



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0252; FRL-9961-82]

Titanium dioxide; 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 titanium dioxide (CAS Reg. No. 13463-67-7) in honey when used as an inert ingredient (colorant) at a concentration of not more than 0.1% by weight in pesticide formulations intended for varroa mite control around bee hives. Bayer Healthcare, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of titanium dioxide resulting from this use.

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-2016-0252, 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 FFDCFA 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-2016-0252 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-2016-0252, 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 July 20, 2016 (81 FR 47150) (FRL-9948-45), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10888) by Technology Sciences Group Inc., on

behalf of Bayer HealthCare, LLC, P.O. Box 390, Shawnee Mission, KS 66201. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of titanium dioxide (CAS Reg. No. 13463-67-7) in honey when used as an inert ingredient (colorant) at a concentration not more than 0.1% by weight in pesticide formulations intended for varroa mite control around bee hives. That document referenced a summary of the petition prepared by Technology Sciences Group Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing an exemption from the requirement of a tolerance in 40 CFR 180.1195, instead of 40 CFR 180.910 as requested. Exemptions under section 180.910 cover residues applied to growing crops and raw agricultural crops after harvest. Because the petitioner requested an exemption to cover residues only in honey resulting specifically from the use in hives, the Agency has determined that the broader exemption in section 180.910 is not appropriate. For ease of reference, the Agency is establishing this exemption in section 180.1195, which contains other limited exemptions for residues of titanium dioxide.

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 FFDCFA 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 FFDCFA 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 FFDCFA 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 carcinogenicity is not a concern 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 fine-particle-size titanium dioxide.

Even assuming the study indicates the potential for carcinogenicity, EPA does not expect any reasonably foreseeable uses of titanium dioxide in pesticide formulations that might result in residential exposures to 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 dose 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, which means there will not be 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 [titanium dioxide] 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 pesticides.

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-2016-0252.

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 (40 CFR 180.920); when used in pesticide formulations applied to animals (40 CFR 180.930); when used as a ultraviolet (UV) protectant in microencapsulated formulations of the insecticide lambda-cyhalothrin at no more than 3.0% by weight (40 CFR 180.1195); and when used as a UV stabilizer in pesticide formulations of napropamide at no more than 5% of the product formulation (40 CFR 180.1195). Titanium dioxide is also approved for use as a colorant in food (21 CFR 73.575); in drugs (21 CFR 73.1575); and in cosmetics (21 CFR 73.2575 and 73.3126).

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. 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.

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 establishment of an exemption from tolerance under 40 CFR 180.1195 for residues in honey of titanium dioxide, when used as an inert ingredient (colorant) in pesticide formulations intended for varroa mite control around bee hives at a maximum concentration of 0.1% by weight, is safe under FFDCA section 408.

V. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of titanium dioxide that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation 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 for sale or distribution for use in beehives with concentrations of titanium dioxide exceeding 0.1% by weight of the formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.1195 for titanium dioxide (CAS Reg. No. 13463-67-7) when used as an inert ingredient (colorant) in pesticide formulations intended for varroa mite control around bee hives at a maximum concentration of 0.1% by weight in the pesticide formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). 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 FFDCFA 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: May 8, 2017.

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. Section 180.1195 is revised to read as follows:

§ 180.1195 Titanium dioxide.

- (a) Titanium dioxide (CAS Reg. No. 13463-67-7) is exempted from the requirement of a tolerance for residues in or on growing crops, when used as an inert ingredient (UV protectant) in microencapsulated formulations of the insecticide lambda cyhalothrin at no more than 3.0% by weight of the formulation and as an inert ingredient (UV stabilizer) at no more than 5% in pesticide formulations containing the active ingredient napropamide.
- (b) Residues of titanium dioxide (CAS Reg. No. 13463-67-7) in honey are exempted from the requirement of a tolerance, when used as an inert ingredient (colorant) in pesticide formulations intended for varroa mite control around bee hives at no more than 0.1% by weight in the pesticide formulation.