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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0444; FRL-9909-83]

Sweet Orange Peel Tincture; 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 sweet orange peel tincture when used as an inert ingredient not to exceed 10% (weight/weight) in pesticide formulations for use as a surfactant, fragrance, and adjuvant on all pre- and post-harvest food commodities. This regulation eliminates the need to establish a maximum permissible level for residues of sweet orange peel tincture.

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-2013-0444, 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), EPA West 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: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; 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-2013-0444 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-2013-0444, 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.htm*.

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 19, 2013 (78 FR 43117) (FRL-9392-9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10547) by AG-Chem Consulting (12208 Quinque Lane, Clifton VA 21024), on behalf of Oro-Agri, Inc., 990 Trophy Club Drive, Trophy Club, TX 76262. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of sweet orange peel tincture when used as an inert ingredient when used as a surfactant, fragrance and adjuvant up to 10% (weight/weight) concentration in pesticide products applied to all pre- and post-harvest food commodities. That document referenced a summary of the petition prepared by AG-Chem Consulting, 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 sweet orange peel tincture including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sweet orange peel tincture 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 sweet orange peel tincture 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.

Sweet orange peel tincture and sweet orange peel oil are chemically the same (EINECS No. 232-433-8; CAS 8028-48-6). The only difference is the method of extraction. Sweet orange peel tincture is extracted in alcohol and the extraction process leads to the formation of a "tincture". Sweet orange peel oil is extracted by cold press expression. Both are extracted from the same plant, Citrus sinensis family Rutaceae. Both forms of the sweet orange peel extract contain d-limonene as its primary component (> 90%) and lesser amounts of myrcene. The EPA has conducted a "Screening-Level Hazard Assessment" of a class of compounds called monoterpene hydrocarbons, d-limonene and myrcene are among the monoterpene hyrdrocarbons assessed. The chemical class was "based on structural similarity, similar molecular weights and functional groups and the expectation that inherent physicochemical, environmental and toxicological properties are predicted to be similar". That analysis also included a review of data on sweet orange peel oil since it is a complex mixture containing greater than 90% monoterpene hydrocarbons (including d-limonene and myrcene), and is expected to have "physicochemical, environmental and toxicological properties similar to the major components…limonene and myrcene". Therefore, the Agency assessed the potential toxicity of sweet orange peel tincture based on the available toxicity data for sweet orange peel oil, and where data for sweet orange peel oil is missing, relied upon available data for the monoterpene hydrocarbons chemical class.

The acute oral and dermal toxicity of sweet orange peel oil is low. The oral LD_{50} was >5,000 milligram/kilogram (mg/kg) in rats and rabbits, respectively.

In a 28-day study with sweet orange peel oil, lesions in the non-glandular stomach and clinical chemistry were observed at 1,500 mg/kg/day (above the limit dose of 1,000 mg/kg/day) in rats. Lesions in the non-glandular stomach is attributed to the irritating

property of the chemical. The NOAEL was 600 mg/kg/day.

In a combined reproductive/developmental toxicity screening test with sweet orange peel oil, stillbirths and pup mortality were observed at 1,500 mg/kg/day. The offspring NOAEL was 750 mg/kg/day**.** Signs of toxicity were not observed in maternal rats, the NOAEL was 1,500 mg/kg/day.

Evidence of mutagenicity was not observed in the Ames test. Although evidence of mutagenicity was observed in mouse lymphoma assay, it was noted that cytotoxic concentrations were not reported and this could contribute to an inflated mutation rate. In addition, d-limonene was not mutagenic in an Ames test, mouse lymphoma, sister chromatid exchange nor in chromosome aberrations in Chinese hamster ovary cells assays. Therefore, based on the weight of evidence sweet orange peel tincture is not expected to be mutagenic.

Evidence of immunotoxicity was not observed. Sweet orange peel oil exhibited no effects on cell-mediated or humoral immune response at doses up to 2,500 mg/kg/day in a plaque-forming cell assay in mice.

Although a carcinogenicity study was not available for sweet orange peel tincture, carcinogenicity studies were available in the rat and mouse for d-limonene. An increased incidence of tumor formation was not observed in a 2 year carcinogenicity study on female rats or in male and female mice treated with d-limonene up to 1,000 mg/kg/day. An increased incidence of tubular cell hyperplasia, adenomas, and adenocarcinomas of the kidney was observed in the male rat. However, these lesions are related to the accumulation of the alpha 2u-globulin protein which is specific to the male rat and is not relevant for human risk assessment. Based on this available information and the data

supporting EPA's conclusion that sweet orange peel tincture is not expected to be mutagenic, EPA concludes that sweet orange peel tincture is not likely to be carcinogenic.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that sweet orange peel tincture has low toxicity. Since no endpoint of concern was identified for sweet orange peel tincture, a qualitative risk assessment is appropriate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to sweet orange peel tincture, EPA considered exposure under the proposed exemption from the requirement of a tolerance (40 CFR 180.910 as an inert ingredient used in pesticide formulations applied to growing crops). EPA assessed dietary exposures from sweet orange peel tincture in food as follows:

Dietary exposure can occur from eating foods containing residues of sweet orange peel tincture. Because no hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

2. *Dietary exposure from drinking water*. Sweet orange peel tincture residues may be found in drinking water. However, since an endpoint of concern was not identified for the dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

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). Sweet orange peel tincture is used as an inert ingredient in pesticide products that could result in short- and intermediate-term residential exposure. However, based on the lack of toxicity, a quantitative exposure assessment from residential exposures was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found sweet orange peel tincture to share a common mechanism of toxicity with any other substances and sweet orange peel tincture does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sweet orange peel tincture does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (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 an assessment of sweet orange peel oil, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has conducted a qualitative assessment. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate point of departure (PODs) to ensure that an adequate MOE exists.

Based on the lack of any endpoints of concern, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to sweet orange peel tincture residues.

V. Other Considerations

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 180.910 for sweet orange peel tincture (CAS Reg. No. 8028-48-6) when used as an inert ingredient in pesticide formulations for use as a surfactant, fragrance and adjuvant up to 10% (weight/weight) on all pre- and post-harvest food commodities.

VII. Statutory and Executive Order Reviews

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 to the requirement of a tolerance 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: August 7, 2014.

Lois Rossi,
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, the table is amended by alphabetically adding entry for "Sweet orange peel tincture***" after the entry for "Sulfuric acid***" to read as follows:

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

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Pesticide Chemical	Limits	Uses
* *	* * *	* *
Sweet orange peel tincture (CAS Reg. No. 8028-48-6)	Not to exceed 10% (weight/weight) in pesticide formulation	Surfactant, fragrance, related adjuvants of surfactants.
* *	* * * * *	* *

[FR Doc. 2014-19450 Filed 08/14/2014 at 8:45 am; Publication Date: 08/15/2014]