

strains each of *Salmonella typhimurium* and *Escherichia coli*. These tests showed ultramarine to be non-toxic and non-mutagenic to the four strains.

3. *Reproductive and developmental toxicity*. Female rats were fed with diets containing up to 100,000 ppm ultramarine before and during pregnancy. There were no maternal deaths and the test report concluded that ultramarine had no teratogenic activity at levels from 100 to 100,000 ppm in the diet.

4. *Subchronic toxicity*—i. *Fifteen-Day test*. Ultramarine was administered to male mice and female rats at increasing dose levels up to the maximum that could be given in a single dose. No deaths were observed in either species over a period of 15 days. The LD<sub>50</sub> is greater than 10,000 mg/kg (rats).

ii. *Ninety-Day test*. In feeding trials on rats and mice, after 90 days at levels of 100,000 part per million (ppm) in the diet the effect of ultramarine was very much like that of inert clay with (LD<sub>50</sub>) greater than 10,000 milligrams/kilograms (mg/kg).

5. *Chronic toxicity*. There are no reported studies on chronic toxicity but ultramarine has a history of well over 100 years of safe manufacture and use with no reports of ill effects of any kind. In the early years of industrial production the work force was subjected to conditions which would be totally unacceptable today. Large amounts of fine ultramarine dust were inhaled and ingested without any reported ill effects. In addition ultramarine was used as a whitening agent for sugar in many parts of the world, again with no reported ill effects. In Europe, the use of ultramarine in lipsticks has been permitted for over 50 years. Its use at levels up to 0.5% for coloring cattle salt licks where it is clearly ingested by the cattle, has been permitted for many years. Ultramarine is also permitted world-wide for use in toys and children's paints including powder and finger paints.

#### C. Aggregate Exposure

1. *Dietary exposure*. In the proposed use of ultramarine as a seed coating it will not come into contact with the grown and harvested crop. As ultramarine is insoluble, it will not be metabolized by the plants grown from the treated seed. There is therefore no risk of dietary exposure.

i. *Food*. For the reasons stated above there is no risk that food produced from the treated seed will contain any ultramarine.

ii. *Drinking water*. As ultramarine and any of its decomposition products are insoluble in water there is no danger of

any leaching into water courses used for production of drinking water.

2. *Non-dietary exposure*. The only anticipated human exposure to ultramarine used for seed coating will be during the coating process and any handling of the coated seed. Good practice should ensure minimal contact and in any case there is no evidence of adverse health effects from exposure to ultramarine during over 100 years of production and use.

#### D. Cumulative Effects

As ultramarine and its decomposition products are totally insoluble and not metabolized by plants or animals there is no risk of any cumulative effect. Also, in the proposed end use there is no risk of long term exposure to humans.

#### E. Safety Determination

1. *U.S. population*. The use of ultramarine as a seed coating does not pose a safety concern for the U.S. population due to its non-toxicity and the absence of exposure.

2. *Infants and children*. Infants and children will not be exposed to ultramarine from its use in seed coating applications. In any case, ultramarine is permitted in the United States and world-wide for use in children's toys, modeling clay, and finger paints.

#### F. International Tolerances

There is no listed threshold limit value or maximum exposure limit for ultramarine. Normal practice is to consider it as a nuisance dust with threshold limit value (TLV) 10 mg/m<sup>3</sup>. The pigment is not listed as a dangerous substance in the European Community or any similar national or international classification; neither is it classified as hazardous for disposal.

[FR Doc. 03-5751 Filed 3-11-03; 8:45 am]

BILLING CODE 6560-50-S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0052; FRL-7295-4]

#### Tebufenozide; 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-2003-0052, must be received on or before April 11, 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:

- Industry (NAICS 111)
- Crop production (NAICS 112)
- Animal production (NAICS 311)
- Food manufacturing, and

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-2003-0052. 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/fedrgrstr/>.

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 on 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-2003-0052. 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-2003-0052. 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-2003-0052.

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-2003-0052. 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: March 4, 2003.

**Debra Edwards,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petitions**

The petitioner's summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by Interregional Research Project Number 4 (IR-4), 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 (IR-4)**

##### *PP 2E6397 and 2E6413*

EPA has received pesticide petitions (2E6397 and 2E6413) from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway, #1 South, North Brunswick, NJ 08902 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of tebufenozide in or on the raw agricultural commodities vegetable, tuberous and corn, except potato, subgroup at 0.01 parts per million (ppm) (2E6397) and grape at 3.0 ppm (2E6413). EPA has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions. Rohm and Haas company was acquired by Dow Agro Sciences LLC, Indianapolis, IN 46268-1054).

##### *A. Residue Chemistry*

1. *Plant metabolism.* The qualitative nature of the residue in plants is adequately understood based upon acceptable apple, sugar beet, and rice metabolism studies. The Agency has concluded that the residue of regulatory concern is tebufenozide *per se*.

2. *Analytical method.* High performance liquid chromatographic

(HPLC) analytical methods using ultraviolet (UV) detection have been validated for grape and sweet potato. The methods involve extraction by blending with solvents, purification of the extracts by liquid-liquid partitions, and final purification of the residues using solid phase extraction column chromatography.

3. *Magnitude of residues.* Complete residue data for tebufenozide on grape and sweet potato have been submitted. The requested tolerances are adequately supported.

##### *B. Toxicological Profile*

1. *Acute toxicity.* Acute toxicity studies with technical grade: Oral lethal dose LD<sub>50</sub> in the rat is >5 grams for males and females - Toxicity Category IV; dermal LD<sub>50</sub> in the rat is equal to 5,000 milligrams/kilogram (mg/kg) for males and females - Toxicity Category III; inhalation LD<sub>50</sub> in the rat is >4.5 milligram/liter (mg/l) - Toxicity Category III; primary eye irritation study in the rabbit is a non-irritant; primary skin irritation in the rabbit >5 mg - Toxicity Category IV. Tebufenozide is not a sensitizer.

2. *Genotoxicity.* Several mutagenicity tests were all negative. These include an Ames assay with and without metabolic activation, an *in vivo* cytogenetic assay in rat bone marrow cells, and *in vitro* chromosome aberration assay in Chinese hamster ovary (CHO) cells, a CHO/HGPRT assay, a reverse mutation assay with *E. Coli*, and an unscheduled DNA synthesis assay (UDS) in rat hepatocytes.

3. *Reproductive and developmental toxicity.* In a prenatal developmental toxicity study in Sprague-Dawley rats 25/group, tebufenozide was administered on gestation days 6-15 by gavage in aqueous methyl cellulose at dose levels of 50, 250, or 1,000 mg/kg/day and a dose volume of 10 milliliter/kilogram (ml/kg). There was no evidence of maternal or developmental toxicity; the maternal and developmental toxicity no observed adverse effect level (NOAEL) was 1,000 mg/kg/day.

In a prenatal developmental toxicity study conducted in New Zealand white rabbits 20/group, tebufenozide was administered in 5 ml/kg of aqueous methyl cellulose at gavage doses of 50, 250, or 1,000 mg/kg/day on gestation days 7-19. No evidence of maternal or developmental toxicity was observed; the maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

4. *Subchronic toxicity.* A 1-year dog feeding study with a lowest observed adverse effect level (LOAEL) of 250 ppm, 9 mg/kg/day for male and female

dogs based on decreases in red blood cells (RBC), hematocrit (HCT), and hemoglobin (HGB), increases in heinz bodies, methemoglobin, mean corpuscular volume (MCV), mean corpuscular hematocrit (MCH), reticulocytes, platelets, plasma total bilirubin, spleen weight, and spleen/body weight ratio. Hematopoiesis and sinusoidal engorgement occurred in the spleen, and hyperplasia occurred in the marrow of the femur and sternum. The liver showed an increased pigment in the Kupffer cells. The NOAEL for systemic toxicity in both sexes is 50 ppm (1.9 mg/kg/day).

5. *Chronic toxicity.* An 18-month mouse carcinogenicity study with no carcinogenicity observed at dosage levels up to and including 1,000 ppm.

A 2-year rat carcinogenicity with no carcinogenicity observed at dosage levels up to and including 2,000 ppm, 97 mg/kg/day and 125 mg/kg/day for males and females, respectively.

6. *Animal metabolism.* The pharmacokinetics and metabolism of tebufenozide were studied in female Sprague-Dawley rats (3–6/sex/group) receiving a single oral dose of 3 or 250 mg/kg of RH-5992 <sup>14</sup>C labeled in one of three positions (A-ring, B-ring or butyl carbon). The extent of absorption was not established. The majority of the radio labeled material was eliminated or excreted in the feces within 48 hours; small amounts (1% to 7% of the administered dose) were excreted in the urine and only traces were excreted in expired air or remained in the tissues. There was no tendency for bioaccumulation. Absorption and excretion were rapid. A total of 11 metabolites, in addition to the parent compound, were identified in the feces; the parent compound accounted for 96% to 99% of the administered radioactivity in the high dose group and 35% to 43% in the low dose group. No parent compound was found in the urine; urinary metabolites were not characterized. The absorption and metabolism of tebufenozide were studied in a group of male and female bile-duct cannulated rats. Over a 72 hour period, biliary excretion accounted for 30% (males) to 34% (females) of the administered dose while urinary excretion accounted for about 5% of the administered dose and the carcass accounted for <0.5% of the administered dose for both males and females. Thus systemic absorption (percent of dose recovered in the bile, urine and carcass) was 35% male to 39% female. The majority of the radioactivity in the bile (20% male to 24% female of the administered dose)

was excreted within the first 6 hours post-dosing indicating rapid absorption. Furthermore, urinary excretion of the metabolites was essentially complete within 24 hours post-dosing. A large amount (67% female to 70% male) of the administered dose was unabsorbed and excreted in the feces by 72 hours. Total recovery of radioactivity was 105% of the administered dose.

7. *Metabolite toxicology.* A total of 13 metabolites were identified in the bile; the parent compound was not identified, i.e. unabsorbed compound, nor were the primary oxidation products seen in the feces in the pharmacokinetics study. The proposed metabolic pathway proceeded primarily by oxidation of the benzylic carbons to alcohols, aldehydes or acids. Bile contained most of the other highly oxidized products found in the feces. The most significant individual bile metabolites accounted for 5% to 18% of the total radioactivity (F and/or M). Bile also contained the previously undetected (in the pharmacokinetics study) “A” Ring ketone and the “B” Ring diol. The other major components were characterized as high molecular weight conjugates. No individual bile metabolite accounted for 5% of the total administered dose. Total bile radioactivity accounted for about 17% of the total administered dose. No major qualitative differences in biliary metabolites were observed between sexes. The metabolic profile in the bile was similar to the metabolic profile in the feces and urine.

8. *Endocrine disruption.* The toxicology profile of tebufenozide shows no evidence of physiological effects characteristic of the disruption of the hormone estrogen. Based on structure-activity information, tebufenozide is unlikely to exhibit estrogenic activity.

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. The current petition requests establishment of tolerances in or on grape at 3.0 ppm and vegetable, tuberous and corn, except potato, subgroup at 0.01 ppm. Risk assessments were conducted by Dow AgroSciences to assess dietary exposures and risks from tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide as follows:

a. *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. Neither neurotoxicity nor systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 mg/kg. No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (limit-dose) during gestation to pregnant rabbits. This risk is considered to be negligible.

b. *Chronic exposure.* The reference dose (RfD) used for the chronic dietary analysis is 0.018 mg/kg/day. In conducting the dietary exposure evaluation model (DEEM) analysis for chronic exposure to and risk from tebufenozide residues in food, Dow AgroSciences used tolerance level residues for all crops and other commodities with established or pending tebufenozide tolerances; and percent crop-treated (PCT) information for some of these crops.

ii. *Drinking water—*a. *Acute exposure.* Because no acute dietary endpoint was determined, Dow AgroSciences concludes that there is a reasonable certainty of no harm from acute exposure from drinking water.

b. *Chronic exposure.* The Agency calculated the Tier I Estimated Environmental Concentrations (EECs) for tebufenozide using generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCI-GROW) (ground water) models for use in the human health risk assessment. For chronic exposure, the worst case EECs for surface water and ground water were 16.5 parts per billion (ppb) and 1.04 ppb, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water.

2. *Non-dietary exposure.* There is a potential for occupational exposure to tebufenozide during mixing, loading and application activities. However the Agency did not identify dermal or inhalation endpoints for tebufenozide and determined that risks from these routes of exposure are negligible.

#### D. Cumulative Effects

Cumulative exposure to substances with a common mechanism of toxicity, 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 a 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 tebufenozide has a common mechanism

of toxicity with other substances, or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, Dow AgroSciences has not assumed that tebufenozide has a common mechanism of toxicity with other substances.

#### *E. Safety Determination*

1. *U.S. population.* Using the exposure assumptions previously described, and taking into account the completeness and reliability of the toxicity data, Dow AgroSciences has concluded that dietary (food only) exposure to tebufenozide will utilize 21% of the chronic population adjusted dose (cPAD) for the U.S. population. EPA generally has no concern for exposures below 100% of the cPAD. Submitted environmental fate studies suggest that tebufenozide is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. The modeling data for tebufenozide indicate levels less than the Agency's DWLOCs. There are no chronic non-occupational/residential exposures expected for tebufenozide. Therefore, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to adults, infants and children from chronic aggregate exposure to tebufenozide residues.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines 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 use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not

raise concerns regarding the adequacy of the standard MOE/safety factor.

Using the exposure assumptions previously described, and taking into account the completeness and reliability of the toxicity data, the dietary (food only) exposure to tebufenozide will utilize 51% of the cPAD for the most highly exposed population subgroup (children 1–6 years old). EPA generally has no concern for exposures below 100% of the cPAD. Despite the potential for exposure to tebufenozide in drinking water and from non-dietary non-occupational exposure, Dow AgroSciences does not expect the aggregate exposure to exceed 100% of the RfD.

#### *F. International Tolerances*

Codex maximum residue levels have been established for residues of tebufenozide in/on pome fruit (1.0 ppm), husked rice (0.1 ppm) and walnut (0.05 ppm). Tebufenozide is registered in Canada, and a tolerance for residues in/on apples is established at 1.0 ppm. EPA has set the pome fruit tolerance at 1.5 ppm based on U.S. field residue trials.

[FR Doc. 03–5912 Filed 3–11–03; 8:45 am]

BILLING CODE 6560–50–S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0022; FRL–7295–9]

#### Dimethenamid; 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–2003–0022, must be received on or before April 11, 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:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:

(703) 305–7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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:

- 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.

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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit I.A. 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–2003–0022. 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