

**PART 148—PERSONAL
DECLARATIONS AND EXEMPTIONS**

1. The general authority citation for Part 148 is revised to read as follows:

Authority: 19 U.S.C. 66, 1496, 1498, 1624. The provisions of this part, except for subpart C, are also issued under 19 U.S.C. 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS));

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**PART 151—EXAMINATION,
SAMPLING, AND TESTING OF
MERCHANDISE**

1. The general authority citation for Part 151 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 20 and 21, Harmonized Tariff Schedule of the United States (HTSUS)), 1624. Subpart A also issued under 19 U.S.C. 1499. * * *

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**PART 152—CLASSIFICATION AND
APPRAISEMENT OF MERCHANDISE**

1. The general authority citation for Part 152 is unchanged, but the specific authority for subpart D and for §§ 152.13 and 152.24 are revised, to read as follows:

Authority: 19 U.S.C. 66, 1401a, 1500, 1502, 1624;

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Subpart D also issued under 19 U.S.C. 1202 (General Note 17, Harmonized Tariff Schedule of the United States (HTSUS));

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Sections 152.13 and 152.24 also issued under 19 U.S.C. 1202 (General Note 17, Harmonized Tariff Schedule of the United States (HTSUS)).

§ 152.13 [Amended]

2. In § 152.13, the reference in paragraphs (b)(1), (b)(2), (c) introductory text, (c)(1), (c)(2), (c)(3), and (d) to "General Note 5" is revised to read "General Note 17".

**PART 177—ADMINISTRATIVE
RULINGS**

1. The general authority citation for Part 177 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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**PART 181—NORTH AMERICAN FREE
TRADE AGREEMENT**

1. The authority citation for Part 181 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624, and the North American Free Trade Agreement

Implementation Act, Pub. L. 103-182, 107 Stat. 2057.

PART 191—DRAWBACK

1. The general authority citation for Part 191 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1313, 1624;

* * * * *

Dated: April 4, 1995.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 95-8745 Filed 4-10-95; 8:45 am]

BILLING CODE 4820-02-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 176 and 178**

[Docket No. 93N-0420]

**Indirect Food Additives: Paper and
Paperboard Components; Adjuvants,
Production Aids, and Sanitizers;
Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct an error in nomenclature for a food additive. The amendment adds alkyl mono- and disulfonic acids, sodium salts (produced from *n*-alkanes in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆) as a component of paper and paperboard in contact with food, as an antistatic agent, and as an emulsifier and/or surface active agent. Additionally, because certain sections contain multiple entries for the additive, FDA is amending its food additive regulations so that all uses of the additive will be combined under single entries in those sections of the regulations.

DATES: Effective April 11, 1995; written objections and requests for a hearing by May 11, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew Zajac, Center for Food Safety and Applied Nutrition (HFS-216), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 21, 1994 (59 FR 3322), FDA published a proposed rule to correct an error in nomenclature for a food additive regulated in §§ 176.170, 176.180, 178.3130, and 178.3400 (21 CFR 176.170, 176.180, 178.3130, and 178.3400). The agency proposed to add alkyl mono- and disulfonic acids, sodium salts (produced from *n*-alkanes in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆) to those sections and to remove: (1) The listing "*n*-alkylsulfonate (alkyl group is in the range C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 176.170; (2) the listing "petroleum sulfonates" from the list of substances in § 176.180; (3) the listings for "sodium *n*-alkylsulfonate (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" and "sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 178.3130; and (4) the listings for "*n*-alkylsulfonate (alkyl group is in the range C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" and "sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 178.3400.

FDA received no comments on its proposal. The agency is, therefore, adopting the proposal as a final rule without any changes.

The agency has previously considered the environmental effects of this rule, as announced in the proposed rule (59 FR 3322, January 21, 1994). No new information or comments have been received that would affect the agency's previous determination that this action will not have a significant impact upon the human environment and that neither an environmental assessment nor an environmental impact statement is required.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined

by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because no current activity is prohibited by this final rule, the compliance costs to firms are zero. Likewise, because no increase in the health risks faced by consumers will result from this final rule, total costs are also zero. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Furthermore, in accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses, and has determined that no significant economic impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

Any person who will be adversely affected by this regulation may at any time on or before May 11, 1995, file with the Dockets Management Branch

(address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Parts 176 and 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 176 and 178 are amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 379e).

2. Section 176.170 is amended in the table in paragraph (b)(2) by removing the entry for “*n*-Alkylsulfonate (alkyl group is in the range C₁₀–C₁₈ with not less than 50 percent C₁₄–C₁₆)” and by alphabetically adding a new entry under the headings “List of substances” and “Limitations” to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * * *	* * * * *
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ –C ₁₈ with not less than 50 percent C ₁₄ –C ₁₆).	For use only: 1. As emulsifiers for vinylidene chloride copolymer coatings and limited to use at levels not to exceed 2 percent by weight of the coating solids. 2. As emulsifiers for vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of types identified in paragraph (c) of this section, Table 1, under Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX and under conditions of use E, F, and G described in Table 2 of paragraph (c) of this section.
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3. Section 176.180 is amended in the table in paragraph (b)(2) by removing the entry for “Petroleum sulfonates” and by alphabetically adding a new

entry under the heading “List of substances” to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
*	*
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ -C ₁₈ with not less than 50 percent C ₁₄ -C ₁₆).	*
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PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

4. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

5. Section 178.3130 is amended in the table in paragraph (b) by removing the entries for “Sodium *n*-alkylsulfonate (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)” and “Sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent

C₁₄-C₁₆)” and by alphabetically adding a new entry under the headings “List of substances” and “Limitations” to read as follows:

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

* * * * *

(b) * * *

List of substances	Limitations
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ -C ₁₈ with not less than 50 percent C ₁₄ -C ₁₆).	For use only:
*	1. As antistatic agents at levels not to exceed 0.1 percent by weight of polyolefin films that comply with § 177.1520 of this chapter: <i>Provided</i> , that the finished olefin polymers contact foods of Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter, and under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.
*	2. As antistatic agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with § 177.1640(c) of this chapter under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
*	*

6. Section 178.3400 is amended in the table in paragraph (c) by removing the entries for “*n*-Alkylsulfonate (alkyl group is in the range C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)” and “Sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)” and by alphabetically adding a new entry under the headings “List of substances” and “Limitations” to read as follows:

§ 178.3400 Emulsifiers and/or surface active agents.

* * * * *

(c) * * *

List of substances	Limitations
Alkyl mono- and disulfonic acids, sodium salts (produced from <i>n</i> -alkanes in the range of C ₁₀ -C ₁₈ with not less than 50 percent C ₁₄ -C ₁₆).	<p>For use only:</p> <ol style="list-style-type: none"> 1. As provided in § 176.170 of this chapter. 2. At levels not to exceed 2 percent by weight of polyvinyl chloride and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. As emulsifiers in vinylidene chloride copolymer or homopolymer coatings at levels not to exceed a total of 2.6 percent by weight of coating solids. The finished polymer contacts food only of the Types I, II, III, IV, V, VIA, VIB, VII, VIII, and IX as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use E, F, and G described in Table 2 of § 176.170 of this chapter. 4. As emulsifiers and/or surface-active agents at levels not to exceed 3.0 percent by weight of polystyrene or rubber-modified polystyrene complying with § 177.1640(c) of this chapter under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
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Dated: April 3, 1995.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-8772 Filed 4-10-95; 8:45 am]

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21 CFR Part 178

[Docket No. 91F-0499]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant in the manufacture of polystyrene and rubber-modified polystyrene articles that contact food. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

DATES: Effective April 11, 1995; written objections and requests for a hearing by May 11, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-

216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 30, 1992 (57 FR 3633), FDA announced that a food additive petition (FAP 2B4295) had been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant in the manufacture of polystyrene and rubber-modified polystyrene articles that contact food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations in § 178.2010(b) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the

action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 11, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch