

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2006-0821; FRL-8133-1]

**Buprofezin; Pesticide Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of buprofezin in or on fruit, stone, group 12, except apricot and peach; and apricot. EPA is also revising existing tolerances for residues of buprofezin in or on canistel; grape; mango; papaya; sapodilla; sapote; black; sapote, mamey; and star apple; and deleting the existing tolerance for "grape, raisin" that is no longer needed as a result of this action. Interregional Research Project No. 4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 27, 2007. Objections and requests for hearings must be received on or before August 27, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** ).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0821. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6463; e-mail address: [madden.barbara@epa.gov](mailto:madden.barbara@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 those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide 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 Access Electronic Copies of this Document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. Can I File an Objection or Hearing Request?*

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0821 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before August 27, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0821, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

**II. Petition for Tolerance**

In the **Federal Register** of October 11, 2006 (71 FR 59781) (FRL-8098-1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5E6979, 5E6980 and 5E6981) by Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390. The petitions requested that 40 CFR 180.511 be amended by establishing a tolerance for residues of the insecticide buprofezin, 2-[(1,1-dimethylethyl)imino]tetrahydro-3(1-

methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one, in or on fruit, stone, group 12 (except peaches and nectarines) at 2 parts per million (ppm) (5E6979); black sapote, canistel, mamey sapote, mango, papaya, sapadilla and star apple at 0.8 ppm (5E6980); and amending the tolerances in or on grape at 0.8 ppm and grape, raisin at 1.2 ppm (5E6981). That notice referenced a summary of the petition prepared by Ninchino America, Inc., the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the residue field trial data supporting the petitions, EPA has modified the proposed tolerances as follows: Fruit, stone, group 12, except apricot and peach at 1.9 ppm; apricot at 9.0 ppm (PP5E6979); black sapote, canistel, mamey sapote, mango, papaya, sapadilla and star apple at 0.90 ppm (PP5E6980); and grape at 2.5 ppm with deletion of the existing tolerance on grape, raisin, since a separate raisin tolerance is no longer needed (PP5E6981). The reason for these changes is explained in Unit V.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCFA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCFA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to the FFDCFA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of the FFDCFA, and the factors specified in section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on

aggregate exposure for the petitioned-for tolerances for residues of buprofezin on fruit, stone, group 12, except apricot and peach at 1.9 ppm; apricot at 9.0 ppm; black sapote, canistel, mamey sapote, mango, papaya, sapadilla and star apple at 0.90 ppm; and grape at 2.5 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by buprofezin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of September 5, 2001 (66 FR 46381), (FRL-6796-6).

#### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UF) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose ("aPAD") and chronic population adjusted dose ("cPAD"). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure ("MOE") called for by the product of all applicable uncertainty/safety factors is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure

will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

A summary of the toxicological endpoints for buprofezin used for human risk assessment can be found at [www.regulations.gov](http://www.regulations.gov) in document "Buprofezin - Human-Health Risk Assessment for the Requested Stone Fruit Registration and the Proposed Amendment for the Grape and Papaya and Related Tropical Fruit Registrations" at pages 9-10 in Docket ID EPA-HQ-OPP-2006-0821.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to buprofezin, EPA considered exposure under the petitioned-for tolerances as well as all existing buprofezin tolerances in 40 CFR 180.511. EPA assessed dietary exposures from buprofezin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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. Such effects were identified in the toxicological studies for buprofezin for the population subgroup, females 13-50 years old; no such effects were identified for the general population or other population subgroups. In estimating acute dietary exposure of females 13-50 years old, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present at tolerance levels for all commodities except meat and milk. Anticipated residues were calculated for meat and milk commodities as follows: Tolerances for meat and milk are established at the analytical method limit of quantitation (LOQ). Since residues were only detected in the livestock feeding study when feed contained 6.8-9.3x the maximum theoretical dietary burden (MTDB), residues in these commodities were normalized to 1x the MTDB in the acute dietary exposure assessment. For fruits and crops with an extended interval

from initial application to harvest (>50 day), additional metabolites of toxicological concern (BF4 and its conjugates, and BF12) that are not included in the tolerance expression were included in the dietary exposure assessment, as appropriate, based on the ratio of metabolite to parent found in plant metabolism studies. No adjustment was made to account for the percent of crops treated with buprofezin in the acute dietary exposure assessment. One hundred (100) percent crop treated (PCT) was assumed for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied upon anticipated residues and percent crop treated information for some commodities. The chronic analysis employed the same anticipated residue estimates for meat and milk as those employed for the acute analysis. For apple, orange, and orange juice, average residues from the 2004 and/or 2005 USDA Pesticide Data Program (PDP) monitoring data were used for estimation of total buprofezin and metabolite residues. For all other plant commodities, tolerance-level or average field trial residues were used. For fruits and crops with an extended interval from initial application to harvest (>50 day), additional metabolites of toxicological concern (BF4 and its conjugates, and BF12) that are not included in the tolerance expression were included in the dietary exposure assessment, as appropriate, based on the ratio of metabolite to parent found in plant metabolism studies. The chronic analysis incorporated screening-level percent crop treated estimates for several registered crops and projected percent crop treated estimates for peach, grape, apricot, nectarine, cherry, and plum. 100 PCT was assumed for commodities for which PDP monitoring data were used to estimate exposures (apple, orange, and orange juice).

iii. *Cancer.* Taking into account its Guidelines for Carcinogen Risk Assessment, EPA classified buprofezin as having suggestive evidence of carcinogenicity, based on the occurrence of liver tumors in female mice only. EPA determined, however, that no quantification of cancer risk was appropriate, because the evidence was limited to one sex of one species. Therefore, a quantitative cancer exposure and risk assessment was not conducted.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of the FFDCA and authorized under section 408(f)(1) of the FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) of the FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue;
- b. The exposure estimate does not underestimate exposure for any significant subpopulation group; and
- c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F) of the FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

PCT for existing uses: Almond 1%; cantaloupe 5%; citrus (citron, hybrids and oil) 1%; cottonseed 1%; grapefruit 1%; honeydew 1%; lemon 1%; lime 1%; orange peel 1%; pear 1%; pumpkin 1%; tomato 1%; and watermelon 1%. Projected PCT for New Uses: Apricot 40%; cherry 76%; grape 21%; nectarine 60%; peach 13%; and plum 35%.

EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available federal, state, and private market survey data for that use, averaging by year, averaging across all years, and rounding up to the nearest multiple of five percent except for those situations in which the average PCT is less than one. In those cases <1% is used as the average and <2.5% is used as the maximum. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the single

maximum value reported overall from available federal, state, and private market survey data on the existing use, across all years, and rounded up to the nearest multiple of five percent. In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), Proprietary Market Surveys, and the National Center for Food and Agriculture Policy (NCFAP) for the most recent six years.

EPA estimates projected percent crop treated (PPCT) for a new pesticide use by assuming that the PCT during the pesticide's initial five years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one pesticide with the greatest PCT) on that site.

Typically, EPA uses USDA/NASS as the primary source for PCT data. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data and calculates the PCT. Comparisons are only made among pesticides of the same pesticide types (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide). The chronic PPCT values for buprofezin are averages derived from the most recent NASS surveys, either for the same pesticide, or for different pesticides, since the same, or different, pesticides may dominate for each year selected. This PPCT, based on the average PCT of the market leader, is appropriate for use in chronic dietary risk assessment. The method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use.

The predominant factors that bear on whether the estimated PPCT could be exceeded are whether a new pesticide use or new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide; and/or whether increasing pest pressure may intensify the use of pesticides as indicated in emergency exemption requests or other readily available information.

All information currently available for the predominant factors mentioned above or relevant to the case in question have been considered for this chemical, and it is the opinion of EPA that it is unlikely that actual PCT for buprofezin will exceed the PCT projections during the next five years. A discussion of the factors considered in making this determination can be found at [www.regulations.gov](http://www.regulations.gov) in the document "Projected Percent Crop Treated for the Insecticide Buprofezin on Six Crops:

Grapes, Apricots, Nectarines, Sweet Cherries, Tart Cherries, and Plums”, which is attached to the document “Buprofezin - Acute and Chronic Dietary Exposure and Risk Assessments” at pages 13–17 in Docket ID EPA–HQ–OPP–2006–0821.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA’s computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA’s risk assessment process ensures that EPA’s exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which buprofezin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for buprofezin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of buprofezin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the EPA’s Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of buprofezin for acute exposures are estimated to be 23.2 parts per billion (ppb) for surface water and 0.1 ppb for ground water. The EECs for chronic exposures are estimated to be 7.8 ppb for surface water and 0.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 23.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 7.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Buprofezin is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA 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.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to buprofezin and any other substances and buprofezin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that buprofezin has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional (“10X”) 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 database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor,

or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to in utero exposure to buprofezin in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the 2-generation reproduction study. There is evidence of thyroid toxicity following subchronic and chronic exposures of rats and dogs to buprofezin; however, data to determine whether young animals are more susceptible to these effects are not available.

3. *Conclusion.* EPA has determined that, due to uncertainties in the toxicity database for buprofezin, the FQPA safety factor of 10X must be retained and applied to all subchronic and chronic exposures whose endpoint is based on thyroid effects. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X for these exposures. For acute exposures, EPA has determined that the FQPA safety factor may be reduced to 1X and that the traditional 10X safety factor to account for interspecies variation must be retained. These decisions are based on the following findings:

i. The toxicity database for buprofezin is not complete as to chronic risk. Based on the evidence of thyroid toxicity following subchronic and chronic exposures of rats (histopathological lesions) and dogs (decreases in serum thyroxine levels and increased thyroid weights), EPA requested a buprofezin comparative thyroid assay study in rats (28-day; young versus adults) to determine if the thyroid effects occur at a lower dose in young versus adult animals. Since this study has not been submitted, EPA concludes that the 10X FQPA safety factor to account for database uncertainty should be retained and applied to all subchronic and chronic exposures whose endpoint is based on thyroid effects. EPA has also determined that the traditional 10X uncertainty factor to account for interspecies variation may be reduced to 3X for these exposures, since it has been established that rats are more susceptible to thyroid effects than humans. The FQPA safety factor of 10X is not applicable to the acute endpoint, since a single dose of buprofezin would not be expected to perturb thyroid homeostasis in the adult or the young

due to the buffering of thyroid hormone concentrations by homeostatic mechanisms for compounds with short half lives, like buprofezin.

ii. There is no indication that buprofezin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that buprofezin results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties in the exposure databases. The dietary food exposure assessments were refined for some commodities using reliable PCT/PPCT information and anticipated residue values calculated from the available monitoring data and field trial results. Dietary drinking water exposure is based on conservative modeling estimates. These assessments will not underestimate the exposure and risks posed by buprofezin.

Therefore, the total uncertainty factor for chronic dietary assessments is 300X (10X FQPA safety factor, 3X uncertainty factor for interspecies variation, and 10X uncertainty factor for intraspecies variation); and the total uncertainty factor for acute dietary assessments is 100X (10X uncertainty factor for interspecies variation and 10X uncertainty factor for intraspecies variation).

#### E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose ("aPAD") and chronic population adjusted dose ("cPAD"). The aPAD and cPAD are calculated by dividing the LOC by all applicable uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to buprofezin will occupy 6% of the aPAD for the population group females 13–49 years old. No acute endpoint of concern was identified for the remaining population groups.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to buprofezin from food and water will utilize 92% of the cPAD for the population group (children 1 to 2 years old) with the greatest exposure. There are no residential uses for buprofezin that result in chronic residential exposure to buprofezin.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Buprofezin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Buprofezin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Buprofezin is classified as having suggestive evidence of carcinogenicity; however, EPA determined it poses a negligible cancer risk to humans because the evidence of carcinogenicity was limited to one sex of one animal test species only.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to buprofezin residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

The gas chromatography/nitrogen phosphorus detector methods used in the field trial studies were adequately validated and similar to the method validated by EPA's Analytical Chemistry Branch (ACB) and forwarded to the Food and Drug Administration for publication in the Pesticide Analytical Manual I. Since adequate method validation and concurrent recoveries were attained in the field trial studies, EPA concludes that the method validated by ACB is appropriate for enforcement of the tolerances associated with these petitions. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft.

Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

There are no Canadian, Mexican, or Codex maximum residue limits (MRLs) established for buprofezin in/on any of the commodities associated with the current petitions.

#### V. Conclusion

Based upon review of the data supporting the petitions, EPA has modified the proposed tolerances as follows: Fruit, stone, group 12, except apricot and peach at 1.9 ppm; apricot at 9.0 ppm (PP5E6979); black sapote, canistel, mamey sapote, mango, papaya, sapadilla and star apple at 0.90 ppm (PP5E6980); and grape at 2.5 ppm with deletion of the existing tolerance on grape, raisin (PP5E6981). EPA determined that the proposed tolerances for these commodities were inappropriate and should be revised based on analyses of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP). Tolerances currently exist for residues of buprofezin in or on grape at 0.4 ppm and grape, raisin at 0.6 ppm. Based upon review of field trial data supporting the current petition and previously submitted processing data for buprofezin on grapes, EPA has determined that residues in raisins will not exceed the tolerance being established for residues of buprofezin in or on grape at 2.5 ppm. Since a separate tolerance for raisins is not needed and the existing raisin tolerance is too low to cover residues of buprofezin from the new use on grapes, EPA is deleting the existing tolerance for grape, raisin. Residues in or on raisins will be covered by the tolerance of 2.5 ppm for grape.

Therefore, tolerances are established for residues of buprofezin, 2-[(1,1-dimethylethyl)imino] tetrahydro-3-(1-methylethyl)-5-phenyl-4H-1,3,5-thiadiazin-4-one, in or on fruit, stone, group 12, except apricot and peach at 1.9 ppm; apricot at 9.0 ppm; black sapote, canistel, mamey sapote, mango, papaya, sapadilla and star apple at 0.90 ppm; and grape at 2.5 ppm. The existing tolerance for residues of buprofezin in or on grape, raisin is deleted.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and

Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCa, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. This final rule directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCa. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 2007.

**Lois Rossi,**

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

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.511 is amended in paragraph (a) in the table as follows:

- i. By removing the entry for "Grape, raisin";
- ii. By alphabetically adding "Apricot" and "Fruit, stone, group 12, except apricot and peach"; and
- iii. By revising the entries for "Canistel," "Grape," "Mango," "Papaya," "Sapodilla," "Sapote, black," "Sapote, mamey," and "Star apple."

The amendments read as follows:

**§ 180.511 Buprofezin; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Apricot .....	9.0
Canistel .....	0.90
Fruit, stone, group 12, except apricot and peach .....	1.9
Grape .....	2.5
Mango .....	0.90

Commodity	Parts per million
Papaya .....	0.90
Sapodilla .....	0.90
Sapote, black .....	0.90
Sapote, mamey .....	0.90
Star apple .....	0.90

\* \* \* \* \*  
 [FR Doc. E7-12161 Filed 6-26-07; 8:45 am]  
**BILLING CODE 6560-50-S**

**GENERAL SERVICES ADMINISTRATION**

**41 CFR Part 302-4**

[FTR Amendment 2007-03; FTR Case 2007-301; Docket 2007-0002, Sequence 3]

**RIN 3090-AI34**

**Federal Travel Regulation; Relocation Allowances—Standard Mileage Rate for Moving Purposes**

**AGENCY:** Office of Governmentwide Policy, General Services Administration (GSA).

**ACTION:** Final rule.

**SUMMARY:** The General Services Administration (GSA), Office of Governmentwide Policy (OGP), plans to establish the Internal Revenue Service (IRS) Standard Mileage Rate for moving purposes as the rate at which agencies will reimburse an employee for using a privately owned vehicle (POV) for relocation. The FTR and any corresponding documents may be accessed at GSA's website at <http://www.gsa.gov/fttr>.

**DATES:** *Effective Date:* September 25, 2007.

**FOR FURTHER INFORMATION CONTACT:** The Regulatory Secretariat (VIR), Room 4035, GS Building, Washington, DC, 20405, (202) 501-4755, for information pertaining to status or publication schedules. For clarification of content, contact Mr. Ed Davis, Office of Governmentwide Policy (M), Office of Travel, Transportation and Asset Management (MT), General Services Administration at (202) 208-7638 or e-mail at [ed.davis@gsa.gov](mailto:ed.davis@gsa.gov). Please cite FTR Amendment 2007-03; FTR case 2007-301.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

Relocation is an area that continuously evolves because of changes in the housing market,