PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Revise § 180.1321 to read as follows:

§ 180.1321 Complex Polymeric Polyhydroxy Acids (CPPA); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide complex polymeric polyhydroxy acids (CPPA) in or on all food commodities, when used in accordance with label directions and good agricultural practices.

[FR Doc. 2022–10162 Filed 5–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0204 and EPA–HQ–OPP–2021–0432; FRL–9745–01–OCSPP]

Mandestrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mandestrobin in or on lettuce, head; lettuce, leaf; and rapeseed subgroup 20A. The Interregional Project Number 4 (IR–4) and the registrant, Valent U.S.A. LLC, requested these tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 12, 2022. Objections and requests for hearings must be received on or before July 11, 2022 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 dockets for this action, identified by docket identification (ID) numbers EPA–HQ–OPP–2021–0204 and EPA–HQ–OPP–2021–0432, are available at *https://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 and the OPP Docket is (202) 566–1744.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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 numbers EPA–HQ–OPP–2022–0204 and EPA–HQ–OPP–2021–0432 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 July 11, 2022. 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 numbers EPA–HQ–OPP–2021–0204 and EPA–HQ–OPP–2021–0432, by one of the following methods:

- *Federal eRulemaking Portal: https://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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 1, 2021 (86 FR 29229) (FRL–10023–95), 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 0E8888) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.690 be amended by establishing tolerances for residues of mandestrobin, 2-[(2,5-dimethylphenoxy)methyl]-α-methoxy-N-methylbenzeneacetamide, in or on the raw agricultural commodities: Lettuce, head at 0.08 parts per million (ppm) and Lettuce, leaf at 4 ppm.

In the **Federal Register** of August 24, 2021 (86 FR 47275) (FRL–8792–02–OCSPP), 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 1F8925) by Valent U.S.A. LLC, 4600 Norris Canyon Road, P.O. Box 5075, San Ramon, CA

94583–0975. The petition requested that 40 CFR 180.690 be amended by establishing a tolerance for residues of mandestrobin, 2-[(2,5-dimethylphenoxy)methyl]-α-methoxy-N-methylbenzeneacetamide, in or on the raw agricultural commodity: Rapeseed subgroup 20A, seed at 0.2 ppm.

These documents referenced a summary of the petition prepared by Valent U.S.A., the registrant, which are available in dockets EPA–HQ–OPP–2021–0204 and EPA–HQ–OPP–2021–0432, *https://www.regulations.gov.* There were no timely comments received in response to either of the notices of filing. One supportive comment from the U.S. Department of Agriculture (USDA) was submitted after the comment period for the rapeseed subgroup 20A notice of filing closed. It was in response to the notice of receipt of applications for new uses and is not applicable to the notice of filing.

Based upon review of the data supporting petition 1F8925, EPA has modified the commodity definition for Rapeseed subgroup 20A, seed. A discussion of this modification can be found in section IV.C.

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 mandestrobin including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with mandestrobin follows.

In an effort to streamline its publications in the **Federal Register,** EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for mandestrobin in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to mandestrobin and established tolerances for residues of that chemical. EPA is incorporating previously published sections from this rulemaking as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of mandestrobin, see Unit III.A. of the October 11, 2016, final rulemaking (81 FR 70038) (FRL–9945–37).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for mandestrobin used for human risk assessment, please reference Unit III.B. of the October 11, 2016, final rulemaking.

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate the exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C of the October 11, 2016, final rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposures from the new uses of mandestrobin on lettuce, head; lettuce, leaf; and rapeseed subgroup 20A. An unrefined chronic dietary (food and drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.0. The chronic assessment used tolerance level residues for all crops and assumed that 100% of the crops were treated with mandestrobin. Empirical and the Agency's default processing factors were used where available. An acute dietary exposure assessment was not conducted since there was no adverse effect observed for a single dose of mandestrobin.

Drinking water exposure. The new uses do not result in an increase in the estimated residue levels in drinking water, so EPA used the same estimated drinking water concentrations in the chronic dietary assessment as identified in the October 11, 2016, rulemaking.

Non-occupational exposure. There are no residential (non-occupational) exposures expected from the proposed new uses of mandestrobin on lettuce, nor from the proposed foliar and seed treatment uses on rapeseed subgroup 20A. However, there are registered uses of mandestrobin on turf grasses that cause non-occupational exposures. EPA's residential exposure assessment has changed since the October 11, 2016, rulemaking based on a revised practice. Because all current mandestrobin labels require handlers to wear specific clothing and personal protective equipment, EPA now assumes that mandestrobin is applied by professional applicators, not residential (homeowner) applicators. Therefore, the current assessment does not consider exposure to residential handlers. For residential post-application exposure, only hand-to-mouth exposures for children 1 to less than 2 years old ($1 < 2$) were assessed, as a dermal endpoint was not selected.

Cumulative exposure. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to mandestrobin and any other substances and mandestrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that mandestrobin has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor (SF) from 10X to 1X for all risk scenarios. See Unit III.D. of the October 11, 2016, final rulemaking for a discussion of the Agency's rationale for that determination.

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 population adjusted dose (aPAD) and

the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary exposure assessment was not conducted since there was no adverse effect observed for a single dose of mandestrobin. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 2.7% of the cPAD for children 1–2 years old, the most highly exposed population subgroup.

The short-term aggregate exposure assessment for children 1 to less than 2 years old includes dietary (food and drinking water) and incidental oral exposure from hand-to-mouth activities from post-application exposure to turf applications. The short-term aggregate risk estimate for children 1 < 2 years old is an MOE of 2,900, which is greater than the level of concern of 100 and is not of concern. An adult aggregate assessment was not conducted because there are no existing/proposed residential handler scenarios. Since the short- and intermediate-term points of departure (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. An acute aggregate exposure assessment was not required due to no adverse effect observed for a single dose for mandestrobin; and chronic aggregate risks to adults and children are equivalent to the dietary (food and drinking water) risks for those respective assessments and are not of concern.

Mandestrobin is classified as ''not likely to be a human carcinogen'' based on the lack of treatment-related tumors in the combined chronic/oncogenicity rat study or in the carcinogenicity mouse study, and the lack of genotoxicity in an acceptable battery of mutagenicity studies.

Therefore, based on the risk assessments and information described above, EPA concludes 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. More detailed information on this action can be found in the document ''Mandestrobin. Human Health Risk Assessment in support of New Uses and Establishment of Permanent Tolerances on Lettuce, Head and Leaf and Rapeseed Subgroup 20A'' in docket IDs EPA–HQ–OPP–2021–0204 and EPA–HQ–OPP–2021–0432.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method for various crops, see Unit IV.A of the October 11, 2016 rulemaking.

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 U.S. tolerance for residues of mandestrobin on rapeseed subgroup 20A is harmonized with the Codex MRL on rapeseed at 0.2 ppm. There are no Codex MRLs for residues of mandestrobin in or on lettuce.

C. Revisions to Petitioned-For Tolerances

The registrant proposed a tolerance on ''Rapeseed subgroup 20A, seed''. EPA is establishing the tolerance requested with the nomenclature ''Rapeseed subgroup 20A'' to conform to EPA's commodity terminology.

V. Conclusion

Therefore, tolerances are established for residues of mandestrobin in or on Lettuce, head at 0.08 ppm; Lettuce, leaf at 4 ppm; and Rapeseed subgroup 20A at 0.2 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 to 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: April 29, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. In § 180.690, amend the table in paragraph (a) by designating the table as table 1 and adding, in alphabetical order, entries for ''Lettuce, head''; ''Lettuce, leaf''; and ''Rapeseed subgroup 20A''.

The additions read as follows:

§ 180.690 Mandestrobin; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Lettuce, head	0.08
Lettuce, leaf	4
Rapeseed subgroup 20A	0.2
* * * * *	

[FR Doc. 2022–10204 Filed 5–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0401; FRL–9783–01–OCSPP]

Streptomyces sp. Strain SYM00257; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Streptomyces* sp. strain SYM00257 in or on all food commodities when used in accordance with label directions and good agricultural practices. Indigo Ag, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Streptomyces* sp. strain SYM00257 under FFDCA when used in accordance with this exemption.

DATES: This regulation is effective May 12, 2022. Objections and requests for hearings must be received on or before July 11, 2022 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–2021–0401, is available at *https://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 and OPP Docket is (202) 566–1744. Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–2427; email address: *BPPDFRNotices@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:

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- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

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C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2021–0401 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 July 11, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although EPA strongly encourages those interested in submitting objections or a hearing request to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), *https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.* At this time, because of the COVID–19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal delivery, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.*

Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is