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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0749; FRL-9942-23]

Clofentezine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clofentezine in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0749, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0749 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0749, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of February 11, 2015 (80 FR 7559) (FRL-9921-94), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8312) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.446 be amended by establishing tolerances for residues of the acaricide clofentezine in or on avocado at 0.3 parts per million (ppm); papaya at 0.3 ppm; fruit, pome, group 11–10 at 0.5 ppm; cherry, subgroup 12–12A at 1.0 ppm; peach, subgroup 12–12B at 1.0 ppm; and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1.0 ppm. Upon the approval of the aforementioned tolerances, IR–4 proposed that the existing tolerances for apple at 0.5 ppm; pear at 0.5 ppm; cherry at 1.0 ppm; nectarine at 1.0 ppm; peach at 1.0 ppm; and grape at 1.0 ppm be removed as unnecessary. That document referenced a summary of the petition prepared by Makhteshim Agan of North America, the registrant, which is available in the docket, *http://www.regulations.gov*. One comment was received in response to the notice of filing, however it related to a different chemical.

III. Aggregate Risk Assessment and Determination of Safety

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

and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for clofentezine including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clofentezine 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.

Subchronic and chronic studies indicate the liver is the primary target organ for clofentezine with secondary effects on the thyroid. Body weight and body weight gain were decreased whereas liver weights were increased and hepatocellular enlargement was reported along with other observations (increases in plasma cholesterol and triglyceride levels). The induction of the liver enzyme, uridine diphosphate glucuronyltransferase (UDPGT) and the subsequent increase in the metabolism and the excretion of the thyroid hormone T4 reduced the availability of T4 required for the general metabolism and the maintenance of homeostasis. The decreased levels of plasma T4 resulted in the stimulation of the thyroid by the pituitary gland to raise the plasma T4 levels. Thyroid changes in the form of colloid depletion, thyroid follicular cell hypertrophy and hyperplasia were observed as a means to regain the homeostasis.

Two pre-natal developmental toxicity studies are available, one in the rat and one in the rabbit. No evidence (quantitative or qualitative) of increased susceptibility was seen in either study (developmental NOAELs were set at or above the limit dose for both studies). There was no evidence (quantitative or qualitative) of increased susceptibility seen following pre-and/or post-natal exposure in rats for 2-generations in the reproduction study (NOAEL set at the highest dose tested).

Clofentezine does cause thyroid tumors in male rats after long-term high exposure resulting in progressive effects on the thyroid that leads to hyperplasia and eventual tumor formation. No mechanism or mode of action has been submitted to the Agency at this time for clofentezine. As a result, clofentezine has been classified as a possible human carcinogen based on male rat thyroid follicular cell adenoma and/or carcinoma combined tumor rates. The Q_1^* value for use in clofentezine risk assessment using the ¾ inter species scaling factor is 3.76×10^{-2} $(mg/kg/day)^{-1}$. Clofentezine is not considered to be a mutagen.

Specific information on the studies received and the nature of the adverse effects caused by clofentezine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled "Clofentezine." Human-Health Risk Assessment to Support a Section 3 Registration Request to Add New Uses on Avocado and Papaya, and New Uses for Pome Fruit Group 11-10, Cherry sub-group 12-12A, Peach sub-group 12-12B, and Small Fruit Vine Climbing except Fuzzy Kiwifruit Subgroup 13-07F based on Existing Tolerances on Representative Commodities" on page 38 in docket ID number EPA-HQ-OPP-2014-0749.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for clofentezine used for human risk assessment is shown in Table 1 of this Unit.

Table 1. --Summary of Toxicological Doses and Endpoints for Clofentezine for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	No appropriate endpoint was identified including developmental toxicity studies in rats and rabbits.		
Chronic dietary (All populations)	NOAEL= 1.25 mg/kg/day UF_A = 10x	Chronic RfD = 0.013	1-year chronic dog study- LOAEL = 25 mg/kg based on

	UF_H = 10x FQPA SF = 1x	mg/kg/day cPAD = 0.013 mg/kg/day	increased liver weights, hepatocellular enlargement, and increased serum cholesterol, triglycerides and alkaline phosphatase levels
Cancer (Oral, dermal, inhalation)	Classification: possible human carcinogen (classification of C), Q* using the ¾ interspecies scaling factor is 3.76×10^{-2} $(mg/kg/day)^{-1}$		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to clofentezine, EPA considered exposure under the petitioned-for tolerances as well as all existing clofentezine tolerances in 40 CFR 180.446. EPA assessed dietary exposures from clofentezine in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for clofentezine; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, a partially refined chronic dietary exposure and risk assessment was

performed that directly incorporated average field trial residues and used percent crop treated information.

iii. *Cancer*. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier non cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that clofentezine should be classified as possible human carcinogen and a linear approach has been used to quantify cancer risk. Cancer risk was quantified using the same estimates as discussed in Unit III.C.1.ii.

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

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

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

Average percent crop treated estimates were used in the chronic and cancer dietary risk assessments for the following crops that are currently registered for clofentezine: Almonds: 5%; apples: 2.5%; apricots: 2.5%; cherries: 5%; grapes: 1%; nectarines: 5%; peaches: 5%; pears: 5%; and walnuts: 5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, 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 reliable information on the regional consumption of food to which clofentezine may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for clofentezine in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clofentezine. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of clofentezine for chronic exposures for non-cancer and cancer assessments are estimated to be 0.062 parts per billion (ppb) for surface water and 0.041 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic and cancer dietary risk assessment, the water concentration of value 0.062 ppb was used to assess the contribution to drinking water.

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

Clofentezine is not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found clofentezine to share a common mechanism of toxicity with any other substances, and clofentezine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clofentezine does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account

for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Two pre-natal developmental toxicity studies were available, one in the rat and one in the rabbit. No evidence (quantitative or qualitative) of increased susceptibility was seen in either study (developmental NOAELs were set at or above the limit dose for both studies). There was no evidence (quantitative or qualitative) of increased susceptibility seen following pre-and/or post-natal exposure in rats for 2-generations in the reproduction study (NOAEL set at the highest dose tested).

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for clofentezine is complete.

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

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

iv. There are no residual uncertainties identified in the exposure databases. The chronic and cancer analyses incorporated anticipated residues (average residues from available field trial data) for all registered and proposed commodities and the latest PCT data available. The

highest estimated drinking water concentrations of clofentezine were incorporated directly into the chronic and cancer assessments. These assessments will not underestimate the exposure and risks posed by clofentezine.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, clofentezine 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 chronic exposure to clofentezine from food and water will utilize <1% of the cPAD for all population groups. There are no residential uses for clofentezine.

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

A short- and intermediate-term adverse effect was identified; however, clofentezine is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-

term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for clofentezine.

4. *Aggregate cancer risk for U.S. population*. Using the exposure assumptions described in this unit for cancer exposure, EPA has concluded that by applying the Q_1* of 3.76 x 10^{-2} mg/kg/day to the exposure value results in a cancer risk estimate of 3.8 x 10^{-7} to the general U.S. population. EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1 x 10^{-6}) or less to be negligible.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography (HPLC)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no Codex MRLs for residues on avocado and papaya.

The U.S. pome fruit tolerance of 0.5 ppm is harmonized with the Codex MRL.

The U.S. tolerance is 1.0 ppm in/on stone fruit (12-12A and 12-12B). The Codex MRL for stone fruit is 0.5 ppm. The clofentezine residues in/on representative stone fruit crops, cherry and peach, from the submitted U.S. field trial data are greater than 0.5 ppm and setting the tolerances for 12-12A and 12-12B at 0.5 ppm to harmonize with Codex could result a tolerance exceedance for U.S. growers. Therefore, the U.S. tolerance cannot be harmonized with Codex MRL for stone fruit at this time.

The U.S. tolerance of 1.0 ppm for the crop subgroup fruit, small, vine climbing, except fuzzy kiwifruit, 13-07F does not harmonize with the Codex MRL of 2.0 ppm. The petitioner requested a 13-07F subgroup tolerance at 1.0 ppm, which would maintain the existing tolerance on grapes at 1.0 ppm consistent with the MRL at 1.0 ppm maintained by several countries including Japan and Korea. EPA is not harmonizing with Codex in order to maintain MRL harmony with several other countries to avoid potential export issues.

V. Conclusion

Therefore, tolerances are established for residues of clofentezine in or on avocado at 0.30 ppm; papaya at 0.30 ppm; fruit, pome, group 11–10 at 0.50 ppm; cherry, subgroup 12–12A

at 1.0 ppm; peach, subgroup 12–12B at 1.0 ppm; and fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F at 1.0 ppm. In addition, the existing tolerances for apple at 0.5 ppm; pear at 0.5 ppm; cherry at 1.0 ppm; nectarine at 1.0 ppm; peach at 1.0 ppm; and grape at 1.0 ppm are removed as unnecessary.

VI. Statutory and Executive Order Reviews

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

Since tolerances and exemptions that are established on the basis of a petition under 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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section

408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action 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: May 31, 2016.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In § 180.446, in the table in paragraph (a)(1):

a. Remove the entries for “Apple”, “Cherry”, “Grape”, “Nectarine”, “Peach”, and “Pear”; and

b. Add alphabetically the entries for “Avocado”, “Cherry, subgroup 12-12A”, “Fruit, pome, group 11-10”, “Fruit, small, vine climbing, except fuzzy kiwifruit, Subgroup 13-07F”, “Papaya”, and “Peach, subgroup 12-12B”.

The additions read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) *General*. (1) * * *

Commodity	Parts per million
* * * * * * *	
Avocado	0.30
Cherry, subgroup 12-12A	1.0
Fruit, pome, group 11-10	0.50
Fruit, small, vine climbing, except fuzzy kiwifruit, Subgroup 13-07F	1.0
* * * * * * *	
Papaya	0.30
Peach, subgroup 12-12B	1.0
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