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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0613; FRL-9991-13]

2-Hydroxypropyl Starch; 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 2-hydroxypropyl starch (CAS Reg. No. 9049-76-7) when used as an inert ingredient (adjuvant) on growing crops only under 40 CFR 180.920. SciReg., Inc., on behalf of Bayer CropScience Biologics GmbH, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-hydroxypropyl starch when used in accordance with the terms of 40 CFR 180.920.

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-2018-0613, 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-2018-0613 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-2018-0613, 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 6, 2019 (84 FR 2115) (FRL-9987-08), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-11130) by SciReg., Inc. (12733 Director's Loop Woodbridge, VA 22192) on behalf of Bayer CropScience Biologics GmbH (Lukaswiese 4, 23970 Wismar Germany). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-hydroxypropyl starch (CAS Reg. No. 9049-76-7) when used as an inert ingredient (adjuvant) 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(c)(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. In making this safety determination, EPA is directed to consider the factors contained in section 408(b)(2)(C) and (D). In particular, 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 2-hydroxypropyl starch including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-hydroxypropyl starch 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 2-hydroxypropyl starch 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.

Starches for commercial use are generally produced from potatoes, cereals, or other sources. They are composed of about 20-25% amylose and 75-80% amylopectin. High-amylose starches typically consist of 50-80% amylose and 20-50% amylopectin. In modified starches, the chemical and physical characteristics of the native substances are altered to improve the functional properties for particular food applications.

2-Hydroxypropyl starch is made by modifying starch derived from potatoes, cereals, or other sources with propylene oxide. Subchronic toxicity studies are available with 2-hydroxypropyl starch. The remaining studies used to evaluate the toxicity of 2-hydroxypropyl

starch are conducted with various other modified starches similar to 2-hydroxypropyl starch in structural, physicochemical, and biological properties. These data are considered appropriate to characterize potential toxicity due to exposure to 2-hydroxypropyl starch.

The acute oral toxicity of 2-hydroxypropyl starch is low in various species such as mice, rats, guinea pigs, rabbits, and cats; the lethal dose, LD_{50} is > 7,000 milligrams/kilogram (mg/kg). No studies are available on acute dermal and inhalation toxicity, skin and eye irritation and dermal sensitization.

No toxicity is observed at doses as high as 9,000 mg/kg/day following 90 days of exposure in oral toxicity studies conducted with 2-hydroxypropyl starch in rats.

Three-generation reproduction toxicity studies conducted with surrogate modified starches in rats are available for review. Fetal susceptibility is not observed. No parental, offspring or reproduction toxicity is seen up to 62% (equivalent to 31,000 mg/kg/day) in rats treated with modified starches.

Chronic toxicity and carcinogenicity studies were also conducted with surrogate modified starches. Reduced body weight is observed at 30% (15,000 mg/kg/day) in a chronic/carcinogenicity study in rats. No other treatment-related effects or tumors were observed at doses <5,000 mg/kg/day in rats and mice.

Mutagenicity studies with a surrogate modified starch were negative. No revertant colonies were observed in an Ames test and no DNA exchange was observed in a sister chromatid exchange assay.

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

Metabolism studies conducted with a surrogate modified starch, sodium octenyl succinate (OSA) in rats via oral and intravenous administration show that these materials are

metabolized and excreted primarily in the urine and feces. Approximately, 10% of unmodified OSA and 30% tricarboxylic acid of OSA are identified metabolites. In a metabolism study with puppy and adult dogs treated orally with ^{14}C-labelled OSA, the material is metabolized and excreted primarily in the urine and feces. Unmodified OSA (55.7% and 59.5%) represents the main metabolite in adult dogs with tricarboxylic acid of OSA representing a small portion (4.4% and 3.6%). 3.8% and 4.7% of other OSA metabolites were recovered from the urine. In puppies, OSA (41.8%) and tricarboxylic acid (10.7%) were identified metabolites. Several in vitro studies show that many strains of bacteria found in the human colon can ferment starches.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that 2-hydroxypropyl starch has very low overall toxicity. Acute oral toxicity studies show LD_{50s} above 7,000 mg/kg/day in multiple species. Repeated dose studies show no toxicity at doses as high as 4,500 mg/kg/day, 4.5 times the limit dose of 1,000 mg/kg/day. Since no toxicity is observed, an endpoint of concern for risk assessment purposes was not identified.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to 2-hydroxypropyl starch, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-hydroxypropyl starch in food as follows:

Dietary exposure (food and drinking water) to 2-hydroxypropyl starch may occur following ingestion of foods with residues from treated crops. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

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 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).

2-hydroxypropyl starch 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 2-hydroxypropyl starch 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."

Based on the available data, 2-hydroxypropyl starch does not have a toxic mechanism; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of 2-hydroxypropyl starch. That qualitative assessment does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of 2-hydroxypropyl starch, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of 2-hydroxypropyl starch 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 2-hydroxypropyl starch residues.

V. Other Considerations

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, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for 2-hydroxypropyl starch (CAS Reg. No. 9049-76-7) when used as an inert ingredient (adjuvant) in pesticide formulations applied to growing crops only.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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 tolerance 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: 3/21/19

Donna Davis,

Acting 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 alphanumerically the inert ingredient "2-hydroxypropyl starch (CAS Reg. No. 9049-76-7)" 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
* * * * * * *		
2-Hydroxypropyl starch (CAS Reg. No. 9049-76-7)		Adjuvant
* * * * * * *		

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