



This document is scheduled to be published in the Federal Register on 10/11/2016 and available online at <https://federalregister.gov/d/2016-24492>, and on FDsys.gov

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0285; FRL-9945-37]

Mandestrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of S-2200 (here after referred to within this document as mandestrobin) in or on multiple commodities which are identified and discussed later in this document. Valent U.S.A., Corporation 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-2014-0285, 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 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-2014-0285 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-2014-0285, 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 Tolerances

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDC section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8224) by Valent U.S.A., Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, California, 94596. The petition requested that 40 CFR 180 be amended by establishing tolerances for residues of the fungicide mandestrobin, (2-[(2,5-dimethylphenoxy)methyl]- α -methoxy-N-methyl-benzeneacetamide), in or on small fruit vine climbing except fuzzy kiwifruit crop subgroup 13-07F, fruit at 5 parts per million (ppm), juice at 7 ppm, and dried fruit at 10 ppm; low growing berry subgroup 13-07G, fruit at 3 ppm; and rapeseed crop subgroup 20A, seed at 0.6 ppm. That document referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA lowered the requested tolerance levels for grape, raisin. Tolerances for juice and dried fruit are not required. At this time, EPA is not granting a tolerance for rapeseed crop group 20A. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDC 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 FFDC 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 FFDC 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 mandestrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mandestrobin as 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 main target organs for mandestrobin toxicity in all mammalian species tested are the liver and gall bladder with effects ranging from hepatocyte hypertrophy and increased liver weight (usually considered not adverse in the absence of corroborative hepatic enzyme changes or histopathology) to centrilobular degeneration, hepatocyte and bile duct pigmentation, periductular inflammation and gall stones. Dogs were more sensitive to the adverse liver effects than rats; mice showed only non-adverse liver effects.

Thyroid effects were observed in rats (increased weight, follicular cell hypertrophy, decreased serum hormone levels) at higher doses than early signs of liver effects suggesting that effects in the thyroid may be secondary to liver effects.

Gonadal effects were observed at higher doses than the liver effects, and were more evident in dogs (immature prostate and/or testes, low sperm count, immature ovaries, decrease uterus weight) but equivocal and/or not adverse in rats. Gonadal effects did not affect the reproductive capacity of rats.

No developmental effects were observed in rats or rabbits, and no adverse reproductive, immunotoxic, or neurotoxic effects were observed in any of the studies. No adverse effects were seen in a route-specific dermal toxicity study. Mutagenicity studies were negative. There is no evidence of carcinogenicity because there was no increase in tumor incidence in rat and mouse long-term studies. The Agency classified mandestrobin as “not likely to be a human carcinogen”.

Specific information on the studies received and the nature of the toxic effects caused by mandestrobin 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: Mandestrobin. Human Health Risk Assessment for Proposed Foliar Uses on Small Fruit Vine Climbing (Except Fuzzy Kiwifruit) (Subgroup 13-07F), Low Growing Berry (Subgroup 13-07G) (Except Cranberry), Turf, and Seed Treatment Uses on Corn (Field, Pop, Sweet), Sorghum Grain (Milo), and Legume Vegetables (Crop Group 6C) (Except Cowpea and Field Pea) at page 18 in docket ID number EPA-HQ-OPP-2014-0285.

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 mandestrobin used for human risk assessment is shown in Table 1.

Table 1.--Summary of Toxicological Doses and Endpoints for Mandestrobin 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 (General population including infants and children) | No toxicity was observed that could be attributed to a single exposure. | | |
| Chronic dietary (All populations) | NOAEL= 92 mg/kg/day | Chronic RfD = 0.92 mg/kg/day cPAD = 0.92 mg/kg/day | Chronic Toxicity- Dog LOAEL = 181 mg/kg/day based on incidence of liver centrilobular degeneration, hepatocyte hypertrophy, hepatocyte pigment, and elevated serum ALP and ALT. |
| Incidental Oral Short-Term (1-30 days) and Intermediate-Term | UF _A = 10x | LOC for MOE | <i>Additional supportive study:</i> |

| | | | |
|---|---|-------|---|
| (1-6 months) | | < 100 | Subchronic Toxicity – Dog NOAEL = 91 mg/kg/day |
| Inhalation Short-Term (1-30 days) and Intermediate-Term (1-6 months) | UF _H = 10x FQPA SF = 1x | | LOAEL = 268 mg/kg/day based on incidence of liver centrilobular degeneration in both sexes and elevated serum ALP in females. |
| Dermal Short-Term (1-30 days) and Intermediate-Term (1-6 months), all populations | No hazard was identified for dermal exposure; therefore a quantitative dermal assessment is not needed. | | |
| Cancer (Oral, dermal, inhalation) | Not likely a human carcinogen. | | |

NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. ALP = alkaline phosphatase. ALT = alanine aminotransferase.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mandestrobin, EPA considered exposure from the petitioned-for tolerances only as there are no existing mandestrobin tolerances. EPA assessed dietary exposures from mandestrobin 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 mandestrobin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. 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, 100 percent crops treated (PCT), and default processing factors for all proposed commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that mandestrobin 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 mandestrobin. 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 mandestrobin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mandestrobin. 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 Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of mandestrobin for chronic exposures for non-cancer assessments are estimated to be 38 parts per billion (ppb) for surface water and 3.9 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 38 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). Mandestrobin is currently proposed for use on turf at golf courses, sod farms, recreational/athletic fields, and residential/commercial lawns. EPA assessed residential exposure using the following scenarios. For residential handlers, the worst-case scenario was determined to be short-term inhalation exposures to adults from mixing, loading, and applying mandestrobin to turf. For post-application exposures, the worst-case scenario was determined to be short-term post-application incidental oral exposure to children from hand-to-mouth activities on turf. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

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 mandestrobin to share a common mechanism of toxicity with any other substances, and mandestrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that mandestrobin 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.* There is no evidence of sensitivity/susceptibility in the offspring following mandestrobin exposure, including developmental toxicity studies in rats and rabbits, and a 2-generation reproductive study in rats. Although pup weights were decreased in the rat reproductive study, this change was observed at the same dose as maternal liver effects, which included periportal/bile duct pigment, periductular inflammatory cell infiltration, and bile duct proliferation.

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 the mandestrobin tolerances being established is complete.

ii. There is no indication that mandestrobin 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 mandestrobin 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 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 mandestrobin 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 mandestrobin.

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, mandestrobin 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 mandestrobin from food and water will utilize 2.6% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of mandestrobin 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). Mandestrobin 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 mandestrobin.

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 19,000 for adults and 2,900 for children 1-2 years old. Because EPA's level of concern for mandestrobin 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). Since the short- and intermediate-term PODs are the same and short-term exposure estimates are greater than their intermediate-term counterparts, the short-term aggregate risk assessment is protective of the intermediate-term aggregate exposure. Therefore a separate intermediate-term aggregate assessment is not necessary.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, mandestrobin 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 mandestrobin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (RM-48C-2A, which uses high performance liquid chromatography with tandem mass spectrometry (HPLC/MS-MS)) 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 FDCA 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, FDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for mandestrobin.

C. Revisions to Petitioned-For Tolerances

Based on an analysis of residue levels from crop field trials, EPA is establishing a tolerance for grape, raisin at 7 ppm, rather than the requested level of 10 ppm. The highest average field trial (HAFT) for grape and the processing factor for raisins supports a 7 ppm tolerance.

The petitioner requested tolerances for juice and dried fruit covered under crop subgroup 13-07F, small fruit. The available processing data for grape, the representative commodity for subgroup 13-07F, indicates that residues in juice will be covered by the tolerance being established for subgroup 13-07F. At this time, the Agency is not aware of any dried commodities derived from crops in subgroup 13-07F other than raisin, for which the Agency is establishing a separate tolerance, as indicated in the paragraph above.

After the petitioner submitted its petition for tolerances on subgroup 13-07G, it withdrew its request to include cranberry; therefore, the Agency is only establishing tolerances for subgroup 13-07G, except cranberry.

At this time, EPA is not establishing a tolerance for rapeseed subgroup 20A. The full three year freezer storage stability data (OPPTS guideline number 860.1380) for crop field trial data are needed to support tolerances. These data are required since samples from crop field trials are often stored for a number of years prior to analysis. Therefore, it is a requirement to ensure that the residues that are found multiple years later are actually representative of the residues that would be found on the day of harvest. This ensures that the Agency has set a tolerance high enough to cover residues expected in/on the commodity of interest. Accordingly, EPA has not made a determination with regard to this petitioned-for tolerance at this time.

V. Conclusion

Therefore, tolerances are established for residues of mandestrobin, 2-[(2,5-dimethylphenoxy)methyl]- α -methoxy-N-methylbenzeneacetamide, in or on berry, low growing,

subgroup 13-07G, except cranberry at 3.0 ppm; fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 5.0 ppm; grape, raisin at 7.0 ppm.

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 tolerances 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 30, 2016.

Jack E. Housenger,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. Add §180.690 to subpart C to read as follows:

§ 180.690 Mandestrobin; tolerances for residues.

(a) *General.* Tolerances are established for residues of mandestrobin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only mandestrobin, 2-[(2,5-dimethylphenoxy)methyl]- α -methoxy-N-methylbenzeneacetamide.

| Commodity | Parts per million |
|---|-------------------|
| Berry, low growing, subgroup 13-07G, except cranberry | 3.0 |
| Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F | 5.0 |
| Grape, raisin | 7.0 |

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

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

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

[FR Doc. 2016-24492 Filed: 10/7/2016 8:45 am; Publication Date: 10/11/2016]