

name, date, and **Federal Register** citation.

## II. Tentative Agenda:

The following topics will be discussed at the 2-day meeting:

(e) Commerce-AAPCO/EPA "Notification Document-AAPCO "Surf Day" Worker Protection Standard-Regional Assessments Pesticide Field Date Base Performance Measurements Authorization Criteria (EPA Inspector Credentialing)  
25(b) Registration/Distribution Issues Mosquito Labeling Workgroup/Update Recent "Disinfectant" Uses/USDA Recommendations  
2(ee) Labeling Situation/Registrant-EPA-SLA Requirements Supplemental Labeling Workgroup Fumigation Risk Mitigation Initiative/Update (MOA, FMP Guidance) Activity Based Reentry Periods POM Working Committee Workgroups/Updates  
EPA Update/Briefing-Office Pesticide Programs Up-date-Office Enforcement Compliance Assurance Up-date

## List of Subjects

Environmental protection, Pesticides.

Dated: April 6, 2001.

**Jay Ellenberger,**

*Acting Director, Field and External Affairs Division, Office of Pesticide Programs.*

[FR Doc. 01-9488 Filed 4-17-01; 8:45 a.m.]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[PF-1016; FRL-6777-4]

### 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 control number PF-1016, must be received on or before May 18, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number

PF-1016 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Suku Oonnithan, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605-0368; e-mail address: oonnithan.suku@epa.gov.

## SUPPLEMENTARY INFORMATION:

### I. General Information

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

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" "Regulation and Proposed Rules" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgrstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-

1016. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

#### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1016 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters

and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1016. Electronic comments may also be filed online at many Federal Depository Libraries.

#### *D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 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: April 5, 2001.

**James Jones,**

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

### **Summary of Petition**

The petitioner summary of pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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.

### **Uniroyal Chemical Company**

*PP 0F6108*

EPA has received a pesticide petition (PP 0F6108) from Uniroyal Chemical Company, Benson Road, Middlebury, CT 06749 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of bifentazate, hydrazine carboxylic acid, 2-(4-methoxy-[1,1-biphenyl]-3-yl)-1-methylethyl ester in or on the raw agricultural commodities (RACs) apple, wet pomace at 1.2 parts per million (ppm); cotton at 0.5 ppm; cotton, gin byproducts (gin trash) at 20 ppm; fruit, pome, group at 0.75 ppm; fruit, stone, group (except cherries) at 1.5 ppm; grape at 0.75 ppm; hop at 15 ppm; and strawberry at 1.5 ppm. As cotton processed commodities fed to animals may be transferred to milk and edible tissue of ruminants, tolerances are also proposed for meat at 0.02 ppm and milk at 0.01 ppm. 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.* The nature of the residues of bifentazate in plants is adequately understood based on three crops; apples, cotton, and citrus. The major residue in all plant metabolism studies is bifentazate. A minor, but significant metabolite is the oxidation product of bifentazate, diazene D3598 [(4-methoxybiphenyl-3-yl)diazene-carboxylic acid isopropyl ester] which was found to inter-convert readily to and from bifentazate in the plant matrix during the analytical procedure. Thus, the proposed tolerance expression is for the parent compound, bifentazate only.

2. *Analytical method.* Uniroyal has developed analytical methodology for detecting and measuring residues of bifentazate in or on RACs. A significant metabolite, D3598 was found to inter-convert readily to and from bifentazate, the analytical method was designed to convert all residues of D3598 to the parent compound, bifentazate for analysis. The method utilizes reversed phase high performance liquid chromatography (HPLC) to separate the bifentazate from matrix derived interferences, and oxidative coulometric electro-chemical detection for the identification and quantification of this analyte. Using this method the limit of quantitation (LOQ) for bifentazate in cotton, grapes, pome fruit, stone fruit, and strawberries was 0.01 ppm. For hops the LOQ was 0.05 ppm. The limit of detection (LOD) for this method, which varies with matrix, is 0.005 ppm.

The analytical method for bifentazate and its major metabolite D3598 in animal samples was designed using the same principles invoked in the plant method, with minor modifications. However, in animal samples, a separate aliquot of the extract, was used to determine combined residues of A1530 (4-hydroxybiphenyl) and its sulfate in milk and meat samples (these metabolites appeared to be significant in goat metabolism studies). The extract was subjected to acid hydrolysis to convert the sulfate conjugate to A1530 (4-hydroxybiphenyl) before it was quantified by HPLC using fluorescence detectors.

3. *Magnitude of residues.* An extensive crop residue program has been conducted for bifentazate in all major growing regions of the United

States for the following crops: peaches and plums (representing stone fruits excluding cherries), apples and pears (representing pome fruits), strawberries, grapes, cotton, and hops. The results of these studies can be summarized as follows:

- For pome fruit, the maximum expected bifentazate residues from a single application at 0.5 lbs active ingredient/acre, are 0.58 ppm in apples and 0.30 ppm in pears harvested 7 days after application.

- The results of an apple processing study indicate that bifentazate residues do not concentrate in apple juice, but do concentrate in wet apple pomace with an average concentration factor (ACF) of 1.76x.

- At a single application rate of 0.5 lbs active ingredient/acre, the maximum expected bifentazate residues in stone fruit harvested 3 days after application are 1.45 ppm in peaches and 0.15 ppm in plums.

- The results of a plum processing study indicate that bifentazate does not concentrate in prunes.

- Following a single application to grapes at 0.5 lbs active ingredient/acre, the maximum bifentazate residues in fruit harvested 14 days after application is 0.62 ppm. The results of a grape processing study indicate that bifentazate residues do not concentrate in juice, but do concentrate in raisins with an ACF of 1.23x, a value well below the maximum theoretical concentration factor for this commodity.

- The maximum bifentazate residue in strawberries harvested 1 day following the last of two treatments at 0.5 lbs active ingredient/acre/treatment, with treatments separated by 21 days (annual plants) or 45 days (ever bearing plants) is 1.1 ppm.

- The maximum expected bifentazate residues in cottonseed and cotton gin trash from a single treatment at 0.75 lbs active ingredient/acre applied 60 days before harvest are 0.31 ppm and 18.4 ppm, respectively. Bifentazate residues do not concentrate in the hulls, meal, or oil from the processing of cottonseed.

- Following a single application to hop plants at a rate of 0.75 lbs active ingredient/acre, the maximum bifentazate residues in green hops harvested 14 days after application is 11 ppm.

These field trial data are adequate to support proposed tolerances of 1.5 ppm for stone fruit (excluding cherries), 0.75 ppm; for pome fruit, 1.2 ppm; for wet apple pomace, 0.75 ppm; for grapes and raisins, 1.5 ppm; for strawberries, 0.5 ppm; for cottonseed, 20 ppm; for cotton gin trash, and 20 ppm; for hops.

### B. Toxicological Profile

1. *Acute toxicity.* Bifentazate technical has low acute oral, dermal, and inhalation toxicity in laboratory animals. The oral LD<sub>50</sub> in the rat and mouse and the dermal LD<sub>50</sub> in the rat were all >5,000 milligrams/kilograms (mg/kg). The inhalation LC<sub>50</sub> in the rat was >4.4 milligrams/Liter (mg/L) for the technical product. In eye and dermal irritation studies, bifentazate technical was not an irritant to eyes or skin irritation and was not a skin sensitizer.

2. *Genotoxicity.* Bifentazate was evaluated and found to be negative in the Ames reverse mutation, mouse lymphoma, chinese hamster ovary (CHO) chromosome aberration and mouse micronucleus assays.

3. *Reproductive and developmental toxicity—i. Rabbit teratology study.* Bifentazate did not produce developmental toxicity in rabbits. Bifentazate technical was administered by oral gavage to pregnant New Zealand white rabbits at dosage levels of 10, 50, and 200 mg/kg/day. No test article related effects were seen at any dose level. The no observed adverse effect level (NOAEL) for maternal and developmental toxicity was greater than 200 mg/kg/day. A range-finding study conducted at dosage levels of 125, 250, 500, 750, and 1,000 mg/kg/day had previously demonstrated maternal mortality at dosage levels of 750 and 1,000 mg/kg/day and abortions at dosage levels of 250 mg/kg/day and greater.

ii. *Rat teratology study.* Bifentazate did not produce developmental toxicity in rats. Bifentazate Technical was administered by oral gavage to pregnant Sprague Dawley CD rats at dosage levels of 10, 100, and 500 mg/kg/day. A reduction in maternal body weight (bwt) gain was seen at dosage levels of 100 and 500 mg/kg/day. Clinical observations at 500 mg/kg/day included red material/staining on body surfaces, pale extremities and brown discharge. No developmental or teratogenic effects were observed at any dosage level. The NOAEL for maternal toxicity was 10 mg/kg/day and the NOAEL for developmental toxicity was greater than 500 mg/kg/day.

iii. *Rat reproduction study.* Bifentazate showed no effects on reproduction in a two-generation rat study. Bifentazate technical was fed to two-generations of male and female Sprague Dawley CD rats at dietary concentrations of 20, 80, and 200 ppm. At a dosage level of 200 ppm there was a reduction in body weight gain in F<sub>0</sub> males and females. Food consumption was unaffected. There was reduction in body weight

gain in F<sub>1</sub> females at all dosage levels and in F<sub>1</sub> males at 80 and 200 ppm in the absence of effects on food consumption. Since the 20 ppm F<sub>1</sub> males did not have a significant reduction in body weight gain, this dosage level can be considered a NOAEL for systemic adult toxicity. The reduction in body weight gain in the F<sub>1</sub> females at 20 ppm would not be considered biologically significant because no effects were observed on reproductive parameters or in the F<sub>2</sub> litter. The reproductive and developmental NOAEL was >200 ppm (10 mg/kg/day).

4. *Subchronic toxicity—i. Rat feeding study.* Bifentazate technical was fed to male and female Sprague Dawley CD rats for 13 weeks at dietary concentrations of 40, 200, and 400 ppm. At dosage levels of 200 and 400 ppm there was a reduction in red blood cell count and hemoglobin. Food intake was reduced for 200 ppm females, and 200 and 400 ppm males. Histopathological effects were seen in the liver, spleen, and adrenal cortex in males and females at 200 and/or 400 ppm. The maximum tolerated dose (MTD) was exceeded in females at 200 ppm, and in males and females at 400 ppm. The NOAEL for subchronic toxicity in rats was 40 ppm (2 mg/kg/day).

ii. *Dog feeding study.* Bifentazate technical was fed to male and female Beagle dogs for 13 weeks at dietary concentrations of 40, 400, and 1,000 ppm. At dosage levels of 400 and 1,000 ppm, there was a reduction in red blood cell count, hemoglobin and hematocrit. Liver weights were increased at 400 and 1,000 ppm and centrilobular hepatocellular hypertrophy was seen in females at 400 ppm, and males and females at 1,000 ppm. The NOAEL for subchronic toxicity in dogs was 40 ppm (1 mg/kg/day).

iii. *Neurotoxicity.* No treatment-related effects were seen on neuro-behavior in a standard functional observation battery conducted at weeks 8 and 13 of the 13-week rat feeding study. No overt signs of anti-cholinergic activity, and no statistically significant effects of cholinesterase activity were found in rats in a 2-week feeding study at dose levels up to 400 ppm. Plasma, erythrocyte, and brain cholinesterase activity were evaluated in male and female rats fed bifentazate-treated diet at 0, 20, 200, or 400 ppm for 2 weeks. All animals survived until study termination and effects were only seen on body weight gain and food consumption. The NOAEL for cholinergic inhibition was greater than 400 ppm (20 mg/kg/day).

5. *Chronic toxicity—i. Dog chronic feeding study.* Bifenazate technical was fed to male and female Beagle dogs for 1-year at dietary concentrations of 40, 400, and 1,000 ppm. At dose levels of 400 and 1,000 ppm there was a reduction in food consumption in males and reduced body weight gain in males and females. There was a reduction in red blood cell count, hemoglobin and hematocrit and an increase in bilirubin at 400 and 1,000 ppm. Histopathological effects on bone marrow, kidney, and liver were also seen at these dose levels. The NOAEL for chronic toxicity in dogs was 40 ppm (1 mg/kg/day).

ii. *Rat chronic feeding/oncogenicity study.* Bifenazate was not oncogenic in rats in a 2-year chronic feeding study. Bifenazate technical was fed to male and female Sprague Dawley CD rats for 2 years at dietary concentrations of 20, 80, and 160 in females or 20, 80, and 200 ppm in males. Body weight gain was reduced in males and females at the high dosage levels. A reduction in red blood cell count and an increase in splenic pigment were seen in females at 160 ppm, while high dose males exhibited a reduction in total cholesterol and an increase in splenic pigment. At a dose level of 80 ppm there was a reduction in body weight gain, a decrease in red blood cell count and an increase in splenic pigment in females. There was no increase in tumor incidence in males or females as a result of bifenazate administration. The NOAEL for chronic toxicity in rats was 20 ppm (1 mg/kg/day).

iii. *Mouse oncogenicity study.* Bifenazate was not oncogenic in a mouse oncogenicity study. Bifenazate Technical was fed to male and female CD-1 mice for 18 months at dietary concentrations of 10, 100, and 175 ppm in females and 10, 100, and 225 ppm in males. Body weight gain was reduced in males and females at the high dose level. A reduction in red blood cell, total leukocyte and lymphocyte counts was seen in males at 225 ppm. There was no increase in tumor incidence in males or females as a result of bifenazate administration.

6. *Animal metabolism—i.* In rat, bifenazate <sup>14</sup>C-Phenyl hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl)-1-methylethyl ester was given orally in two dose levels: Low (10 mg/kg) and high (1,000 mg/kg). Although 2/3 of the dosed radioactivity was excreted in the feces, bifenazate depicted a good degree of absorption as indicated from the level of radioactivity in the bile. In the bile radioactivity study, about 70% of the C-14 was collected from the cannulated bile ducts

of low dosed rats indicating an active level of absorption and enterohepatic circulation.

The major metabolites present in feces, urine and bile resulted from several well known metabolic reactions, including hydrazine oxidation to diazene (D3598), molecular scission with loss of the hydrazine carboxylic acid portion of the molecule to yield 4-methoxybiphenyl (D1989) followed by demethylation to form 4-hydroxybiphenyl (A1530). Metabolites resulted from aromatic hydroxylation, and conjugation with glucuronic acid or sulfate were also identified.

ii. *Pharmacokinetic parameters.* The maximum plasma concentration ( $C_{max}$ , calculated as ppm bifenazate equivalents) was reached much earlier following the low dose (5–6 h) than the high dose (18–24 h). Elimination half-lives ( $t_{1/2}$ ) were marginally longer at the high dose (12–16 h) than at the low dose (12–13 h). There were no obvious and consistent sex differences in the pharmacokinetic parameters.

7. *Metabolite toxicology.* In a single dose oral toxicity limit test in rats, the oral LD<sub>50</sub> of the diazene product of bifenazate (D3598) was estimated to be approximately 5,000 mg/kg. At 2 hours and at 7 days post-dosing, no effects were seen on erythrocyte cholinesterase inhibition (ChE) in male or female rats. In addition, no effect on plasma ChE was seen in males at these time points. An apparent inhibition of plasma cholinesterase was seen in females at 7 days only. Since this effect was seen only in plasma of females at one time point, it is most likely a pseudo cholinesterase effect without biological significance. In a dermal toxicity screen, the LD<sub>50</sub> of the diazene was estimated to be >2,000 mg/kg.

Mutagenicity screens with the D3598 showed it to be weakly positive in the *Salmonella* plate incorporation assay (Ames) in TA98 with activation and negative in the L5178Y mouse lymphoma and mouse micronucleus assays.

8. *Endocrine disruption.* There are no known reported adverse reproductive or developmental effects in domestic animals or wildlife as a result of exposure to this chemical.

A standard battery of toxicity tests have been conducted on bifenazate. No effects were seen in the reproduction or teratology studies to indicate that bifenazate has an effect on the endocrine system. Bifenazate administration to rats for 90 days at dose levels of 200 and 400 ppm resulted in an increased incidence of vacuolation in the zona fasciculata of the adrenal cortex in male rats. No effect was seen

at a dose level of 40 ppm (2 mg/kg/day). However, in the chronic rat feeding study, no effect was seen on the adrenal cortex in male rats fed 200 ppm for 1-year. Furthermore, fasting glucose levels were not reduced at any dose level in males or females in either study. The zona fasciculata is the site of cortisol production and cortisol is required for gluconeogenesis during fasting. The finding that fasting glucose levels are not affected would suggest that adrenal cortex functionality is not impaired at any dose level by bifenazate.

### C. Aggregate Exposure

Bifenazate is a new miticide proposed for uses on pome fruits, stone fruits, cotton, strawberries, grapes, and hops. Three WP 50% formulations of bifenazate are registered for control of mites in ornamental plants grown and/or maintained in containers, or in the ground, in greenhouses, and shade houses, nurseries, including christmas tree, and conifer plantations, landscapes, interiorscapes, residential areas, public, commercial, industrial institutional areas, recreational sites, such as campgrounds, golf courses, parks, and athletic fields, and rights of way and other easements.

1. *Dietary exposure.* Based on dietary, drinking water, and non-occupational exposure assessments, there is reasonable certainty of no harm to the U.S. population, any population subgroup, or infants and children from short-term or chronic exposure to bifenazate.

i. *Food.* Dietary exposure was estimated using DEEMs™, field trial residue data and anticipated percent crop treated. The acute 99.9<sup>th</sup> percentile dietary exposure to the population subgroup females 13–50 years old was estimated as 0.002413 mg/kg bwt/day, with a margin of exposure (MOE) of 82,874. The exposure to the U.S. population (total) was 0.003247 mg/kg bwt/day (MOE 61,596), and for infants and children was 0.008480 mg/kg bwt/day (MOE 23584) and 0.006751 mg/kg bwt/day (MOE 29,625), respectively. The chronic dietary exposure to the U.S. population (total) was estimated as 0.000038 mg/kg bwt/day, and was 0.4% of the reference (RfD). Exposure to non-nursing infants, the highest exposed population subgroup, was 0.000132 mg/kg bwt/day (1.3% of the RfD), and exposure to children was 0.000104 mg/kg bwt/day (1.0% of the RfD). Dietary exposure from bifenazate is well within EPA's standard acceptable MOEs and RfDs.

ii. *Drinking water.* Exposure to bifenazate in drinking water is not anticipated, and is, in fact, unlikely to

occur. Bifenazate is not expected to contaminate ground water. Bifenazate degrades rapidly in water and soil, and is immobile in soil. There is no established maximum contaminant level for residues of bifenazate in drinking water, and no health advisory levels for bifenazate have been established. Using Tier I screening models generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCI-GRO) (ground water), estimated environmental concentration (EEC) of bifenazate EEC was  $\leq 2.14$  parts per billion (ppb) for surface water, and  $< 0.0001$  ppb for ground water. As these values are much lower than the drinking water levels of concern, exposure to potential residues in drinking water is expected to be negligible.

2. *Non-dietary exposure.* Food uses described in this petition are strictly agricultural and will not add to any existing residential non-dietary exposure. Such exposure has already been assessed in the process through which Floramite®, Floramite® GS, and Floramite® LS (50% WP formulations) were registered for ornamental uses. Residential exposures from ornamental uses are expected to be very limited, if any at all, since broad spectrum insecticides (rather than selective insecticides) are generally used for residential settings. Quantitative risk estimation calculated MOEs of 1,400 and 3,100 for homeowners and children, respectively, using default values in EPA draft SOPs for Residential Exposure Assessment. Use of product-specific foliar residue decline data would be expected to lower calculated MOEs. The MOEs, reflecting the limited potential for exposure from residential uses, were all greater than 1,000, and well within acceptable limits.

#### D. Cumulative Effects

The mechanism of action of bifenazate on the mammalian red blood cell, which is target organ in the species tested, remains to be elucidated. The lack of information on bifenazate mode of action precludes an assessment of cumulative effects.

#### E. Safety Determination

1. *U.S. population.* Based on the toxicology data base and available information on anticipated residues, the acute dietary exposure MOE was  $> 82,000$  for females 13–50 years old. This is well above EPA's standard of acceptable MOE of 100. Chronic dietary exposure to the U.S. population (total) was 0.4% of the RfD. Exposure to potential residues in drinking water is expected to be negligible, as drinking

water levels of concern (DWLOC's) are substantially higher than modeled acute and long-term EEC's. The MOE's from the limited potential for short-term exposure from residential uses was  $> 1,000$ . Based on these assessments, it can be concluded that there is reasonable certainty of no harm to the U.S. population or any population subgroup from exposure to bifenazate.

2. *Infants and children.* The acute dietary exposure MOE was  $> 22,000$  for infants and children, and are well above EPA's standard acceptable MOE of 100. The chronic dietary exposure was 1.3% of the RfD for infants, and 1% for children. Exposure to potential residues in drinking water is expected to be negligible, as DWLOC's are substantially higher than modeled acute and long-term EEC's. The MOE's from the limited potential for short-term exposure from residential uses was  $< 1,000$ . Based on these assessments, it can be concluded that there is reasonable certainty of no harm to infants and children from exposure to bifenazate.

#### F. International Tolerances

To date no Codex, Canadian or Mexican tolerances exist for bifenazate. [FR Doc. 01-9492 Filed 4-17-01; 8:45 a.m.]  
BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6967-3]

### Final Additions to the Final Guidelines for the Certification and Recertification of the Operators of Community and Nontransient Noncommunity Public Water Systems; Final Allocation Methodology for Funding to States for the Operator Certification Expense Reimbursement Grants Program

AGENCY: Environmental Protection Agency.

ACTION: Final notice.

**SUMMARY:** In this notice, the Environmental Protection Agency (EPA) is finalizing additions to the Final Guidelines for the Certification and Recertification of the Operators of Community and Nontransient Noncommunity Public Water Systems, which were published in the **Federal Register** on February 5, 1999 (64 FR 5916). Specifically, EPA is finalizing its approach and schedule for review of state operator certification programs for the purpose of making Drinking Water State Revolving Fund (DWSRF) withholding determinations, and clarifying the meaning of the term "validated exam" in the Guidelines. In

addition, EPA is also finalizing the allocation methodology and the process that will be used to award grants to states for the operator certification expense reimbursement grants program. This notice also provides the amount of funding that each state is eligible to receive from the grants program.

**DATES:** This final notice is effective April 8, 2001.

**ADDRESSES:** Public comments on the Proposed Additions to the Final Guidelines for the Certification and Recertification of the Operators of Community and Nontransient Noncommunity Public Water Systems; Proposed Allocation Methodology for Funding to States for the Operator Certification Expense Reimbursement Grants Program are available for review at Water Docket (docket #W-98-07), Environmental Protection Agency, Room EB57, 401 M Street, SW, Washington, DC 20460. For access to the Docket materials, call (202) 260-3027 between 9 a.m. and 3:30 p.m. Eastern Time for an appointment and reference Docket #W-98-07.

**FOR FURTHER INFORMATION CONTACT:** For technical inquiries, contact Jenny Jacobs, Office of Ground Water and Drinking Water (4606), U.S. EPA, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The telephone number is (202) 260-2939 and the e-mail address is [jacobs.jenny@epa.gov](mailto:jacobs.jenny@epa.gov). For copies of this notice and EPA's Final Guidelines for the Certification and Recertification of the Operators of Community and Nontransient Noncommunity Public Water Systems, contact the Safe Drinking Water Hotline, toll free at (800) 426-4791. Copies can also be obtained from EPA's website at <http://www.epa.gov/safewater/opcert/opcert.htm>. EPA plans to republish the guidelines with the revisions made today and post them on EPA's website at <http://www.epa.gov/safewater/opcert/opcert.htm>.

#### SUPPLEMENTARY INFORMATION:

##### Regional Contacts

- I. Linda Tsang, U.S. EPA Region I, One Congress Street, Suite 1100 (CMU), Boston, MA 02114, (617) 918-1395
- II. Gerard McKenna, U.S. EPA Region II, Drinking Water Section, Water Programs Branch, 290 Broadway, New York, NY 10007-1866, (212) 637-3838
- III. Barbara Smith, U.S. EPA Region III, Drinking Water Branch (3WP22), 1650 Arch Street, Philadelphia, PA 19103-2020, (215) 814-5786
- IV. Janine Morris, U.S. EPA Region IV, Atlanta Federal Center, 61 Forsyth