

D. Safety Determination

1. *U.S. population.* ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobuteryl anhydride-tall oil fatty acid copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children.* ICI believes sufficient information was submitted in the petition to assess the hazards of polyethylene glycol-polyisobuteryl anhydride-tall oil fatty acid copolymer. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to infants and children.

[FR Doc. 99-6184 Filed 3-16-99; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-863; FRL-6065-5]

Notice of Filing; Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-863, must be received on or before April 16, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted

through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bipin Gandhi, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 707A, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-8380; e-mail: gandhi.bipin@epamail.epa.gov. **SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-863] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII

file format. All comments and data in electronic form must be identified by the docket control number [PF-863] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 3, 1999.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Rhodia Inc.

PP 8E4956

EPA has received a pesticide petition (PP 8E4956) from Rhodia Inc., CN 7500 Cranbury, NJ 08512-7500, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to request exemption from the requirements of a tolerance for a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles, in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

The **Federal Register** of July 7, 1995 (60 FR 35396) announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). The EPA included octyloxypoly(ethyleneoxy)ethyl phosphate (C8 ethoxylated phosphate ester) among the inerts of minimal risk indicating:

1. "On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects."

2. "These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk."

3. "A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received."

Additionally, EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(d): a-alkyl (C10-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles.

The extension of the alkyl range to include the C8 analog will not alter the residue profile of the phosphate esters and their salts. In fact, a number of exemptions including the C8 alkyl moiety are found in 40 CFR 180.1001, including n-octyl alcohol, alkyl amine acetates, alkyl ethoxylates and alkyl sulfate isopropylamine salts. Further, it is widely acknowledged that alcohol ethoxylates of the C10 - C16 range contain minor amounts of the C8 and lower alkyl analogs, as well as C18 and higher analogs. This petition merely requests expansion of the existing exemption from tolerance for the C10 - C16 range to include C8 alkyl ethoxylate phosphates and their salts.

The addition of the isopropylamine salts of these phosphate esters acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides.

B. Toxicological Profile

1. *Acute toxicity.* As part of the EPA policy statement on inert ingredients published in the **Federal Register** of

April 22, 1987 (52 FR 13305) (FRL-3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Rhodia Inc. believes that the data and information described below is adequate to ascertain the toxicology and characterize the risk associated with the use of a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles.

While not highly acutely toxic, alkyl ethoxylate phosphate esters are known to be severely irritating to skin and eyes. However, their corresponding salts have a reduced irritation potential. For the specific alkylethoxylate phosphate ester salt blend that Rhodia Inc. petitions for exemption from the requirements of a tolerance, the acute oral LD₅₀ (rat) is greater than 2,000 milligram kilogram (mg/kg), and the acute dermal LD₅₀ (rat) is greater than 2,000 mg/kg. The product is considered to be an eye irritant. The product is non-irritating to rabbit skin and is negative for skin sensitization.

2. *Genotoxicity.* An Ames test conducted on the product (blended alkyl ethoxylate phosphates, isopropylamine salts) was negative.

3. *Reproductive and developmental toxicity.* The broad range of structurally similar products which are presently approved for use in pesticide formulations has not been reported to cause reproductive or developmental toxicity.

4. *Subchronic toxicity.* Similar compounds are not known to exert significant subchronic toxic effects.

5. *Chronic toxicity.* Similar compounds are not known to exert significant chronic toxic effects.

6. *Metabolite toxicology.* Alcohol ethoxylates are already exempted from the requirements of a tolerance under 40 CFR 180.1001 (c).

7. *Endocrine disruption.* There is no evidence that this product has endocrine disruptor effects, individually or in combination with any other chemical. Further, this product is not part of a class of compounds that has

previously been alleged to cause endocrine effects.

C. Aggregate Exposure

1. *Food.* As noted above, a-alkyl (C10 - C16)-w-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles have already been exempted from the requirements of a tolerance under 40 CFR 180.1001(d). The expansion of the alkyl range to include the C8 alkyl moiety is not expected to significantly affect the dietary exposure to these compounds. The inclusion of the isopropylamine salts of these phosphate esters merely acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides, and thus approval of this petition would not be expected to substantially increase the dietary intake of these compounds.

2. *Drinking water.* This class of products have been shown to readily biodegrade and are therefore, not likely to be present in potable water supplies.

3. *Non-dietary exposure.* Phosphate esters of alkyl ethoxylates, and their salts are extensively used industrially as water-soluble lubricants, as detergents and household cleaners, and in personal care products in addition to their use as emulsifiers, dispersants and suspending agents in pesticide formulations. The slight contribution to total exposure resulting from granting the petition is not expected to significantly alter the risk profile.

D. Cumulative Effects

As stated above, there are a wide range of structurally similar compounds that are used in many products to which the U.S. population is exposed. Rhodia Inc. is unaware of any cumulative effects occurring from such uses. Further, the use of the product that is the subject of the tolerance exemption petition is not likely to significantly increase daily exposure to this class of similar compounds.

E. Safety Determination

1. *U.S. population.* In its notice **Federal Register**, July 7, 1995, (60 FR 35396) which reclassified octyloxypoly(ethyleneoxy)ethyl phosphate from List 3 to List 4B (inerts of minimal risk), the Agency has stated :

i. "On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution

Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects."

ii. "These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk."

iii. "A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received."

Expansion of the uses of the product to food uses is not likely to significantly increase the U.S. population's exposure to the product and related compounds. Therefore, there is a reasonable certainty that no harm to the U.S. population will result from the use described.

2. *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 pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. There is no available data to indicate any additional sensitivity of infants and children to this product or to other similar products which have been in use for many years and for numerous uses. There is no data which suggests that there is a basis to require an additional margin of safety to be applied.

F. International Tolerances

Rhodia Inc. has demonstrated to the satisfaction of the Australian Environmental Protection Authority and the Australian National Registration Authority that certain formulations of blended alkyl ethoxylate phosphate esters and salts are safe for use in and near aquatic environments. Further, because of its enhanced properties, use of this blend allows reduction of the total chemical burden of the pesticide inert ingredients on the environment.

The alkyl ethoxylate phosphate monohydrogen and dihydrogen esters and their salts, including the isopropylamine salts are being used as inert ingredients in registered pesticide formulations applied to food crops in 14 nations including European, African, South American and Pacific Rim nations. These include: United Kingdom, France, Italy, Spain, Japan,

Australia, New Zealand, Brazil and Argentina.

Rhodia Inc. therefore respectfully requests that an exemption from the requirements of a tolerance be established for a-alkyl (C8-C16)-w-hydroxy poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3 - 20 moles, in or on raw agricultural commodities.

2. Rhodia Inc.

PP 8E4990

EPA has received a pesticide petition (PP 8E4990) from Rhodia Inc., CN 7500, Cranbury, NJ 08512-7500, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to request exemption from the requirement of a tolerance for butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters, and to include use with water-soluble herbicide formulations in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

The **Federal Register** of July 7, 1995 (60 FR 35396) announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). The EPA included butylpolyethoxyethanol esters of phosphoric acid among those substances on List 4B, indicating:

1. "On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects."

2. "These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk."

3. "A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and

to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received."

Additionally, EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(d) the residues of butoxytriethyleneglycol phosphate when used as a surfactant for arsenical herbicides.

The addition of the isopropylamine salts of this phosphate ester to the list of substances considered exempt from the requirements of a tolerance merely acknowledges the fact that isopropylamine is a common counterion in water-soluble herbicides.

B. Toxicological Profile

1. *Acute toxicity.* As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL 3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without the data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Rhodia Inc. believes that the data and information described below is adequate to ascertain the toxicology and characterize the risk associated with the use of butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters.

Alkyl ethoxylate phosphate esters are known to be severely irritating to skin and eyes. However, their corresponding salts have a reduced irritation potential. For the specific alkyl ethoxylate phosphate ester blend that Rhodia Inc. petitions for exemption from the requirements of a tolerance, acute oral LD₅₀ (rat) is greater than 2,000 milligram kilogram (mg/kg), and the acute dermal LD₅₀ (rat) is greater than 2,000 mg/kg. The product is non-irritating to rabbit skin and is negative for skin sensitization. The product is considered to be an eye irritant.

2. *Genotoxicity.* An Ames test conducted on the blended alkyl ethoxylate phosphate salts was negative.

3. *Reproductive and developmental toxicity.* The broad range of structurally similar compounds has not been reported to produce reproductive or developmental toxicity.

4. *Subchronic toxicity.* Similar compounds are not known to exert significant subchronic toxic effects.

5. *Chronic toxicity.* Similar compounds are not known to exert significant chronic toxic effects.

6. *Metabolite toxicology.* Alcohol ethoxylates are already exempted from the requirements of a tolerance under 40 CFR 180.1001(c). Diethyleneglycol monobutyl ether, ethyleneglycol monobutyl ether and n-butanol are specifically exempted from the requirements of a tolerance under 40 CFR 180.1001(d). Triethylene glycol monobutyl ether, a likely metabolite, has been reported Patty's Industrial Hygiene and Toxicology, Fourth Edition, Volume II, Part D, ed. George D. Clayton, and Florence E. Clayton (New York: John Wiley & Sons, 1994), 2,860 to exhibit low acute toxicity by oral and dermal routes, to be non-toxic by the inhalation route, and to cause eye irritation and slight skin irritation.

7. *Endocrine disruption.* There is no evidence that this product has endocrine disruptor effects, individually or in combination with any other chemical. Further, this product is not part of a class of compounds that has previously been alleged to cause endocrine effects.

C. Aggregate Exposure

1. *Food.* As noted above, butoxytriethyleneglycol phosphate has already been exempted from the requirements of a tolerance under 40 CFR 180.1001(d). The addition of the expanded use to include use with water-soluble herbicides is not expected to significantly affect the dietary exposure to these compounds. The inclusion of the isopropylamine salts of these phosphate esters merely acknowledges the fact that isopropylamine is already a common counterion in water-soluble herbicides. Thus approval of this petition would not be expected to substantially increase the dietary intake of these compounds.

2. *Drinking water.* The product has been shown to readily biodegrade and therefore is not likely to be present in potable water supplies.

3. *Non-dietary exposure.* Phosphate esters of alkyl ethoxylates are widely used industrially as water-soluble lubricants, as detergents and household cleaners, and in personal care products in addition to their use as emulsifiers, dispersants and suspending agents in pesticide formulations. Given the widespread use of this group of compounds, the additional exposure resulting from granting the petition is not expected to significantly alter the risk profile.

D. Cumulative Effects

As stated above, there are a wide range of structurally similar compounds that are used in many products to which the U.S. population is exposed. Rhodia Inc. is unaware of any cumulative effects occurring from such uses. Further, the use of the product that is the subject of the tolerance exemption petition is not likely to significantly increase daily exposure to this class of similar compounds.

E. Safety Determination

1. *U.S. population.* In its notice of July 7, 1995 (60 FR 35396); which moved butylpolyethoxyethanol esters of phosphoric acid from List 3 to List 4B (inerts of minimal risk), EPA stated:

i. "On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects."

ii. "These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk."

iii. "List of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received."

Expansion of the uses of the product to food uses is not likely to significantly increase the U.S. population's exposure to the product and related compounds. Therefore, there is a reasonable certainty that no harm to the U.S. population will result from the use described.

2. *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 pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. There is no available data to indicate any additional sensitivity of infants and children to this product or to other similar products which have been in use for many years and for numerous uses. There is no data which suggests that there is a basis to require an additional margin of safety to be applied.

F. International Tolerances

Rhodia Inc. has demonstrated to the satisfaction of the Australian Environmental Protection Authority and the Australian National Registration Authority that certain formulations of blended alkyl ethoxylate phosphate esters and salts are safe for use in and near aquatic environments. Further, because of its enhanced properties, use of this blend allows reduction of the total chemical burden on the environment.

The alkyl ethoxylate phosphate monohydrogen and dihydrogen esters and their salts, including the isopropylamine salts are being used as inert ingredients in registered pesticide formulations applied to food crops in 14 nations including European, African, South American and Pacific Rim nations. These include: United Kingdom, France, Italy, Spain, Japan, Australia, New Zealand, Brazil and Argentina.

Rhodia Inc. therefore, respectfully requests that an exemption from the requirements of a tolerance be established for butoxytriethyleneglycol phosphate and the corresponding ammonium, calcium, isopropylamine, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters, and to include use with water-soluble herbicide formulations in or on raw agricultural commodities under 40 CFR 180.1001(d). [FR Doc. 99-6183 Filed 3-16-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[NCEA-CD-99-1015; FRL-6310-4]

Air Quality Criteria for Carbon Monoxide (External Review Draft); Estimation of Carbon Monoxide Exposures and Associated Carboxyhemoglobin Levels in Denver Residents Using pNEM/CO (Version 2.0) (Draft)

AGENCY: Environmental Protection Agency.

ACTION: Notice of two drafts for public review and comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA), National Center for Environmental Assessment, is announcing the availability of an external review draft of the document, Air Quality Criteria for Carbon Monoxide. Required under sections 108 and 109 of the Clean Air Act, the purpose of this document is to provide an assessment of the latest, relevant