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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0614; FRL-9982-73]

Tin 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 tin oxide (CAS Reg. No. 18282-10-5) when used as an inert ingredient (seed treatment colorant) not to exceed 40% by weight in pesticide formulations applied to growing crops. Exponent on behalf of Aceto Corporation 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 tin oxide.

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-2017-0614, 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-2017-0614 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-2017-0614, 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 March 21, 2018 (83 FR 12311) (FRL-9974-76), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11058) by Exponent (1150 Connecticut Ave., NW,

Suite 1100 Washington, DC 20036), on behalf of Aceto Corporation (Aceto, 4 Tri Harbor Court, Port Washington, NY 11050). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of tin oxide (CAS Reg. No. 18282-10-5) when used as an inert ingredient (seed treatment colorant) in pesticide formulations applied to growing crops not to exceed 40% by weight. That document referenced a summary of the petition prepared by Exponent on behalf of Aceto Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no timely comments received in response to the notice of filing.

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 tin oxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with tin 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 tin oxide 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.

Although limited data are available on tin oxide, tin oxide belongs to the chemical class of water insoluble inorganic tins; therefore, the Agency used data available on inorganic tins, specifically tin (II) chloride (CAS Reg No. 21651-19-4) to fill data gaps.

The acute oral toxicity of tin oxide is very low. The lethal dose, $(LD)_{50}$>20,000 milligrams/kilograms (mg/kg) in rats and mice. There is no eye irritation in Leghorn eggs nor in bovine cornea.

The only repeated dose studies available with tin oxide are the 28-day and 13-week oral toxicity studies in rats. No toxicity is observed in either study up to 1,000 and 500 mg/kg/day, respectively of tin oxide, the highest dose tested in both studies.

Although developmental and reproduction toxicity studies are not available on tin oxide, evidence of potential developmental or reproduction toxicity is not observed in the available studies with tin oxide and no toxicity is seen up to 500 mg/kg/day, the highest dose tested. Available reproduction and developmental studies with tin (II) chloride that show no maternal, offspring or reproduction toxicity at 40 mg/kg/day, the highest dose tested, in rats, although these studies are of limited value since the doses tested were not high enough to assess developmental and reproduction effects. Nevertheless, there is no concern for fetal susceptibility due to dietary exposure to tin oxide because it is insoluble and is not expected to be absorbed or cause systemic toxicity. Also, no toxicity is observed in reproduction organs at 500 and 1,000 mg/kg/day, the highest doses tested in the 13- and 4-week, respectively, oral toxicity studies in rats.

Carcinogenicity studies with tin (II) chloride in rats and mice indicate that inorganic tins are not carcinogenic at 40 and 60 mg/kg/day, respectively, the highest dose tested.

In an *in vitro* mutagenicity assay, tin oxide caused micronuclei and karyorrhexis in lung macrophages. The toxicologic significance of this finding is equivocal.

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

The absorption of inorganic tin compounds from the gastrointestinal tract in humans and animals is very low with as much as 98% excreted directly in the feces. Because of their limited absorption, inorganic tin compounds have low systemic toxicity.

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 13-week oral toxicity study in rats is selected for the chronic dietary exposure scenario. No toxicity is observed up to 500 mg/kg/day, the highest dose tested. The

lowest NOAEL in the database is found in the developmental and reproduction toxicity studies in the rat. In these studies, no treatment related adverse toxicity is observed at 800 ppm (40 mg tin/kg/day), the highest dose tested in both studies. However, the developmental and reproduction toxicity studies are not considered appropriate for risk assessment since tested doses are not high enough to assess developmental and reproduction toxicity. Therefore, the 13-week toxicity study in rats treated with tin oxide is used for the chronic dietary exposure scenario. There is no concern for the lack of developmental and reproduction toxicity studies because tin oxide is an insoluble tin and is not expected to be absorbed or cause systemic toxicity. Further supporting the lack of toxicity, no systemic toxicity or adverse effects are observed up to 500 mg/kg/day, the highest dose tested, in the 13-week toxicity study in rats. Based on the weight of evidence, there is no concern for increased susceptibility and no additional uncertainty factor is necessary. The standard inter- and intra-species uncertainty factors of 10x are applied. Dermal and inhalation endpoints were not selected as tin oxide is not expected to be dermally absorbed because it is insoluble, and not expected to be absorbed in the lungs due to its particle size.

C. Exposure Assessment

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

Dietary exposure (food and drinking water) to tin oxide can occur following ingestion of foods with residues from treated crops with pesticide formulations

containing tin oxide. In addition, dietary exposure can occur from exposure to non-pesticidal sources of tin oxide. FDA has approved the use of tin oxide as a colorant in food-contact articles at a maximum level of 1.1% by weight in colorants otherwise composed of mica and titanium dioxide, provided that the maximum loading rate for the colorant in the food-contact material does not exceed 3% by weight for polymers, 5% for paper and paperboard, 15% for coatings, or 30% for ink formulations. See Food and Drug Administration (FDA) threshold of regulation (TOR) exemption 98-004. It may be used, in combination with silicon dioxide and titanium dioxide, as a colorant for food-contact polymers, paper and paperboard, coatings, and in printing inks applied to non-food-contact surfaces of food-contact articles. The food contact substance will be used at a level not to exceed 6% of the total colorant weight. See FDA, Food Contact Notification (FCN) 000431. Tin oxide can also be used as a pigment for all polyolefins for food contact applications as long as the use level does not exceed 0.5% by weight of the polymer and is subject to certain limitations. See FDA, Food Contact Notification (FCN) 235.

Because no adverse effects attributable to a single exposure of tin oxide are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 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 tin oxide. In the absence of specific residue data, EPA utilized a highly conservative

assumption that the residues on all commodities are 47 ppm based on the effective application rate of tin oxide when used as a colorant for seed treatment pesticide products and the presumption that all applied tin oxide would be present in the edible portions of crops derived from treated seed. 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 tin oxide, 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 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).

Tin oxide is not expected to be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, as the requested use is for commercial use only. However, tin oxide is present in cosmetics and personal care products. The typical reported concentration for tin oxide in cosmetics and

personal care products ranges from 0.03 to 1.3%. Based on the 2013 Cosmetic Ingredient Review (CIR) document, tin oxide is used in dusting powders (up to 0.03%), body and hand cosmetic sprays (up to 0.06%), and other fragrance preparations (up to 0.08%).

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 tin oxide to share a common mechanism of toxicity with any other substances, and tin 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 tin 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 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.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X for the chronic dietary assessment for the following reasons. First, the toxicity database for tin oxide contains subchronic, carcinogenicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Although no developmental and reproduction toxicity studies with tin oxide are available, there is no concern for fetal susceptibility because tin oxide is insoluble and is not expected to be absorbed or cause systemic toxicity. Further supporting the lack of toxicity, no adverse effects or systemic toxicity are observed up to 500 mg/kg/day, the highest dose tested, in the 13-week toxicity study in rats. Based on the weight of evidence, there is no concern for increased susceptibility and, the Agency has concluded that reducing the FQPA SF to 1X is appropriate.

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.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tin oxide from food and water will utilize 38.3% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the available data, oral exposure to tin oxide residues from non-pesticide uses is expected to be negligible compared to the conservative estimates of exposure resulting from the proposed use as a colorant for seed treatment pesticides, and not expected to significantly impact dietary exposure.

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

Tin oxide is not expected to be used as an inert ingredient in pesticide products that could result in short- and intermediate-term residential exposure as the request is strictly for commercial seed treatment use only, although tin oxide is currently approved for use in cosmetic, manufacturing applications

Dermal exposure to residues of tin oxide is not expected to result in systemic toxicity as tin oxide is insoluble and not absorbed through the skin. Inhalation exposure is possible due to its use in cosmetics and personal care products. However, as reported in the CIR 2013 on tin oxide, inhalation exposure to tin oxide particles are not expected

as 95-99% of the particles are >10 micrometers (um) and not expected to enter the lungs. Because of the lack of adverse effects from dermal or inhalation exposure, the Agency does not expect these residential exposures to pose risks of concern.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two rodent carcinogenicity studies, tin oxide is not expected to pose a cancer risk to humans.

5. *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 tin 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. The Agency ensures compliance with the limitation in the tolerance exemption through the registration of pesticides with formulations that satisfy the limitation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for residues of tin oxide (CAS Reg. No. 18282-10-5) when used as an inert ingredient (colorant) in pesticide seed treatment formulations applied to growing crops not to exceed 40% by weight.

VII. Statutory and Executive Order Reviews

This action establishes an exemption to the requirement for 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 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: November 1, 2018.

Michael L. 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:

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

2. In §180.920, add alphabetically the inert ingredient "Tin oxide (CAS Reg. No. 18282-10-5)" to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
**	***	**
Tin oxide (CAS Reg. No. 18282-10-5)	Not to exceed 40% by weight for use in seed treatment pesticide formulations only	Colorant
**	***	**

[FR Doc. 2018-24585 Filed: 11/8/2018 8:45 am; Publication Date: 11/9/2018]