard. This death is addressed by extending the upper limit of the voluntary standard's lower bunk end structures entrapment provisions from 9 inches above the lower bunk's sleeping surface to the bottom of the upper bunk and by also including a test for neck entrapment in this area. The Commission expects the costs of this requirement to be design-related only, and small. Indeed, for some bunk beds, material costs may decrease since less material may be required to comply with these requirements than are currently being used. Again, the design costs for these modifications to the end structures can be amortized over the subsequent production run of the bed.

4. *Effect on market.* The small additional costs from any wall-side guardrail and end-structure modifications are not expected to affect the market for bunk beds, either alone

or added to the costs of compliance to ASTM's provisions.

5. *Conclusion.* The Commission has no reason to conclude that any of the standard's requirements have costs that exceed the requirement's expected benefits. Further, the total effect of the rule is that the benefits of the rule will exceed its costs by about 4–23 times. Accordingly, the Commission concludes that the benefits expected from the rule will bear a reasonable relationship to its costs.

D. *The rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury for which the rule is being promulgated.* 1. The Commission considered relying on the voluntary standard, either alone or combined with a third-party certification program. However, the Commission concludes that a mandatory program will be more effective in reducing these deaths, each of which is caused by an unreasonable risk of entrapment. Accordingly, these alternatives would not prevent or adequately reduce the risk of injury for which the rule is being promulgated.

2. The Commission also considered a suggestion that bunk beds that conformed to the voluntary standard be so labeled. Consumers could then compare conforming and nonconforming beds at the point of purchase and make their purchase decisions with this safety information in mind. This, however, would not necessarily reduce injuries, because consumers likely would not know there is a voluntary standard and thus would not see any risk in purchasing a bed that was not labeled as conforming to the standard.