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[FR Doc. 05-10846 Filed 5-31-05; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-2005-0115; FRL-7712-1]

Two Isopropylamine Salts of Alkyl C₄ and Alkyl C₈₋₁₀ Ethoxyphosphate esters; Exemption from the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes two exemptions from the requirement of a tolerance for residues of 2-propanamine, compound with α -phosphono- ω -butoxypoly (oxy-1,2-ethanediy) (2:1) and 2-propanamine, compounds with polyethylene glycol dihydrogen phosphate C₈₋₁₀-alkyl ether (2:1), referred to as 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, when used as inert ingredients (emulsifier, solvent and cosolvent) in pesticide formulations applied only to growing crops. Rhodia, Inc, CN 7500, Cranbury, NJ 08512-7500, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of these two chemicals.

DATES: This regulation is effective June 1, 2005. Objections and requests for hearings must be received on or before August 1, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0115. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard

copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., 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.

FOR FURTHER INFORMATION CONTACT:

Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; e-mail address: campbell.princess@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.**

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B. How Can I Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at (<http://www.epa.gov/edocket/>), 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 E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 1999 (64 FR 13195) (FRL-6065-5) EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104-170), announcing the filing of pesticide petitions (PP 8E4990 and 8E4956) by Rhodia Inc, CN 7500, Cranbury, NJ 08512-7500.

The petitions requested that 40 CFR 180.1001(d) newly re-designated as 40 CFR 180.920 be amended to include exemptions from the requirement of a tolerance for residues of 2-Propanamine, compound with α -phosphono- ω -butoxypoly (oxy-1,2-ethanediy) (2:1) (CAS Reg. No. 43140-31-2) and 2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C₈₋₁₀-alkyl ether (2:1) (CAS Reg. No. 431062-72-5). The 1999 notice included a summary of the petition prepared by the petitioner requesting, to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for these two chemicals when used as inert ingredients in pesticide formulations applied only to growing crops. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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 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. . . ."

EPA performs a number of analyses to determine the risks from aggregate

exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as

carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Toxicological Profile

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 and considered its validity, completeness and reliability and the

relationship of this information 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 these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters are discussed in this unit.

A. Submitted Studies

The petitioner has also submitted supporting toxicity information to the Agency which is summarized in Table 1.

The acute toxicity profile is presented in Table 1.

TABLE 1: ACUTE TOXICITY PROFILE OF 2 ISOPROPYLAMINE SALTS OF ALKYL C₄ AND ALKYL C₈₋₁₀ ETHOXYPHOSPHATE ESTERS

Study	Result	Category
Acute oral (Rats)	LD ₅₀ > 2,000 mg/kg	III
Acute dermal (Rats)	LD ₅₀ > 2,000 mg/kg	III
Eye irritation	Slightly irritating	III
Dermal irritation (Rabbits)	Not irritating	III
Dermal sensitizer (GP)	Not a sensitizer	NA

The petitioner also submitted the following mutagenicity assays, as described in Table 2:

TABLE 2: MUTAGENICITY ASSAYS CONDUCTED USING:

Type of Assay	Test Culture	Results
Ames	<i>S. typhimurium</i> TA 98, TA 100, TA 102, TA 1535, TA 1537	Negative

B. Structure Activity Relationship (SAR) Assessment

Toxicity for these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters was assessed, in part, by a process called structure-activity relationship (SAR). In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

The SAR conclusions for these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters and several structurally related analogs were as follows: Absorption would be poor through the skin, good through the lungs, and moderate through the GI tract. Absorption of the amine will be good through the lungs and GI tract based on analogs. The SAR also indicated a concern for lung toxicity and irritation to mucous membranes if inhaled based on surfactancy. There is concern for neurotoxicity from the amine salt. No concerns for developmental or reproductive effects, carcinogenicity, or mutagenicity were noted. The overall rating for human health is low/ moderate concern.

C. Conclusions

EPA has reviewed the toxicity data for these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters and concludes as follows:

The acute toxicity data demonstrated that these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters exhibited low acute toxicity, Category III, based on the Agency's rating of toxicity categories I through IV, highest to lowest. These 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters are slight eye irritants. Other data reviewed by the Agency indicated that these two salts are not mutagenic.

The SAR indicated that absorption would be poor through the skin, good through the lungs, and moderate through the GI tract. The SAR also

reflected the typical concerns for lung toxicity and irritation to mucous membranes if inhaled based on surfactancy. Such concerns are addressed by use of personal protection equipment as determined by end-product acute inhalation testing, or by limitations on the amount of surfactant in a formulated pesticide. There are also typical concerns for neurotoxicity based on the inclusion of an amine salt in the chemical structure, and for lung toxicity and irritation to mucous membranes if inhaled based on surfactancy. As a chemical class amine salts are generally reported to have neurotoxic effects. However, there is an overall lack of documentation in the public literature to support a specific concern for neurotoxicity for isopropylamine salts. The SAR rated these two isopropylamine salts as low to moderate for human health concerns. This rating reflects the concerns associated with the irritation to mucous membranes commonly caused by surfactants.

The SAT in OPPT (Office of Pollution Prevention and Toxics) has reviewed information on several surfactants. As a broad class of chemicals surfactants are often corrosive and irritating to mucous membranes. These properties make animal toxicity testing of surfactants difficult, and require interpretation of the test results as to whether the effects are attributed to the corrosive/irritant effects or other mechanisms of toxicity.

Based on the SAR assessment, the review and evaluation of the submitted data, and given the Agency's understanding of the toxicological properties of surfactants, EPA concludes that these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters are of lower toxicity. There is a concern for corrosive/irritation effects of these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters. Based on these concerns which are those of surfactants as a class, EPA is requiring a limitation on the use of these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, not to exceed 15% in the formulated product. Based on previously conducted quantitative and qualitative risk assessments on related surfactant chemicals which the Agency has exempted from the requirement of a tolerance, the Agency believes that this limitation is sufficiently protective for the corrosive effects common to the surfactancy of these two salts.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA 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).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

1. *Dietary exposure — Food.* In order to assess dietary exposure the Agency considered that these two isopropylamine salts could be present in all raw and processed agricultural commodities. The Agency has estimated a generic dietary exposure estimate for an inert ingredient of 0.12 milligrams/kilogram/day (mg/kg/day). To assure that the exposure is not underestimated, it is assumed that the inert ingredients are used on all crops and 100% of all crops are "treated" with the inert ingredient. The generic dietary exposure estimate is based on an application rate of 5 pounds per acre. Information from the petitioner indicates that the anticipated use rate of these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters is expected to be much less than one pound per acre. The expected dietary exposure estimate would therefore be considerably less than 0.024 mg/kg/day. Given the low levels of exposure and the low systemic toxicity of these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, the concern for risk to human health is low.

2. *Drinking water.* Based on its biodegradation models, the Agency estimated that the time for complete ultimate biodegradation is weeks to months. There is also strong to very strong sorption to soils and sediments. Due to the strong adherence to soils and sediments, and ready biodegradation the

substances would only be minimally available in surface waters. Thus, only low drinking water exposure is expected, and the concern for risk to human health is low.

VI. 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 consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticide chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters and any other substances. These 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

VII. Safety Factor for the Protection of Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data unless EPA concludes that a different margin of safety will be safe for infants and children. For 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, the SAR did not identify any concerns for developmental or reproductive toxicity. The identified concerns for 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters are corrosion/irritation. EPA has not used a safety factor analysis to assess the risk.

For the same reasons a tenfold safety factor is unnecessary.

VIII. Determination of Safety for U.S. Population

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, and that under reasonably foreseeable circumstances aggregate exposure to 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters will pose no appreciable risk to human health. Accordingly, EPA finds that exempting 2-Propanamine, compound with α -phosphono - ω - butoxypoly (oxy-1,2-ethanediyl) (2:1) (CAS Reg. No. 43140-31-2) and 2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C₈₋₁₀- alkyl ether (2:1) (CAS Reg. No. 431062-72-5) from the requirement of a tolerance will be safe for the general population including infants and children.

IX. Other Considerations

A. 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 these products, 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters, for endocrine effects may be required.

B. Analytical Method(s)

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.

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for these 2 isopropylamine salts of alkyl C₄ and alkyl C₈₋₁₀ ethoxyphosphate esters nor have any CODEX Maximum Residue

Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Therefore, an exemption from the requirement for a tolerance is established for 2-Propanamine, compound with α -phosphono - ω - butoxypoly (oxy-1,2-ethanediyl) (2:1) (CAS Reg. No. 43140-31-2) and 2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C₈₋₁₀- alkyl ether (2:1) (CAS Reg. No. 431062-72-5).

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2005-0115 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 1, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that

information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0115, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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 final 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 final 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 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 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 rule.

XIII. Congressional Review Act

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: May 20, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is 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), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
2-Propanamine, compound with α -phosphono ω -butoxypoly (oxy-1,2-ethanediyl) (2:1) (CAS Reg. No. 43140-31-2).	Not more than 15% in the formulated product.	Surfactant
2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C ₈₋₁₀ -alkyl ether (2:1) (CAS Reg. No. 431062-72-5).	Not more than 15% in the formulated product.	Surfactant
* * *	* *	* *

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[FR Doc. 05-10845 Filed 5-31-05; 8:45 am]

BILLING CODE 6560-50-S

FEDERAL MARITIME COMMISSION**46 CFR Part 531****Non-Vessel-Operating Common Carrier Service Arrangements****AGENCY:** Federal Maritime Commission.**ACTION:** Final rule, technical amendment.

SUMMARY: In compliance with the Paperwork Reduction Act, this technical amendment revises 46 CFR part 531.99 and Form FMC-78 to reflect the Office of Management and Budget's current control number.

DATES: Effective June 1, 2005.

FOR FURTHER INFORMATION CONTACT: Amy W. Larson, General Counsel, Federal Maritime Commission, 800

North Capitol Street, NW., Washington, DC 20573-0001, (202) 523-5740; Austin L. Schmitt, Director of Operations, Federal Maritime Commission, 800 N. Capitol Street, NW., Washington, DC 20573-0001, (202) 523-0988.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act, the Federal Maritime Commission is issuing this technical revision to 46 CFR 531.99 and Form FMC-78 to reflect the current Office of Management and Budget ("OMB") information collection control number for 46 CFR part 531, reflected in 46 CFR 531.99 and Form FMC-78. The former OMB control number was 3072-0067, expiring May 31, 2005. The current OMB control number is 3072-0070, expiring March 31, 2008. This technical rule makes no other changes to the part.

List of Subjects for 46 CFR Part 531

Exports, Non-vessel-operating common carriers, Ocean transportation intermediaries.

■ Accordingly, 46 CFR part 531 is revised as follows:

PART 531—[AMENDED]

■ 1. The authority citation for part 531 continues to read as follows:

Authority: 46 U.S.C. app. § 1715.

■ 2. Revise the last two sentences of §531.99 to read as follows:

§ 531.99 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * The valid control number for this collection of information is 3072-0070. The valid control number for form FMC-78 is 3072-0070.

■ 3. In Exhibit 1 to 46 CFR Part 531, NVOCC Service Arrangement Registration [Form FMC-78], change the OMB control number and expiration date to "3072-0070" and "March 1, 2008." Thus Form FMC-78 will read as follows:

BILLING CODE 6730-01-P