

included in the list of products described in 21 CFR 1308.34.

NEW EXEMPT ANABOLIC STEROID PRODUCTS

Trade name	Company	Form	Ingredients	Quantity
Esterified Estrogens and Methyltestosterone, USP (1.25 mg/2.5 mg).	Interpharm, Inc .....	Tablets .....	Esterified Estrogens .....	1.25 mg/Tablet.
Esterified Estrogens and Methyltestosterone, USP (0.625 mg/1.25 mg).	Interpharm, Inc .....	Tablets .....	Methyltestosterone .....	2.5 mg/Tablet.
Methyltestosterone and Esterified Estrogens (2.5 mg/1.25 mg).	Interpharm, Inc .....	Tablets .....	Esterified Estrogens .....	0.625 mg/Tablet.
Methyltestosterone and Esterified Estrogens (Half Strength) (1.25 mg/0.625 mg).	Lannett Company, Inc.	Tablets .....	Methyltestosterone .....	1.25 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (1.25 mg/2.5 mg) Tablet.	Lannett Company, Inc.	Tablets .....	Esterified Estrogens .....	2.5 mg/Tablet.
Esterified Estrogens/Methyltestosterone, (0.625 mg/1.25 mg) Tablet.	ANDAPharm, LLC ..	Tablets .....	Methyltestosterone .....	0.625 mg/Tablet.
	ANDAPharm, LLC ..	Tablets .....	Esterified Estrogens .....	1.25 mg/Tablet.
	ANDAPharm, LLC ..	Tablets .....	Methyltestosterone .....	2.5 mg/Tablet.
	ANDAPharm, LLC ..	Tablets .....	Esterified Estrogens .....	0.625 mg/Tablet.
	ANDAPharm, LLC ..	Tablets .....	Methyltestosterone .....	1.25 mg/Tablet.

Dated: August 24, 2006.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2005-0035; FRL-8084-6]

Benthiavalicarb-Isopropyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This regulation establishes tolerances for the combined residues of benthiavalicarb-isopropyl, isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate, in or on imported grape at 0.25 parts per million (ppm), tomato at 0.45 ppm, and grape, raisin at 1.0 ppm. K-I Chemical U.S.A., Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective September 1, 2006. Objections and requests for hearings must be received on or before October 31, 2006, 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-2005-0035. All documents in the docket are listed in the index for the docket. 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:** Mary Waller, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9354; e-mail address: [waller.mary@epa.gov](mailto:waller.mary@epa.gov).

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 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; farmers; 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 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 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 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file

an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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-2005-0035 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 on or before October 31, 2006.

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 your copies, identified by docket ID number EPA-HQ-OPP-2005-0035, 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. Background and Statutory Findings

In the **Federal Register** of March 9, 2005 (70 FR 11648) (FRL-7699-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E6545) by K-I Chemical U.S.A., Inc., 11 Martine Ave., Suite 970, White Plains, NY 10606. The petition requested that 40 CFR part 180 be amended by establishing tolerances for the combined residues of the

fungicide isopropyl[(S)-1-[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbomoyl-2-methylpropyl]carbamate in or on the raw agricultural commodity imported grapes at 0.5 ppm, grape processed commodities juice and wine at 0.5 ppm, imported tomato at 0.5 ppm, tomato processed commodities at 0.5 ppm, and tomato paste at 1.5 ppm. That notice included a summary of the petition prepared by K-I Chemical U.S.A., Inc., the registrant. One comment from a private citizen was received in response to the notice of filing. EPA's response to this comment is discussed in Unit IV.

Section 408(b)(2)(A)(i) of FFDCA 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 FFDCA 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 FFDCA 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..."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of FFDCA and a complete description of the risk assessment process, see <http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm>.

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of FFDCA, 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, consistent with section 408(b)(2) of FFDCA, for a tolerance for combined residues of benthiavalicarb-isopropyl on imported grape at 0.25 ppm, tomato at

0.45 ppm, and grape, raisin at 1.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance 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 toxic effects caused by benthiavalicarb-isopropyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> under document ID number EPA-HQ-OPP-2005-0035-0001.

### B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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.

The linear default risk methodology (Q\*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q\* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://www.epa.gov/oppfead1/trac/science>.

A summary of the toxicological endpoints for benthiavalicarb-isopropyl used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BENTHIAVALICARB-ISOPROPYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Dose used in risk assessment, UF	Special FQPA SF and level of concern for risk assessment	Study and toxicological effects
Acute dietary All populations including infants and children when applicable	NOAEL = N/S UF = N/A Acute RfD = N/A	FQPA SF = N/A	No studies resulted in toxic effects attributable to one or two exposures. Therefore an acute endpoint was not selected for dietary exposure.
Chronic dietary (All populations)	NOAEL= 9.9 milligrams/kilograms/day (mg/kg/day) UF = 100 Chronic RfD = 0.099 mg/kg/day	FQPA SF = 1X cPAD = 0.099 mg/kg/day	Chronic oral toxicity in rats LOAEL = 249.6 mg/kg/day based on nephrotoxicity and hepatotoxicity.
Cancer (Oral, dermal, inhalation)	Likely to be carcinogenic to humans	Q1* = 6.2795 x 10 <sup>-2</sup>	Based on increases in male mouse liver combined adenomas and/or carcinomas and/or blastomas.

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no-observed-adverse-effect-level, LOAEL = lowest-observed-adverse-effect-level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Benthiavalicarb-isopropyl is a new chemical and these are the first tolerances to be proposed for this chemical. Risk assessments were conducted by EPA to assess dietary exposures from benthiavalicarb-isopropyl 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. No such effects were identified in the toxicological studies for benthiavalicarb-isopropyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII), for each commodity: Estimates of percent crop imported (PCI) were used in place of percent crop treated (PCT) values as PCI values more appropriately estimate exposure to benthiavalicarb-isopropyl since the chemical is not being proposed for registration in the United States and residues will only result on imported grape and tomato commodities. Average field trial values of 0.06958 ppm for grapes, 0.1133 ppm for greenhouse grown tomatoes, and 0.00767 ppm for field grown tomatoes were used. It is

unlikely that average field trial values and PCI values will be exceeded in the future. Average field trial values almost always exceed the expected residue levels found on crops at the time of consumption. When field trials are performed, the maximum allowable application rate is used and crops are harvested at the minimum PHI. Samples are stored frozen until analysis to ensure minimal degradation of residues. However, in actual practice, growers will not usually use the maximum application rates for economic reasons. Additionally, it has been observed from previous analysis, that monitoring data are often one to two orders of magnitude lower than field trial data. Moreover, the registrant is planning on marketing benthiavalicarb-isopropyl in Europe only. For this risk assessment, PCI estimates were assumed for all imports, not just grape and tomato commodities from Europe. Lastly, the Agency assumes 100% of the imported crop will be treated. The actual PCI will likely be considerably lower. The following processing factors derived from processing studies were used: 0.47 for grapes juice, 0.97 for grape wine, 3.67 for raisins, 1.16 for tomato puree, and 0.49 for tomato juice. Default processing factors of 5.4 for tomato paste and 14.3 for dried tomatoes were used.

iii. *Cancer.* The cancer exposure assessment was conducted using the same exposure assumptions as were used in the chronic exposure assessment.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of 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 chemicals that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA 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. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. For the present action, EPA will issue such data call-ins for information relating to anticipated residues as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Such data call-ins 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 FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings:

Condition 1, that 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.

Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group.

Condition 3, if 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

FFDCA, EPA may require registrants to submit data on PCT.

The Agency used PCI information as follows: Tomatoes—36%, processed tomato commodities—5.8%, grapes—45%, grape juice—44%, wine—23%, and raisins—10%.

The Agency believes that the three conditions listed in Unit III. have been met. With respect to Condition 1, PCI estimates are derived from the U.S. Department of Agriculture, Economic Research Service data which are reliable and have a valid basis. The Agency is reasonably certain that the percentage crop imported values will not be exceeded in the future. The conservative assumptions were made that 100% of the grape and tomato commodities imported from all over the world would be treated. Data for grape commodities were taken from 5 year averages and were compared to the annual data points of each data source. It was observed that crop production patterns and consumption and preferences were more stable and changed more slowly. For tomatoes commodities, data was taken from 1998 to 2004 with no increases occurring over that time period. It is very unlikely that estimates of import would be exceeded in the near future due to crop production patterns and consumption and preferences are more stable and change more slowly. 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 the national food consumption surveys, EPA does not have available information on the regional consumption of food to which benthiavalicarb-isopropyl may be applied in a particular area.

2. *Dietary exposure from drinking water.* The proposed tolerances are for imported commodities only, and there are no current or proposed U.S. registrations for this chemical. Therefore, there is no potential for exposure to benthiavalicarb-isopropyl through drinking water, and a drinking water assessment was not performed.

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).

There are no products containing benthiavalicarb-isopropyl proposed or registered for residential use or that may be applied by commercial applicators to residential sites. Therefore, a residential exposure assessment was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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 benthiavalicarb-isopropyl and any other substances and benthiavalicarb-isopropyl does not appear to produce a toxic metabolite produced by other substances. Although benthiavalicarb-isopropyl is a carbamate compound, it is not a member of the class of insecticides known as the N-methyl carbamates for which the Agency is presently conducting a cumulative risk assessment. The substituents on the benthiavalicarb-isopropyl nitrogen atom are much larger than the methyl group in the insecticides. While the N-methyl carbamates are neurotoxicants based on their ability to inhibit the enzyme cholinesterase, there is no evidence of neurotoxicity or neuropathology in the hazard database for benthiavalicarb-isopropyl. Benthiavalicarb-isopropyl is also not a member of the thiocarbamate class of herbicides or the dithiocarbamate class of fungicides. For the purposes of this tolerance action, therefore, EPA has not assumed that benthiavalicarb-isopropyl 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

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

1. *In general.* Section 408 of FFDCA 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 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. 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 safety factor value based on the use of traditional UFs and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for pre/postnatal toxicity. Developmental studies in two species (both rat and rabbit) and a 2-generation reproduction study in rats did not show any evidence of developmental or reproductive toxicity. Evidence suggests that there is no concern for fetuses exposed to benthiavalicarb-isopropyl *in utero* or post-natally. There was no evidence of neurotoxicity throughout the entire toxicology database and there was an absence of adverse developmental and reproductive effects. A developmental neurotoxicity study is not necessary at this time. The Agency determined that reliable data support reducing the FQPA SF to 1X. This determination was based on the following:

- There is no evidence of increased susceptibility to fetuses or pups following *in utero* or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study.
- There are no residual uncertainties concerning pre and postnatal toxicity and no neurotoxicity concerns.
- The toxicological database is complete for FQPA assessment.
- The chronic and cancer dietary food exposure assessments utilizes anticipated residues (ARs) calculated from average field trial data and worldwide estimates of PCI for most commodities. Although refined, the assessments are based on reliable data and will not underestimate exposure or risk.
- There is no potential for drinking water exposure.

• There is no potential for residential exposure.

3. *Conclusion.* There is a complete toxicity data base for benthiaivalicarb-isopropyl and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be removed. The FQPA factor is removed because there are no residential uncertainties for pre/postnatal toxicity.

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

1. *Acute risk.* An acute endpoint was not identified in any of the toxicity studies. Therefore, no acute risk is expected from exposure to benthiaivalicarb-isopropyl.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to benthiaivalicarb-isopropyl from food will utilize <1 % of the cPAD for the U.S. population, <1 % of the cPAD for all infants <1 year old, and <1 % of the cPAD for children 1–2 years old, the most highly exposed population subgroup. There are no residential uses for benthiaivalicarb-isopropyl. There are no current or proposed U.S. registrations of benthiaivalicarb-isopropyl and as a result there is no expectation of exposure through drinking water. Therefore, EPA does not expect the aggregate exposure (dietary) to exceed 100% of the cPAD.

3. *Aggregate cancer risk for U.S. population.* Applying the cancer potency (Q1\*) value of 0.063 (mg/kg/day)<sup>-1</sup> to the exposure value results in a cancer risk estimate of  $1.6 \times 10^{-6}$ . This cancer risk estimate falls within the range of  $1 \times 10^{-6}$ , the risk level considered to be negligible by EPA; therefore, the estimated cancer risk is below the Agency's level of concern.

4. *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, and to infants and children from aggregate exposure to benthiaivalicarb-isopropyl residues.

#### IV. Other Considerations

##### A. Analytical Enforcement Methodology

Adequate enforcement methodology, Gas Chromatography/Nitrogen-Phosphorous detector (GC/NPD) Method RCC. Ho. 665943 is available to enforce the tolerance expression. 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*.

##### B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue limits (MRLs) for benthiaivalicarb-isopropyl.

##### C. Response to Comments

One comment was received from a private citizen objecting to profiteering, animal testing, and establishing tolerances. The comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to benthiaivalicarb-isopropyl, including all anticipated dietary exposures and other exposures for which there is reliable information. The EPA has responded to this private citizen's generalized comments on numerous previous occasions, for example, on January 7, 2005 (70 FR 1354) (FRL-7681-9) and on October 29, 2004 (69 FR 63096) (FRL-7691-4).

#### V. Conclusion

Therefore, the tolerances are established for combined residues of benthiaivalicarb-isopropyl, isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl] amino] carbonyl]-2-methylpropyl]carbamate, in or on imported grape at 0.25 ppm, tomato at 0.45 ppm, and grape, raisin at 1.0 ppm. As residues do not concentrate in wine, the 0.25 ppm grape tolerance is adequate to cover residues in wine. A separate tolerance for wine is not needed. Based on processing factors and highest average field trial values for field grown tomatoes which are used for processing, separate tolerances are not required for processed tomato commodities.

#### VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 due to its lack of significance, 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption

provisions of section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

## VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: August 25, 2006.

**Anne E. Lindsay,**

*Acting Director, 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 180.618 is added to read as follows:

### § 180.618 Benthialdicarb-isopropyl; tolerance for residues.

(a) *General.* Tolerances are established for the combined residues of benthialdicarb-isopropyl, isopropyl[(S)-1-[[[(1R)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate and isopropyl[(S)-1-[[[(1S)-1-(6-fluoro-2-benzothiazolyl)ethyl]amino] carbonyl]-2-methylpropyl]carbamate, in or on the following raw agricultural commodities:

Commodity	Parts per million
Grape, imported ....	0.25
Grape, raisin .....	1.0
Tomato .....	0.45

Note: There are no U.S. registrations as of July 30, 2006.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect of inadvertent residues.* [Reserved]

[FR Doc. 06-7313 Filed 8-31-06; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0373; FRL-8081-9]

### 2, 6-Diisopropyl-naphthalene; Time-Limited Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of 2, 6-Diisopropyl-naphthalene, resulting from post-harvest applications to potato, in or on fat (cattle, goat, hog, horse, and sheep) at 0.8 part per million (ppm); liver (cattle, goat, hog, horse, and sheep) at 0.3 ppm; meat (cattle, goat, hog, horse, and sheep) at 0.1 ppm; meat byproducts (cattle, goat, hog, horse, and sheep) at 0.1 ppm; milk at 0.1 ppm; potato at 2.0 ppm; and potato, wet peel at 6.0 ppm. Loveland Products, Inc. had requested permanent tolerances (in or on whole potato and potato peels at 2 and 6 ppm, respectively) under the Federal Food, Drug, and Cosmetic Act

(FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The time-limited tolerances will expire on August 1, 2009.

**DATES:** This regulation is effective September 1, 2006. Objections and requests for hearings must be received on or before October 31, 2006, 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-2006-0373. All documents in the docket are listed in the index for the docket. 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 Building), 2777 S. Crystal Drive, Arlington, VA. The 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.

### FOR FURTHER INFORMATION CONTACT:

Denise Greenway, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8263; e-mail [address:greenway.denise@epa.gov](mailto:address:greenway.denise@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### I. General Information

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

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be