



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0574; FRL-9978-36]

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 [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days*

*after date of publication in the **Federal Register***], 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 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 Printing 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-2017-0574 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 *[insert date 60 days after date of*

publication in the Federal Register]. 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-2017-0574, 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 February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11059) by Nutri Ag, Inc. (now d/b/a Nutrenare-AG, Inc.) 4740 N. Interstate 35 E, Waxahachie, TX 75165. The petition requested that the 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 under 40 CFR 180.910 be amended to include use as a stabilizer, at a concentration not to exceed 15% by weight of the pesticide formulation. That document referenced a summary of the petition prepared by OMC Ag Consulting on behalf of Nutrenare-AG, Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. While comments were submitted to the docket, none raised any issues related to the Agency's safety assessment of zinc oxide.

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 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 Data for Zinc, 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 exposures. As noted 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 the NAS RDA, 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 does not appear 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 and the dietary exposure (expressed as median intake) of zinc from food, would be significantly less than the Tolerable Upper Intake Levels for zinc. Therefore, EPA concludes that aggregate exposure to residues of zinc oxide will not pose a risk to the U.S. population, including infants and children, and that there is a reasonable certainty

that no harm will result to the general population, or to infants and children from aggregate exposure to zinc oxide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. EPA is establishing limitations on the amount of zinc oxide that may be used as a stabilizer 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 exemption 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:

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

2. In §180.910, revise the zinc oxide entry in the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	*	* * *
Zinc oxide (CAS Reg. No. 1314-13-2)	Not more than 15% by weight in pesticide formulations when used as stabilizer	Coating agent, stabilizer
* * *	*	* * *