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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2014-0574; FRL-9933-00]**

**Halosulfuron-methyl; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of halosulfuron-methyl in or on the pome fruit group 11–10 and a tolerance with regional registration for residues of halosulfuron-methyl in or on the small vine climbing fruit, except fuzzy kiwifruit, subgroup 13–07F. 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-2014-0574, 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](mailto: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](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-2014-0574 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-2014-0574, 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 4E8297) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, Suite 201 W, 500 College Road East, Princeton, NJ 08540. The petition requested that 40 CFR 180.479 be amended by establishing tolerances for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino sulfonyl]-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the raw agricultural commodities: Fruit, pome, group 11-10 at 0.05 parts per million (ppm), and fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm (associated with a regional registration). That document referenced a summary of the petition prepared by the Canyon Group, c/o Gowan Company, the registrant, which is available in the docket, <http://www.regulations.gov>. No comments were received on the notice of filing.

Based upon available data, EPA is establishing tolerances as requested.

## **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 halosulfuron-methyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with halosulfuron-methyl 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.

With repeated dosing, the available data on halosulfuron-methyl did not demonstrate a target organ or tissue in any of the test animals. Reduction in body weight was seen in the 90-day and 1-year oral toxicity studies in dogs. Reduced body weights were also seen in rat studies at higher dose levels than those seen in dogs. An effect on the hematological parameters was detected in the dog studies, but the magnitude of changes was slight and the effect was considered to be marginal. Thus, the slight hematological changes were not considered to be adverse.

In the prenatal developmental toxicity study in rats, increases in resorptions, soft tissue (dilation of the lateral ventricles) and skeletal variations, and decreases in body weights were seen in the fetuses compared to clinical signs and decreases in body weights and food consumption in the maternal animals at a similar dose level. In the rabbit developmental toxicity study, increases in resorptions and post-implantation losses and decreases in mean litter size were observed in the presence of decreases in body weight and food consumption in maternal animals. The fetal effects seen in developmental toxicity studies in rats and rabbits represented a qualitative increase in susceptibility. However, a clear no-observed-adverse-effect-level (NOAEL) for these effects was established in both rat and rabbit developmental toxicity studies. No quantitative susceptibility was found in studies following pre-and/or post-natal exposures. Halosulfuron-methyl did not produce any effects on reproductive parameters in the 2-generation reproduction study in rats. No neurotoxic effects were observed in the acute or subchronic neurotoxicity studies up to 2,000 mg/kg or 760 mg/kg/day, respectively. In addition, no adverse effect was found in a 21-day dermal toxicity study at doses up to the limit dose (1,000 mg/kg/day).

Halosulfuron-methyl is negative for mutagenicity in a battery of genotoxicity studies and is classified as “not likely to be carcinogenic to humans” based on lack of evidence for carcinogenicity in mice and rats following long-term dietary administration.

Specific information on the studies received and the nature of the adverse effects caused by halosulfuron-methyl as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Halosulfuron-Methyl. Human Health Risk Assessment for a Proposed Use on Pome Fruit Crop Group 11-10 and Small Fruit Vine Climbing Subgroup, Except Fuzzy Kiwifruit, Subgroup 13-07F” at page 28 in docket ID number EPA-HQ-OPP-2014-0574.

### *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://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for halosulfuron used for human risk assessment is discussed in Unit III. B. of the final rule published in the **Federal Register** of December 3, 2012 (77 FR 71555) (FRL-9370-6). However, there is one change to the prior toxicity endpoint and point of departure selections for halosulfuron-methyl discussed in the 2012 document. The previous toxicity endpoint for dermal exposure assessments was based on the results of a 21-day dermal toxicity study, where the no observed effect level (NOEL) and lowest observed effect level (LOEL) were established at 100 and 1,000 mg/kg/day, respectively. The LOEL was based on "total body weight gains in males." However, following a reevaluation of this study according to the current evaluation standard, there was only 4%

reduction in absolute body weight in the affected 1,000 mg/kg/day males. This reduction was not considered to be adverse and no other adverse effect was reported in this study. No LOAEL could be established, and the NOAEL was 1,000 mg/kg/day. Based on this re-evaluation, halosulfuron-methyl did not cause adverse effects at the limit dose (1,000 mg/kg/day), and no toxicity endpoint could be established for the dermal exposure scenario. In addition, no quantitative susceptibility was found in studies following pre-and/or post-natal exposures. Hence, no dermal exposure assessment was necessary.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to halosulfuron-methyl, EPA considered exposure under the petitioned-for tolerances as well as all existing halosulfuron-methyl tolerances in 40 CFR 180.479. EPA assessed dietary exposures from halosulfuron-methyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for halosulfuron-methyl. Exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID). This software uses 2003-2008 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA. As to residue levels in food, EPA assumed tolerance-level residues and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that halosulfuron-methyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for halosulfuron-methyl. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for halosulfuron-methyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of halosulfuron-methyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of halosulfuron-methyl for acute exposures are estimated to be 59.2 parts per billion (ppb) for surface water and 0.065 ppb for ground water and for chronic exposures are estimated to be 59.2 ppb for surface water and 0.065 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 59.2 ppb was used to assess the contribution to drinking water. For chronic dietary risk

assessment, the water concentration of value 59.2 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).

Halosulfuron-methyl is currently registered for use by residential handlers on residential turf. EPA re-assessed residential exposure for aggregate risk assessment reflecting the removal of the dermal POD. EPA assessed short-term (1-30 days) exposure to halosulfuron-methyl for residential handlers (inhalation exposure) and children 1 to < 2 years old (post-application incidental oral exposures).

The residential exposure scenario used in the adult aggregate assessment reflects inhalation exposure from mixing/loading/applying halosulfuron-methyl via backpack sprayer or manually pressurized handwand to turf.

The residential exposure scenario used in the children 1 to <2 years old aggregate assessment reflects hand-to-mouth incidental oral exposures from post-application exposure to treated turf.

Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 halosulfuron-methyl to share a common mechanism of toxicity with any other substances, and halosulfuron-methyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that halosulfuron-methyl 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://www.epa.gov/pesticides/cumulative>.

#### *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.* There was no quantitative evidence of increased susceptibility following pre- and/or post-natal exposure to halosulfuron-methyl. Qualitative susceptibility was seen in the prenatal developmental toxicity study in rats and in rabbits; however, this qualitative susceptibility was of low concern because (1) in both studies, there were clear NOAELs/ LOAELs for developmental and maternal toxicities; (2) the developmental effects were seen in the presence of maternal toxicity; and (3) the effects were only seen at the

high dose levels. In rats, the developmental effects were seen at a dose (750 mg/kg/day) which was approaching the limit-dose (1,000 mg/kg/day). Furthermore, the PODs for risk assessment are protective of the effects which occur at high doses.

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 halosulfuron-methyl is considered complete.
- ii. There is no indication that halosulfuron-methyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There was no quantitative evidence of increased susceptibility following pre- and/or post-natal exposure and the qualitative susceptibility observed in the developmental toxicity studies in rats and rabbits was of low concern for the reasons outlined in section III.D.2.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to halosulfuron-methyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by halosulfuron-methyl.

#### *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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to halosulfuron-methyl will occupy <1% of the aPAD for females 13-49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to halosulfuron-methyl from food and water will utilize 5.7% of the cPAD for children 1-2 years old, the population subgroup receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of halosulfuron-methyl is not expected.

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

Halosulfuron-methyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to halosulfuron-methyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 25,000 for adults and 1,800 for children 1 to < 2 years old. Because EPA's level of concern for halosulfuron-methyl is a MOE of 100 or below, these MOEs are not of concern.

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

An intermediate-term adverse effect was identified; however, halosulfuron-methyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for halosulfuron-methyl.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, halosulfuron-methyl is not expected to pose a cancer risk to humans.

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

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Adequate enforcement methodology (gas chromatography (GC) thermionic-specific detection (TSD, nitrogen specific)) 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.

The Codex has not established a MRL for halosulfuron-methyl for any of the crops covered by this Final Rule.

## **V. Conclusion**

Therefore, a tolerance is established for residues of halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonylamino sulfonyl]-3-chloro-1-methyl-1*H*-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the fruit, pome, group 11-10 at 0.05 ppm, and a tolerance with regional registration is established for fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.05 ppm. In addition, the existing tolerance for the commodity "Apple" in paragraph (a)(2) of §180.479 is removed since it is covered by the newly established fruit, pome, group 11-10 tolerance.

## **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: September 4, 2015.

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 § 180.479:

a. Remove the entry for “Apple” from the table in paragraph (a)(2);

b. Add alphabetically the entry for “Fruit, pome, group 11-10” to the table in paragraph (a)(2), and

c. Revise paragraph (c).

The additions and revision read as follows:

**§ 180.479 Halosulfuron-methyl; tolerances for residues.**

(a) \* \* \*

(2) \* \* \*

Commodity	Parts per million
* * *	* * *
Fruit, pome, group 11-10	0.05
* * *	* * *

\* \* \*

(c) *Tolerances with regional registrations.* Tolerances with regional registrations are established for residues of the herbicide halosulfuron-methyl, methyl 5-[(4,6-dimethoxy-2-pyrimidiny)amino]carbonylamino]sulfonyl]-3-chloro-1-methyl-1H-pyrazole-4-carboxylate, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only halosulfuron-methyl.

Commodity	Parts per million
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.05

\* \* \* \* \*

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