§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

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Commodity	Parts per million	Expiration/revocation date
Avocado	0.02	9/20/00
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300828; FRL–6072–6]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of Tebufenozide, benzoic acid, 3,5-dimethyl-, 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide in or on berry (crop group 13), cranberry, and mint. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective April 7, 1999. Objections and requests for hearings must be received by EPA on or before June 7, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300828], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300828], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300828]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 272, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7610, e-mail: jackson.sidney@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 9, 1999 (64 FR 6351) (FRL–6058–3), 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) (Pub. L. 104–170) announcing the filing of pesticide petitions (PP) 8E5021, 8E4983, and 8E5019 for tolerance by IR–4 . This notice included a summary of the petition prepared by the Rohm and Haas Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.482 be amended by establishing tolerances for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-, 1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide, in or on the berry crop group at 3.0 parts per million (ppm), cranberry at 1.0 ppm, and mint at 10.0 ppm.

I. Background and Statutory Findings

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).

II. 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 tebufenozide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of tebufenozide on the berry crop group at 3.0 ppm, cranberry at 1.0 ppm, and mint at 10.0 ppm. EPA's assessment of the dietary 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 tebufenozide are discussed in this unit.

1. *Acute toxicity*. Results of a battery of toxicological studies using technical grade product show tebufenozide has low acute toxicity. Tebufenozide was practically non-toxic by ingestion of a single oral dose in rats and mice (LD_{50} > 5,000 milligram/kilogram (mg/kg)) and was practically non-toxic by dermal application lethal dose(LD) LD_{50} > 5,000

mg/kg. Tebufenozide was not significantly toxic to rats after a 4–hr inhalation exposure with a lethal concentration(LC) LC_{50} value of 4.5 mg/L (highest attainable concentration), is not considered to be a primary eye irritant or a skin irritant and is not a dermal sensitizer. An acute neurotoxicity study in rats did not produce any neurotoxic or neuropathologic effects.

2. *Genotoxicty*. Tebufenozide technical was negative (non-mutagenic) in an Ames assay with and without hepatic enzyme activation and in a reverse mutation assay with *E. coli*. Tebufenozide technical was negative in a hypoxanthine guanine phophoribosyl transferase (HGPRT) gene mutation assay using Chinese hamster ovary (CHO) cells in culture when tested with and without hepatic enzyme activation. In isolated rat hepatocytes, tebufenozide technical did not induce unscheduled DNA synthesis (UDS) or repair when tested up to the maximum soluble concentration in culture medium. Tebufenozide did not produce chromosome effects *in vivo* using rat bone marrow cells or *in vitro* using Chinese hamster ovary cells (CHO). On the basis of the results from this battery of tests, it is concluded that tebufenozide is not mutagenic or genotoxic.

3. *Reproductive and developmental toxicity*— i. *Reproductive toxicity*. In a 1993 2–generation reproduction study in Sprague-Dawley rats, the parental (systemic) no observable adverse effect levels (NOAEL) was 0.8 and 0.9 mg/kg/day for males and females, respectively. The parental (systemic) lowest observable adverse effect level(LOAEL) was 11.5 and 12.8 mg/kg/day for males and females, respectively, based on decreased body weight, body weight gain, and food consumption in males. An increased incidence and/or severity of splenic pigmentation was also observed. The reproductive NOAEL was 11.5 and 12.8 mg/kg/day for males and females, respectively. The reproductive LOAEL was 154.8 and 171.1 mg/kg/day for males and females, respectively, based on an increase in the number of pregnant females with increased gestation duration and dystocia. Effects in the offspring consisted of decreased number of pups per litter on postnatal days 0 and/or 4.

In a 1995 2–generation reproduction study designed to evaluate parental (systemic) toxicity in rats, the NOAEL was 1.6 and 1.8 mg/kg/day in males and females, respectively. The LOAEL was 12.6 and 14.6 mg/kg/day in males and females, respectively, based on histopathological findings of congestion and extramedullary hematopoiesis in the spleen. The offspring NOAEL was 12.6 and 14.6 mg/kg/day in males and females, respectively. The offspring LOAEL was 126.0 and 143.2 mg/kg/day in males and females, respectively, based on decreased body weight on postnatal days 14 and 21.

ii. *Developmental toxicity*. In a prenatal developmental toxicity study in Sprague-Dawley rats, there was no evidence of maternal or developmental toxicity at the highest dose level of 1,000 mg/kg/day. The maternal and developmental toxicity NOAEL was 1,000 mg/kg/day .

In a prenatal developmental toxicity study conducted in New Zealand white rabbits, tebufenozide was administered in doses of 50, 250, or 1,000 mg/kg/day on gestation days 7–19. No evidence of maternal or developmental toxicity was observed. The maternal and developmental toxicity NOAEL was 1,000 mg/kg/day.

4. *Subchronic toxicity*. i. The NOAEL in a 90–day rat feeding study was 200 ppm (13 mg/kg/day for males, 16 mg/kg/day for females). The LOAEL was 2,000 ppm (133 mg/kg/day for males, 155 mg/kg/day for females). Decreased body weights in males and females was observed at the LOAEL of 2,000 ppm. As part of this study, the potential for tebufenozide to produce subchronic neurotoxicity was investigated. Tebufenozide did not produce neurotoxic or neuropathologic effects when administered in the diets of rats for 3 months at concentrations up to and including the limit dose of 20,000 ppm (NOAEL = 1,330 mg/kg/day for males, 1,650 mg/kg/day for females).

ii. In a 90–day feeding study with mice, the NOAEL was 20 ppm (3.4 and 4.0 mg/kg/day for males and females, respectively). The LOAEL was 200 ppm (35.3 and 44.7 mg/kg/day for males and females, respectively). Decreases in body weight gain were noted in male mice at the LOAEL of 200 ppm.

iii. A 90–day dog feeding study gave a NOAEL of 50 ppm (2.1 mg/kg/day for males and females). The LOAEL was 500 ppm (20.1 and 21.4 mg/kg/day for males and females, respectively). At the LOAEL, females exhibited a decrease in rate of weight gain and males presented an increased reticulocyte.

iv. A 10–week study was conducted in the dog to examine the reversibility of the effects on hematological parameters that were observed in other dietary studies with the dog. Tebufenozide was administered for 6 weeks in the diet to 4 male dogs at concentrations of either 0 or 1,500 ppm. After the sixth week, the dogs receiving treated feed were switched to the control diet for 4 weeks. Hematological parameters were measured in both groups prior to treatment, at the end of the 6–week treatment, after 2 weeks of recovery on the control diet and after 4 weeks of recovery on the control diet. All hematological parameters in the treated/recovery group were returned to control levels indicating that the effects of tebufenozide on the hemopoietic system are reversible in the dog.

v. In a 21–day dermal toxicity study of tebufenozide, rats (6/sex/dose) received repeated dermal administration of either the technical 96.1% product RH–75,992 at 1,000 mg/kg/day (Limit-Dose) or the formulation (23.1% a.i.) product RH–755,992 2F at 0, 62.5, 250, or 1,000 mg/kg/day, 6 hours/day, 5 days/week for 21 days. The high dose was administered as the ''neat'' compound, while the low and mid-dose were prepared as dilutions with distilled water. While the untreated group received no treatment, the solvent control group received a ''2F Formulation Blank'' at a solvent volume equal to that received by the formulation high-dose group.

Under conditions of this study, RH–75,992 Technical or RH–75,992 2F demonstrated no systemic toxicity or dermal irritation at the highest dose tested 1,000 mg/kg/ during the 21 day study.

Based on these results, the NOAEL for systemic toxicity and dermal irritation in both sexes is 1,000 mg/kg/day, the highest dose tested. A LOAEL for systemic toxicity and dermal irritation was not established.

5. *Chronic toxicity/Carcinogenicity*. i. A 1–year feeding study in dogs resulted in decreased red blood cells, hematocrit, and hemoglobin and increased Heinz bodies, reticulocytes, and platelets at the LOAEL of 8.7 mg/kg/day. The NOAEL for systemic toxicity was 1.8 mg/kg/day.

ii. An 18–month mouse carcinogenicity study showed no signs of carcinogenicity at dosage levels up to and including 1,000 ppm, the highest dose tested.

iii. In a combined rat chronic/carcinogenicity study, the NOAEL for chronic toxicity was 100 ppm (4.8 and 6.1 mg/kg/day for males and females, respectively) and the LOAEL was 1,000 ppm (48 and 61 mg/kg/day for males and females, respectively). No carcinogenicity was observed at the dosage levels up to 2,000 ppm (97 mg/kg/day and 125 mg/kg/day for males and females, respectively).

B. Toxicological Endpoints

1. *Acute toxicity*. Toxicity observed in oral toxicity studies were not

attributable to a single dose (exposure). No neurological or systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 mg/kg. No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (Limit-Dose) during gestation to pregnant rats or rabbits. The Agency concludes that this risk is negligible. Therefore, no toxicological endpoint is required for acute toxicity.

2. *Short- and intermediate-term toxicity*. Since there are no registered residential uses, there were no dermal and inhalation endpoints established for tebufenozide. No dermal or systemic toxicity was seen in rats receiving 15 repeated dermal applications of the technical (97.2%) product at 1,000 mg/kg/day (Limit-Dose) as well as a formulated (23% a.i.) product at 0, 62.5, 250, or 1,000 mg/kg/day over a 21–day period. The Agency noted that in spite of the hematological effects seen in the dogs study, similar effects were not seen in rats receiving the compound via the dermal route indicating poor dermal absorption. Also, no developmental endpoints of concern were evident due to the lack of developmental toxicity in either rat or rabbit studies. The Agency concludes that this risk is negligible and no toxicological endpoint is required for short- and intermediate-term toxicity.

3. *Chronic toxicity*. EPA has established the Reference dose (RfD) for tebufenozide at 0.018. This RfD is based on a chronic toxicity study in dogs which found growth retardation, alterations in hematology parameters, changes in organ weights, and histopathological lesions in the bone, spleen and liver at 8.7 mg/kg/day.

4. *Carcinogenicity*. Tebufenozide has been classified as a Group E, ''no evidence of carcinogenicity for humans,'' chemical by the Agency's RfD Committee.

5. *Animal metabolism*. The absorption, distribution, excretion and metabolism of tebufenozide in rats was investigated. Tebufenozide is partially absorbed, is rapidly excreted and does not accumulate in tissues. Although tebufenozide is mainly excreted unchanged, a number of polar metabolites were identified. These metabolites are products of oxidation of the benzylic ethyl or methyl side chains of the molecule. These metabolites were detected in plant and other animal (rat, goat, hen) metabolism studies.

6. *Metabolite toxicology*. Common metabolic pathways for tebufenozide have been identified in both plants (grape, apple, rice and sugar beet) and animals (rat, goat, hen). The metabolic pathway common to both plants and animals involves oxidation of the alkyl substituents (ethyl and methyl groups) of the aromatic rings primarily at the benzylic positions. Extensive degradation and elimination of polar metabolites occurs in animals such that residues are unlikely to accumulate in humans or animals exposed to these residues through the diet.

7. *Endocrine disruption*. The toxicology profile of tebufenozide shows no evidence of physiological effects characteristic of the disruption of the hormone estrogen. Based on structure-activity information, tebufenozide is unlikely to exhibit estrogenic activity. Tebufenozide was not active in a direct *in vitro* estrogen binding assay. No indicators of estrogenic or other endocrine effects were observed in mammalian chronic studies or in mammalian and avian reproduction studies. Ecdysone has no known effects in vertebrates. Overall, the weight of evidence provides no indication that tebufenozide has endocrine activity in vertebrates.

C. Exposures and Risks

1. *From food and feed uses*. Tolerances have been established (40 CFR 180.482) for the residues of tebufenozide, in or on a variety of raw agricultural commodities. Currently established tolerances for residues of tebufenozide are listed under 40 CFR 180.482 and include permanent tolerances for residues in/on pecans (0.01 ppm) and walnuts (0.1 ppm), import tolerances for residues in/on apples (1.0 ppm) and wine grapes (0.5 ppm), and time-limited tolerances on various plant and animal commodities.

The metabolic fate of tebufenozide in animals is currently under review by the Agency, therefore, in this risk assessment, only existing and proposed uses of tebufenozide on raw agricultural commodities are considered as no livestock feed items are derived from berry (crop group 13), cranberry and mint. Risk assessments were conducted by EPA to assess dietary exposures from tebufenozide as follows:

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated (PCT) for assessing chronic dietary risk only if the Agency can make the following findings: 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; that the exposure estimate does not underestimate exposure for any significant subpopulation group; and 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 percent of crop treated as required by the section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

To refine chronic dietary exposure and risk estimates obtained by the use of the Dietary Exposure Evaluation Model (DEEM), which incorporates data from the Continuing Survey of Food Intakes by Individuals (CSFII) for a specified period.

The Agency believes that the three conditions, discussed in section 408 (b)(2)(F) in this unit concerning the Agency's responsibilities in assessing chronic dietary risk findings, have been met. The PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of the PCT, the Agency is reasonably certain that the percentage of the food treated is not likely to be underestimated. The 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 tebufenozide may be applied in a particular area.

i. *Acute exposure and risk*. No endpoints were selected for acute dietary exposure. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. Toxicity observed in oral toxicity studies were not attributable to a single dose (exposure). No neurological or systemic toxicity was observed in rats given a single oral administration of tebufenozide at 0, 500, 1,000 or 2,000 mg/kg. No maternal or developmental toxicity was observed following oral administration of tebufenozide at 1,000 mg/kg/day (Limit-Dose) during gestation to pregnant rats or rabbits. This risk assessment is not required. The Agency considers acute exposure/risk to be negligible.

ii. *Chronic exposure and risk.* The residue of concern for tebufenozide in plant and animal commodities is the parent compound per se. The RFD used for the chronic dietary analysis is 0.018 mg/kg/day. In performing chronic dietary exposure and risk analysis, the Agency used the Dietary Exposure Evaluation Model (DEEM), which incorporates data from the CSFII for the period, 1989 to 1992. Some refinement to the dietary exposure estimates was made through the use of percent-of-crop-treated data. The resulting Anticipated Residue Contributions (ARC) for the U.S. population and various DEEM population subgroups can be determined. Of these subgroups, the highest exposure is projected for children ages 1–6 years, whose chronic intake is estimated as 73% of the RfD. Percent RFD values for other subgroups include: U.S. population for the 48 states (36), all infants less than 1 year old (52) and children 7 to 12 years old (46). Generally, in the absence of additional safety factors, the Agency is not concerned with exposures less than 100% of the RfD. Thus, for all populations, the chronic human health risk from exposure to tebufenozide in foods is below the Agency's level of concern.

2. *From drinking water.* Available data suggest that tebufenozide ranges from moderately persistent to persistent and is mobile; thus, tebufenozide could potentially leach to ground water and runoff to surface water under certain environmental conditions. There is no Maximum contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the ''Pesticides in Groundwater Database (EPA 734–12–92–001, September 1992). The Agency concludes that there is reasonable certainty that no harmful exposure exist from drinking water.

Chronic exposure and risk. Monitoring data are not available to assess the human exposure to tebufenozide via drinking water. In lieu of these data, the Agency has calculated the Tier I estimated concentrations in drinking water (DWECs) for tebufenozide using Generic expected environmental concentration (GENEEC) (surface water) and Screening concentration In Ground Water (SCI-GROW) (ground water) for use in the human health risk assessment. According to Agency records, the maximum application rate for tebufenozide is 0.25 lb a.i. x 5 applications per year on pecans. This application scenario was used to calculate the DWECs for the human health risk assessment due to the wide range of aerobic soil half-life of 6 (California Loam) and 729 (worst case soil with low microbial activity) days. For surface water, the chronic (56–day) values are 13.3 parts per billion (ppb) and 16.5 ppb for the half-lives of 66 and 729 days, respectively. The ground water screening concentrations are 0.16 ppb and 1.04 ppb for the half-lives of 66 and 729 days, respectively. These values represent upper-bound estimates of the concentrations that might be found in surface and ground water due to the use of tebufenozide on pecans.

In performing this risk assessment, the Agency has calculated drinking water levels of concern (DWLOCs) for each of the DEEM population subgroups. Within each subgroup, the population with the highest estimated exposure was used to determine the maximum concentration of tebufenozide that can occur in drinking water without causing an unacceptable human health risk. As a comparison value, the Agency has used the 16.5 ppb value in this risk assessment, as this represents a worst-case scenario. The DWLOCs for tebufenozide are above the DWEC of 16.5 ppb for all population subgroups. Therefore, the Agency believes that the human health risk from exposure to tebufenozide through drinking water is not likely to exceed the Agency's level of concern.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary no observed adverse effect levels (NOAEL's)) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause tebufenozide to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with tebufenozide in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. *From non-dietary exposure.* Tebufenozide is not currently registered for use on residential non-food sites. The Agency concludes that there are no chronic, short- or intermediate-term non-dietary exposure.

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

EPA does not have, at this time, available data to determine whether tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebufenozide 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. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Since no acute toxicity endpoints were identified for tebufenozide, the Agency concludes that acute aggregate risk from the use of the pesticide will not pose an unacceptable risk to human health.

2. *Chronic risk.* In aggregating risks, the Agency has considered only dietary exposure. Due to lack of endpoints and/or relevant use registrations, assessment

of exposure via non-dietary routes (e.g., dermal, inhalation, non-dietary oral) are not required. Using the Anticipated Residue Contribution exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebufenozide from food will utilize 36% of the RFD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years old) at 73% of the RFD and is discussed below. EPA generally has no concern for exposures below 100% of the RFD because the RFD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health.

Since the dietary risk for tebufenozide is below the Agency's level of concern and the estimated concentrations of tebufenozide in drinking water are below EPA's drinking water level of concern, the Agency believes that establishment of the requested tolerances for tebufenozide will not pose an unacceptable aggregate health risk to infants, children, or adults.

3. *Short- and intermediate-term risk*. In aggregating risks, the Agency has considered only dietary exposure. Due to lack of endpoints and/or residential use registrations, the agency concludes that short- and intermediate-term risk via non-dietary routes (e.g., dermal, inhalation, non-dietary oral) will not pose an unacceptable risk to human health.

4. *Aggregate cancer risk for U.S. population*. Tebufenozide is classified as a Group E chemical (no evidence of carcinogenicity in humans). The Agency concludes that the aggregate cancer risk for the U. S. population is not impacted by the establishment of these proposed tolerances.

5. *Determination of safety*. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tebufenozide residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of tebufenozide EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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 pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*. Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits. See discussion under Unit II.A. of this preamble.

iii. *Reproductive toxicity study*. Multi-generation reproduction toxicity studies in rats showed no increased sensitivity in pups as compared to adults and offsprings. See discussion under Unit II.A. of this premble.

iv. *Pre- and post-natal sensitivity*. The Agency determined that available data provide no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to tebufenozide.

v. *Conclusion*. The Agency believes that reliable data support using the standard hundredfold safety factor for assessing sensitivity to residues of tebufenozide and that an additional tenfold margin of safety for infants and children is not warranted. There is a complete toxicity database for tebufenozide and exposure data are complete or estimated based on data that reasonably account for potential exposures.

2. *Acute risk*. No acute toxicity endpoints for tebufenozide have been identified and this risk assessment is not required.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to tebufenozide from food only will utilize 52% and 73% of the RfD for all infants (<1 yr old) and children (1–6 yr old), respectively. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure from tebufenozide in food, drinking water and from non-dietary exposure to exceed the Agency level of concern.

4. *Short- or intermediate-term risk*. Since no short- or intermediate-term toxicological endpoints were identified by the Agency for tebufenozide and there are no registered uses that would result in residential exposure, the Agency concludes that this risk criterion is negligible and the subject tolerances adequately protect the safety of infants and children.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to tebufenozide residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of tebufenozide in plants (grapes, apples, rice and sugar beets) is adequately understood for the purpose of these tolerances. The metabolism of tebufenozide in all crops was similar and involves oxidation of the alkyl substituents of the aromatic rings primarily at the benzylic positions. The extent of metabolism and degree of oxidation are a function of time from application to harvest. In all crops, parent compound comprised the majority of the total dosage. None of the metabolites were in excess of 10% of the total dosage.

Since there are no animal feed items associated with the berry crop group, cranberry and mint tops (leaves and stems), a discussion of the qualitative nature of the residue in animals is not germane to this action.

B. Analytical Enforcement Methodology

High performance liquid chromatographic (HPLC) analytical methods using ultraviolet (UV) detection have been validated for blueberries, raspberries, cranberries, and mint foliage. The methods involve extraction by blending with solvents, purification of the extracts by liquid-liquid partitions and final purification of the residues using solid phase extraction column chromatography. The limits of quantitation is 0.005 ppm for blueberries, 0.01 ppm for mint foliage, and raspberries, 0.02 ppm for mint oil, and 0.05 ppm for cranberries.

C. Magnitude of Residues

Field residue trials were conducted with a 70WP formulation in geographically representative regions of the United States. A total of eight field residue trials were conducted in blueberries. The average blueberry residue value from all trials was 0.81 ppm.

A total of six field residue trials were conducted in cranberries. The average cranberry residue value from all trials was 0.30 ppm.

A total of five field residue trials were conducted in mint. The average mint foliage residue value from all trials was 7.11 ppm. Mint oil was prepared from foliage from two residue trials. The average oil residue was 0.23 ppm. Since residues do not concentrate in oil, a tolerance is not needed.

A total of five field residue trials were conducted in raspberries. The average raspberry residue value from all trials was 0.62 ppm.

D. International Residue Limits

There are currently no CODEX, Canadian or Mexican maximum residue levels (MRLs) established for tebufenozide in blueberries, cranberries or mint, therefore no harmonization issues are required for this action.

IV. Conclusion

Therefore, the tolerance is established for residues of tebufenozide in the berry crop group at 3.0 ppm, cranberry at 1.0 ppm, and mint at 10.0 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by June 7, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300828] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive

Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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 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**. This 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: March 24, 1999.

James Jones,

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. 346a and 371.

2. In § 180.482, by revising the introductory text to paragraph (a) and by adding alphabetically the following entries to the table in paragraph (a).

§ 180.482 Tebufenozide; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide, in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * *	*
Berry (crop group 13)	3.0
Cranberry	1.0
* * * *	*
Peppermint, tops	10.0
Spearmint, tops	10.0

* * * * *

[FR Doc. 99–8341 Filed 4–6–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300823; FRL–6070–3]

RIN 2070–AB78

Trichoderma harzianum KRL-AG2 (ATCC #20847) or Strain T–22; Revision of Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide active ingredient *Trichoderma harzianum* KRL-AG2 (ATCC #20847) also known as strain T–22 when applied/used as seed treatments, on cuttings and transplants, or as soil