commercial operations or programs and policies.''

The air agency did not evaluate environmental justice considerations as part of its submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA performed an environmental justice analysis, as described in the section titled ''Environmental Justice Considerations'' in the proposed rule associated with this action (88 FR 72723, October 23, 2023). The analysis was done for the purpose of providing additional context and information about this rulemaking to the public, not as a basis of the action. Due to the nature of the action being taken here, this action is expected to have a neutral impact on the air quality of the affected area. In addition, there is no information in the record upon which this action is based inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 30, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Air pollution control, Incorporation by reference, Reporting and recordkeeping requirements.

Dated: February 22, 2024.

Earthea Nance,

Regional Administrator, Region 6.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 62 as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart E—Arkansas

■ 2. Amend § 62.850 by revising paragraphs (c)(1) and (2) and removing and reserving paragraph (c)(3) to read as follows:

§ 62.850 Identification of plan.

* * * * *

(c) * * *

(1) Kraft pulp mills.

(2) Municipal solid waste landfills.

(3) [Reserved]

■ 3. Revise § 62.855 to read as follows:

§ 62.855 Identification of plan—negative declaration.

Submittal from the Arkansas Department of Energy and Environment, Division of Environmental Quality (ADEQ) dated June 20, 2022, and supplemented on August 24, 2022, and August 31, 2022, certifying that there are no known existing sulfuric acid plants subject to the Sulfuric Acid Plants Emission Guidelines and 40 CFR part 60, subpart Cd, within its jurisdiction.

■ 4. Revise § 62.865 to read as follows:

§ 62.865 Identification of plan.

(a) *Identification of plan.* Control of air emissions from existing kraft pulp mills, as adopted by the State of Arkansas on January 28, 2022, and submitted on June 20, 2022, by the Governor in a letter dated May 12, 2022. The plan includes the regulatory provisions cited in paragraph (d) of this section, which EPA incorporates by reference.

(b) *Identification of sources.* The plan, as adopted by the State of Arkansas on January 28, 2022, and submitted on June 20, 2022, applies to existing kraft pulp mills subject to the Kraft Pulp Mills Emission Guidelines (*i.e.,* kraft pulp mills, as defined in 40 CFR 60.281(a), that commenced construction, reconstruction, or modification on or before September 24, 1976) within its jurisdiction in the State of Arkansas.

(c) *Effective date.* The effective date of the plan is April 1, 2024.

(d) *Incorporation by reference.* The material listed in this paragraph (d) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact the EPA Region 6 office at 1201 Elm Street, Suite 500, Dallas, Texas 75270; phone 214–665–2200. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the State of Arkansas, Office of the Secretary of State, Arkansas Register, State Capitol, Room 026, Little Rock, AR 72201, *arkansasregister@sos.arkansas.gov, https://www.sos.arkansas.gov/rules-regulations/arkansas-register/.*

(1) Arkansas Pollution Control and Ecology Commission (APC&EC) Rule No. 19, Rules of the Arkansas Plan of Implementation for Air Pollution Control, Chapter 8, 111(d) Designated Facilities, approved January 28, 2022.

(2) [Reserved]

[FR Doc. 2024–04102 Filed 2–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0595; FRL–11726–01–OCSPP]

1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, when used as an inert ingredient (colorant/dye) on growing crops and raw agricultural commodities pre- and post-harvest in/on animals, limited to a maximum concentration of 0.5% in a pesticide formulation, and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils not to exceed 300 ppm in the end-use concentration. Spring Regulatory Sciences on behalf of Colorants Solutions (new name Heubach Colorants USA LLC) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an

exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, when used in accordance with the terms of those exemptions.

DATES: This regulation is effective March 1, 2024. Objections and requests for hearings must be received on or before April 30, 2024 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–2022–0595, 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 the OPP docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, 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 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–2022–0595 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 April 30, 2024. 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–2022–0595, 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#express*.

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

II. Petition for Exemption

In the **Federal Register** of August 30, 2022 (87 FR 52868, FRL–9410–04), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11698) by Spring Regulatory Sciences, 6620 Cypresswood Dr., Suite 250, Spring, TX 77379 on behalf of Heubach Colorants USA LLC, 4000 Monroe Road, Charlotte, NC 28205. The petition requested that 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8) when used as an inert ingredient (colorant/dye) in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest under 40 CFR 180.910, in/on animals under 40 CFR 180.930, and in food contact sanitizing solutions under 40 CFR 180.940(a). That document referenced a summary of the petition prepared by Spring Regulatory Sciences on behalf of Heubach Colorants USA LLC, the petitioner, which is available in the docket, *https://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the petitioner's request to limit the maximum concentration to no more than 0.5% of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione under 40 CFR 180.910, and 40 CFR 180.930, and not to exceed 300 ppm in the end-use concentration under 40 CFR 180.940(a). This limitation is based on the Agency's risk assessment which can be found at *https://www.regulations.gov* in document IN–11698; 1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione. Human Health Risk Assessment and Ecological Effects Assessment to Support Inert Ingredient Approval for use in Pesticide Formulations in docket ID number EPA–HQ–OPP–2022–0595.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol

dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. 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 tolerance 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. When making a safety determination for an exemption for the requirement of a tolerance FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in section 408(b)(2)(C) and (D). 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. . . .'' Section 408(b)(2)(D) lists other factors for EPA consideration making safety determinations, *e.g.,* the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among others.

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. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, 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 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione exhibits low levels of acute toxicity via the oral and dermal routes of exposure. In the rat, the oral and dermal LD_{50}s are greater than 2,000 milligrams/kilogram (mg/kg). Acute inhalation toxicity is not expected due to the very low vapor pressure. It is not irritating to the rabbit eye. It is not expected to be irritating to the skin based on the absence of skin irritation in the acute dermal toxicity study and low exposure. It is not a dermal sensitizer.

The most sensitive effects were observed in a 28-day oral toxicity study with 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione. Increased levels of methemoglobin, total bilirubin and bile acids and decreased blood urea nitrogen were observed in female rats at the lowest observed adverse level (LOAEL) of 330 mg/kg/day. The no observed adverse effect level (NOAEL) is 110 mg/kg/day. Fetal susceptibility was not observed in the reproduction/developmental toxicity screening study in rats. Maternal (decreased thyroid hormone levels) and offspring (decreased bodyweights) toxicity was observed at the same dose, the LOAEL of 1,000 mg/kg/day. The NOAEL is 300 mg/kg/day. No reproduction toxicity effects are seen in the available studies. The concern for carcinogenicity is low, based on QSAR metabolism data showing the absence of metabolites associated with carcinogenicity and negative results in *in vitro* mutagenicity studies.

Neurotoxicity and immunotoxicity toxicity studies are not available for review. However, no evidence of neurotoxicity or immunotoxicity was observed in the submitted studies.

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 *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program.*

An acute dietary endpoint was not selected because no effect attributable to a single dose was identified in the

database. The 28-day oral toxicity study in rats is selected for the chronic dietary exposure scenario as well as short- and intermediate-term incidental oral, dermal and inhalation exposure scenarios. The NOAEL is 110 mg/kg/day, and the LOAEL is 330 mg/kg/day based on increased levels of methemoglobin, total bilirubin and bile acids and decreased blood urea nitrogen in females. This study is appropriate for the duration of exposure, it is protective of the general population, and it is protective of the most sensitive lifestage (children). The standard inter- and intra-species uncertainty factors of 10× are applied. An additional 10× uncertainty factor was applied to account for the use of a short-term study for chronic dietary exposure. The default factor of 100% is applied for the dermal absorption rate and the inhalation absorption rate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione in food as follows:

In conducting the dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 4.02, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2005–2010 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Update to D361707: Dietary Exposure and Risk Assessments for the Inerts.'' (12/21/2021) and can be found at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2018–0090. In the dietary exposure assessments, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione that may be in pesticide formulations (limited to no more than 0.5%) present at the maximum limitation rather than at equal quantities with the active ingredient.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for chronic dietary risk assessments for 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione.

To assess dietary exposure due to its use in antimicrobial products, the EPA calculated the Estimated Daily Intake (EDI) and Daily Dietary Dose (DDD) as described in the Food Drug Administration (FDA) model, based on a maximum concentration of 300 ppm in the pesticide formulation. The assessment considered: application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on FDA guidelines (2003).

2. *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).

Although there are non-pesticidal uses for 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, no reliable exposure information is available to EPA on those uses. 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. Therefore, screening level residential handler and post-application risk assessments have been performed for common residential exposure scenarios, using assumptions detailed in the 2012 Residential SOPs (available at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*).

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.''

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 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione to share a common mechanism of toxicity with any other substances, and 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that 1,4-bis[[3-[2-(2-

hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione 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/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10×) 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 Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10×, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the evaluation of available toxicity studies, there is low concern for pre- and postnatal susceptibility from exposure to chemical name. The FQPA safety factor has been reduced to 1× because: (1) the toxicity database is adequate to characterize potential pre- and postnatal risk; (2) the established PoD (110 mg/kg/day) will be protective of the body weight decreases in offspring seen at 1,000 mg/kg/day in the combined reproduction/developmental toxicity screening study in rats; (3) no evidence of neurotoxicity was observed in the database; and (4) the assumptions for the exposure assessment are conservative and unlikely to underestimate risk.

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, 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione 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 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione from food and water will utilize ~20.4% and 53.3% of the cPAD for the U.S. population and children 1 to 2 years old and non-nursing infants (the most highly exposed populations).

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

1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione is currently used as an inert ingredient in non-pesticidal products and pesticidal products that are registered for uses that could result in short- and intermediate-term residential exposures, and the Agency has determined that it is appropriate to aggregate chronic exposures through food and water with short- and intermediate-term residential exposures to 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione. Although, there are non-pesticide exposures (*i.e.* colorant for fabric and home care products including laundry) to 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione, aggregate exposures consider exposure due to pesticide uses only since no reliable exposure information is available for non-pesticidal uses.

Using the exposure assumptions described in this unit for short- and intermediate-term exposures, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in an aggregate risk index (ARI) of 4.3 for adults. Adult residential exposure combines high end dermal and inhalation handler exposure from aerosol spray/trigger pump with a high-end post application dermal exposure from contact with treated lawns. The combined short- and intermediate-term aggregated food, water, and residential pesticide exposures result in an aggregate ARI of 1.69 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione is an ARI of 1 or below, these ARIs are not of concern.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione in or on any food commodities. EPA is establishing a limitation on the amount of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione that may be used in pesticide formulations applied pre- and post-harvest, in/on animals; and in food contact sanitizing solutions. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 0.5% 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione in the final pesticide formulations to be applied pre- and post-harvest, in/on animals; and not to exceed 300 ppm in the end-use concentration when ready for use antimicrobial formulations (food-contact surface sanitizing solutions).

B. Revisions to Petitioned-For Tolerances

FFDCA section 408(d)(4)(A)(i) permits the Agency to finalize a tolerance that varies from that sought by the petition. EPA is establishing a tolerance exemption for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8) with concentration limits not sought by the petition based on the Agency's risk assessment.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of 1,4-bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8) when used as an inert ingredient (colorant/dye) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and in/

on animals under 40 CFR 180.930, limited to a maximum concentration of 0.5% in a pesticide formulation and in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a) not to exceed 300 ppm in the end-use concentration.

VII. Statutory and Executive Order Reviews

This action establishes exemptions 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 exemptions 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: February 26, 2024.

Charles Smith,

Director, Registration 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. In § 180.910, amend table 1 to 180.910 by adding in alphabetical order an entry for ''1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8)'' to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* *	* * *	* *
1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8).	0.5% by weight	Dye, coloring agent.
* *	* * *	* *

■ 3. In § 180.930, amend table 1 to 180.930 by adding in alphabetical order an entry for ''1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8)'' to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.930

Inert ingredients	Limits	Uses
* *	* * *	* *
1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione (CAS Reg. No. 123944–63–8).	0.5% by weight	Dye, coloring agent.
* *	* * *	* *

■ 4. In § 180.940, amend table 1 to paragraph (a) by adding in alphabetical order an entry for ''1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione'' to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Pesticide chemical	CAS Reg. No.	Limits
* *	* * *	* *
1,4-Bis[[3-[2-(2-hydroxyethoxy)ethoxy]propyl]amino]-9,10-anthracenedione.	123944–63–8	When ready for use, the end-use concentration is not to exceed 300 ppm.
* *	* * *	* *

* * * * *

[FR Doc. 2024–04355 Filed 2–29–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0295; FRL–11719–01–OCSPP]

Various Fragrance Components in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of various fragrance components listed in Unit II of this document when they are used as inert ingredients in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils when the end-use concentration does not exceed 100 parts per million (ppm). Innovative Reform Group, on behalf of The Clorox Company, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of various fragrance components, when used in accordance with the terms of those exemptions.

DATES: This regulation is effective March 1, 2024. Objections and requests for hearings must be received on or before April 30, 2024 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–2020–0295, 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 the OPP docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, 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 40 CFR part 180 through the Office of the Federal