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).

VII. 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 28, 2019.

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 § 180.449, amend the table in paragraph (a) as follows:
■ a. Add alphabetically the entries ''Arugula''; ''Carrot, roots''; ''Celtuce''; ''Fennel, Florence, fresh leaves and stalk''; ''Garden cress''; ''Leaf petiole vegetable subgroup 22B''; and ''Leafy greens subgroup 4–16A'';
■ b. Remove the entry for ''Lychee'';
■ c. Add alphabetically the entries ''Tropical and subtropical, small fruit, inedible peel, subgroup 24A'' and ''Upland cress'';
■ d. Remove the entry for ''Vegetable, leafy, except brassica group 4''; and
■ e. Add alphabetically the entries ''Vegetable, legume, dried shelled, except soybean, subgroup 6C''; ''Vegetable, legume, edible podded, subgroup 6A''; and ''Vegetable, legume, succulent shelled, subgroup 6B''.

The additions read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Arugula	0.1
* * * * *	
Carrot, roots	0.03
* * * * *	
Celtuce	0.1
* * * * *	
Fennel, Florence, fresh leaves and stalk	0.1
* * * * *	
Garden cress	0.1
* * * * *	
Leaf petiole vegetable subgroup 22B	0.1
Leafy greens subgroup 4–16A	0.1
* * * * *	
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	0.01
Upland cress	0.1
* * * * *	
Vegetable, legume, dried shelled, except soybean, subgroup 6C	0.01
Vegetable, legume, edible podded, subgroup 6A	0.08
Vegetable, legume, succulent shelled, subgroup 6B	0.08
* * * * *	

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[FR Doc. 2019–19400 Filed 9–6–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0203; FRL–9998–48]

Alcohols, $C_{2–33}$, Manuf. of By-Products From, Overheads; 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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads when used as an inert ingredient (solvent) in pesticide products applied to growing crops and raw agricultural commodities after harvest, and to animals. Spring Trading Company, on behalf of Sasol Chemicals (USA) 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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads when used in accordance with the terms of those exemptions.

DATES: This regulation is effective September 9, 2019. Objections and requests for hearings must be received on or before November 8, 2019, 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–2018–0203, 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 Publishing 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–2018–0203 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 November 8, 2019. 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–2018–0203, 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 August 24, 2018 (83 FR 42818) (FRL–9982–37), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11098) by Spring Trading Company (203 Dogwood Trail, Magnolia, TX 77354) on behalf of Sasol Chemicals (USA) LLC (12120 Wickchester Lane, Houston, TX 77079). The petition requested that the 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and to animals under 40 CFR 180.930. That document referenced a summary of the petition prepared by Spring Trading Company on behalf of Sasol Chemicals (USA) LLC, the petitioner, which is available in the docket, *http://www.regulations.gov.* One relevant 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, in making a determination of safety for the exemption, to take into account the factors in subparagraphs (b)(2)(C) and (D). 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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with alcohols, $C_{2–33}$, manuf. of, by-products from, overheads follow.

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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads 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.

$C_{2–33}$ manuf. of, by-products from, overheads are the by-products obtained as solvent stripper overheads after removal of non-alkoxide components during the manufacture of alcohols from ethylene by the Ziegler process. It consists predominantly of paraffins, olefins, naphthenes and esters having carbon numbers in the range $C_{2–34}$ and melting in the range of approximately −17.5 °C to −4.1 °C.

The acute oral and dermal toxicity is low in rats treated with alcohols, $C_{2–33}$, manuf. of, by-products from, overheads; the lethal dose, LD_{50} is >2,000 milligrams/kilogram (mg/kg). It is not a dermal sensitizer in the guinea pig. Acute inhalation toxicity studies are not available for review. Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are not a skin or eye irritant in rabbits.

Three repeated dose studies via oral exposure are available with alcohols, $C_{2–33}$, manuf. of, by-products from, overheads in rats: A 14-day range finding toxicity study; a combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests in rats; and a 2-generation toxicity study in rats. Following 14 days of oral exposure to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads in rats, no toxicity is seen at 1,000 mg/kg/day. In the combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests in rats, parental and offspring toxicities are observed at 1,000 mg/kg/day. Parental and reproduction toxicities are manifested as an increased number of females giving birth to dead pups and offspring toxicity is manifested as reduced pup viability. The NOAELs are 500 mg/kg/day. In the 2-generation reproduction toxicity study, offspring toxicity is manifested as reduced pup viability. The NOAEL is 500 mg/kg/day. In a reproduction toxicity study in rats, parental, offspring and reproduction toxicities are seen at 1,000 mg/kg/day. Parental toxicity manifests as reduced body weights and/or weight gain in F_0 females during mating and in F_1 females during gestation and reduced food consumption, offspring toxicity manifests as delayed vaginal opening and preputial separation and reduced ovarian follicles and reproduction toxicity manifests as lower numbers of implantation sites and lower litter size with correlating lower litter weight noted in both generations. The NOAELs are 500 mg/kg/day. Increase fetal susceptibility is not observed as offspring toxicity occurs in the presence of maternal toxicity. The combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests and the 2-generation toxicity study in rats are considered co-critical, the chronic reference dose (cRfD) of 5.0 mg/kg/day is based on these studies and is protective of the effects observed at 1,000 mg/kg/day.

Carcinogenicity studies with alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are not available. However, based on the lack of mutagenicity in the Ames test, alcohols, $C_{2–33}$, manuf. of, by-products are not expected to be carcinogenic.

Neurotoxicity studies are not available for review. However, detailed functional observations (FOB), grip strength, pain perception, landing foot splay and motor activity were performed in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats and no adverse effects were observed.

Immunotoxicity studies are not available for review. However, evidence of immunotoxicity is not observed in the submitted studies.

In the 2-generation reproduction toxicity study, alcohols, $C_{2–33}$, manuf. of, by-products from, overheads caused a slight delay in sexual maturation in rat pups. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruption Screening Program (EDSP) have been developed, $C_{2–33}$, manuf. of, by-products from, overheads may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

The combined repeated dose toxicity study with the reproduction/developmental toxicity screening test and a 2-generation reproduction toxicity study are considered co-critical and these studies are selected for the chronic dietary exposure scenario as well as the dermal and inhalation intermediate and long-term exposure scenarios. The NOAELs are 500 mg/kg/day in these studies. Effects are seen at the limit dose, 1,000 mg/kg/day, in both studies. Parental effects are confined to female rats and included an increased number of females giving birth to dead pups and reduced body weights and/or weight gain in F_0 females during mating and in F_1 females during gestation and reduced food consumption in the reproduction/developmental toxicity screening test and the 2-generation reproduction toxicity study, respectively. Offspring toxicity is manifested as reduced pup viability and reduced mean delay of vaginal opening and preputial separation and reduced ovarian follicles, respectively. Reproduction toxicity is observed in the both studies and include a lower numbers of implantation sites and lower litter size with correlating lower litter weight in the F_0 and F_1 generations in the reproduction/developmental toxicity screening tests; and increased number of females giving birth to dead pups in the reproduction toxicity study. The standard inter- and intra-species

uncertainty factors of 10x are applied. The default factor of 100% is applied for the dermal and inhalation absorption rates. The chronic reference dose (cRfD) is 5.0 mg/kg/day. The level of concern (LOC) and margin of exposure is 100.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from alcohols, $C_{2–33}$, manuf. of, by-products from, overheads in food as follows:

Dietary exposure (food and drinking water) to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™, Version 3.16) and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for alcohols, $C_{2–33}$, manuf. of, by-products from, overheads. In the absence of specific residue data, EPA has developed an approach that uses surrogate information to derive upper-bound exposure estimates for the subject inert ingredient. Upper-bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for alcohols, $C_{2–33}$, manuf. of, by-products from, overheads, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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).

Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted an assessment to represent conservative residential exposure by assessing alcohols, $C_{2–33}$, manuf. of, by-products from, overheads in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios). The Agency's assessment of adult residential exposure combines high end dermal and inhalation handler exposure from liquids/backpack sprayer/home garden with a high-end post application dermal exposure from contact with treated lawns. The Agency's assessment of children's residential exposure includes total post-application exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures).

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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads to share a common mechanism of toxicity with any other substances, and alcohols, $C_{2–33}$, manuf. of, by-products from, overheads does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that alcohols, $C_{2–33}$, manuf. of, by-products from, overheads do 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

1. *In general.* 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 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.

2. *Prenatal and postnatal sensitivity.* The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10X is reduced to 1X for the chronic dietary assessment based on the following reasons. The toxicity database for alcohols, $C_{2–33}$, manuf. of, by-products from, overheads contain the following studies; combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats, 2-generation reproduction toxicity in rats, Ames test and micronucleus assay. No evidence of neurotoxicity was observed in the functional observation battery. There is no indication of immunotoxicity in the available studies; therefore, there is no need to require an immunotoxicity study. Fetal susceptibility is not observed as fetal toxicity occurs in the present of maternal toxicity in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test and the 2-generation reproduction toxicity study. In addition, the chronic reference dose (cRfD) is protective of any observed effects since it is based on the effects observed in these studies. Therefore, the Agency has concluded that reducing the FQPA SF to 1X is appropriate.

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 PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads from food and water will utilize 14.1% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 332 for adults. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/backpack sprayer/home garden with a high-end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 309 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for alcohols, $C_{2–33}$, manuf. of, by-products from, overheads is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to alcohols, $C_{2–33}$, manuf. of, by-products from, overheads.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1105 for adults. Adult residential exposure combines liquids/backpack sprayer/home garden use with a high-end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 431 for children. Because EPA's level of concern for alcohols, $C_{2–33}$, manuf. of, by-products from, overheads is an MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of mutagenicity, alcohols, $C_{2–33}$, manuf. of, by-products from, overheads are not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, 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 alcohols, $C_{2–33}$, manuf. of, by-products from, overheads 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 commenter believed that all analyses should be provided on alcohols, $C_{2–33}$, manuf. of, by-products from, overheads residues prior to its use as an inert ingredient in solvents and that no tolerance or tolerance exemption should be allowed. Under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide chemical tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide chemical meets the safety standard imposed by the statute. EPA has sufficient data to evaluate the potential adverse effects from exposure to this pesticide chemical, including data on the potential for long-term effects. After evaluating that data and other information, EPA has determined that the tolerance exemptions for this chemical are safe. The commenter has provided no other information for the Agency to consider in making its safety determination.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under residues of alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and applied to animals under 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This action establishes exemptions 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), 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 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 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: August 21, 2019.

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 § 180.910, add alphabetically the inert ingredient ''Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0)'' 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
* * * * *	*	*
Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0)	.....	Solvent.
* * * * *	*	*

■ 3. In § 180.930, add alphabetically the inert ingredient ''Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0)'' to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * *	*	*
Alcohols, $C_{2–33}$, manuf. of, by-products from, overheads (CAS Reg. No. 876065–86–0)	.....	Solvent.
* * * * *	*	*

[FR Doc. 2019–19398 Filed 9–6–19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG–2018–0041]

COMDTINST M16721.48 Merchant Mariner Medical Manual

AGENCY: Coast Guard, DHS.

ACTION: Notification of availability.

SUMMARY: The Coast Guard announces the availability of the Merchant Mariner Medical Manual, Commandant Instruction Manual (COMDTINST M16721.48). The guidance in this Manual should assist medical practitioners, the maritime industry, individual mariners, and Coast Guard personnel in evaluating a mariner applicant's physical and medical status to meet the requirements of the merchant mariner medical certificate. This Manual incorporates and consolidates prior guidance on the medical evaluation of merchant mariners contained in several Coast Guard documents. The Manual includes guidance on the medical certificate and related processes, including procedures for application, issuance, and cancellation of the medical certificate.

DATES: The Merchant Mariner Medical Manual, COMDTINST M16721.4, is effective on September 9, 2019.

FOR FURTHER INFORMATION CONTACT: For information about this document or to suggest changes, call or email Adrienne Buggs, M.D., United States Coast Guard, Office of Merchant Mariner