Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 29, 2022.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2022–09742 Filed 5–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0632; FRL–9800–01–OCSPP]

Complex Polymeric Polyhydroxy Acid (CPPA); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an exemption from the requirement of a tolerance for residues of complex polymeric polyhydroxy acid (CPPA) by establishing use in or on all food commodities when used, in accordance with label directions and good agricultural practices. This regulation eliminates the need to establish a maximum permissible level for residues of CPPA.

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–2021–0632, 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 (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; 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:

- 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 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(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–2021–0632 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 number EPA–HQ–OPP–2021–0632, 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/contacts.html*.

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

II. Background and Statutory Findings

In the **Federal Register** of November 23, 2021 (86 FR 66512) (FRL–8792–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide tolerance petitions (PP 1F8918 and 1F8928) by FBSciences, Inc., 153 N. Main St. Ste 100, Collierville, TN 38017. The petitions requested that the existing exemption from the requirement of a tolerance at 40 CFR 180.1321 for residues of complex polymeric polyhydroxy acids (CPPA) be amended by adding uses as a fungicide and insecticide in accordance with label directions and good agricultural practices. Those documents referenced summaries of the petitions prepared by the petitioner, FBSciences, Inc, which are available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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 . . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 CPPA including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with CPPA follows.

A. Toxicological Profile

Complex Polymeric Polyhydroxy Acids (CPPA) is derived from naturally occurring organic matter (NOM) in soils and ground and surface waters. NOM is ubiquitous in soil and water. It is formed as a result of the decomposition of plants, animal, and microbial materials in soil and water, and is comprised of a variety of humic substances such as tannins, humic acids and fulvic acids. CPPA contains a complex mixture of these naturally occurring organic substances.

EPA has previously assessed CPPA toxicity and concluded that, with regard to the overall toxicological profile, CPPA is of minimal toxicity. Specifically, based on acute studies, CPPA is of low acute oral toxicity, acute inhalation toxicity and acute dermal and is non-irritating to the skin and eye. The chemical is not a skin sensitizer. All human health toxicity subchronic data requirements were satisfied by a combination of guideline studies and studies obtained from the open scientific literature for (90-day oral, developmental toxicity, reproductive toxicity and mutagenicity data). (See ''Biopesticides Registration Action Document, Complex Polymeric Polyhydroxy Acids (CPPA),'' which can be found on *https://regulations.gov* in Docket Number EPA–HQ–OPP–2009–0917; the document identification number is EPA–HQ–OPP–2009–0917–0011.)

There were no adverse subchronic effects for any route of exposure. The active ingredient was determined to be non-mutagenic, and no adverse effects were identified relative to either developmental toxicity or reproductive toxicity. Moreover, there are no known effects on endocrine systems via oral, dermal, or inhalation exposure. Based on this toxicological profile, EPA did not identify any toxicological endpoints of concern for CPPA.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoint of concern has been identified for CPPA.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* As part of its previous qualitative risk assessment for CPPA, the Agency considered the potential for dietary (food and drinking water) exposure to residues of this substance. CPPA is derived from naturally occurring organic matter (NOM) in soils and ground and surface waters, which is already present as an undesirable component of drinking water due to organoleptic effects. No significant exposure via drinking water or food beyond what is already present is expected when CPPA is used according to the product label directions. The active ingredient has a half-life of 25.7 days in the environment, is applied at extremely low application rates and is not directly applied to water; therefore, residues of CPPA are unlikely to accumulate in drinking water or exceed the levels at which NOM is already present. In the unlikely event that exposure to the active ingredient via drinking water does occur, the health risk(s) would be expected to be minimal based on the lack of acute oral toxicity (and overall lack of toxicity for all routes of exposure) of CPPA and the fact that CPPA (humic acids, fulvic acids and tannins) are substances that are ubiquitous in soil and water.

2. *From non-occupational exposure.* Based on the Agency's current practices, a quantitative post-application inhalation exposure and risk assessment has not been performed for CPPA. Currently, there are no proposed residential uses for this active ingredient. However, even if non-occupational (residential) exposures were to occur, CPPA is presumed to have negligible risk in these scenarios due to low acute inhalation toxicity (Toxicity Category IV)) and minimal irritation to the eye or skin (Toxicity Category IV). Additionally, no adverse effects have been identified in repeat-dose toxicology studies.

3. *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 that CPPA shares a common mechanism of toxicity with any other substances, and they do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed CPPA 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 *https://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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. An FQPA safety factor is not required at this time for CPPA because EPA has conducted a qualitative dietary assessment based on low toxicity and anticipated negligible exposure to the active ingredient.

E. Aggregate Risk

Based on the available data and information, EPA has previously concluded that a qualitative aggregate risk assessment is appropriate to support the pesticidal uses (plant growth regulator and nematicide) of CPPA, and that risks of concern are not anticipated from aggregate exposure to the substance. This conclusion is based on the low toxicity of the active ingredient and expected degradation of CPPA in the environment. For the new uses (as an insecticide and fungicide), EPA similarly concludes that the use of CPPA will be safe, *i.e.,* that there is a reasonable certainty that no harm will result from aggregate exposures to CPPA. In fact, EPA concludes that how CPPA is used as a pesticide (*i.e.,* plant growth regulator, fungicide, etc.) is immaterial and that any use as a pesticide will be safe due to the lack of toxicity of CPPA. This lack of toxicity negates the need to compare exposure across use patterns and, therefore, supports all pesticidal uses of CPPA.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled ''Revised Science Review in Support of Adding a New Use as a Fungicide and Insecticide for the End-Use Product (EP) FBS Defense 500 with 0.9% Complex Polymeric Polyhydroxy Acid (CPPA) as its Active Ingredient'' available in the docket for this action as described under **ADDRESSES**.

IV. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of CPPA.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Revisions to Petitioned-For Tolerances

The petitioner requested that the exemption for CPPA be amended by adding the additional use patterns for CPPA of ''insecticide'' and ''fungicide'', so that the exemption would apply to residues resulting from those additional uses. EPA has considered the available toxicity data and environmental fate information and concludes that the use restriction is unnecessary. Due to the lack of toxicity for this pesticide, EPA concludes that exposures will be safe regardless of the pesticidal use pattern and is modifying the regulatory text to reflect any pesticidal use, including, but not limited to, plant growth regulatory, nematocide, fungicide, and insecticide.

VI. Conclusions

Therefore, EPA is amending the currently established exemption for residues of complex polymeric polyhydroxy acids (CPPA) when used on all food commodities in accordance with label directions and good agricultural practices.

VII. Statutory and Executive Order Reviews

This action amends an exemption from the requirement of a tolerance 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).

VIII. 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 3, 2022.

Charles Smith,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I 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. 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.

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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).

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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