

### Appendix C to Part 1191— Architectural Barriers Act: Scoping [Corrected]

2. On page 26140, in the first column, adding a new instruction after amendment 3.p to read “In F233.2, revising the first, second, and third sentences;”

3. On page 26140, in the first column, in amendment 3.t, the instruction “Redesignating sections F233.3.2 F233.3.3.1, F233.3.3.2, F233.3.4, F233.4.2, F233.4.3, F233.4.4, F233.4.4.1, F233.4.4.2, and F233.4.5 as F233.3.3, F233.3.4, F233.3.4.1, F233.3.4.2, F233.3.5, F233.4.3, F233.4.4, F233.4.5, F233.4.5.1, F233.4.5.2, and F233.4.6, respectively” is corrected to read “Redesignating sections F233.3.2, F233.3.3, F233.3.3.1, F233.3.3.2, F233.3.4, F233.4.1.2, F233.4.2, F233.4.3, F233.4.4, F233.4.4.1, F233.4.4.2, and F233.4.5 as F233.3.3, F233.3.4, F233.3.4.1, F233.3.4.2, F233.3.5, F233.4.2, F233.4.3, F233.4.4, F233.4.5, F233.4.5.1, F233.4.5.2, and F233.4.6, respectively.”

4. On page 26141, in the second column, first full paragraph, first line, replace “F223.3.4” with “F233.3.4”.

5. On p. 26142, in the second column, in amendment 4.f, the instruction “In 606.4, adding a sentence at the end of the section;” is corrected to read, “In 606.4, revising the heading to read “Faucets and water spray units”, and adding a sentence at the end of the section.”

David M. Capozzi,

Executive Director.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0517; FRL-9916-23]

### 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 (solvents) in pesticide formulations applied to animals.

ExxonMobil Chemical Company 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 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 September 26, 2014. Objections and requests for hearings must be received on or before November 25, 2014, 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-2011-0517, 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:** Lois Rossi, 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](mailto: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](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-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 November 25, 2014. 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-2011-0517, 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 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 4E6935, 4E6934, and 4E6937 respectively) by ExxonMobil Chemical Company, 13501 Katy Freeway, Houston, TX 77079. The petitions requested that 40 CFR 180.930 be amended by establishing exemptions 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 (solvents) in pesticide formulations applied to animals. Those documents referenced summaries of the petitions prepared by ExxonMobil Chemical Company. There were two comments received in response to the notices of filing. EPA's response to these comments is discussed in Unit V.B of this document.

## 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 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 and are not expected to be carcinogenic, based on the available toxicity data.

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 the NOAEL and the LOAEL are identified. 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 Table 1 of this unit.

**TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND 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 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.	Prenatal Developmental Toxicity Study in Rats. LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption.
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.	Prenatal Developmental Toxicity Study in Rats. LOAEL = 450 mg/kg/day based on decreased body weight gain and decreased food consumption.
Inhalation, short-term .....	NOAEL = 110 ppm (156 mg/kg/day). UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100.	3-day inhalation neurotoxicity study in rats. LOAEL = 365 ppm based on low to moderate gait abnormalities.
Cancer (Oral, dermal, inhalation) .....	Based on structure-activity relationship (SAR) analysis and structural alerts, not expected to be carcinogenic.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. 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).

*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 and Chronic Exposure.* In conducting the acute and 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) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. 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 case 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, EPA made specific adjustments to the dietary exposure assessment to account for evaporative loss, which is an important consideration for compounds such as C<sub>9</sub> rich aromatic hydrocarbons, C<sub>10-11</sub> rich aromatic hydrocarbons, and C<sub>11-12</sub> rich aromatic hydrocarbons.

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 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).

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. 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 specifically; 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. It is reasonable to assume that the potential inhalation exposure and levels in groundwater 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 would not exceed these modeled levels for other gasoline additives, as 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 used as gasoline additives at concentrations less than the gasoline additives for which modeled information are available.

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 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 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 (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 Safety Factor (FQPA 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 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 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 1X. 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 complete, except for an immunotoxicity study. 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, EPA has determined that an additional uncertainty factor is not needed to account for the lack of this study.

ii. There is no indication 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, as 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. Given the similar physicochemical and toxicological properties of the hydrocarbons assessed for this rule, EPA concludes that C<sub>10-11</sub> and C<sub>11-12</sub> rich aromatic hydrocarbons would demonstrate a similar lack of neurotoxic effects; therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. 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.

iv. 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 reasonable

worst-case expected residue levels. 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. Moreover, EPA used conservative assumptions about potential residential exposure from use of these hydrocarbons in gasoline. 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 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.* 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 11% 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 2.1% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential pesticidal 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. Also, as noted in Unit IV.C.3., while 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 may result in some potential exposure via drinking water, such drinking water exposures are already addressed by the conservative

assumptions for drinking water concentrations utilized in the chronic dietary exposure assessment.

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. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure.

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 contained in pesticide products registered for any specific use patterns that could result in short-term residential exposure. However, potential short term 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 may occur as a result of non-pesticide use as a gasoline additive. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposure result in estimated worst-case MOEs exceeding 10,000 for adults and children. Because EPA's level of concern 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 a 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). An intermediate-term adverse effect was identified. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. 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 contained in pesticide products registered for any specific use patterns (nor are there any nonpesticidal uses) that could result in intermediate short-term residential exposure. EPA considers the chronic risk assessment to cover intermediate-term risk. Based on the results of the chronic risk assessment, EPA concludes that there is not an intermediate-term risk.

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; 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 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. Response to Comments*

One commenter opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

A second commenter asserted that the subject chemical should not be allowed for use on food and that short-term tests (which, the commenter asserts, are the only tests EPA requires) are not sufficient to protect the public from harm. Although it is difficult to know exactly what the commenter means by "short-term tests," the Agency believes the comment to be inapplicable to the action at hand. Several repeat-dose testing studies are available for these hydrocarbons. The Agency has found that data acceptable for assessing the hazard of these aromatic hydrocarbons and concluded that these exemptions will be safe.

#### **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.930 for 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 an inert ingredient (solvent) in pesticide formulations applied to animals.

**VII. Statutory and Executive Order Reviews**

This final rule establishes exemptions from the requirement of a tolerance under FFDCa section 408(d) 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 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 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: September 17, 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 § 180.930, add alphabetically the following inert ingredients in the table to read as follows:

**§ 180.930 Inert ingredients applied to animals; exemption 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.
* * * * *		

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**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 69**

[WC Docket No. 05-25; RM-10593; FCC 12-153]

**Special Access Proceeding; Effective Date for Data Collection**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** The Federal Communications Commission (Commission) has received approval for the information collection requirement contained in the Special Access Proceeding from the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520).

**DATES:** On December 11, 2012, the Commission adopted a Report and Order and Further Notice of Proposed Rulemaking (*Report and Order*) regarding the special access data

collection and stated that the information collection would not go into effect until OMB approved the collection and the Commission published a notice in the **Federal Register** announcing the effective date of the collection. FCC 12-153, 78 FR 2572 (Jan. 11, 2013). On August 15, 2014, OMB approved the data collection requirement and assigned this new information collection OMB Control Number 3060-1197, as required by PRA. Accordingly, the information collection requirement contained in the *Report and Order* is effective September 26, 2014. The Commission's Wireline Competition Bureau (Bureau) will