

The Exemption from the Requirement of Tolerance for Residues of Titanium Dioxide

AGENCY:

Environmental Protection Agency (EPA).

ACTION:

Final rule.

SUMMARY:

This regulation amends the exemption from the requirement of a tolerance for residues of titanium dioxide (CAS Reg. No. 13463-67-7) when used as an inert ingredient in pesticide formulations applied to growing crops to allow for use as a carrier. SciReg. Inc., on behalf of Bayer CropScience Biologics GmbH, 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 titanium dioxide resulting from this use.

DATES:

This regulation is effective August 1, 2018. Objections and requests for hearings must be received on or before October 1, 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-2018-0150, 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 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-2018-0150 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 October 1, 2018. 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-2018-0150, 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 start printed page 37441 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 May 18, 2018 (83 FR 23247) (FRL-9976-87), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a,

announcing the filing of a pesticide petition (PP IN-11085) by SciReg. Inc., on behalf of Bayer CropScience Biologics GmbH, Lukaswiese 4, 23970 Wismar, Germany. The petition requested that the 40 CFR 180.920 exemption from the requirement of a tolerance for residues of titanium dioxide (CAS Reg. No. 13463-67-7) be amended to allow for use as a carrier when used as an inert ingredient in pesticide formulations applied to growing crops only. That document referenced a summary of the petition prepared by SciReg. Inc., on behalf of Bayer CropScience Biologics GmbH, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no 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 titanium dioxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with titanium dioxide 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.

The available toxicity studies on titanium dioxide via the oral route of exposure clearly demonstrate a lack of toxicity. The several studies in mice, rats, dogs, cats, rabbits and other species of varying durations do not indicate toxicity, even at very high doses (e.g., 50,000 ppm or 2,500 mg/kg/day dietary exposure for two years in rats). There are no studies on the dermal toxicity of titanium dioxide and there is no expected toxicity via the dermal route of

exposure because as an insoluble solid material, titanium dioxide is not absorbed via the skin.

The available inhalation studies indicate that the primary toxicity of titanium dioxide is due to deposition of the inhaled particles. Although these studies suggest equivocal evidence of carcinogenicity due to prolonged exposure to titanium dioxide particles, EPA has determined that these effects are not relevant for assessing risk from exposure to titanium dioxide when used as an inert ingredient in pesticide formulations based on the following. First, tumors were only observed in two of the available studies and only in one species. In one study, those tumors were only observed in rats continually exposed to ultrafine particles of titanium dioxide. In the second study, tumors were only observed from exposure to fine particles of titanium dioxide at extremely high concentrations (250 mg/m³), in which the animals experienced overloading of lung clearance, with chronic inflammation resulting in lung tumors. All but one of the tumors in the second study were subsequently reclassified as non-neoplastic or non-cancerous in nature. No tumors were observed in studies involving mice.

The titanium dioxide used in pesticide formulations is considered pigmentary grade, not ultrafine or nanoscale. Consequently, the tumors observed from exposure to ultrafine particles of titanium dioxide are not relevant for assessing exposure to the type of titanium dioxide used in pesticide formulations. Following the reclassification of the tumors observed in the second inhalation study, EPA does not consider these effects to be strong evidence of carcinogenicity from exposure to fineparticle-sized titanium dioxide. Further, EPA does not expect any reasonably foreseeable uses of titanium dioxide in pesticide formulations that might result in residential exposures that would approach the levels of exposure necessary to elicit the effects seen in the available inhalation study. The levels at which effects were observed in that study greatly exceed any reasonable Start Printed Page 37442dose for toxicity testing and any likely residential exposure levels. Moreover, when used as an inert in pesticide formulations, titanium dioxide will be bound to other materials, with no significant inhalation exposure to titanium dioxide particles themselves.

This position is consistent with the National Institute of Occupational Health and Safety's (NIOSH) recent assessment that ultrafine but not fine titanium dioxide would be considered a "potential occupational carcinogen." The NIOSH Current Intelligence Bulletin "Occupational Exposure to Titanium Dioxide" concludes that

“[t]he lung tumors observed in rats after exposure to 250 mg/m³ of fine TiO₂ [titanium dioxide] were the basis for the original NIOSH designation of TiO₂ as a “potential occupational carcinogen.” However, because this dose is considered to be significantly higher than currently accepted inhalation toxicology practice, NIOSH concluded that the response at such a high dose should not be used in making its hazard identification.” NIOSH concluded that the data is insufficient to classify fine titanium dioxide as a potential occupational carcinogen.

Because the predominant form of titanium dioxide used commercially, and the form used as an inert ingredient in pesticide formulations, is pigment grade, which is not in the ultrafine or nanoscale particle size range but rather in the fine particle size range, EPA concludes that carcinogenicity is not a concern from exposure to titanium dioxide resulting from its use as an inert ingredient in pesticide formulations.

Specific information on the studies received and the nature of the adverse effects caused by titanium dioxide 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 the final rule published in the Federal Register of July 27, 2012 (77 FR 44151) (FRL-9354-6) and in the Agency’s risk assessment which can be found at <http://www.regulations.gov> in document “Titanium Dioxide; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When used as an Inert Ingredient in Pesticide Formulations” in docket ID number EPA-HQ-OPP-2018-0150.

B. Toxicological Points of Departure/Levels of Concern

Because the available data indicate no toxicity via the oral route of exposure, no endpoint of concern for that route of exposure has been identified in the available database. This conclusion is in agreement with the conclusion of the World Health Organization (WHO) Committee on Food Coloring Materials that no Acceptable Daily Intake (ADI) need be set for the use of titanium dioxide based on the range of acute, sub-acute, and chronic toxicity assays, all showing low mammalian toxicity. Similarly, no significant toxicity of titanium dioxide is expected via the dermal route of exposure, so no endpoint was identified.

Because the effects seen in inhalation studies occurred at doses above the levels at which pesticide exposure is expected and for

particle sizes that are different from the size of titanium dioxide used in pesticide formulations, the Agency has concluded that those risks are not relevant for assessing risk from pesticide exposure and therefore, did not identify an endpoint for assessing inhalation exposure risk.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to titanium dioxide, EPA considered exposure under the proposed exemption from the requirement of a tolerance and all other existing exemptions from the requirement of a tolerance for residues of titanium dioxide. EPA assessed dietary exposures from titanium dioxide in food as follows:

Residues of titanium dioxide are exempt from the requirement of a tolerance when used as an inert ingredient in many different circumstances: When used in pesticide formulations applied to growing crops as a pigment/coloring agent in plastic bags used to wrap growing bananas or colorant on seeds for planting (40 CFR 180.920); when used in pesticide formulations applied to animals (40 CFR 180.930); when used as a UV protectant in microencapsulated formulations of the insecticide lambda-cyhalothrin at no more than 3.0% by weight (40 CFR 180.1195); when used as a UV stabilizer in pesticide formulations of napropamide at no more than 5% of the product formulation (40 CFR 180.1195); when used in pesticide placed at entrance to bee hives intended to control varroa mites in hive at a maximum of 0.1% wt/wt (40 CFR 180.1195); and when used in anthraquinone pesticide formulations at a maximum of 45% wt/wt (40 CFR 180.1195). Titanium dioxide is also approved for use as a colorant in food (21 CFR 73.575).

Although dietary exposure may be expected from use of titanium dioxide in pesticide formulations applied to bee hives and on other crops (as well as from other non-pesticidal sources), a quantitative exposure assessment for titanium dioxide was not conducted because no endpoint of concern was identified in the database.

2. Dietary exposure from drinking water. Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures from drinking water may be expected from use on food crops.

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).

Titanium dioxide may be used in non-pesticide products such as paints, printing inks, paper and plastic products around the home. It has also been approved for use in drugs (21 CFR 73.1575) and in cosmetics (21 CFR 73.2575 and 73.3126). Additionally, titanium dioxide may be used as an inert ingredient in pesticides that include residential uses; however based on the discussion in Unit IV.B., a quantitative residential exposure assessment for titanium dioxide was not conducted.

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.”

Because titanium dioxide does not have a toxic mode of action or a mechanism of toxicity, this provision does not apply.

D. Safety Factor for Infants and Children

Due to titanium dioxide’s low potential hazard and the lack of a hazard endpoint, it was determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for titanium dioxide. For the same reasons that a quantitative risk assessment based on a safety factor approach is not appropriate for titanium dioxide, an FQPA SF is not needed to protect the safety of infants and children. Start Printed Page 37443

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on titanium dioxide, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to titanium dioxide under reasonable foreseeable circumstances. Therefore, the exemption from tolerance under 40 CFR 180.920 for residues of titanium dioxide, when used as an inert ingredient in pesticide formulations is safe under FFDCA section 408.

V. 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.

VI. Conclusions

Therefore, EPA is amending the exemption from the requirement of a tolerance in 40 CFR 180.920 for residues of titanium dioxide (CAS Reg. No. 13463-67-7) when used as an inert ingredient (carrier) in pesticide formulations.

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); 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: July 11, 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, revise the inert ingredient “Titanium dioxide (CAS Reg. No. 13463-67-7)” in the table to read as follows:

§ 180.920

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

Inert ingredients	Limits	Uses
Titanium dioxide (CAS Reg. No. 13463-67-7)		Pigment, colorant, carrier.