

population and various population subgroups, including the most sensitive subgroup, children 1 to 2 years old. Therefore, Makhteskim-Agan of North America Inc., concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to novaluron residues.

#### *F. International Tolerances*

There are no Canadian, Mexican, or Codex maximum residue limits established for novaluron. Therefore, international harmonization is not an issue at this time.

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0025; FRL-7345-5]

### Gamma-Cyhalothrin; 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 identification (ID) number OPP-2004-0025, must be received on or before March 26, 2004

**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:**

William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8587; e-mail address: [sproat.william@epa.gov](mailto:sproat.william@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 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 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-2004-0025. 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 EPA's 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.1. 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-2004-0025. 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-2004-0025. 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-2004-0025.

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-2004-0025. 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: February 12, 2004.

**Lois Rossi,**

*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 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.

#### Pytech Chemicals GmbH

PP 4F6812

EPA has received a pesticide petition (4F6812) from Pytech Chemicals GmbH, 9330 Zionsville Road, Indianapolis, IN 46268 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by adding gamma-cyhalothrin ((S)- $\alpha$ -cyano-3-phenoxybenzyl (Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoripropenyl)-2,2-dimethylcyclopropanecarboxylate) to the tolerance expression of lambda-cyhalothrin, ((S)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,1-dimethylcyclopropanecarboxylate and (R)- $\alpha$ -cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate). Gamma-cyhalothrin is the isolated active isomer of lambda-cyhalothrin. 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

1. *Plant metabolism.* Gamma-cyhalothrin relies on the metabolism data conducted on lambda-cyhalothrin, which has been thoroughly tested and is adequately understood.

2. *Analytical method.* An adequate analytical method is available for enforcement purposes.

3. *Magnitude of residues.* Gamma-cyhalothrin, the isolated active isomer, will be applied at half the application rates of lambda-cyhalothrin. Comparison studies of gamma-cyhalothrin versus lambda-cyhalothrin used on the representative crops of tomatoes, sweet corn, broccoli, and cottonseed prove that the established tolerances for lambda-cyhalothrin will be sufficient to cover the potential residues of gamma-cyhalothrin.

#### B. Toxicological Profile

1. *Acute toxicity.* The acute oral lethal dose (LD)<sub>50</sub> was >50 milligrams/kilogram body weight (mg/kg bwt) in male rats and 55 mg/kg bwt in female rats, acute dermal LD<sub>50</sub> was >1,500 mg/kg bwt in male rats and 1,643 mg/kg bwt in female rats and the 4-hour lethal concentration (LC)<sub>50</sub> for male rats was

40.2 milligrams/meter (mg/m<sup>3</sup>) and, for female rats, 28.2 mg/m<sup>3</sup>.

2. *Genotoxicity.* The following genotoxicity tests were all negative: *Salmonella*, *E.coli* reverse mutation assay, mouse bone marrow micronucleus test, *in vitro* chromosomal aberration in rat lymphocytes, and mouse lymphoma forward mutation assay.

3. *Reproductive and developmental toxicity.* A developmental toxicity study in rats given gavage doses of 0, 0.1, 0.5, and 2 mg/kg/day with no developmental toxicity observed under the conditions of the study. The developmental no observed adverse effect level (NOAEL) is greater than 2 mg/kg/day, the highest dose tested (HDT). The maternal NOAEL and lowest observed adverse effect level (LOAEL) are established at 0.5 and 2 mg/kg/day, respectively, based on reduced body weight, body weight gain, and feed consumption.

4. *Subchronic toxicity.* A 90-day feeding study in rats fed doses of 0, 2.5, 10, 50, and 100 parts per million (ppm) with a NOAEL of 50 ppm and a LOAEL of 100 ppm based on mortality, decreased feed consumption, decreased body weights, and increased relative liver and kidney weight at 100 ppm.

5. *Chronic toxicity.* Gamma-cyhalothrin, and lambda-cyhalothrin are contained within the chemical cyhalothrin. Cyhalothrin consists of four isomers, lambda-cyhalothrin consists of two of these isomers and gamma-cyhalothrin is the single active isomer contained in both. The chronic studies were conducted on cyhalothrin.

6. *Metabolite toxicology.* The Agency has previously determined that the metabolites of lambda-cyhalothrin are not of toxicological concern and need not be included in the tolerance expression. Given this determination, it is concluded that there is no need to discuss metabolite toxicity.

7. *Endocrine disruption.* No studies have been conducted to investigate the potential of gamma-cyhalothrin to induce estrogenic or other endocrine effects. However, no evidence of such effects has been noted in the battery of toxicity studies which have been conducted on cyhalothrin/lambda-cyhalothrin, and there is no reason to suspect that any such effects would be likely.

#### C. Aggregate Exposure

The Agency has conducted an extensive assessment of the aggregate exposure. Results are reported in the **Federal Register** of September 27, 2002 (FR 67 60902) (FRL-7200-1).

#### D. Cumulative Effects

For purposes of this request, it has been assumed that cyhalothrin (i.e., gamma-cyhalothrin, and lambda-cyhalothrin) does not have a common mechanism of toxicity with other substances.

#### E. Safety Determination

The Agency has conducted an extensive assessment of the aggregate exposure. Results are reported in the **Federal Register** of September 27, 2002.

#### F. International Tolerances

There are Codex maximum residue levels established or pending for residues of cyhalothrin, as the sum of all isomers, in or on the following crops and commodities.

Crop	MRL (mg/kg)
Apricots	0.2
Cabbage, head	0.2
Cherries	0.2
Cotton seed	0.02
Cottonseed, oil	0.02
Oil seed (including rapeseed oil)	0.02
Peaches	0.2
Plums	0.1
Pome fruit	0.1
Potatoes	0.02
Tree nuts (shelled and unshelled)	0.05

Canadian maximum residue levels of 0.1 ppm for pome fruit, stone fruit, and canola are established in Canada for lambda-cyhalothrin based on the "negligible" residue clause of Canadian Food and Drug Act Regulations (B.15.002(1)).

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7626-9]

### Generic Ecological Assessment Endpoints

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Availability.

**SUMMARY:** This notice announces the availability of a final report titled,