the Federal Government and Indian tribes, or otherwise have any unique impacts on local governments. 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

Although this action does not 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this rule in the Federal Register. This rule 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 16, 2018.

Michael Goodis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


2. In § 180.960, the table is amended by adding alphabetically the following polymers to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

<table>
<thead>
<tr>
<th>Polymer</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignosulfonic acid, calcium, comp. with 1,6 hexanediamine polymer with</td>
<td>1905409–74–6</td>
</tr>
<tr>
<td>guanidine hydrochloride (1:1), minimum number average molecular weight</td>
<td></td>
</tr>
<tr>
<td>(in amu): 4,500 daltons</td>
<td></td>
</tr>
</tbody>
</table>

[FR Doc. 2018–18407 Filed 8–23–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Zinc Oxide; 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 zinc oxide (CAS Reg. No. 1314–13–2) when used as an inert ingredient in pesticide formulations applied to growing crops or raw agricultural commodities after harvest, to include use as a stabilizer, at a concentration not to exceed 15% by weight of the pesticide formulation. Nutrenare-AG, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an amended new use for an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of zinc oxide when used in accordance with the limitations of the exemption.

DATES: This regulation is effective August 24, 2018. Objections and requests for hearings must be received on or before October 23, 2018, 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–2017–0574, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, 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

1. [List of codes, e.g., 111111, 222222, etc.]

2. [Further details on how to contact the agency, e.g., mailing address, phone number, email address, etc.]

3. [Information on how to access the docket, including the website address and the time period for public comment, e.g., http://www.regulations.gov, comments must be received by [date].]
B. How can I get electronic access to other related information?


You may also access related information (data and analytical results) from the electronic docket at http://www.epa.gov/dockets/. You may access this docket in either hard copy or electronic format by visiting the docket in the OPD Dockets Office, and/or by following the instructions at http://www.epa.gov/dockets/contacts.html.

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 inert ingredients: 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(b)(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 zinc oxide including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with zinc 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.

Zinc (typically in the form of zinc salts and zinc oxide) is ubiquitous in the environment, is widely distributed in plants and animals, and occurs in the earth’s crust at an average concentration of approximately 70 milligrams per kilogram (mg/kg). Zinc is also an essential nutrient in the body and a normal part of metabolism in all living organisms. Zinc is recommended for nutritional use and exists naturally in food. The U.S. Food and Drug Administration considers zinc oxide as generally recognized as safe for use as a nutrient in foods. See 21 CFR 182.8991.

Zinc oxide is one of several zinc salts the Agency has evaluated in reregistration and in registration review. The Agency’s current risk assessment for zinc oxide relies heavily on the Agency’s previous analysis, including the 2009 risk assessment, which is entitled “Summary of Human Health Effects: Zinc Salts, and Zeolites Registration Review Decision Document” and is included in the zinc salts registration review docket at http://www.regulations.gov, using document number EPA–HQ–OPP–2009–0011–0002.

The 2009 zinc salts risk assessment concluded that “The Agency has reviewed all toxicity studies submitted for the zinc salts and has determined that the toxicological database is sufficient. The Agency has not selected toxicological endpoints for zinc salts. The toxicological database for the zinc salts case is currently comprised of published and unpublished studies either submitted to the Agency or obtained directly from published open literature.” That risk assessment also referenced the Agency’s Reregistration Eligibility Decision (RED) for Zinc Salts of August, 1992.

With regard to acute toxicity, the Agency’s database includes information indicating that zinc oxide presents low to no acute toxicity. With regard to subchronic and chronic toxicity, the Agency has reviewed the scientific literature about zinc, which has been extensively researched as a natural component of the earth’s crust and being widely distributed in plants and animals, an essential nutrient in the body and part of the metabolism of living things, and naturally occurring in foods.

For toxicological concerns, there are adequate toxicology studies in the zinc database to evaluate incidental oral exposure in the 2009 risk assessment, at high levels, oral exposure to zinc in animal studies may result in toxic effects such as pancreatic and renal lesions as well as histological alterations in the pituitary and adrenal glands. In general, the levels of zinc causing these toxicological effects occur at much higher dose levels than the level recommended for nutritional use and that is naturally available in food. The 2009 risk assessment noted that zinc compounds have not been classified as cancerous compounds.

B. Toxicological Points of Departure/Levels of Concern

As noted in the previous section, the 2009 risk assessment did not identify any toxicological endpoints of concern because of the ubiquity of zinc in the environment and presence in food, its role as an essential element, and FDA’s consideration of zinc as GRAS for use as a nutrient in food. That assessment concluded that the toxicological effects seen in the database indicated effects at much higher levels than the level recommended for nutritional use, and what is naturally found in food. To supplement those conclusions, the Agency considered the findings of the National Academy of Sciences’ (NAS) Institute of Medicine, Food and Nutrition Board; the European Food Safety Authority’s (EFSA) Panel on Dietetic Products, Nutrition and Allergies; and the European Commission’s Scientific Committee on Food (SCF).

The NAS, EFSA, and SCF have considered zinc in its role as an essential nutrient. These organizations have established upper limit intake levels for zinc. The NAS upper limit intake level for zinc is referred to as the Tolerable Upper Intake Level (UL) and is defined as the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals. The NAS UL for zinc is 40 mg/day for adults. The EFSA and SCF Tolerable Upper Intake Level for zinc is 25 mg/day for adults. Both of these values are based on adverse effects associated with chronic intake of supplemental zinc, particularly those attributable to copper deficiency, with these adverse effects observed at zinc exposure levels in humans above 60 mg/day.

The NAS Recommended Dietary Allowance (RDA) for zinc is based upon replacement of endogenous zinc loss in the body via normal metabolic processes and is established at 8 mg/day for women and 11 mg/day for men. (The EFSA Dietary Reference Values and the SCF Population Reference Intake are consistent with these baseline values, ranging from 7 mg/day to 12 mg/day for adults.) NAS also noted that the median intake of zinc from food in the United States was approximately 9 mg/day for women and 14 mg/day for men. The estimated worst-case dietary exposures to zinc from the use of zinc oxide as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest is 2 mg/day, a value significantly less than both the RDA and UL for zinc.

Because the Agency does not anticipate aggregate exposures to zinc oxide to approach the UL, it has not selected toxicological endpoints for zinc oxide for use in a quantitative risk assessment.

C. Exposure Assessment

1. Dietary exposure. In evaluating dietary exposure to zinc oxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA qualitatively assessed dietary exposures from zinc oxide in food as follows:

Dietary exposure to zinc oxide can occur following ingestion of foods with residues from treated crops, animals or food contact surfaces. In addition, dietary exposure is expected from the presence of zinc oxide naturally occurring in foods and from use as a nutrient. Based on the insoluble nature of zinc oxide, use on food crops would not be expected to result in residues of zinc oxide in drinking water, although zinc may be present naturally in water at low concentrations.

2. 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). Zinc oxide may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion above, a quantitative residential exposure assessment for zinc oxide was not conducted.

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 zinc oxide to share a common mechanism of toxicity with any other substances, and zinc oxide exposure is not expected to produce a toxic metabolite produced by other substances. For the purposes of this
tolerance action, therefore, EPA has assumed that zinc 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

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA 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.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Exposures resulting from the use of zinc oxide as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after 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 use on growing crops or raw agricultural commodities after harvest for sale or distribution containing zinc oxide as a stabilizer that exceeds 15% by weight of zinc oxide.

VI. Conclusions

Therefore, the exemption from the requirement of a tolerance for residues of zinc oxide when used as an inert ingredient in pesticide formulations applied to growing crops or raw agricultural commodities after harvest under 40 CFR 180.910 is amended to include use as a stabilizer, at a concentration not to exceed 15% by weight of the pesticide formulation.

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); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or 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 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: August 16, 2018.

Michael Goodis,
Director, Registration Division.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
2. In § 180.910, revise the zinc oxide entry in the table to read as follows:

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide (CAS Reg. No. 1314–13–2).</td>
<td>Not more than 15% by weight in pesticide formulations when used as stabilizer</td>
<td>Coating agent, stabilizer.</td>
</tr>
</tbody>
</table>

This rule removes an unneeded requirement in the DFARS that required a technical interchange between the Government and certain contractors. This rule removes the requirement for major contractors to have a technical interchange with the Government prior to generating independent research and development costs. Removal of this requirement will result in freeing contractors to pursue IR&D projects without including the Government in those preliminary decisions.

DoD has performed a regulatory cost analysis on this rule. The following is a summary of the estimated public annualized cost savings, calculated in 2016 dollars at a 7-percent discount rate in perpetuity:

- Annualized 7%: $1.7 million
- Present Value 7%: $24.0 million

To access the full Regulatory Cost Analysis for this rule, go to the Federal eRulemaking Portal at www.regulations.gov, search for “DFARS Case 2017–D041,” click “Open Docket,” and view “Supporting Documents.”