

proteins and the genetic materials necessary for their production in raw agricultural commodities. The complete absence of toxicity in high dose acute oral studies, the lack of sequence homology with known protein toxins, rapid digestion in a gastric matrix, and minimal allergenicity potential provide a reasonable certainty of no harm for the U.S. general population potentially exposed to Cry3Bb1 proteins.

2. *Infants and children.* Nondietary exposure to infants and children is not anticipated due to the patterns of use for this plant-incorporated protectant. The submitted data provide no evidence of adverse threshold effects for Cry3Bb1 proteins that would warrant application of an additional safety factor for the protection of infants and children. Furthermore, the provisions for consumption patterns, special susceptibility, and cumulative effects do not apply.

#### G. Effects on the Immune and Endocrine Systems

The lack of Cry3Bb1 toxicity in high dose acute oral studies and its rapid degradation in a mammalian digestive system suggests minimal risk for adverse effects on the immune system. This pesticidal active ingredient is a protein, derived from sources that are not known to exert an influence on the endocrine system.

#### H. Existing Tolerances

There is an existing time-limited tolerance exemption for *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production in food and feed commodities of field corn, sweet corn and popcorn (40 CFR 180.1214). Unless amended, this exemption is scheduled to expire on May 1, 2004.

#### I. International Tolerances

No Codex maximum residue levels have been established for this plant-incorporated protectant at this time. [FR Doc. 03-26414 Filed 10-21-03; 8:45 am]

BILLING CODE 6560-50-S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0345; FRL-7330-1]

#### Formaldehyde, polymer with à-[bis(1-phenylethyl)phenyl]-ù-hydroxypoly(oxy-1,2 ethanediyl); 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-2003-0345, must be received on or before November 21, 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:** James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0371; e-mail address: [parker.james@epa.gov](mailto:parker.james@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 ID number OPP-2003-0345. 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-2003-0345. 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](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2003-0345. 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-2003-0345.

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-2003-0324.

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: October 10, 2003.

**Debra Edwards,**

Director, Registration Division, Office of Pesticide Programs.

#### Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by Nichino America and represents the view of Nichino America. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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.

#### Nichino America

PP 3E6753

EPA has received a pesticide petition (3E6753) from Nichino America, 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.960, by establishing a tolerance exemption for residues of formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  when used as an inert ingredient in a pesticide product. 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

Nichino America is petitioning that formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  be exempt from the requirement of a tolerance based upon the definition of a low risk polymer under 40 CFR 723.250(e). Consequently, Nichino America believes that the analytical method to determine residues, the residues present in plant material, and the magnitude of formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  in raw agricultural commodities, is not relevant.

#### B. Toxicological Profile

1. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  is a polymer as defined 40 CFR 723.250(2)(b). It is composed of at least 3 monomer units and 1 other reactant.

2. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  consists of a simple weight majority of the polymer molecules. The monomer sequences form uninterrupted strings in the polymer and distribution of the molecular weight of the polymer is due largely to the number of monomer units in the individual molecules.

3. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  consists of a number average molecular weight of 1,803 with less than 0.45% of its oligomeric material weighing below 500 daltons and less than 0.45% of its oligomeric material weighing less than 1,000 daltons.

4. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  will not become cationic in an aquatic environment. It contains no moieties capable of obtaining a cationic charge.

5. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  is composed of carbon, hydrogen, and oxygen; therefore, it meets the criteria of elemental composition. Namely it must be composed of at least two of the following elements (and no other elements than those listed); carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.

6. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  is not designed nor reasonably expected to degrade, decompose, or depolymerize under normal use conditions

7. Formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  is composed of molecules that are listed on the TSCA Inventory or manufactured under an applicable TSCA section 5 exemption.

8. Although, formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  does not exceed the number average molecular weight of 10,000 and therefore is not subject to the water absorption limitation, it nonetheless still satisfies the criteria of being a non-water absorbing species.

#### C. Aggregate Exposure

1. *Dietary exposure.* The physical-chemical characteristics of formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  leads to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from food or drinking water nor from an aggregate exposure.

2. *Non-dietary exposure.* The physical-chemical characteristics of formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  lead to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from non-dietary means.

#### D. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by formaldehyde, polymer with  $\text{[bis(1-phenylethyl)phenyl]-}\ddot{\text{u}}\text{-hydroxypoly(oxy-1,2 ethanediyl)}$  would be cumulative with any other chemical. Given the compound's categorization as a low risk polymer, and its proposed use in pesticide formulations, there is no expectation of increased risk due to cumulative exposure.

#### E. Safety Determination

1. *U.S. population.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.

2. *Infants and childrens.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.

### F. International Tolerances

There are no CODEX maximum residue limits established for formaldehyde, polymer with  $\alpha$ -[bis(1-phenylethyl)phenyl]- $\beta$ -hydroxypoly(oxy-1,2 ethanediyl) in or on crops or commodities at this time.

[FR Doc. 03-26667 Filed 10-21-03; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0257; FRL-7322-5]

### Mesosulfuron-methyl; 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-2003-0257, must be received on or before November 21, 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](mailto:tompkins.jim@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 ID number OPP-2003-0257. 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.

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###### 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