Rule 45.2 Asbestos Removal Fees (Adopted 8/4/92)
Rule 50 Opacity (Adopted 2/20/79)
Rule 52 Particulate Matter-Concentration (Adopted 5/23/72)
Rule 53 Particulate Matter-Process Weight (Adopted 7/18/72)
Rule 54 Sulfur Compounds (Adopted 6/14/94)
Rule 56 Open Fires (Adopted 3/29/94)
Rule 57 Combustion Contaminants-Specific (Adopted 6/14/77)
Rule 60 New Non-Mobile Equipment-Sulfur Dioxide, Nitrogen Oxides, and Particulate Matter (Adopted 7/8/72)
Rule 62.7 Asbestos—Demolition and Renovation (Adopted 6/16/92)
Rule 63 Separation and Combination of Emissions (Adopted 11/21/78)
Rule 64 Sulfur Content of Fuels (Adopted 4/13/99)
Rule 67 Vacuum Producing Devices (Adopted 7/5/83)
Rule 68 Carbon Monoxide (Adopted 6/14/77)
Rule 71 Crude Oil and Reactive Organic Compound Liquids (Adopted 12/13/94)
Rule 71.1 Crude Oil Production and Separation (Adopted 6/16/92)
Rule 71.2 Storage of Reactive Organic Compound Liquids (Adopted 9/26/89)
Rule 71.3 Transfer of Reactive Organic Compound Liquids (Adopted 6/16/92)
Rule 71.4 Petroleum Sumps, Pits, Ponds, and Well Cellars (Adopted 6/8/93)
Rule 71.5 Glycol Dehydrators (Adopted 12/13/94)
Rule 72 New Source Performance Standards (NSPS) (Adopted 4/10/01)
Rule 73 National Emission Standards for Hazardous Air Pollutants (NESHAPS (Adopted 04/10/01)
Rule 74 Specific Source Standards (Adopted 7/6/76)
Rule 74.1 Abrasive Blasting (Adopted 11/12/91)
Rule 74.2 Architectural Coatings (Adopted 11/13/01)
Rule 74.6 Surface Cleaning and Degreasing (Adopted 1/08/02)
Rule 74.6.1 Cold Cleaning Operations (Adopted 7/9/96)
Rule 74.6.2 Batch Loaded Vapor Degreasing Operations (Adopted 7/9/96)
Rule 74.7 Fugitive Emissions of Reactive Organic Compounds at Petroleum Refineries and Chemical Plants (Adopted 10/10/95)
Rule 74.8 Refinery Vacuum Producing Systems, Waste-water Separators and Process Turnarounds (Adopted 7/5/83)
Rule 74.9 Stationary Internal Combustion Engines (Adopted 11/14/00)
Rule 74.10 Components at Crude Oil Production Facilities and Natural Gas Production and Processing Facilities (Adopted 3/10/95)
Rule 74.11 Natural Gas-Fired Residential Water Heaters—Control of $NO_X$ (Adopted 4/9/85)
Rule 74.11.1 Large Water Heaters and Small Boilers (Adopted 9/14/99)
Rule 74.12 Surface Coating of Metal Parts and Products (Adopted 9/10/96)
Rule 74.15 Boilers, Steam Generators and Process Heaters (Adopted 11/8/94)
Rule 74.15.1 Boilers, Steam Generators and Process Heaters (Adopted 6/13/00)
Rule 74.16 Oil Field Drilling Operations (Adopted 1/8/91)
Rule 74.20 Adhesives and Sealants (Adopted 1/14/97)
Rule 74.23 Stationary Gas Turbines (Adopted 1/08/02)
Rule 74.24 Marine Coating Operations (Adopted 9/10/96)
Rule 74.24.1 Pleasure Craft Coating and Commercial Boatyard Operations (Adopted 1/08/02)
Rule 74.26 Crude Oil Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.27 Gasoline and ROC Liquid Storage Tank Degassing Operations (Adopted 11/8/94)
Rule 74.28 Asphalt Roofing Operations (Adopted 5/10/94)
Rule 74.30 Wood Products Coatings (Adopted 9/10/96)
Rule 75 Circumvention (Adopted 11/27/78)
Rule 100 Analytical Methods (Adopted 7/18/72)
Rule 101 Sampling and Testing Facilities (Adopted 5/23/72)
Rule 102 Source Tests (Adopted 11/21/78)
Rule 103 Continuous Monitoring Systems (Adopted 2/9/99)
Rule 154 Stage 1 Episode Actions (Adopted 9/17/91)
Rule 155 Stage 2 Episode Actions (Adopted 9/17/91)
Rule 156 Stage 3 Episode Actions (Adopted 9/17/91)
Rule 158 Source Abatement Plans (Adopted 9/17/91)
Rule 159 Traffic Abatement Procedures (Adopted 9/17/91)
Rule 220 General Conformity (Adopted 5/9/95)
Rule 230 Notice to Comply (Adopted 11/9/99)

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[OPP–2002–0346; FRL–7285–5]**

### Propanoic Acid, and its Calcium and Sodium Salts; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to establish an exemption from the requirement of a tolerance for residues of propanoic acid, and its calcium and sodium salts when used as either an inert or active ingredient in pesticide formulations that are applied to growing crops or raw agricultural commodites (RAC) before or after harvest, and for pesticide formulations that are applied to animals, under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This document also proposes to reorganize the existing tolerance exemptions for propanoic acid and its salts.

**DATES:** Comments, identified by docket ID number OPP–2002–0346, must be received on or before March 14, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Treva Alston, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 308–8373 and e-mail address: alston.treva@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### *B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0346. The official public docket consists of the documents specifically referenced in this action, any public comments received, and

other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title;_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### *C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select''search,'' and then key in docket ID number OPP–2002–0346. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2002–0346. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC, 20460–0001, Attention: Docket ID Number OPP–2002–0346.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm.

119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Attention: Docket ID Number OPP–2002–0346. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

*D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Background and Statutory Findings

In the **Federal Register** of February 12, 1997 (62 FR 6228) (FRL–5583–9), EPA issued a notice under section 408 of the FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 6F4770) by Nayfa Industries, Inc., c/o 1625 K St., N.W., Suite 501, Washington, D.C. 20006. The petition requested that 40 CFR 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the fungicide propionic acid, also known as propanoic acid (CAS Reg. No. 79–09–4) in or on the raw agricultural commodities sugarbeets, potatoes, and sweet potatoes. This notice included a summary of the petition prepared by Nayfa Industries, Inc., the petitioner. There were no comments received in response to the notice of filing. The Agency has not yet issued a final rule for this petition, and has, in fact, determined to issue a proposed rule.

The Agency is now issuing this rule as a proposal for two reasons: First, the calcium and sodium salt forms of propanoic acid are being added to the existing exemptions from the requirement of a tolerance of propanoic acid (40 CFR 180.1023). Second, based on a review and evaluation of the available data, the Agency believes that a broader use than what was requested by the petitioner is appropriate. The Agency is proposing to remove the existing tolerance exemptions for propionic acid and sodium propionate in 40 CFR 180.1001(c). These exemptions from the requirement of a tolerance will be covered by the proposed revisions to 40 CFR 180.1023. No uses would be lost as a result of these actions. Since the 1997 publication of the Notice of Filing, the Agency has completed the Tolerance Reassessment process for propanoic acid. Based on the results of that reassessment, EPA on its own initiative, under section 408(e) of the FFDCA, 21 U.S.C. 346a, is proposing to establish an unlimited exemption from the requirement of a tolerance for residues of propanoic acid (CAS Reg. No. 79–09–4); propanoic acid, calcium salt (CAS Reg. No. 4075–81–4); and propanoic acid, sodium salt (CAS Reg. No. 187–40–6), when used as either an active or inert ingredient in pesticide formulations that are applied to growing crops or raw agricultural commodities and in pesticide formulations that are applied to animals.

The data used by the Agency to make the safety determination for propanoic acid included data that was generated using the sodium and calcium salts of propanoic acid. Often, when conducting animal tests using an acid, such as propanoic acid, as the test substance, the acid must be neutralized (converted to a salt - in this case the calcium and sodium salt) to conduct the tests. Therefore, the Agency is proposing that these two salts of propanoic acid also be included in the tolerance exemption expression.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemptionfrom the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure.

Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for the establishment of an exemption from the requirement of a tolerance for residues of propanoic acid and its calcium and sodium salts. EPA's assessment of exposures and risks associated with establishing the exemption from the requirement of a tolerance follows.

## III. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the

toxic effects caused by propanoic acid and its calcium and sodium salts are discussed in this unit.

Propanoic acid is a three carbon acid with a molecular formula of $CH_3CH_2COOH$. It is considered to be a medium strong acid. It occurs naturally in animal and dairy products such as butter and cheese. Propanoic acid and the salts of propanoic acid are direct food additives. (discussed in unit III.7.) The toxicological database for propanoic acid was determined to be adequate for reregistration eligibility at the time that the Reregistration Eligibility Document (RED) was completed in September 1991. A comprehensive search of the open literature from 1991 forward and a search for in-house toxicological data failed to reveal any new information on propanoic acid which would change the toxicological findings in the RED. Therefore, the toxicological findings/ data from the Propionic Acid RED (which also addresses the calcium and sodium salts) are applicable to this current evaluation.

1. *Acute toxicity.* Technical propanoic acid is of moderate to low acute toxcity via the oral, dermal, and inhalation routes of exposure (toxicity category of III), and is not a skin sensitizer. However, propanoic acid is acutely toxic in eye and dermal irritation tests (toxicity category I).

2. *Subchronic toxicity.* No subchronic toxicity data are available on propanoic acid itself; however, data on calcium and sodium propionate are used to assess subchronic toxicity. Rats fed calcium or sodium propionate at one percent of the diet (equivalent to 750 milligrams/kilogram/ day (mg/kg/day) of propanoic acid) for four weeks followed by 3% (equivalent to 1,200 mg/kg/day of propanoic acid) for three weeks showed no changes in weight gain compared to the the controls. Rats fed 5% propanoic acid in the diet (approximately 5,000 mg/kg body weight) for 110 days developed lesions of the forestomach.

Propanoic acid was given in the feed to dogs at 220, 735, or 2,066 mg/kg/day for 90 days. The high dose dogs showed reduced food consumption, increased incidence of epithelial hyperplasia in the esophagus, and increased nitrite in the urine. These effects were no longer present in dogs held for a six week recovery period. In a limited 90–day dog study with calcium propionate (2,523 mg/kg/day) the dogs showed vomiting and diarrhea.

3. *Chronic toxicity.* Twenty male rats per group were fed four percent propanoic acid in the diet for 2 years. The highest dose animals had hyperplasia and hyperplastic ulcers in the forestomach. Rats fed bread containing sodium propionate (4,000 mg/kg/day) for a year showed no adverse effects, nor did rats fed a similar diet for 32 weeks, other than an initial depression of growth.

4 *Developmental toxicity.* No maternal or fetal effects were seen upon feeding calcium propionate to pregnant animals at rates up to 300 mg/kg/day for hamsters and rabbits.

5. *Mutagenicity*

Propanoic acid gave negative results in mutagencity assays in five strains of *S. Typhimurium*, and one strain of *S. Cerevisiae,* with and without activation.

Additional data on calcium and sodium propionate indicated that both tested negative for mutagenicity in *S. Typhimurium,* and *S. Cerevisiae.*

6. *Metabolism* Propanoic acid is produced in large quantities in ruminants (dairy cows), thus accounting for its presence in butter and dairy products. In humans, propanoic acid is one of the metabolic products from the breakdown of several amino acids. Propanoic acid is formed as the body oxidizes longer chain odd-numbered fatty acids or the side chain of cholesterol. It is a normal intermediary metabolite in the body that is utilized by most organs and tissues, and can be metabolized to glucose, carbohydrates, amino acids, and lipids.

If directly ingested, propanoic acid is rapidly absorbed from the mammalian gastrointestinal tract, and thus enters a known metabolic pathway.

7. *FDA uses.* The Food and Drug Administration (FDA) has approved various uses of propanoic acid, and its calcium and sodium salts. Under 21 CFR 178.1010, propanoic acid can be used in food contact surface sanitizing solutions when the ready-for-use end-use concentration does not exceed 297 ppm. The calcium salt of propanoic acid is affirmed Generally Recognized As Safe (GRAS) under 21 CFR 184.1221. It is used as a mold inibitor in bread. The sodium salt of propanoic acid is affirmed GRAS under 21 CFR 184.1784. It is used as a mold inhibitor in cakes and unleavened goods and as a chemical preservative in animal drugs and feeds. Propanoic acid is affirmed GRAS under 21 CFR 184.1081. It is an antimicrobial agent and a flavoring agent.

8. *Findings of the United Nations Food and Agriculture Organization/ World Health Organization (FAO/WHO) Expert Committee on Food Additives.* Propanoic acid has been examined at several meetings of the FAO/WHO Joint Expert Committee on Food Additives (JECFA). The Seventeenth Report contained the following information: ''In human plasma propionic acid represents 0% to 4% of the total fatty acid and is a by-product of normal intermediate metabolism. Absorbed propionate is removed by the liver, kidneys, heart, muscle and adipose tissue. The liver can deal with 4.5 g free acid or 5.8 g sodium propionate per hour.''

In 1973, the Committee determined that ''propionate is a normal intermediary metabolite, and a normal constituent of foods.'' Based on an understanding of this metabolic information, the Committee also determined that it was not necessary to specify an estimate of acceptable daily intake (ADI) in man. It was specified as ''unlimited.'' This finding was reviewed in 1997: The 1973 ADI was maintained.

9. *Conclusions on the Toxicity of Propanoic Acid and its Calcium and Sodium Salts.* Propanoic acid demonstrates an acute toxicity profile that is consistent with that of an acid: it is highly acutely toxic for eye and dermal irritation, i.e., it is corrosive to the eyes and skin. These effects are most appropriately addressed through the use of protective equipment and labeling, not through establishment of tolerance exemptions.

The JECFA monograph deemed propanoic to be of such low concern that the acceptable daily intake is ''not specified.'' A consideration in this decision was the understanding that ''propionate is a normal intermediary metabolite, and a normal constituent of foods.'' Propanoic acid and its calcium and sodium salts are FDA affirmed GRAS direct food additives.

When considering the oral exposure pathway, the most relevant in establishing a tolerance exemption, propanoic acid and its calcium and sodium salts have low toxic potential. There are no concerns for mutagencity, carcinogenicity, or developmental or reproductive concerns. Propanoic acid is a normal component of metabolism in the human body. The human body has a known pathway to metabolize propanoic acid. No additional data are necessary to assess the toxicity of these chemicals.

## IV. Aggregate Assessment

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens. lawns, or buildings (residential and other indoor uses).

For propanoic acid and its calcium and sodium salts a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given their low toxic potential for the oral route of exposure, that humans of all ages are highly exposed to propanoic acid from natural sources, and the human body has a known pathway for metabolizing propanoic acid.

**V.Cumulative Effects**

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify or revoke a tolerance or tolerance exemption, the Agency considers ''available information'' concerning the cumulative effects of a particular chemical's residues and other substances that have a common mechanism of toxicity.'' Propanoic acid and its calcium and sodium salts are lower toxicity chemicals. EPA does not have, at this time, available data to determine whether propanoic acid and its calcium and sodium salts have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

**VI. Determination of Safety for U.S. Population, Infants and Children**

Based on the available data, the lower toxicity of propanoic acid and its calcium and sodium salts, and considering the FDA affirmed GRAS uses and the JEFCA finding of the unlimited ADI, EPA concludes that propanoic acid and its calcium and sodium salts do not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to propanoic acid and its calcium and sodium salts. For propanoic acid and its calcium and sodium salts, due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk. For the same reasons and especially considering the available developmental toxicity information, the additional tenfold safety factor for the protection of infants and children is unnecessary.

**VII. Other Considerations**

1. *Endocrine disruptors.* FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing propanoic acid and its calcium and sodium salts for endocrine effects may be required.

2. *Analytical enforcement methodology* An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

3. *Existing exemptions* Several tolerance exemptions for the residues of propionic acid, have been established in 40 CFR 180.1023. Under 40 CFR 180.1023(a) propionic acid or a mixture of methylene bispropionate and oxy(bismethylene) bisproprionate is exempted from the requirement of a tolerance when used as a fungicide on 22 commodities. In addition exemptions from the requirement of tolerances from residues of propionic acid (see 40 CFR 180.1023(b)) have been established in or on meat and meat byproducts of cattle, sheep, hogs, goats, horses, and poultry, milk, and eggs when applied as a bactericide/fungicide to livestock drinking water, poultry litter, and storage areas for silage and grain. The two above exemptions are only being modified for the nomenclature change from propionic to propanoic acid.

The current exemption under 40 CFR 180.1023(c) will be replaced by a new tolerance exemption which covers the existing exemptions under (c), but is broader and will also include the calcium and sodium salts of propanoic acid.

Exemptions from the requirement of a tolerance have been established in 40 CFR 180.1001(c) for sodium propionate with a use as a preservative and for propionic acid with a use as a catalyst in the pesticide formulation. These exemptions are now duplicative and will be removed.

*D. International Residue Limits*

The Agency is not aware of any country requiring a tolerance for propanoic acid and its calcium and sodium salts nor have any CODEX Maximum Residue Levels (MRLS) been established for any food crops at this time.

**VIII. Conclusion**

Based on the information in the record, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of propanoic acid, calcium propionate, and sodium propionate. Accordingly, EPA finds that exempting propanoic acid; propanoic acid, calcium salt; and propanoic acid, sodium salt from the requirement of a tolerance will be safe. With the establishment of this tolerance exemption in 40 CFR180.1023(c), the existing tolerance exemptions for inert ingredients in 40 CFR 180.1001(c) are duplicative and can be removed.

**IX. Regulatory Assessment Requirements**

This proposed rule establishes a consolidated and expanded exemption from the requirement for a tolerance under section 408(d) of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant impact on a substantial

number of small entities. Small entities include small businesses, small organizations, and small governmental organizations. After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Establishing an exemption from the requirement of a pesticide tolerance (or, expanding and consolidating a tolerance exemption, as is proposed today), is in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

### X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq*., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 2, 2003.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

## PART 180— [AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

## PART 180.1001 [Amended]

2. Section 180.1001 is amended in paragraph (c) by removing from the table, the entries for ''propionic acid'' and ''sodium propionate.''

3. Section 180.1023 is amended in paragraph (a) and (b) by revising the term ''propionic acid'' to read ''propanoic acid;'' and by revising paragraph (c) to read as follows:

**§ 180.1023 Propanoic acid and its sodium and calcium salts; exemptions from the requirement of a tolerance.**

* * * * *

(c) Residues of propanoic acid (CAS Reg. No. 79–09–4), propanoic acid, calcium salt (CAS. Reg. No. 4075–81–4), and propanoic acid, sodium salt (CAS Reg. No. 137–40–6) are exempted from the requirement of a tolerance when used as either an active or inert ingredient in accordance with good agricultural practice in pesticide formulations applied to growing crops, to raw agricultural commodities after harvest, and to animals.

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 300

**[FRL–7436–6]**

## National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of intent to delete the Wildcat Landfill Superfund Site from the National Priorities List.

**SUMMARY:** The Environmental Protection Agency (EPA) Region III is issuing a notice of intent to delete the Wildcat Landfill Superfund Site (Site), located in Kent County, near Dover, Delaware, from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), is found at Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA, with the concurrence of the State of Delaware, through the Delaware Department of Natural Resources and Environmental Control, has determined that responsible parties or other persons have implemented all appropriate response actions required under CERCLA and, therefore, no further response action pursuant to CERCLA is appropriate. However, this deletion does not preclude future actions under CERCLA.

In the ''Rules and Regulations'' section of today's **Federal Register**, EPA is publishing a direct final notice of deletion of the Wildcat Landfill Superfund Site without prior notice of