[FR Doc. 2020–18650 Filed 9–15–20; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0312; FRL–10003–75]

1-Octanamine, N, N-dimethyl-, N-oxide; 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 1-octanamine, N,N-dimethyl-, N-oxide (CAS Reg. No. 2605–78–9) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, at a concentration of not more than 15% by weight in pesticide formulations. The Spring Trading Company, on behalf of Oxiteno 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-octanamine, N,N-dimethyl-, N-oxide when used in accordance with the terms of the exemption.

DATES: This regulation is effective September 16, 2020. Objections and requests for hearings must be received on or before November 16, 2020 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–2017–0312, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0312 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 November 16, 2020. 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–2017–0312, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Petition for Exemption

In the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL–9965–43), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11046) by the Spring Trading Company on behalf of Oxiteno USA, LLC, 9801 Bay Area Blvd., Pasadena, TX 77507. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of 1-octanamine, N,N-dimethyl-, N-oxide (CAS Reg. No. 2605–78–9) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by the Spring Trading Company on behalf of Oxiteno USA, LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* Comments were received on the notice of filing. EPA's

response to these comments is discussed in Unit V.C.

Based upon review of the data supporting the petition, EPA is establishing the requested exemption but with a limitation that the end-use product not contain 1-octanamine, N,N-dimethyl-, N-oxide in a concentration that exceeds 15% by weight. The reasons for this limitation are explained in the Agency's risk assessment which can be found at *http://www.regulations.gov* in document ''IN–11046; 1-Octanamine, N,N-dimethyl-, N-oxide—Human Health Risk and Ecological Effects Assessment of Request for Food Use Inert Ingredient in docket ID number EPA–HQ–OPP–2017–0312.''

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(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. . . .''

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 appreciable risks 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-octanamine, N,N-dimethyl-, N-oxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1-octanamine, N,N-dimethyl-, N-oxide 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-octanamine, N,N-dimethyl-, N-oxide as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document entitled ''IN–11046; 1-Octanamine, N,N-dimethyl-, N-oxide—Human Health Risk and Ecological Effects Assessment of Request for Food Use Inert Ingredient'' at pages 3–5 in docket ID number EPA–HQ–OPP–2017–0312.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

The toxicity endpoint selected for use in risk assessment is taken from the 28-day, repeat-dose toxicity study of 1-octanamine, N,N-dimethyl-, N-oxide in which a NOAEL was established at 150 mg/kg/day based on decreases in body weight, food consumption, mortality, clinical signs of toxicity, decreased motor activity, histopathology of the kidney and spleen, and effects on hematology and clinical chemistry parameters seen at 750 mg/kg/day. The uncertainty factors include 10X for interspecies extrapolation, 10X for intraspecies variation, and a 1X for the FQPA Safety Factor, bringing the combined uncertainty factor to 100. The resultant chronic Population Adjusted Dose (cPAD) is 1.5 mg/kg/day.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1-octanamine, N,N-dimethyl-, N-oxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 1-

octanamine, N,N-dimethyl-, N-oxide in food as follows:

Because no acute endpoint of concern was identified, a quantitative acute dietary exposure assessment is unnecessary. In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model (DEEM)—FCID™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. Dietary exposure is estimated using the Agency's Dietary Exposure Estimate Model (DEEM). The Inert Dietary Exposure Evaluation Model (I–DEEM) is a highly conservative model with the assumption 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 between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. In the case of1-octanamine, N,N-dimethyl-, N-oxide, a 15% by weight limitation in formulation was incorporated into the model.

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 ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* 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-octanamine, N,N-dimethyl-, N-oxide, a conservative drinking water concentration value of 100 ppb based on screening-level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

1-Octanamine, N,N-dimethyl-, N-oxide 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, and in non-pesticide products such as household products, personal care products and cosmetics. In a conservative effort to assess residential exposure, EPA has conducted a screening-level assessment using high-end residential exposure scenarios, such as pesticides used on lawns/turn, as antimicrobial cleaning products and in pet spot on applications.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 1-octanamine, N,N-dimethyl-, N-oxide to share a common mechanism of toxicity with any other substances, and 1-octanamine, N,N-dimethyl-, N-oxide does do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1-octanamine, N,N-dimethyl-, N-oxide does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* FFDCA Section 408(b)(2)(c) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No evidence of increased quantitative or qualitative susceptibility was seen in developmental toxicity studies in rats and rabbits with 1-octanamine, N,N-dimethyl-, N-oxide. No adverse effects on reproductive parameters were observed in a 2-generation rat reproductive study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The database for 1-octanamine, N,N-dimethyl-, N-oxide is considered adequate for FQPA assessment.

ii. A combined repeated dose toxicity study with a reproduction/developmental toxicity screening test showed no effect on reproductive parameters of fertility in the absence of maternal toxicity.

iii. Although no neurotoxicity studies are available, no clinical signs of neurotoxicity were observed. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. Immunotoxicity studies were not available. However, there were no test-item related signs of immunotoxicity noted in the repeat-dose study.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and incorporated a limitation of 15% by weight in pesticide formulation. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 1-octanamine, N,N-dimethyl-, N-oxide in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by 1-octanamine, N,N-dimethyl-, N-oxide.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate

PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, no adverse effects were attributed to a single exposure of the acute dietary exposure from food and water to -octanamine, N,N-dimethyl-, N-oxide. Therefore, 1-octanamine, N,N-dimethyl-, N-oxide 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-octanamine, N,N-dimethyl-, N-oxide, from food and water will utilize 14.1% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of 1-octanamine, N,N-dimethyl-, N-oxide is not expected.

3. *Short-term risk.* Short-term aggregate exposure considers short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). 1-Octanamine, N,N-dimethyl-, N-oxide is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 1-octanamine, N,N-dimethyl-, N-oxide.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1978 for adults and 589 for children. Because EPA's level of concern for 1-octanamine, N,N-dimethyl-, N-oxide is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for 1-octanamine, N,N-dimethyl-, N-oxide.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in a rodent carcinogenicity study, 1-octanamine, N,N-dimethyl-, N-oxide is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 1-octanamine, N,N-dimethyl-, N-oxide residues.

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-octanamine, N,N-dimethyl-, N-oxide in or on any food commodities. EPA is establishing limitations on the amount of 1-octanamine, N,N-dimethyl-, N-oxide that may be used in pesticide formulations applied pre- and post-harvest. These limitations 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 15% by weight of 1-octanamine, N,N-dimethyl-, N-oxide in the final pesticide formulation.

B. Response to Comments

Two comments were received concerning the safety and impact of pesticides on food and human health. Although the Agency recognizes that some individuals believe that no residue of pesticides should be allowed in or on food, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes the establishment of pesticide tolerances or exemptions where the Agency determines that tolerance or exemption meets the safety standard imposed by the statute. EPA has sufficient data to support a safety determination for the exemption from the requirement of a tolerance for 1-octanamine, N,N-dimethyl-, N-oxide. The commenters have provided no additional information supporting a determination that the exemption is not safe.

C. Revisions to Petitioned-For Tolerances

Based upon an evaluation of the data included in the petition, EPA is establishing an exemption from the requirement of a tolerance for residues of 1-octanamine, N,N-dimethyl-, N-oxide when used in pesticide formulations as an inert ingredient (surfactant), not to exceed 15% by weight of the formulation, instead of the unlimited use requested. Because unlimited use of 1-Octanamine, N,N-dimethyl-, N-oxide resulted in aggregate risks of concern, EPA is establishing a 15% limitation in formulation to support the safety finding of these tolerance exemptions. The concern for unlimited use of theses inert ingredients is documented on page 4 of the Agency's risk assessment documents ''IN–11046; 1-Octanamine, N,N-dimethyl-, N-oxide—Human Health Risk and Ecological Effects Assessment of Request for Food Use Inert Ingredient'' which can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2017–0312.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for 1-octanamine, N,N-dimethyl-, N-oxide when used as an inert ingredient (surfactant) limited to 15% by weight in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). 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 (CRA)

Pursuant to the CRA (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: August 26, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 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, add alphabetically the inert ingredient ''1-Octanamine, N,N-dimethyl-,N-oxide (CAS Reg. No. 2605–78–9)'' to the table 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-Octanamine, N,N-dimethyl-, N-oxide (CAS Reg. No. 2605–78–9).	Not to exceed 15% of pesticide formulation	Surfactant.
* * *	* *	* *

[FR Doc. 2020–19347 Filed 9–15–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[EPA–R04–UST–2020–0248; FRL–10013–46–Region 4]

Commonwealth of Kentucky: Final Approval of State Underground Storage Tank Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Commonwealth of Kentucky (Commonwealth or State) has applied to the Environmental Protection Agency (EPA) for final approval of its Underground Storage Tank (UST) program under Subtitle I of the Resource Conservation and Recovery Act (RCRA or Act). The EPA has reviewed the Commonwealth's application (State Application) and has made a final determination that the Commonwealth's UST program (UST Program) described in the State Application satisfies all the requirements necessary to qualify for final approval. Thus, the EPA is granting final approval to the State to operate its UST Program for petroleum and hazardous substances. On July 1, 2020, the EPA provided notification and an opportunity for comment on the Agency's tentative determination to approve the State's UST Program. No comments were received on the Agency's tentative determination and no further opportunity for comment will be provided.

DATES: This final determination and approval for the State's UST Program is effective September 16, 2020.

ADDRESSES: The documents that form the basis for this action are available electronically through *www.regulations.gov* (Docket ID No. EPA–R04–UST–2020–0248).

FOR FURTHER INFORMATION CONTACT: Ben Singh, RCRA Programs and Cleanup Branch, Land, Chemicals and Redevelopment Division, U.S. Environmental Protection Agency, Region 4, Atlanta Federal Center, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960; Phone number: (404) 562–8922; email address: *singh.ben@epa.gov*. Please contact Ben Singh by phone or email for further information.

SUPPLEMENTARY INFORMATION:

I. Background

Section 9004 of RCRA, 42 U.S.C. 6991c, authorizes the EPA to approve state UST programs to operate in lieu of the Federal UST program. Pursuant to RCRA section 9004(b), approval may be granted if the state program provides for adequate enforcement of compliance with the UST standards of RCRA section 9004(a); is ''no less stringent'' than the