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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0179; FRL-9974-14]

Distillates (petroleum), Solvent-Dewaxed Heavy Paraffinic; 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 distillates (petroleum), solvent-dewaxed heavy paraffinic (CAS Reg. No. 64742-65-0) when used as an inert ingredient (carrier) in pesticide products applied to growing crops and raw agricultural commodities after harvest and to animals. SciReg., Inc., on behalf of HollyFrontier Refining & Marketing 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 distillates (petroleum), solvent-dewaxed heavy paraffinic when used in accordance with the terms of those exemptions.

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-2017-0179, 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-2017-0179 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-2017-0179, 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 September 15, 2017 (82 FR 43352) (FRL-9965-43), EPA issued a document pursuant to FFDC section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-11015) by SciReg., Inc. (12733 Director's Loop Woodbridge, VA 22192) on behalf of HollyFrontier Refining & Marketing LLC (401 Plymouth Road, Suite 350, Plymouth Meeting, PA 19462). The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing exemptions from the requirement of a tolerance for residues of distillates (petroleum), solvent-dewaxed heavy paraffinic (CAS Reg. No. 64742-65-0) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest and in pesticides applied to animals. That document referenced a summary of the petition prepared by SciReg., Inc. on behalf of HollyFrontier Refining & Marketing LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.B.

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. Section 408(c)(2)(B) requires EPA to take into account the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2) when making this exemption safety determination. 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 distillates (petroleum), solvent-dewaxed heavy paraffinic including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with distillates (petroleum), solvent-dewaxed heavy paraffinic 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 distillates (petroleum), solvent-dewaxed heavy paraffinic 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.

Petroleum materials are defined by how they are processed, physical properties and product use specifications. Distillates (petroleum), solvent-dewaxed heavy paraffinic are characterized as highly and severely refined distillate base oils. Petroleum materials processed in this manner behave similarly. Therefore, toxicity data on highly and severely refined distillate

base oils are used as read across data to characterize the toxicity of similarly processed petroleum materials. Since limited toxicity data exist on distillates (petroleum), solvent-dewaxed heavy paraffinic, toxicity data on other highly and severely refined distillate base oils are used to characterize toxicity due to distillates (petroleum), solvent-dewaxed heavy paraffinic.

The acute oral toxicity is low in rats for distillates (petroleum), solvent-dewaxed heavy paraffinic; the lethal dose, LD₅₀ is > 15,000 milligrams/kilogram (mg/kg). Distillates (petroleum), solvent-dewaxed heavy paraffinic has low acute dermal toxicity; the LD₅₀ is > 5,000 mg/kg in rabbits. In rats, acute inhalation toxicity is also low, the LD₅₀ is > 4.0 milligrams/liter (mg/L). It is not a dermal sensitizer in the guinea pig. Skin and eye irritation studies are not available.

Oral repeated dose studies are not available on distillates (petroleum), solvent-dewaxed heavy paraffinic; however, studies are available on a similarly processed petroleum material (C₁₀-C₁₃ dearomatized solvent). Following 90 days of exposure via gavage to C₁₀-C₁₃ dearomatized solvent, the bench mark dose lower confidence limit (BMDL) was established at 1,857 mg/kg/day based on increased serum alanine aminotransferase (ALT) levels in rats.

No systemic toxicity is observed up to 2,000 mg/kg/day following 28 days or 13 weeks of dermal exposure to distillates (petroleum), solvent-dewaxed heavy paraffinic in rabbits and rats. No systemic toxicity is observed in a 90-day or 13-week dermal toxicity studies in male rats at 1,000 mg/kg/day and 2,000 mg/kg/day of distillates (petroleum), solvent-dewaxed heavy paraffinic, respectively. In an OECD guideline developmental toxicity study via dermal exposure, no systemic or dermal toxicity is observed at 2,000 mg/kg/day.

Following inhalation exposure, multiple lung effects are observed at 0.52 g/m³ (0.52 mg/L). However, the lung effects were not due to chemical toxicity but rather the irritating nature of distillates (petroleum), solvent-dewaxed heavy paraffinic.

No maternal, offspring or reproduction toxicity is observed up to 1,150 mg/kg/day in a 2-generation reproduction toxicity study in rats on a similarly processed petroleum, distillates (petroleum), hydrotreated heavy paraffinic.

Although no carcinogenicity studies with distillates (petroleum), solvent-dewaxed heavy paraffinic are available, none of the available data concerning highly and severely refined distillate base oils indicate any toxicological endpoint of concern up to 1,000 mg/kg/day. Additionally, a Derek Nexus structural alert analysis was conducted with distillates (petroleum), solvent-dewaxed heavy paraffinic and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, distillates (petroleum), solvent-dewaxed heavy paraffinic is not expected to be carcinogenic.

Evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies. Therefore, distillates (petroleum), solvent-dewaxed heavy paraffinic is not expected to be neurotoxic or immunotoxic.

Metabolism studies show that mineral oils and aliphatic petroleum hydrocarbons are poorly absorbed across the gastrointestinal tract lining and rapidly eliminated unchanged in the feces. Also, dermal absorption and inhalation absorption is very poor.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies support a conclusion that distillates (petroleum), solvent-dewaxed heavy paraffinic have very low overall toxicity. The NOAELs in a 90-day oral and reproduction toxicity studies on similarly processed petroleum distillates were > 1,000 mg/kg/day; the limit dose. Effects observed in inhalation studies are due to irritating effects rather than systemic toxicity. Since toxicity was only observed at doses above the limit dose, an endpoint of concern for risk assessment purposes was not identified. Therefore, a qualitative

risk assessment was conducted for acute and chronic dietary exposures and short and intermediate dermal and inhalation exposures.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to distillates (petroleum), solvent-dewaxed heavy paraffinic, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from distillates (petroleum), solvent-dewaxed heavy paraffinic in food as follows:

Dietary exposure (food and drinking water) to distillates (petroleum), solvent-dewaxed heavy paraffinic may occur following ingestion of foods with residues from treated crops or animals. 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).

Distillates (petroleum), solvent-dewaxed heavy paraffinic 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 distillates (petroleum), solvent-dewaxed heavy paraffinic 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, distillates (petroleum), solvent-dewaxed heavy paraffinic does not have a toxic mechanism; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCFA 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 Safety Factor (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.

Based on the lack of threshold effects, EPA has not identified any toxicological endpoints of concern and is conducting a qualitative assessment of distillates (petroleum), solvent-dewaxed heavy paraffinic. 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 distillates (petroleum), solvent-dewaxed heavy paraffinic, 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 distillates (petroleum), solvent-dewaxed heavy paraffinic 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 distillates (petroleum), solvent-dewaxed heavy paraffinic 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.

B. Response to Comments

One comment was received urging the Agency not to allow residues of pesticides in or on food. Although the Agency recognizes that some individuals believe that no residue of pesticides should be allowed in or on food, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes the establishment of pesticide tolerances or exemptions where the Agency determines that tolerance or exemption meets the safety standard imposed by the statute. EPA has sufficient data to support a safety determination for the exemption from the requirement of a tolerance for distillates (petroleum), solvent-dewaxed heavy paraffinic. The commenter provided no additional information supporting a determination that the exemption is not safe.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of distillates (petroleum), solvent-dewaxed heavy paraffinic (CAS Reg. No. 64742-65-0) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops and raw

agricultural commodities after harvest under 40 CFR 180.910 and when applied to animals under 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This action establishes tolerance exemptions 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 exemptions 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 FFDC 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: February 12, 2018.

Michael 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 §180.910, add alphabetically the inert ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Distillates (petroleum), solvent-dewaxed heavy paraffinic (CAS Reg. No. 64742-65-0)		Carrier
* * *	* * *	*

3. In §180.930, add alphabetically the inert ingredient to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

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Inert ingredients	Limits	Uses
* * *	* * *	*
Distillates (petroleum), solvent-dewaxed heavy paraffinic (CAS Reg. No. 64742-65-0)		Carrier
* * *	* * *	*

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