22, 2001). This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, 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 by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a State rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 21, 2002. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. Section 307(b)(2).

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 16, 2002.

**Keith Takata,**

*Acting Regional Administrator, Region IX.*

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

## Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(297)(i)(D) to read as follows:

**§ 52.220 Identification of plan.**

* * * * *

(c) * * *

(297) * * *

(i) * * *

(D) Monterey Bay Unified Air Pollution Control District.

(*1*) Rule 427, adopted on January 16, 1980 and amended on December 19, 2001.

* * * * *

[FR Doc. 02–21435 Filed 8–21–02; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–2002–0203; FRL–7194–3**

## Iprovalicarb; Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an import tolerance for residues of iprovalicarb in or on grape at 2.0 parts per million (ppm). Tomen Agro, Inc. and Bayer Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

**DATES:** This regulation is effective August 22, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0203, must be received on or before October 21, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–2002–0203 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Dennis McNeilly, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6742; e-mail address: mcneilly.dennis@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 | Examples of Potentially Affected Entities |
|---|---|---|
| Industry | 111 | Crop production |
| | 112 | Animal production |
| | 311 | Food manufacturing |
| | 32532 | 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'', ''Regulations 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/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/ Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–2002–0203. The official record consists of the documents specifically referenced in this action, 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 Hwy., 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.

## II. Background and Statutory Findings

In the **Federal Register** of September 22, 2000 (65 FR 57338) (FRL–6737–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170), announcing the filing of a pesticide petition (PP 9E6020) by Tomen Agro, Inc; and, Bayer Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105; and, 8400 Hawthorn Road, Kansas City, MO 64120, respectively. This notice included a summary of the petition prepared by Tomen Agro, Inc. and Bayer Corp., the registrant. Iprovalicarb is an amino acid amide carbamate that belongs to a new class of chemicals derived from natural amino acids. Iprovalicarb acts both as a contact and systemic fungicide and is proposed for use in the European Union for control of Oomycete fungi, such as downy mildew. Review of this import tolerance was completed in cooperation with Canada's Pest Management Regulatory Agency. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing import tolerances for residues of the fungicide iprovalicarb, [2-methyl-1[[[(1S)-(4-methylphenyl) ethyl] amino]carbonyl] propyl]carbamic acid methylethylester, in or on grape and raisin at 2.0 ppm. An additional tolerance for the processed food, raisins, is not necessary because any residue in raisin from this use will be covered by the tolerance for grape.

Section 408(b)(2)(A)(i) of the 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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with 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, consistent with section 408(b)(2), for an import tolerance for residues of iprovalicarb on grape at 2.0 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. The nature of the toxic effects caused by iprovalicarb are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.3100 | 90–Day oral toxicity, mice | NOAEL = 325.0 for males; 696.5 for females mg/kg/day<br>LOAEL = 1,724.6 for males, 3,599.5 for females mg/kg/day based on elevated water intake and changes in hematological parameters (erythrocyte count, MCV) in males; increases in liver weights and plasma cholesterol in females. |
| 870.3100 | 90–Day oral toxicity, rat | NOAEL = 372.7 for males; 561.4 for females mg/kg/day<br>LOAEL = 1,524.0 for males, 2,585.9 for females mg/kg/day based on males: decrease in plasma triglycerides and increase in leukoyte counts, alkaline phosphatase levels, pale livers and increased relative liver weights; females: increased food intake, decreased body weight gain and food efficiency and increased plasma cholesterol levels. |
| 870.3150 | 90–Day oral toxicity, dog | NOAEL = 9.1 mg/kg/day<br>LOAEL = 62.5 mg/kg/day based on increased absolute and relative liver weight, hepatocellular hypertrophy, increased serum activity of activity of alkaline phosphatase and decreased plasma protein levels. |
| 870.3700 | Prenatal developmental in rodents (rat) | Maternal NOAEL = 1,000 mg/kg/day<br>LOAEL = >1,000 mg/kg/day based on the absence of treatment related toxicity in the dams at the highest dose tested.<br>Developmental NOAEL = 1,000 mg/kg/day<br>LOAEL = >1,000 mg/kg/day based on the absence of treatment related toxicity in the fetuses at the highest dose tested. |
| 870.3700 | Prenatal developmental in nonrodents(rabbit) | Maternal NOAEL = 1,000 mg/kg/day<br>LOAEL = >1,000 mg/kg/day based on the absence of treatment related toxicity in the dams at the highest dose tested.<br>Developmental NOAEL = 1,000 mg/kg/day<br>LOAEL = >1,000 mg/kg/day based on the absence of treatment related toxicity in the fetuses at the highest dose tested. |
| 870.3800 | Reproduction and fertility effects, rat | Parental/Systemic NOAEL = 214.9 mg/kg/day<br>LOAEL = 2,509 mg/kg/day based on increased relative liver weights in both sexes and bile duct proliferation in $F_0$ and $F_1$ parental males.<br>Reproductive NOAEL = 214.9 mg/kg/day<br>LOAEL = 2,509 mg/kg/day based on decreased mean litter weight at day 28 ($F_1$ and $F_2$), reduced body weight development in $F_1$ and $F_2$ pups.<br>Offspring NOAEL = 214.9 mg/kg/day<br>LOAEL = 2,509 mg/kg/day based on reduced body weight development during lactation and increased relative liver weights of the pups. |
| 870.4100 | Chronic toxicity, dog | NOAEL = 2.62 mg/kg/day<br>LOAEL = 24.69 mg/kg/day based on biochemical and morphological liver effects, e.g., swelling, distinct lobulation and discoloration, increases in absolute and relative liver weights, and activities of ALT and ALP, hepatocellular hypertrophy and periportal fatty change. |
| 870.4200 | Carcinogenicity, mice | NOAEL = 58.5 mg/kg/day<br>LOAEL = 283.4 mg/kg/day based on increased blood urea nitrogen concentration, decreased kidney weights and histopathological changes in the kidneys. No evidence of carcinogenicity. |
| 870.4300 | Combined chronic toxicity/ Carcinogenicity, rats | NOAEL = 26.0 mg/kg/day<br>LOAEL = 262.5 mg/kg/day based on histopathological changes in the liver (bile duct hyperplasia). Evidence of carcinogenicity, consisting of treatment-related rare and uncommon tumors in multiple organs/tissues in male and female rats. |
| 870.5100 | Gene mutation | Negative with and without S9 activation up to 5,000 micrograms/plate in bacterial reverse mutation test (*S. typhimurium).* |
| 870.5300 | *In vitro* mammalian cell gene mutation | Negative with and without S9 activation up to 125 micrograms/mL (with S9) and 150 micrograms/mL (without S9) in *in vitro* mammalian cell forward mutation test (Chinese hamster lung fibroblasts). |
| 870.5375 | *In vitro* mammalian chromosomal aberration tests | Negative with and without S9 activation up to 150 micrograms/ml in *in vitro* mammalian cell assay (Chinese hamster ovary cells). |
| 870.5385 | Mammalian chromosomal aberration | Negative at 2,000 mg/kg in *in vivo* bone marrow micronucleus assay (mice). |

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

| Guideline No. | Study Type | Results |
|---|---|---|
| 870.5550 | Unscheduled DNA synthesis | Negative up to 500 micrograms/ml in *in vitro* mammalian cell assay (rat primary hepatocytes). |
| 870.6200 | Acute neurotoxicity screening battery, rat | NOAEL = 2,000 mg/kg/day<br>LOAEL = >2,000 mg/kg/day based on no effects at the highest dose tested. |
| 870.6200 | Subchronic neurotoxicity screening battery | Systemic. NOAEL = 86.0 mg/kg/day<br>LOAEL = 342.0 mg/kg/day based on decreased body weight and increased food consumption.<br>Neurotoxicity. NOAEL = 1,434 mg/kg/day for males and 2,314 mg/kg/day for females<br>LOAEL = >1,434 mg/kg/day for males and >2314 mg/kg/day for females based on no effects at the highest dose tested. |
| 870.7485 | Metabolism and pharmaco-kinetics | Up to 99% excreted via urine and feces within 72 hours. Material metabolized extensively; small percentage passed through rat unchanged. Twelve metabolites identified. Proposed biotransformation pathway via oxidation of methyl group on aromatic ring, leading to carboxylic acid metabolite via hydroxymethyl-derivative. |
| | Special studies | 28–Day Dietary - Dog: NOAEL was 3.0 mg/kg/day for males and 3.4 mg/kg/day for females. The LOAEL was 31.5 mg/kg/day for males and 35.0 mg/kg/day for females based on hepatocellular hypertrophy, vacuolated hepatocytes and elevated serum alkaline phosphatase activity.<br>28–Day Dietary + 28–Day Recovery - Dog: The microsomal enzyme induction LOAEL was 2.93–3.01 mg/kg/day (the highest dose tested). The NOAEL was 0.77 mg/kg/day.<br>Liver foci test for tumor initiating effects - Rats (males only): Negative for tumor initiating potential in rat liver.<br>28–Day Dietary Rat: NOAEL = 579.3 mg/kg/day for males and 195.8 mg/kg/day for females. LOAEL=1,934.4 mg/kg/day for males and 572.8 mg/kg/day for females based on increases in alkaline phosphatase, cholesterol and relative liver weights in males; increases in cholesterol and triglycerides as well as absolute and relative liver weights in females. |

*B. Toxicological Endpoints*

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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences. No special uncertainty factors were appropriate or used in the dietary risk assessment.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC. In this case because this is an import tolerance only, there is only dietary risk.

The linear default risk methodology (Q1*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q1* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q1* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1 x $10^{-6}$ or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer}$ = point of departure/exposures) is calculated. A summary of the toxicological endpoints for iprovalicarb used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR IPROVALICARB FOR USE IN HUMAN RISK ASSESSMENT

| Exposure Scenario | Dose Used in Risk Assessment, UF | FQPA SF[1] and Level of Concern for Risk Assessment | Study and Toxicological Effects |
|---|---|---|---|
| Chronic Dietary all populations | NOAEL= 2.6 mg/kg/day UF = 100 Chronic RfD = 0.026 mg/kg/day. | FQPA SF = 1X cPAD = chronic RfD/FQPA SF = 0.026 mg/kg/day. | 1–Year Dog Study LOAEL = 24.69 mg/kg/day based on liver effects: swelling, enlargement, distinct lobulation and discoloration, increased absolute and relative liver weights, and accompanying hepatocellular hypertrophy and fatty change, and elevated serum liver enzyme activities. |
| Cancer (oral) | $Q_1$* = 4.5 X $10^4$ (mg/kg/day)$^{-1}$ | ..... | Combined chronic toxicity/carcinogenicity, two–year rat study $Q_1$* based on the combined follicular cell adenomas and carcinomas in the thyroid gland of female rats. |

[1] The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* This is the first feed and/or food use for iprovalicarb in the United States. This activity reflects the establishment of a U.S. import tolerance on grape without a U.S. registration and therefore the only exposure that occurs is dietary. Risk assessments were conducted by EPA to assess dietary exposures from iprovalicarb in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. Iprovalicarb is of low acute oral toxicity in rats with no adverse effects observed at doses well above the limit test dose (>5,000 mg/kg). In addition, rat and rabbit teratology studies and an acute neurotoxicity rat study, presented no effects indicative of early toxicity. Also, in sub-chronic feeding and reproduction toxicity studies, there were no treatment-related effects that could be attributable to a single dose. It is for these reasons that an acute analysis was not conducted, i. e., due to the lack of any appropriate toxicological end-point. Accordingly, an acute risk analysis was not appropriate and was not conducted.

ii. *Chronic exposure.*In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A DEEM® chronic dietary exposure analysis was performed using tolerance residue levels and 100% crop treated. Data from a grape processing study indicated that iprovalicarb residues did not concentrate in grape processed commodities; therefore, the DEEM® concentration factors for grape (i.e.: juice, juice-concentrate, raisin) were set at 1, indicating no concentration of residues. The DEEM® analysis included wine, sherry and raisin. EPA does not expect the chronic risk to exceed 100% of the cPAD, as shown in the following Table 3:

TABLE 3.—CHRONIC (NON-CANCER) EXPOSURE TO IPROVALICARB

| Population Subgroup | Dietary exposure (mg/kg/day) | cPAD (mg/kg/day) | %cPAD (Food) |
|---|---|---|---|
| U.S. Population | 0.000688 | 0.026 | 2.6 |
| All infants (<1 year old) | 0.001282 | 0.026 | 4.9 |
| Children (1–6 years old) | 0.002443 | 0.026 | 9.3 |
| Children (7–12 years old) | 0.000668 | 0.026 | 2.6 |

iii. *Cancer.* In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999) the Agency has classified iprovalicarb into the category ''Likely to be carcinogenic to humans'' based on the following weight-of-the-evidence considerations:

Iprovalicarb induced rare and infrequently occurring tumors in Wistar rats. At the high dose, males developed malignant osteosarcomas and females also developed benign transitional cell papillomas of the urinary bladder. At the mid and high doses, females also developed malignant mixed Mullerian tumors of the uterus and follicular cell adenomas and carcinomas in the thyroid gland. Although the incidences of these tumors were low, they are rare or uncommon in Wistar rats. Most of these tumors were induced above the limit dose (1,000 mg/kg/day) which was adequate and not excessively toxic. In mice, no treatment-related increase in tumors was observed in animals treated above the limit dose which was adequate and not excessively toxic.

Iprovalicarb is not mutagenic. Although mechanistic studies suggested that iprovalicarb may not be a tumor initiator, these studies were inadequate to establish the definitive mode of action for tumor induction in rats.

The Agency is using a linear low-dose extrapolation ($Q_1$*) approach for estimating the human cancer risk based

on the most potent tumor in rats. This approach is supported by the lack of confirmation of the mode of action of iprovalicarb. The most potent $Q_1$* for iprovalicarb was determined to be 4.5 x $10^{-4}$ $(mg/kg/day)^{-1}$ based on combined follicular cell adenomas and carcinomas in the thyroid gland of the female rat.

Percent crop treated and/or anticipated residues were not used.

2. *Dietary exposure from drinking water*. Residues in drinking water are not expected to result as a consequence of establishing an import tolerance for iprovalicarb residues in or on grape. Iprovalicarb is not registered for use in the United States. Therefore, exposures through drinking water is unlikely.

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).

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

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether iprovalicarb has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, iprovalicarb 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 iprovalicarb 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

*D. Safety Factor for Infants and Children*

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity*. There is no evidence for increased susceptibility of fetuses to *in utero* exposure of iprovalicarb in either the rat developmental or rabbit developmental studies. In both studies, the NOAEL for both maternal and developmental toxicity was the highest dose tested.

Based on the results in the 2-generation reproduction study in rats, a qualitative increased susceptibility of the neonates (as compared with adults) was demonstrated for iprovalicarb. The parental systemic NOAELs were based on decreased body weights and liver weights as well as bile duct proliferation; for females, the parental systemic NOAELs were based on increased relative liver weights. Reproductive LOAELs were not attained (greater than higest dose tested (HDT), limit dose). In offspring, the NOAELs were based on decreased mean litter weight on day 28, reduced body weight during lactation, and increased pup relative liver weights as well as reduced lactation index in $F_1$. There was considered to be an increase in sensitivity of the neonates (as compared with adults) because of the lower lactation index (decreased pup survival) and decreased pup body weight. Although there is evidence of qualitative susceptibility in the 2-generation reproduction study, the Agency concludes that there is a low level of concern (and no residual uncertainty) because: (1) The increased susceptibility (decrease in pup survival) was seen only at the highest dose tested (2,074 mg/kg/day) which is twice the limit dose; (2) the decrease in pup survival was seen only in one generation ($F_1$, not replicated in $F_2$); (3) there are clearly defined NOAELs/LOAELs for parental and offspring toxicity; and (4) the effects seen in the offspring occurred at a much higher dose (192 mg/kg/day) than that used to establish the chronic RFD (NOAEL of 2.6 mg/kg/day).

3. *Conclusion*. There is a complete toxicity database for an import tolerance for iprovalicarb and exposure data are complete or are estimated based on data that reasonably accounts for potential dietary exposures. The Agency concludes that there are reliable data that indicate there are no (residual) concerns for pre- and/or postnatal toxicity following exposure to iprovalicarb and therefore, no additional safety factor (1X) is necessary to protect the safety of infants and children.

*E. Aggregate Risks and Determination of Safety*

1. *Acute risk*. Iprovalicarb is of low acute oral toxicity in rats with no adverse effects observed at doses well above the limit test dose (>5,000 mg/kg). In addition, rat and rabbit teratology studies and an acute neurotoxicity rat study, presented no effects indicative of early toxicity. Also, in sub-chronic feeding and reproduction toxicity studies, there were no treatment-related effects that could be attributable to a single dose. It is for these reasons that iprovalicarb is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to iprovalicarb from food will utilize 2.6% of the cPAD for the U.S. population, 4.9% of the cPAD for All infants (<1 year old), 9.3% of the cPAD for children 1–6 years old and 2.6% of the cPAD for children 7–12 years old. There are no residential uses for iprovalicarb.

In addition, there is not any potential for chronic dietary exposure to iprovalicarb in drinking water because the only use is an import tolerance. There are no U.S. registered products or uses at this time. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IPROVALICARB

| Population Subgroup | cPAD (mg/kg/day) | %cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|---|---|---|
| U.S. Population | 0.026 | 2.6 | N/A | N/A | N/A |

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO IPROVALICARB—Continued

| Population Subgroup | cPAD (mg/kg/day) | %cPAD (Food) | Surface Water EEC (ppb) | Ground Water EEC (ppb) | Chronic DWLOC (ppb) |
|---|---|---|---|---|---|
| All infants (<1 year old) | 0.026 | 4.9 | N/A | N/A | N/A |
| Children (1–6 years old) | 0.026 | 9.3 | N/A | N/A | N/A |
| Children (7–12 years old) | 0.026 | 2.6 | N/A | N/A | N/A |

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).

Iprovalicarb 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 do not exceed the Agency's level of concern. Residues in water, both surface and ground water, are expected to be zero because there are no U.S. uses, only this import tolerance for grape.

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).

Iprovalicarb 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 do not exceed the Agency's level of concern. Residues in water, both surface and ground water, are expected to be zero because there are no U.S. uses, only this import tolerance for grape.

5. *Aggregate cancer risk for U.S. population*. The lifetime risk of developing cancer from iprovalicarb exposure is determined for the U.S. population (total) only. The estimated exposure to iprovalicarb is 0.000688 mg/kg/day. Applying the $Q_1$* of 4.5 x $10^{-4}$ $(mg/kg/day)^{-1}$ to the exposure value results in a cancer risk estimate of 3.1 x $10^{-7}$. This risk is negligible.

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, and to infants and children from aggregate exposure to iprovalicarb residues.

## IV. Other Considerations

### *A. Analytical Enforcement Methodology*

The enforcement analytical residue analytical method is an liquid chromotography/mass spectrometry method. The limit of quantitation is 0.05 ppm in grape, wine, juice and raisin. Recovery and sensitivity of the method is considered adequate (95–114%).

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Paul Golden, USEPA (7503C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (410) 305–2960; e-mail address: www.epa.gov/oppbead1/methods/ (RAM Mailbox).

### *B. International Residue Limits*

No maximum residue levels have yet been established by the CODEX Alimentarius Commission for iprovalicarb in/on grape or raisin.

## V. Conclusion

Therefore, tolerances are established for residues of iprovalicarb, [2-methyl-1[[[(1S)-(4-methylphenyl)ethyl] amino]carbonyl] propyl]carbamic acid methylethylester, in or on grape at 2.0 ppm.

## VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

### *A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–2002–0203 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 21, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters

Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–2002–0203, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

*B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

## VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). 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.

## VIII. Submission to Congress and the Comptroller General

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 record keeping requirements.

Dated:August 15, 2002.

**Joseph J. Merenda,**

*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), 346(a) and 374.

2. Section 180.581 is added to read as follows:

**§ 180.581 Iprovalicarb; tolerances for residues.**

(a) *General.* Tolerances are established for residues of iprovalicarb, [2-methyl-1[[[(1S)-(4-methylphenyl) ethyl] amino]carbonyl] propyl]carbamic acid methylethylester, in or on the following commodities.

| Commodity | Parts per million |
|---|---|
| Grape[1] | 2.0 |

[1] No U.S. registration as of July 31, 2002.

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

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

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

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