



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0308; FRL-12327-01-OCSP]

### Various Fragrance Components in Pesticide Formulations; Tolerance Exemption

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of various fragrance components listed in Unit II of this document when they used as inert ingredients in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils when the end-use concentration does not exceed 33 parts per million (ppm). Innovative Reform Group, on behalf of The Clorox 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 various fragrance components, when used in accordance with the terms of those exemptions.

**DATES:** This regulation is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Objections and requests for hearings must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0308, is available at <https://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 and the OPP docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: [RDNRNotices@epa.gov](mailto:RDNRNotices@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 Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

#### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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-2021-0308 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

EPA's Office of Administrative Law Judges (OALJ), where the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Service and Filing", dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_Upload.nsf/HomePage?ReadForm](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_Upload.nsf/HomePage?ReadForm).

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-2021-0308, by one of the following methods:

- *Federal eRulemaking Portal*: <https://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 <https://www.epa.gov/dockets/where-send-comments-epa-dockets#express>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the *Federal Register* of June 1, 2021 (86 FR 29229) (FRL-10023-95), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11401) by Innovative Reform Group, on behalf of The Clorox Company, 4900 Johnson Dr., Pleasanton, CA 94588. The petition requested that 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of: (1-Methyl-2-(1,2,2-trimethylbicyclo[3.1.0]hex-3-ylmethyl)cyclopropyl)methanol (CAS Reg. No. 198404-98-7); 1,4-Cineole (CAS Reg. No. 470-67-7); 1-Octen-3-ol (CAS Reg. No. 3391-86-4); 1-p-Menthene-8-thiol (CAS Reg. No. 71159-90-5); 2,3-Hexanedione (CAS Reg. No. 3848-24-6); 2,5-Dimethylpyrazine (CAS Reg. No. 123-32-0); 2,6-Dimethyl-4-heptanonem (CAS Reg. No. 108-83-8); 2,6-Dimethylpyrazine (CAS Reg. No. 108-50-9); 2-Ethyl-1-hexanol (CAS Reg. No. 104-76-7); 2-Ethyl-3-methylpyrazine (CAS Reg. No. 15707-23-0); 2-Heptanone (CAS Reg. No. 110-43-0); 2-Isobutyl-3-methoxypyrazine (CAS Reg. No. 24683-00-9); 2-Isopropyl-4-methylthiazole (CAS Reg. No. 15679-13-7); 2-Methoxy-3-(1-methylpropyl)pyrazine (CAS Reg. No. 24168-70-5); 2-Methyl-4-propyl-1,3-oxathiane (CAS Reg. No. 67715-80-4); 2-Methylpyrazine (CAS Reg. No. 109-08-0); 2-Nonanone (CAS Reg. No. 821-55-6); 2-Octanone (CAS Reg. No. 111-13-7); 2-sec-Butylcyclohexanone (CAS Reg. No. 14765-30-1); 2-Tridecanone (CAS Reg. No. 593-08-8); 2-Undecanone (CAS Reg. No. 112-12-9); 3,4-Dimethyl-

1,2- cyclopentadione (CAS Reg. No. 13494-06-9); 3-Heptanone (CAS Reg. No. 106-35-4); 3-Methyl-1- cyclopentadecanone (CAS Reg. No. 541-91-3); 3-Methyl-2-(2-pentenyl)- 2-cyclopenten-1-one, (Z)- (CAS Reg. No. 488-10-8); 3-Methyl-2-(2E)-2-penten-1-yl-2-cyclopenten-1-one (CAS Reg. No. 6261-18-3); 3-Methyl-2-(n-pentanyl)- 2-cyclopenten-1-one (CAS Reg. No. 1128-08-1); 3-Methyl-5-(2,2,3-trimethylcyclopent-3-en- 1-yl)pent-4-en-2-ol (CAS Reg. No. 67801-20-1); 3-Octanone (CAS Reg. No. 106-68-3); 4-Acetyl-6-t-butyl-1,1-dimethylindan (CAS Reg. No. 13171-00-1); 4-Hydroxy-2,5-dimethyl- 3(2H)-furanone (CAS Reg. No. 3658-77-3); 5-Methyl-2- thiophenecarboxyaldehyde (CAS Reg. No. 13679-70-4); 5-Methyl-2-phenyl-2- hexenal (CAS Reg. No. 21834-92-4); 6,10-Dimethyl-5,9- undecadien-2-one (CAS Reg. No. 689-67-8); 6-Methyl-3,5-heptadien- 2-one (CAS Reg. No. 1604-28-0); 6-Methyl-5-hepten-2-one (CAS Reg. No. 110-93-0); 8-Decen-5-olide (CAS Reg. No. 32764-98-0); Acetoin (CAS Reg. No. 513-86-0); Allyl cinnamate (CAS Reg. No. 1866-31-5); Allyl heptanoate (CAS Reg. No. 142-19-8); Allyl hexanoate (CAS Reg. No. 123-68-2); Allyl propionate (CAS Reg. No. 2408-20-0); alpha- Amylcinnamaldehyde (CAS Reg. No. 122-40-7); α- Butylcinnamaldehyde (CAS Reg. No. 7492-44-6); α- Hexylcinnamaldehyde (CAS Reg. No. 101-86-0); α-Isobutylphenethyl alcohol (CAS Reg. No. 7779-78-4); Cajeput oil (Melaleuca leucadendron L.) (CAS Reg. No. 8008-98-8); Cardamom (Elettaria cardamomum (L.) Maton) (CAS Reg. No. 85940-32-5); Cardamom seed oil (Elettaria cardamomum (L.) Maton) (CAS Reg. No. 8000-66-6); d,l-Isomenthone (CAS Reg. No. 491-07-6); d-Camphor (CAS Reg. No. 464-49-3); d-Fenchone (CAS Reg. No. 4695-62-9); dl-Camphor (CAS Reg. No. 21368-68-3); Ethyl maltol (CAS Reg. No. 4940-11-8); Ethyl vanillin (CAS Reg. No. 121-32-4); Eucalyptol (CAS Reg. No. 470-82-6); Eucalyptus oil (Eucalyptus globulus Labill) (CAS Reg. No. 8000-48-4); Isoamyl phenethyl ether (CAS Reg. No. 56011-02-0); Isojasmone (CAS Reg. No. 11050-62-7); Linalool oxide (CAS Reg. No. 60047-17-8); (Z)-Linalool oxide (CAS Reg. No. 5989-33-3); (E)-Linalool oxide (CAS Reg. No. 34995-77-2); Maltol (CAS Reg. No. 118-71-8); Maltol isobutyrate (CAS Reg. No. 65416-14-0); Menthone (CAS Reg. No. 10458-14-7); Methyl

dihydrojasmonate (CAS Reg. No. 24851-98-7); Methyl phenethyl ether (CAS Reg. No. 3558-60-9); Methyl cyclopentenolone (CAS Reg. No. 80-71-7); Nerol oxide (CAS Reg. No. 1786-08-9); Nootkatone (CAS Reg. No. 4674-50-4); Origanum oil (CAS Reg. No. 8007-11-2); Piperonal (CAS Reg. No. 120-57-0); Piperonyl acetate (CAS Reg. No. 326-61-4); p-Mentha-8-thiol-3-one (CAS Reg. No. 38462-22-5); Rosemary oil (*Rosemarinus officinalis* L.) (CAS Reg. No. 8000-25-7); Rue oil (*Ruta graveolens* L.) (CAS Reg. No. 8014-29-7); Sage oil, Spanish (*Salvia lavandulaefolia* Vahl.) (CAS Reg. No. 8022-56-8); Tetrahydro-4-methyl-2- (2-methylpropen-1-yl)pyran (CAS Reg. No. 16409-43-1); Theaspirane (CAS Reg. No. 36431-72-8); when used as an inert ingredient (fragrance components) in pesticide formulations applied to food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment with end-use concentrations not to exceed 33 ppm. That document referenced a summary of the petition prepared by Innovative Reform Group on behalf of The Clorox Company, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the

requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(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. When making a safety determination for an exemption for the requirement of a tolerance FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in section 408(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....” Section 408(b)(2)(D) lists other factors for EPA consideration making safety determinations, *e.g.*, the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among others.

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 harm 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 the various fragrance components identified in Unit II of this document, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with these various fragrance components follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by various fragrance components identified in Unit II, 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.

The Agency assessed these fragrance components via the Threshold of Toxicological Concern (TTC) approach as outlined by the European Food Safety Authority (EFSA) in their 2019 guidance document on the use of TTC in food safety assessment. Information regarding the database of studies and chemicals used to derive TTCs are reviewed therein. The TTC approach has been used by the Joint Expert Committee on Food Additives of the United Nations' (U.N.) Food and Agriculture Organization and the World Health Organization (JECFA), the former Scientific Committee on Food of the European Commission, the European Medicines Agency, and EFSA.

Information from JECFA reports as well as predictive toxicology using the Organisation for Economic Co-operation and Development (OECD) Quantitative Structure-Activity

Relationships (QSAR) Toolbox was used to confirm that the fragrances listed in Unit II have low carcinogenic potential and are thus good candidates for the application of the TTC method.

Although 24 chemicals had in silico carcinogenicity alerts, JECFA concluded and EPA concurs that all fragrances listed in Unit II have low carcinogenic potential, based on in vitro and/or in vivo genotoxicity studies available on the chemical or structurally related chemicals. Therefore, the TTC method can be applied to these fragrances.

TTCs are derived from a conservative and rigorous approach to establish generic threshold values for human exposure at which a very low probability of adverse effects is likely. By comparing a range of compounds by Cramer Class (classes I, II, and III which correspond to the probability of low, moderate, and high toxicity) and NOEL (no-observed-effect-level), fifth percentile NOELs were established for each Cramer Class as “Human Exposure Thresholds”. These values were 3, 0.91 and 0.15 mg/kg/day for classes I, II, and III, respectively.

#### *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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program>.

The human exposure threshold value for threshold (*i.e.*, non-cancer) risks is based upon Cramer structural class. All of the fragrance components listed in Unit II are in Cramer Class II, which is defined as chemicals of simple structure and efficient modes of metabolism, suggesting low oral toxicity. Therefore, the NOEL of 0.91 mg/kg/day is selected as the point of departure for all exposure scenarios assessed (chronic dietary, incidental oral, dermal and inhalation exposures).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to each of the fragrance components listed in Unit II (*e.g.* ingesting foods that come in contact with surfaces treated with pesticide formulations containing these fragrance components, and drinking water exposures), EPA considered exposure under the proposed exemptions at a concentration not to exceed 33 ppm for each of the listed fragrance components as well as any other sources of dietary exposure. EPA assessed dietary exposures from the fragrance components listed in Unit II in food as follows:

The dietary assessment for food contact sanitizer solutions calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI). The assessment considered application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on U.S. Food and Drug Administration guidelines.

2. *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).

The fragrance components listed in Unit II may be used as 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 a conservative assessment of potential residential exposure by assessing various fragrance components in disinfectant-type uses (indoor scenarios). The Agency's assessment of adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, wiping, and aerosol spray uses. The Agency's assessment of children's residential exposure includes total post-application exposures associated with contact with treated indoor surfaces (dermal and hand-to-mouth exposures).

3. *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 the fragrance components listed in Unit II to share a common mechanism of toxicity with any other substances, nor do they appear to produce a toxic metabolite produced by other substances. For the purposes of the tolerance exemptions established in this rule, therefore, EPA has assumed that the fragrance components listed in Unit II do not have common mechanisms 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 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### *D. Additional Safety Factor for the Protection of Infants and Children*

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

infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. The FQPA SF has been reduced to 1X in this risk assessment because clear NOELs and LOELs were established in the studies used to derive the endpoints (which included developmental and reproductive toxicity studies), maternal and developmental-specific 5th percentile NOELs indicate low potential for offspring susceptibility, and the conservative assumptions made in the exposure assessment are unlikely to underestimate risk.

#### *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 aggregate risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effects resulting from a single oral exposure were identified and no acute dietary endpoint was selected for any of the fragrance components listed in Unit II. Therefore, these fragrance components are not expected to pose an acute risk.

2. *Short-term aggregate 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). For residential handler short-term exposure scenarios, MOEs ranged from 13,000 to 230,000, while for residential post-application exposure scenarios, MOEs ranged from 15,000 to 32,000. These MOEs are greater than the level of concern (LOC) of 100 and

therefore are not of concern. The short-term aggregate MOE is 455 for adults and 168 for children, which are greater than the LOC of 100 and therefore are not of concern.

3. *Intermediate-term aggregate risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential (dermal and inhalation) exposure plus chronic dietary exposure (food and drinking water). As the same endpoints were selected for short-term and intermediate-term exposures, intermediate-term aggregate risk is equal to the short-term aggregate risk, and it is not of concern.

4. *Chronic aggregate risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to the fragrance components listed in Unit II from food and water will utilize 21% of the cPAD for the U.S. population and 58% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic residential exposure to residues of these fragrance components is not expected. Therefore, the chronic aggregate risk is equal to the chronic dietary exposure for children 1 to 2 years old (58% of the cPAD).

5. *Aggregate cancer risk for U.S. population.* There is low concern for genotoxicity/carcinogenicity in humans for the fragrance components listed in Unit II of this document. Therefore, the assessment under the TTC value for non-cancer risks is protective for all risks, including carcinogenicity.

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 residues of the fragrance components listed in Unit II.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of the fragrance components listed in Unit II of this document in or on any food commodities. EPA is, however, establishing limitations on the

amount of these fragrance components that may be used in antimicrobial pesticide formulations. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that contains these fragrance components in excess of 33 ppm in the final pesticide formulation.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established for residues of various fragrance components listed in Unit II of this document when used as an inert ingredient (fragrance component) in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils with an end-use concentration not to exceed 33 ppm under 40 CFR 180.940(a).

## **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). 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: November 18, 2024.

**Charles Smith,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

### **PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.940 is amended by adding in alphabetical order the following inert ingredients to table 1 to paragraph (a):

- a. Acetoin
- b. 4-acetyl-6-*t*-butyl-1,1-dimethylindan
- c. Allyl cinnamate
- d. Allyl heptanoate
- e. Allyl hexanoate
- f. Allyl propionate
- g. 1,3-Benzodioxole-5-carboxaldehyde
- h. Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-, (1R, 4R)-
- i.  $\alpha$ -Butylcinnamaldehyde
- j. 2-sec-Butylcyclohexanone
- k. Cajeput oil (*Melaleuca leucadendron* L.)

- l. Camphor
- m. Cardamom (*Elettaria cardamomum* (L.) Maton)
- n. Cardamom seed oil (*Elettaria cardamomum* (L.) Maton)
- o. Cyclopentaneacetic acid, 3-oxo-2-pentyl-, methyl ester
- p. Cyclopropanemethanol, 1-methyl-2-[(1,2,2-trimethylbicyclo[3.1.0]hex-3-yl)methyl]-
- q. Diisobutyl ketone
- r. 3,4-Dimethyl-1,2-cyclopentadione
- s. 2,5-Dimethylpyrazine
- t. 2,6-Dimethylpyrazine
- u. 6,10-Dimethylundeca-5,9-dien-2-one
- v. Ethyl amyl ketone
- w. Ethyl maltol
- x. 2-Ethyl-3-methylpyrazine
- y. Ethylvanillin
- z. Eucalyptus oil
- aa. Fenchone
- bb. Heptanal, 2-(phenylmethylene)-
- cc. 3-Heptanone
- dd. 2,3-Hexanedione
- ee. 1-Hexanol, 2-ethyl-
- ff.  $\alpha$ -Hexylcinnamaldehyde
- gg. 4-Hydroxy-2,5-dimethyl-3(2H)-furanone
- hh. 2-Isobutyl-3-methoxypyrazine
- ii.  $\alpha$ -Isobutylphenethyl alcohol
- jj. Isojasmone
- kk. d,l-Isomenthone

ll. 2-Isopropyl-4-methylthiazole

mm. Linalool oxide

nn. (E)-Linalool oxide

oo. (Z)-Linalool oxide

pp. Maltol isobutyrate

qq. p-Mentha-8-thiol-3-one

rr. p-Menthan-3-one

ss. p-Menthane, 1,8-epoxy-

tt. 1-p-Menthene-8-thiol

uu. 2-Methoxy-3-(1-methylpropyl)pyrazine

vv. Methyl n-amyl ketone

ww. 3-Methyl-1-cyclopentadecanone

xx. Methylcyclopentenolone

yy. 6-Methyl-3,5-heptadien-2-one

zz. 6-Methyl-5-hepten-2-one

aaa. 3-Methyl-2-(n-pentanyl)-2-cyclopenten-1-one

bbb. 3-Methyl-2-(2E)-2-penten-1-yl-2-cyclopenten-1-one

ccc. 3-Methyl-2-(2-pentenyl)-2-cyclopenten-1-one, (Z)-

ddd. Methyl phenethyl ether

eee. 5-Methyl-2-phenyl-2-hexenal

fff. 2-Methyl-4-propyl-1,3-oxathiane

ggg. 5-Methyl-2-thiophenecarboxyaldehyde

hhh. 3-Methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-ol

iii. 2-Methylpyrazine

jjj. Nerol oxide

kkk. 2-Nonanone

- lll. Nootkatone
- mmm. 2-Octanone
- nnn. 1-Octen-3-ol
- ooo. Oils, rosemary
- ppp. Oils, sage
- qqq. Origanum oil, Spanish
- rrr. 7-Oxabicyclo(2.2.1.)heptane, 1-methyl-4-(1-methylethyl)-
- sss. Phenylethyl isoamyl ether
- ttt. Piperonyl acetate
- uuu. 4H-Pyran-4-one, 3-hydroxy-2-methyl-
- vvv. Rue oil (*Ruta graveolens* L.)
- www. Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran
- xxx. Tetrahydro-6-(3-pentenyl)-2H-pyran-2-one
- yyy. Theaspirane
- zzz. 2-Tridecanone
- aaaa. 2-Undecanone

The additions read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

**Table 1 to Paragraph (a)**

Pesticide Chemical	CAS Reg. No.	Limits
* *	* *	* *
Acetoin	513-86-0	When ready for use, the end-use concentration is not to exceed 33 ppm

* * *		
4-acetyl-6- <i>t</i> -butyl-1,1-dimethylindan	13171-00-1	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Allyl cinnamate	1866-31-5	When ready for use, the end-use concentration is not to exceed 33 ppm
Allyl heptanoate	142-19-8	When ready for use, the end-use concentration is not to exceed 33 ppm
Allyl hexanoate	123-68-2	When ready for use, the end-use concentration is not to exceed 33 ppm
Allyl propionate	2408-20-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
1,3-Benzodioxole-5-carboxaldehyde	120-57-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Bicyclo[2.2.1]heptan-2-one, 1,7,7-trimethyl-, (1 <i>R</i> , 4 <i>R</i> )-	464-49-3	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
$\alpha$ -Butylcinnamaldehyde	7492-44-6	When ready for use, the end-use concentration is not to exceed 33 ppm
2-sec-Butylcyclohexanone	14765-30-1	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		

Cajeput oil (Melaleuca leucadendron L.)	8008-98-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Camphor	21368-68-3	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Cardamom (Elettaria cardamomum (L.) Maton)	85940-32-5	When ready for use, the end-use concentration is not to exceed 33 ppm
Cardamom seed oil (Elettaria cardamomum (L.) Maton)	8000-66-6	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Cyclopentaneacetai acid, 3-oxo-2- pentyl-, methyl ester	24851-98-7	When ready for use, the end-use concentration is not to exceed 33 ppm
Cyclopropanemethanol, 1-methyl- 2-[(1,2,2- trimethylbicyclo[3.1.0]hex-3- yl)methyl]-	198404-98-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Diisobutyl ketone	108-83-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
3,4-Dimethyl-1,2-cyclopentadione	13494-06-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		

2,5-Dimethylpyrazine	123-32-0	When ready for use, the end-use concentration is not to exceed 33 ppm
2,6-Dimethylpyrazine	108-50-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
6,10-Dimethylundeca-5,9-dien-2-one	689-67-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
Ethyl amyl ketone	106-68-3	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
Ethyl maltol	4940-11-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
2-Ethyl-3-methylpyrazine	15707-23-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
Ethylvanillin	121-32-4	When ready for use, the end-use concentration is not to exceed 33 ppm
Eucalyptus oil	8000-48-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
Fenchone	4695-62-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *

Heptanal, 2-(phenylmethylene)-	122-40-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
3-Heptanone	106-35-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
2,3-Hexanedione	3848-24-6	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
1-Hexanol, 2-ethyl-	104-76-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
$\alpha$ -Hexylcinnamaldehyde	101-86-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
4-Hydroxy-2,5-dimethyl-3(2H)-furanone	3658-77-3	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
2-Isobutyl-3-methoxypyrazine	24683-00-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *
$\alpha$ -Isobutylphenethyl alcohol	7779-78-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* *	* *	* *

Isojasmone	11050-62-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
d,l-Isomenthone	491-07-6	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
2-Isopropyl-4-methylthiazole	15679-13-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Linalool oxide	60047-17-8	When ready for use, the end-use concentration is not to exceed 33 ppm
(E)-Linalool oxide	34995-77-2	When ready for use, the end-use concentration is not to exceed 33 ppm
(Z)-Linalool oxide	5989-33-3	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Maltyl isobutyrate	65416-14-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
p-Mentha-8-thiol-3-one	38462-22-5	When ready for use, the end-use concentration is not to exceed 33 ppm
p-Menthan-3-one	10458-14-7	When ready for use, the end-use concentration is not to exceed 33 ppm
p-Menthane, 1,8-epoxy-	470-82-6	When ready for use, the end-use concentration is not to exceed 33 ppm

1-p-Menthene-8-thiol	71159-90-5	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *	* * *	
2-Methoxy-3-(1-methylpropyl)pyrazine	24168-70-5	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *	* * *	
Methyl n-amyl ketone	110-43-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *	* * *	
3-Methyl-1-cyclopentadecanone	541-91-3	When ready for use, the end-use concentration is not to exceed 33 ppm
Methylcyclopentenolone	80-71-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *	* * *	
6-Methyl-3,5-heptadien-2-one	1604-28-0	When ready for use, the end-use concentration is not to exceed 33 ppm
6-Methyl-5-hepten-2-one	110-93-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *	* * *	
3-Methyl-2-(n-pentanyl)-2-cyclopenten-1-one	1128-08-1	When ready for use, the end-use concentration is not to exceed 33 ppm
3-Methyl-2-(2E)-2-penten-1-yl-2-cyclopenten-1-one	6261-18-3	When ready for use, the end-use concentration is not to exceed 33 ppm
3-Methyl-2-(2-pentenyl)-2-cyclopenten-1-one, (Z)-	488-10-8	When ready for use, the end-use concentration is not to exceed 33 ppm

* * *		
Methyl phenethyl ether	3558-60-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
5-Methyl-2-phenyl-2-hexenal	21834-92-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
2-Methyl-4-propyl-1,3-oxathiane	67715-80-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
5-Methyl-2-thiophenecarboxyaldehyde	13679-70-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
3-Methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-ol	67801-20-1	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
2-Methylpyrazine	109-08-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Nerol oxide	1786-08-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
2-Nonanone	821-55-6	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		

Nootkatone	4674-50-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
2-Octanone	111-13-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
1-Octen-3-ol	3391-86-4	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Oils, rosemary	8000-25-7	When ready for use, the end-use concentration is not to exceed 33 ppm
Oils, sage	8022-56-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Origanum oil, Spanish	8007-11-2	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
7-Oxabicyclo(2.2.1.)heptane, 1-methyl-4-(1-methylethyl)-	470-67-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Phenylethyl isoamyl ether	56011-02-0	When ready for use, the end-use concentration is not to exceed 33 ppm
* * * * *		
Piperonyl acetate	326-61-4	When ready for use, the end-use concentration is not to exceed 33 ppm

* * *		
4H-Pyran-4-one, 3-hydroxy-2-methyl-	118-71-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Rue oil (Ruta graveolens L.)	8014-29-7	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
Tetrahydro-4-methyl-2-(2-methylpropen-1-yl)pyran	16409-43-1	When ready for use, the end-use concentration is not to exceed 33 ppm
Tetrahydro-6-(3-pentenyl)-2H-pyran-2-one	32764-98-0	When ready for use, the end-use concentration is not to exceed 33 ppm
Theaspirane	36431-72-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
2-Tridecanone	593-08-8	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		
2-Undecanone	112-12-9	When ready for use, the end-use concentration is not to exceed 33 ppm
* * *		

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