

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0319; FRL-7281-9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

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

DATES: Comments, identified by docket ID number OPP-2002-0319, must be received on or before January 6, 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: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@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, pesticide manufacturer, or antimicrobial pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Industry (NAICS 111), e.g., Crop Production.
- Industry (NAICS 112), e.g., Animal Production.
- Industry (NAICS 311), e.g., Food manufacturing.
- Industry (NAICS 32532), e.g., Pesticide Manufacturing.
- Industry (NAICS 32561), e.g., Antimicrobial Pesticide.

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-2002-0319. 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/>.

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. 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.1. 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-2002-0319. 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-2002-0319. 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) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2002-0319.

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-2002-0319. 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. Make sure to submit your comments by the deadline in this notice.

7. 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. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a 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 FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: November 20, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

3E6523

EPA has received a pesticide petition (PP 3E6523) from Akzo Nobel Industrial Specialties, Inc., 15200 Alameda Road, Houston, TX 77053 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.960 to establish an exemption from the requirement of a tolerance for α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates, poly(oxyethylene) content is 4-12 moles. 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

Analytical method. Akzo Nobel is petitioning that α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates be exempt from the requirement of a tolerance based upon the definition of a low risk polymer under 40 CFR 723.250(e). Therefore, an analytical method to determine residues of α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates in raw agricultural commodities (RACs) is not required.

B. Toxicological Profile

As part of the EPA policy statement on inert ingredients, 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 required studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. Akzo Nobel Industrial Specialties, Inc. believes that the data and the information described below are adequate to ascertain the toxicology and characterize the risk associated with the use of α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles which represent C₈ alkyl ether citrate (CAS Registration Number: 330977–00–9), C₁₀-C₁₆ alkyl ether citrates (CAS Registration Number: 330985–58–5) and C₁₆-C₁₈-alkyl ether citrates (CAS Registration Number: 330985–61–0) as inert ingredients in pesticide formulations.

In the case of certain chemical substances that are defined as “polymers” the EPA has established a set of criteria which identify categories of polymers that present low risk. These criteria (codified in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that are not readily absorbed. These properties generally limit a polymer’s ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The EPA believes that polymers meeting

the criteria noted below will present minimal or no risk.

α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates, poly(oxyethylene) content is 4–12 moles which represent C₈ alkyl ether citrate (CAS Registration Number: 330977–00–9), C₁₀-C₁₆ alkyl ether citrates (CAS Registration Number: 330985–58–5) and C₁₆-C₁₈-alkyl ether citrates (CAS Registration Number: 330985–61–0) conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria that are used to identify low risk polymers.

1. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates are not cationic polymers, nor are they reasonably anticipated to become cationic polymers in a natural aquatic environment.

2. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates contain as an integral part of their composition the atomic elements carbon, oxygen, and hydrogen.

3. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates do not contain as an integral part of their composition any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

4. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates are not designed, nor are they reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates are not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates are not water absorbing polymers.

7. α -Hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates do not contain any group as reactive functional groups.

8. The minimum number-average molecular weights of polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates are listed as shown below:

- C₈ alkyl ether citrate (CAS Registration Number: 330977–00–9) 1,300 daltons
- C₁₀-C₁₆ alkyl ether citrates (CAS Registration Number: 330985–58–5) 1,100 daltons
- C₁₆-C₁₈-alkyl ether citrates (CAS Registration Number: 330985–61–0) 1,300 daltons

Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

9. The polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates have number-average molecular weights greater than 1,100 and contain less than 10% oligomeric material below molecular weight of 500 and less than 25% oligomeric material below 1,000 molecular weight.

In addition, the monomers/reactants that are used for the production of polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates have prior clearances by the Food and Drug Administration (FDA) under 21 CFR for food contact applications, and by the Environmental Protection Agency under 40 CFR for use in pesticide formulations applied to raw agricultural commodities (RAC).

1. Citric acid (CAS Registration Number: 77–92–9) was affirmed by FDA as generally recognized as safe (GRAS) under 21 CFR 184.1033 for use in food for human consumption.

2. Citric acid (CAS Registration Number: 77–92–9) is cleared under 40 CFR 180.1001(c) and (e) as an inert ingredient in pesticide formulations applied to RAC. It is included in Inerts - List 4A.

3. Fatty alcohols are widely present in oils, fats and waxes which are used in human food. Some waxes (bees wax, candelilla wax and carnauba wax) are GRAS substances (21 CFR Part 184). Bees wax and carnauba wax are in Inerts - List 4B.

4. C₈-C₁₈ Alcohols are List 3 inerts. Ethoxylated C₁₀-C₁₆ alcohols (CAS Registration Number: 68002–97–1) and ethoxylated C₁₆-C₁₈ alcohols (CAS Registration Number: 68439–49–6) are included in Inerts - List 3. Ethoxylated C₉-C₁₆ alcohols (CAS Registration Number: 97043–91–9) are in Inerts - List 4B.

C. Aggregate Exposure

Although exposure to three polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C₈-C₁₈-alkyl ether citrates may occur through dietary sources, the chemical characteristics of these polymers lead to the conclusion that there is a reasonable certainty of no harm from aggregate exposure to these polymers.

The Agency has maintained that polymers meeting the polymer exemption criteria will present minimal risk to human health when used as inert ingredients in pesticide products applied to food crops. EPA has also established exemptions from tolerance for polymeric materials used as pesticide inert ingredients that it considers to be intrinsically safe based on the fact that they are listed on the TSCA Inventory or meet the requirements of the amended TSCA polymer exemption and are thereby not subject to the requirements of the pre-manufacturing notification.

Any exposure resulting from the approval of three polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C_8 - C_{18} -alkyl ether citrates in pesticide formulations for use on growing crops or to RAC after harvest is not warranted.

D. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by three polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C_8 - C_{18} -alkyl ether citrates having a number average molecular weight of at least 1,100 would be cumulative with those of any other chemical substance(s). Given the categorization of these polymers as a "low risk polymer" (40 CFR 723.250) and their proposed use as inert ingredients in pesticide formulations, there is no reasonable expectation of increased risk due to cumulative exposure.

E. Safety Determination

1. *U.S. population.* As a matter of policy, EPA has in the past established exemptions from tolerance for polymeric substances used as pesticide inert ingredients that it considers to be intrinsically safe based on the fact that they are listed on the TSCA Inventory or meet the requirements of the amended TSCA polymer exemption and are thereby not subject to the requirements of premanufacture notice (PMN). The Agency has maintained that polymers meeting the polymer exemption criteria will present minimal risk to human health when used as inert ingredients in pesticide formulations.

2. *Infants and children.* FFDCA section 408 provides that EPA shall supply an additional tenfold margin of safety for infants and children in the case of threshold effects where prenatal and/or postnatal toxicity are found or there is incompleteness of the database, 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.

Due to the low expected toxicity of these three polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C_8 - C_{18} -alkyl ether citrates, a safety factor analysis is not required for assessing the risk. For the same reasons the additional safety factor is unnecessary.

F. International Tolerances

Akzo Nobel Industrial Specialties, Inc. is not aware of any country requiring a tolerance for the three polymers represented by α -hydro- ω -hydroxy-poly(oxyethylene) C_8 - C_{18} -alkyl ether citrates having a number average molecular weights of at least 1,100. Nor have there been any CODEX Maximum Residue Levels (MRLs) established for any food crops at this time.

[FR Doc. 02-30946 Filed 12-5-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0211; FRL-7283-3]

Imazethapyr; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP-2002-0211, must be received on or before January 6, 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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305 5697; e-mail address: tompkins.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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-2002-0211. 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.

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