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#### List of Subjects

Environmental protection, Business and industry, Government contracts, Government property, Security measures.

Dated: October 30, 2003.

**Arnold E. Layne,**

*Director, Information Resources and Services Division, Office of Pesticide Programs.*

[FR Doc. 03-28108 Filed 11-10-03; 8:45 am]

BILLING CODE 6560-50-S

#### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0039; FRL-7333-4]

#### Cyprodinil; 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-2002-0039, must be received on or before December 12, 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:** Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: [brothers.shaja@epa.gov](mailto:brothers.shaja@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-2002-0039. 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 EPA's 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. 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-2002-0039. 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-2002-0039. 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-2002-0039.

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-2002-0039. 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 4, 2003.

**Debra Edwards,**

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.

#### Interregional Research Project Number 4 (IR-4)

##### PP 8E5012

EPA has received a pesticide petition (8E5012) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR 180.532 by extending the time-limited tolerance to December 31, 2004, for residues of cyprodinil, 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine in or on the raw agricultural commodities onion, dry bulb at 0.60 part per million (ppm); onion, green at 4.0 ppm; and strawberry at 5.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; 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. Syngenta Crop Protection, Inc., Greensboro, NC 27409 is the manufacturer of the chemical pesticide, cyprodinil. Syngenta Crop Protection, Inc., prepared and submitted the following summary of information, data, and arguments in support of the pesticide petitions. This summary does not necessarily reflect the findings of EPA.

#### A. Residue Chemistry

1. *Plant metabolism.* The metabolism of cyprodinil is adequately understood for the purpose of the proposed tolerances.

2. *Analytical method.* Syngenta has developed and validated analytical methodology for enforcement purposes. This method (Syngenta Crop Protection, Inc., Method AG-631B) has passed the Agency petition method validation for several commodities and is currently the enforcement method for cyprodinil. An extensive data base of method validation data using this method on various crop commodities is available.

3. *Magnitude of residues.* Complete residue data to support the requested tolerances for strawberry, onion, dry bulb, and onion, green have been submitted. The requested tolerances are adequately supported.

#### B. Toxicological Profile

An assessment of toxic effects caused by cyprodinil is discussed in Unit III.A. and Unit III.B. of the **Federal Register** dated June 22, 2001 (66 FR 33478) (FRL-6778-1).

1. *Animal metabolism.* The metabolism of cyprodinil in rats is adequately understood.

2. *Metabolite toxicology.* The residues of concern for tolerance setting purposes is the parent compound. Based on structural similarities to genotoxic nucleotide analogs, there was concern that the pyrimidine metabolites (CGA-249287, NOA-422054) may be more toxic than the parent compound. However, EPA's review indicates similar results in an acute oral and mutagenicity studies with both the parent compound and the CGA-249287 metabolite. EPA concluded that the toxicity of the CGA-249287 and NOA-422054 metabolites is no greater than that of the parent, conditional on submission and review of confirmatory data of an acute oral toxicity study and bacterial reverse mutation assay for the NOA-422054 metabolite. Although the metabolites CGA-232449 and CGA-263208 were determined to be of potential toxicological concern, they are not expected to be more toxic than cyprodinil *per se*.

3. *Endocrine disruption.* Cyprodinil does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that cyprodinil might have any effects on endocrine function related to development and reproduction. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

#### C. Aggregate Exposure

1. *Dietary exposure.* A Tier III acute and chronic dietary exposure evaluation was made using the Dietary Exposure Evaluation Model (DEEM™), version 7.76 from Exponent. Empirically derived processing studies for apple juice (0.39X), apple pomace (5.22X), grape juice (0.29X), dried prunes (2.05X), and lychee fruit peeling factor (0.0092X) were used in these assessments. The apple juice processing factor was used as a surrogate for pear juice and all other processing factors used DEEM™ defaults. All consumption data for these assessments were taken from the United States Department of Agriculture (USDA) Continuing Survey of Food Intake by Individuals (CSFII) with the 1994-1996 consumption database and the

Supplemental CSFII children's survey (1998) consumption database. These exposure assessments included all registered uses and pending uses on watercress, bushberries, caneberries, juneberries, lignonberries, pistachios, salal. A notice of filing for the pending uses was published in the **Federal Register** of May 1, 2002 (67 FR 21671) (FRL-6833-4). In addition to the registered and pending uses, this notice of filing includes exposure assessments for: Brassica, head and stem (Subgroup 5A), Brassica, leafy greens (Subgroup 5B), turnip, greens, carrot, herbs (Subgroup 19A), lychee, longan, and Spanish lime. Secondary residues in animal commodities were estimated based on theoretical worst-case, yet nutritionally adequate animal diets and transfer information from feeding studies.

i. *Food.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection, Inc., has estimated aggregate exposure from all crops for which tolerances are established or proposed. These assessments utilized residue data from field trials where cyprodinil was applied at the maximum intended use rate and samples were harvested at the minimum pre-harvest interval (PHI) to obtain maximum residues. Percent of crop treated values were estimated based upon economic, pest, and competitive pressures. The values used in these assessments were: Almonds, pome fruits, stone fruits, and grapes 100%; onions 9%; strawberries 42%; watercress 95%; berries 13%; pistachios, herbs 80%; crop group 5A and 5B, carrots, turnip, greens, lychee, longan, and Spanish lime 10%.

ii. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. EPA has not conducted an acute dietary risk assessment since no toxicological endpoint of concern was identified during the review of the available data.

iii. *Chronic exposure.* The cyprodinil Tier III chronic dietary exposure assessment was based upon residue field trial results. For the purpose of aggregate risk assessment, the exposure values were expressed in terms of margin of exposure (MOE) which was calculated by dividing the no observable adverse effect level (NOAEL) by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the reference dose (RfD). Chronic exposure to the most exposed subpopulation (children 1 and 2 years old) resulted in a MOE of 1,203 (7.48%

of the chronic RfD of 0.03 milligram/kilogram body weight/day (mg/kg bwt/day). Since the benchmark MOE for this assessment was 100 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta Crop Protection, Inc., believes that there is a reasonable certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses for cyprodinil.

*iv. Drinking water.* The degradation of cyprodinil is microbially mediated with an aerobic soil metabolism half-life of less than 46 days. Cyprodinil Koc's vary from 1,550 to 2,030 and cyprodinil exhibits a strong binding affinity for soil. Cyprodinil is stable to hydrolysis but degrades rapidly under photolytic conditions.

Estimated Environmental Concentrations (EECs) of cyprodinil in drinking water were determined by EPA. EPA Screening Concentration in Groundwater (SCI-GROW) model was used to determine acute and chronic EECs in ground water and the Agency's surface water model Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) was used to determine acute and chronic EECs in surface water. Based on the model outputs, the EECs of cyprodinil are 0.04 part per billion (ppb) for acute and chronic exposure to ground water and 32 ppb and 6 ppb for acute and chronic exposure, respectively, to surface water.

*2. Non-dietary exposure.* There is a potential residential post-application exposure to adults and children entering residential areas treated with cyprodinil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected.

*3. Chronic aggregate exposure.* Based on the completeness and reliability of the toxicity data supporting these petitions, Syngenta Crop Protection, Inc., believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues arising from all current and proposed cyprodinil uses, including anticipated dietary exposure from food, water, and all other types of non-occupational exposures.

#### *D. Cumulative Effects*

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of particular pesticide's residues

and "other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances.

#### *E. Safety Determination*

The chronic dietary exposure analysis (food only) showed that exposure from all established and proposed cyprodinil uses would be 7.48% of the chronic RfD for the most sensitive subpopulation, children 1 and 2 years old. EPA has determined that reliable data support using the standard MOE and uncertainty factor (100 for combined interspecies and intraspecies variability) for cyprodinil and that an additional safety factor of 10 is not necessary to be protective of infants and children.

Acute drinking water levels of comparison (DWLOC) were calculated based on an acute population adjusted dose (PAD) of 1.5 mg/kg/day. For the acute assessment, the females (13–50 years) subpopulation generated an acute DWLOC of approximately 44,600 ppb. The acute EEC of 32 ppb is considerably less than 44,600 ppb. For the chronic assessment, the children 1 and 2 years old subpopulation generated the lowest chronic DWLOC of approximately 280 ppb. Thus, the chronic DWLOC of 280 ppb is considerably higher than the chronic EEC of 6 ppb.

Syngenta Crop Protection, Inc., has considered the potential aggregate exposure from food, water, and non-occupational exposure routes, and concluded that aggregate exposure is not expected to exceed 100% of the chronic RfD and that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to cyprodinil.

#### *F. International Tolerances*

There are no Codex maximum residue levels established for cyprodinil.

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**BILLING CODE 6560-50-S**

### **ENVIRONMENTAL PROTECTION AGENCY**

[OPP-2003-0355; FRL-7333-2]

#### **Issuance of an Experimental Use Permit**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

**FOR FURTHER INFORMATION CONTACT:** Dani Daniel, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5409; e-mail address: [daniel.dani@epa.gov](mailto:daniel.dani@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this Action Apply to Me?*

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, 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-2003-0355. 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