

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) (Pub. L. 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 10, 2011.

**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 § 180.920, the table is amended by adding alphabetically the following inert ingredient:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* Diethylene Glycol MonoEthyl Ether (CAS Reg. No. 111-90-0).	* Without limitation .....	* Solvent, stabilizer and/or antifreeze.
* * * * *	* * * * *	* * * * *

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2011-0517; FRL-8876-2]

**C<sub>9</sub> Rich Aromatic Hydrocarbons, C<sub>10-11</sub> Rich Aromatic Hydrocarbons, and C<sub>11-12</sub> Rich Aromatic Hydrocarbons; 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 C<sub>9</sub> rich aromatic hydrocarbons; C<sub>10-11</sub> rich aromatic hydrocarbons; and C<sub>11-12</sub> rich aromatic hydrocarbons, when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. ExxonMobil Chemical Company submitted a petition to EPA under the Federal Food, Drug, and

Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons.

**DATES:** This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, 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:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2011-0517. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 308-8811; *e-mail address:* [leifer.kerry@epa.gov](mailto:leifer.kerry@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. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *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.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

#### *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-2011-0517 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 August 22, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0517, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Petition for Exemption

In the **Federal Register** of January 25, 2006 (71 FR 4135) (FRL-7750-4) for C<sub>9</sub> rich aromatic hydrocarbons, January 23, 2006 (71 FR 3512) (FRL-7750-3) for C<sub>10-11</sub> rich aromatic hydrocarbons, and February 1, 2006 (71 FR 5321) (FRL-7750-5) for C<sub>11-12</sub> rich aromatic hydrocarbons, EPA issued notices pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of pesticide petitions (PP 5E6935, 5E6934, and 4E6937 respectively) by ExxonMobil Chemical Company, 13501 Katy Freeway, Houston, TX 77079. The petitions requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of C<sub>9</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-95-6), C<sub>10-11</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-5), and C<sub>11-12</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-5) when used as inert ingredients (solvents) in pesticide formulations applied to raw agricultural commodities and growing crops under 40 CFR 180.910. Those notices referenced summaries of the petitions prepared by ExxonMobil, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notices 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 of 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 section 408(c)(2)(A) of FFDCA, 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 C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons 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.

C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are products of the petroleum distillation and refining process. These substances are various fractions of aromatic petroleum hydrocarbons with specific boiling point ranges and flash points. Each of the substances is comprised of a complex mixture of aromatic hydrocarbon molecules in the range of 9 to 12 carbon atoms. Since C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons differ only in the proportions of the various hydrocarbon molecules within the C<sub>9</sub> to C<sub>12</sub> range, they have similar physicochemical and toxicological properties and have therefore been assessed together.

C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons exhibit low acute toxicity by oral, inhalation and dermal routes (toxicity Category III or IV by all exposure routes). They are minimally irritating to eyes and skin

and negative for dermal sensitization effects. Subchronic oral and inhalation toxicity studies indicate these substances to be relatively non-toxic. Reversible effects to the liver, thyroid, stomach, spleen, and urinary bladder were reported at mid and high doses in a subchronic oral toxicity study in rats. A developmental inhalation study in mice indicates no evidence of developmental effects or any adverse effects in maternal animals at dose levels below 715 milligrams/kilogram/day (mg/kg/day). An oral developmental study in rats indicates maternal effects (decreased body weight gain and food consumption) at the mid-dose (150 mg/kg/day) but no developmental effects at the highest dose tested (450 mg/kg/day). An inhalation reproduction study in rats indicates reduced body weight gain in parents and offspring at mid and high doses (715 and 2,145 mg/kg/day). Based on neurotoxicity studies, C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are not expected to cause any nervous system damage. Due to their complex, multi-constituent nature, there are no substance-specific absorption, metabolism, distribution and excretion studies done specifically on C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons. However, sufficient metabolism data are available on other aromatic hydrocarbons to show that as a class they are typically well-absorbed, widely distributed between tissues, extensively metabolized and rapidly excreted. C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are of low toxicological concern for developmental and reproductive effects, based on the available toxicity data, and are not expected to be carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons as well as the no-observed-adverse-effect-level (NOAEL)

and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov>

in the document "Exemptions From the Requirement of a Tolerance for C<sub>9</sub> Rich Aromatic Hydrocarbons, C<sub>10-11</sub> Rich Aromatic Hydrocarbons, C<sub>11-12</sub> Rich Aromatic Hydrocarbons," at pp 5-17 in docket ID number EPA-HQ-OPP-2006-0517.

*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>.

A summary of the toxicological endpoints for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR C<sub>9</sub>, C<sub>10-11</sub>, AND C<sub>11-12</sub> RICH AROMATIC HYDROCARBONS FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) .....	NOAEL = 150 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD = 1.5 mg/kg/day ..... aPAD = 1.5 mg/kg/day	OCSPP Harmonized Test Guideline 870.3700 Prenatal Developmental Toxicity Study in Rats Maternal LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR C<sub>9</sub>, C<sub>10–11</sub>, AND C<sub>11–12</sub> RICH AROMATIC HYDROCARBONS FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations) ....	NOAEL= 150 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 1.5 mg/kg/day ..... cPAD = 1.5 mg/kg/day	OCSPP Harmonized Test Guideline 870.3700 Prenatal Developmental Toxicity Study in Rats Maternal LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption
Cancer (Oral, dermal, inhalation) ..	Based on structure-activity relationship (SAR) analysis and structural alerts, not expected to be carcinogenic.		

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC=level of concern.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons in food as follows:

i. *Acute exposure.* In conducting the acute dietary exposure assessment for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons, EPA used food consumption information from the U.S. Department of Agriculture (USDA) [1994–1996 and 1998] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data can be found at <http://www.regulations.gov> in the document “Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,” in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue

level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product relative to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA’s decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA’s assumption that all foods contain the inert ingredient at

the highest tolerance level, *i.e.*, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, and then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10–11</sub> rich aromatic hydrocarbons, and C<sub>11–12</sub> rich aromatic hydrocarbons. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound chronic dietary exposure estimates for the subject inert ingredient. This

approach is as described in Unit IV. C.1.i.

iii. *Cancer.* The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. Therefore, a cancer dietary exposure assessment is not necessary to assess cancer risk.

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 C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments. 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).

C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that involve residential uses nor are there any other non-pesticidal residential uses for these inert ingredients, thus no residential exposures to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are expected. The primary non-pesticidal uses of C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are as gasoline additives. Residential exposures to these substances as a result of their use as gasoline additives could occur via inhalation during refueling and from potential transport of gasoline containing C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons into groundwater. There are no reliable data upon which to quantitatively assess such exposures to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons; however, modeled data for other gasoline additives suggest that inhalation exposures would be at levels of <5 micrograms/kilogram/day, and that

levels in groundwater would not exceed 0.2–16 ppb.

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 C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons to share a common mechanism of toxicity with any other substances, and C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons 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 Web site 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 (10×) 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 10×, 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 available mammalian toxicology database for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons is complete with respect to assessing increased susceptibility to infants and children. There were no adverse effects on the offspring of rats following prenatal and postnatal exposure in the OCSPP Harmonized

Test Guideline 870.3700 oral developmental toxicity study at the highest dose tested of 450 mg/kg/day. In a 3-generation inhalation toxicity study in rats, reproductive effects were seen only at dose levels above that at which parental effects were noted.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1×. That decision is based on the following findings:

i. The toxicity database for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons is largely complete, missing only a developmental neurotoxicity study and an immunotoxicity study. EPA has determined that an additional uncertainty factor is not needed to account for the lack of these studies for the following reasons:

- There were no neurotoxic effects observed at the highest dose tested in a 90-day inhalation neurotoxicity study in rats with a C<sub>9</sub> aromatic hydrocarbon material. There is no evidence that C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

- There is no evidence that C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons result in increased susceptibility in *in utero* rats in the prenatal developmental studies or in young rats in a 3-generation reproduction study.

- An immunotoxicity study is not available; however, there is no evidence of immune system involvement in the available toxicity database for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons, therefore, there is no need to add additional UFs to account for the lack of an immunotoxicity study.

ii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons in drinking water. These assessments will not underestimate the exposure and risks posed by C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich

aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons.

#### *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 population adjusted dose (aPAD) and chronic population adjusted dose (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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons will occupy 2.8% of the aPAD for children (1 to 2 years old), the population group receiving the greatest exposure. Therefore, C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons 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 C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons from food and water will utilize 0.6% of the cPAD for children (1 to 2 years old), the population group receiving the greatest exposure. There are no residential pesticide uses for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons. As noted in Unit IV.C.3., non-pesticidal drinking water exposure to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons may be possible from potential transport of gasoline containing C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons into groundwater; however, those potential exposures are addressed by the use of a conservative drinking water concentration value of 100 ppb used to assess the contribution to drinking water for the chronic dietary risk assessments, therefore no further assessment of this potential exposure is needed.

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). A short-term adverse effect was identified; however, C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons. As noted in Unit IV.C.3., there may be short-term inhalation exposures to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons when these substances are present as gasoline additives during gasoline refueling, however those exposures would be expected to be at levels at least three orders of magnitude below any level of concern and therefore have not been included in a quantitative short-term risk assessment.

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). An intermediate-term adverse effect was identified; however, C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons are not currently used as inert ingredients in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich

aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons, and C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons 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 C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons 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. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons.

## VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of C<sub>9</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-95-6), C<sub>10-11</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-5), and C<sub>11-12</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-

5) when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

**VII. Statutory and Executive Order Reviews**

This final rule establishes exemptions from tolerance under section 408(d) of FFDCA in response to petitions 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 section 408(d) of FFDCA, 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 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 section 408(n)(4) of FFDCA. 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) (Pub. L. 104-4).

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), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

**VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides

that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 10, 2011.

**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 adding alphabetically the following inert ingredients to read as follows:

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

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * * * *		
C <sub>9</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-95-6) .....		Solvent.
* * * * *		
C <sub>10-11</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-5) .....		Solvent.
* * * * *		
C <sub>11-12</sub> rich aromatic hydrocarbons (CAS Reg. No. 64742-94-5) .....		Solvent.
* * * * *		