## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R05–OAR–2013–0214; FRL–9914–25–Region 5]**

### Approval and Promulgation of Air Quality Implementation Plans; Indiana; Solvent Degreasing Operations Rule

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

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a request submitted by the Indiana Department of Environmental Management (IDEM) on March 14, 2013, to revise the Indiana state implementation plan (SIP) solvent degreasing operation rule. The state's submission seeks to extend vapor pressure limitations (previously applying to four counties) state-wide, add certain exemptions and streamline the rule by repealing and consolidating certain provisions. There is also a revised definition for ''cold cleaner degreaser.''

**DATES:** Comments must be received on or before August 25, 2014.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R05–OAR–2013–0214 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: blakley.pamela@epa.gov.*
3. *Fax:* (312) 692–2450.
4. *Mail:* Pamela Blakley, Chief, Control Strategies Section (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Pamela Blakley, Chief, Control Strategies Section (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

**FOR FURTHER INFORMATION CONTACT:** Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

**SUPPLEMENTARY INFORMATION:** In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: July 14, 2014.

**Susan Hedman,**

*Regional Administrator, Region 5.*

[FR Doc. 2014–17475 Filed 7–24–14; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

**[EPA–HQ–OPP–2013–0821; FRL–9910–53]**

### Fragrance Components; Proposed Exemption From the Requirement of a Tolerance

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to establishes an exemption from the requirement of a tolerance for residues of various fragrance component substances (when used as inert ingredients) in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils.

**DATES:** Comments must be received on or before September 23, 2014.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2013–0821, 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

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

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *rossi.lois@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. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the

disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

## II. This Proposal

EPA on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to establish an exemption from the requirement of a tolerance for residues of acetaldehyde (CAS Reg. No. 75–07–0), acetic acid (CAS Reg. No. 64–19–7), allyl cyclohexyl propionate (CAS Reg. No. 2705–87–5), butryic acid (CAS Reg. No. 107–92–6), butyl alcohol (CAS Reg. No. 71–36–3), citral (CAS Reg. No. 5392–40–5), citronellol (CAS Reg. No. 106–22–9), citronellyl acetate (CAS Reg. No. 150–84–5), β-damascone, (Z)- (CAS Reg. No. 23726–92–3), decanal (CAS Reg. No. 112–31–2), (E)-4-decenal (CAS Reg. No. 65405–70–1), decanoic acid (CAS Reg. No. 334–48–5), 1-decanol (CAS Reg. No. 112–30–1), 2,6-dimethyl-5-heptanal (CAS Reg. No. 106–72–9), 2-dodecanol, (2E)- (CAS Reg. No. 20407–84–5), d-limonene (CAS Reg. No. 5989–27–5), ethyl 2-methylbutyrate (CAS Reg. No. 452–79–1), (E)–geraniol (CAS Reg. No. 106–24–1), (E)-geraniol acetate (CAS Reg. No. 105–87–3), heptanal (CAS Reg. No. 111–71–7), heptanoic acid (CAS Reg. No. 111–14–8), heptyl alcohol (CAS Reg. No. 111–70–6), hexanal (CAS Reg. No. 66–25–1), hexanoic acid (CAS Reg. No. 142–62–1), (Z)-3-hexenol (CAS Reg. No. 928–96–1), (Z)-3-hexenol acetate (CAS Reg. No. 3681–71–8), hexyl acetate (CAS Reg. No. 142–92–7), hexyl alcohol (CAS Reg. No. 111–27–3), lauric acid (CAS Reg. No. 143–07–7), lauric aldehyde (CAS Reg. No. 112–54–9), lauryl alcohol (CAS Reg. No. 112–53–8), methyl-α-ionone (CAS Reg. No. 127–42–4), 3-methyl-2-butenyl acetate (CAS Reg. No. 1191–16–8), 2-methylundecanal (CAS Reg. No. 110–41–8), myristaldehyde (CAS Reg. No. 124–25–4), myristic acid (CAS Reg. No. 544–63–8), neryl acetate (CAS Reg. No. 141–12–8), n-hexanol (CAS Reg. No. 111–27–3), nonanal (CAS Reg. No. 124–19–6), nonanoic acid (CAS Reg. No. 112–05–0), nonyl alcohol (CAS Reg. No. 143–08–8), octanal (CAS Reg. No. 124–13–0), octanoic acid (CAS Reg. No. 124–07–2), 1–octanol (CAS Reg. No. 111–87–5), palmitic acid (CAS Reg. No. 57–10–3), propionic acid (CAS Reg. No. 79–09–4), stearic acid (CAS Reg. No. 57–11–4), 2-tridecanal (CAS Reg. No. 7774–82–5), 3,5,5-trimethylhexanal (CAS Reg. No. 5435–64–3), undecanal (CAS Reg. No. 112–44–7), undecyl alcohol (CAS Reg. No. 112–42–5), valeraldehyde (CAS Reg. No. 110–62–3), and valeric acid (CAS Reg. No. 109–52–4) when used as fragrance components (i.e., inert ingredients) in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at end–use concentrations not to exceed 100 parts per million (ppm).

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of FFDCA section 408 and a complete description of the risk assessment process, see *http://www.epa.gov/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm.*

Consistent with FFDCA section 408(b)(2)(D), 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, consistent with FFDCA section 408(b)(2), for an exemption from tolerance for residues of fragrance components listed in Unit II. used as inert ingredients in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at end-use concentrations not to exceed 100 ppm. EPA's assessment of exposures and risks associated with establishing the exemptions from tolerance for the fragrance components listed in Unit II. follows:

### *A. Toxicological Profile*

In the case of the fragrance components listed in Unit II. above, each of these substances has been approved for use as a synthetic flavoring substance in food under 21 CFR 172.515 based on a substance-specific evaluation conducted by the U.S. Food and Drug Administration (FDA). Additionally, the fragrance components listed in Unit II. above have been evaluated and approved for use as food flavoring agents by the Joint Food and Agricultural Organization of the United Nations/World Health Organization Expert Committee on Food Additives (JECFA) and the European Food Safety Agency (EFSA) as part of their assessment of more than 2,800 food flavoring substances. The EFSA and JECFA food flavoring substance were conducted under an approach titled the Threshold of Toxicological Concern (TTC). Under this approach, generic human exposure threshold values for both non-cancer and cancer endpoints are set at a level below which there would be no appreciable risk to human health. These generic values allow for the safety assessment of substances even

in the absence of substance-specific hazard data.

The derivation of TTC human exposure threshold values for non-cancer endpoints is based on an extensive reference database compiled by Munro, (Ref. 1) which included data on chronic, subchronic, reproductive and developmental toxicity studies primarily derived from the reports of the US National Toxicology Program (NTP), the toxicological monographs of JECFA, the EPA Integrated Risk Information System (IRIS), and the Developmental and Reproductive Toxicology (DART) database compiled by the US National Library of Medicine. These sources were considered to contain well-validated toxicological data for well-defined chemical structures, covering pesticides, food additives, industrial and other types of chemicals. Only studies using the oral route of administration (gavage, diet, drinking water, or capsule) were included. In all, the reference database contained 2941 no-observed-adverse-effect levels (NOAELs) from studies conducted on 613 substances, and from these the most conservative (lowest) NOAEL for each substance was entered on the published database. The NOAELs in the reference database were those selected by the original authors of each study, apart from the studies in the IRIS database, for which the NOAELs were selected by the EPA. Munro commented that some authors were highly conservative in their selection of a NOAEL, but such NOAELs were still used for the database to maintain a conservative approach. Munro also stated that, in the calculation of the TTC values, NOAELs from subchronic studies were divided by a factor of 3 to approximate the NOAELs that are likely to be derived from a chronic study.

The chemicals in the Munro database were divided into three structural classes, based on a ''decision tree'' developed earlier by Cramer et al. (Ref. 2) Cramer Class I are chemicals of simple structure, with efficient modes of metabolism, suggesting low oral toxicity; Cramer Class III are chemicals with structures suggesting significant toxicity or which did not permit any strong initial presumption of safety, and Cramer Class II are chemicals with structures that were less innocuous than Cramer Class I but without features suggesting significant toxicity. Human exposure threshold values were derived by taking the lower 5th percentile value of the distribution of NOAELs for the substances in each of the three Cramer structural classes, multiplying by 60 to convert the values expressed as milligrams/kilograms (mg/kg) of body weight (bw) per day into mg/person per day, and then dividing by a factor of 100 to ensure a margin of safety.

For substances without structural alerts for cancer, the TTC human exposure values for non-cancer risks are considered protective of any potential cancer risk. For substances with a structural alert for cancer, a separate TTC value has been derived. Originally, FDA developed human exposure threshold values to protect against all chronic risks, including the endpoint of cancer, without regard to whether the substance had a structural alert for carcinogenicity (Ref. 3, 4, 5). FDA derived these threshold values using mathematical modeling of risks from animal bioassay data on over 500 known genotoxic and non-genotoxic carcinogens, based on their carcinogenic potency. In 1995, FDA incorporated the threshold value in its threshold of regulation (TOR) policy for substances present in food contact materials. (Ref 6). Under the TOR, substances used in food contact materials that are present in the diet at concentrations below the threshold level are exempted from regulation as food additives. Subsequently, FDA modified this approach by adopting lower threshold values for substances with a structural alert for carcinogenicity. Kroes et al. (Ref. 7) This FDA approach as to substances with structural alerts for carcinogenicity was further refined and adopted by EFSA and JEFCA for use in the TTC approach.

The TTC approach has been incorporated in the evaluations made by JECFA and EFSA in which the organizations both concluded that the each of the substances listed in Unit II. were safe for use as flavoring agents in foods. Under 21 CFR 170.39 *Threshold of regulation for substances used in food-contact articles,* FDA has issued exemptions from regulation as food additives for a number of substances based on human exposure threshold values.

*B. Toxicological Points of Departure/ Levels of Concern*

The human exposure threshold value for threshold (i.e., noncancer) risks is based upon Cramer structural class. In the case of the fragrance components listed in Unit II., all of the substances are included in the Cramer Class I category, which is defined as chemicals of simple structure and efficient modes of metabolism, suggesting low oral toxicity. An EFSA Scientific Committee critical evaluation of the human threshold values for threshold risks concluded that ''the use of the 5th percentile No-observed-adverse-effect-level (NOAEL) and an uncertainty factor of 100 to derive the TTC value gives a very low probability (somewhere between 0–5%) of any appreciable non-cancer risk to human health from exposures to substances below the Cramer Class I TTC value of 30 μg/kg/day'' (Ref. 8)

Use of TTC values for risk assessment of the fragrance components listed in Unit II. is a more conservative alternative to the chemical-specific Population Adjusted Dose (PAD) or Reference Dose (RfD) approach typically used in Agency risk assessments. For example, in the case of substances having chemical structures described by Cramer Class I for which chemical-specific risk assessments have been performed, these substances have PAD/RfD values which are often orders of magnitude greater than the corresponding TTC values (Ref 9). A summary of the safe exposure levels corresponding to each of the exposure scenarios considered the aggregate exposure assessment of the fragrance components listed in Unit II. is given below:

1. *Acute dietary (all populations).* There were no effects that could be attributed to a single dose in the database. Therefore, a quantitative acute dietary assessment is not necessary.

2. *Chronic dietary (all populations).* Concerns for chronic dietary exposures exceeding the TTC value of 30 μg/kg/day.

3. *Incidental oral short-term (1 to 30 days).* Concerns for incidental oral short-term exposures exceeding the TTC value of 30 μg/kg/day.

4. *Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).* Concern for dermal exposures exceeding the TTC value of 30 μg/kg/day based on oral toxicity data and conservative assumption of 100% dermal absorption.

5. *Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).* Concern for inhalation exposures exceeding the TTC value of 30 μg/kg/day based on oral toxicity data. Based on subchronic inhalation data for a number of fragrance substances, including some of fragrance components listed in Unit II., in which no adverse effects were noted at exposure levels up to 1% of ambient air (Ref. 10), it is reasonable to assume that in the case of the fragrance components listed in Unit II. inhalation toxicity would not be observed at doses below which oral toxicity is observed.

6. *Cancer (Oral, dermal, inhalation).* The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for potential genotoxicity/carcinogenicity for any of

the fragrance components. No structural alerts for genotoxicity/carcinogenicity relevant to human exposure to these substances as flavoring agents/fragrance components were identified, therefore the use of the TTC human exposure threshold for non-threshold risks for these fragrance components is not applicable. In these circumstances, assessment under the TTC value for non-cancer risks is protective for all risks, including carcinogenicity.

The risk assessment and use of human threshold values for evaluation of food flavoring agents by JECFA and EFSA has focused on oral toxicity and dietary exposure to substances via food and feed. However, the applicability of the TTC approach to substance exposure by routes other than the oral route has been considered by the ESFA Scientific Committee. The Scientific Committee determined that when several routes of exposure are to be taken into account they should be reflected in the exposure assessment used in the application of the TTC approach and that ''the application of the TTC approach to routes of exposure other than oral can be done via route-to-route extrapolation, as is often done in conventional risk assessment in cases where only oral toxicity data are available.''

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to the fragrance components listed in Unit II., EPA considered exposure under the proposed tolerance exemptions at a concentration not to exceed 100 ppm for each of the fragrance components listed in Unit II. as well as any other sources of dietary exposure. The use limitation of 100 ppm was incorporated by the Agency to reflect maximum concentrations of these fragrance components in antimicrobial pesticide formulations as well as to ensure that exposures to these fragrance components will be below levels of concern. In conducting the dietary exposure assessment for the fragrance components listed in Unit II., EPA considered dietary exposure from potential residues in or on food resulting from the use as inert ingredients in antimicrobial pesticide product formulations from treated food contact surfaces; and from food that contains the fragrance components as flavoring agents. As to the residue levels in or food resulting from the inert ingredient uses, in the absence of actual dietary exposure data resulting from this use, the EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use of the fragrance components in food contact sanitizing antimicrobial pesticide products. This same methodology has been utilized by EPA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of the fragrance components can be found at *http://www.regulations.gov* in document; ''Various Fragrance Components: Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations,'' pp. 5–8 in docket ID number EPA–HQ–OPP–2013–0821.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicity database for the fragrance components listed in Unit II., therefore a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, the Agency believes the assumptions used to estimate chronic dietary exposures lead to an extremely conservative assessment of chronic dietary risk due to a series of compounded conservatisms. First, when a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (residual solution). In the absence of any other data, EPA has used an estimated worst-case concentration of 1 mg of solution per square centimeter (cm) of treated surface area for this quantity. Second, the conservatism of this methodology is compounded by EPA's decision to assume a worst case scenario that all food that an individual consumes will come into contact with 4,000 $cm^2$ of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility. The surface area of counter tops that comes in contact with food is expected to be smaller than the surface area for food utensils. As a conservative estimate, EPA assumed that 2,000 $cm^2$ of treated counter top surface area, comes into contact with an individual's food per day. Third, EPA assumes that 100% of the material present on food contact surfaces will migrate to food (Ref 11).

iii. *Cancer.* Based on the data summarized in Unit III. A., EPA has concluded that the fragrance components listed in Unit II. are not expected to be carcinogenic to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The proposed use of the fragrance components listed in Unit II. in antimicrobial pesticide products has only a limited opportunity to result in contamination of drinking water because these types of products are used inside of structures. There is the possibility of exposure to drinking water sources via down-the-drain releases and discharges to waste water treatment plants; however, based on the extremely low concentrations of the fragrance components in pesticide formulations, combined with the biodegradability of the fragrance components, there would be at most a negligible exposure to surface water or ground water. Therefore, the use of these fragrance components as inert ingredients is not expected to contribute to dietary exposure from drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticide, and flea and tick control on pets).

The use of the fragrance components in food contact surface antimicrobial pesticide products could result in short- and intermediate-term residential exposures, adult handler dermal and inhalation exposure; post-application dermal and inhalation exposure and child's post- application dermal and incidental oral exposure. In addition, non pesticidal uses of these substances as fragrance components in consumer products may also result in residential dermal and inhalation exposure. However, these pesticidal and non pesticidal non-dietary exposures would be negligible in comparison to the highly conservative estimates of dietary exposure as discussed in Unit III.C.1. above. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 the fragrance components listed in Unit II. to share a common mechanism of toxicity with any other substances, and these fragrance components do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that these fragrance components 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 (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The use of a threshold exposure level as described in Unit II. above is health protective of any toxicity to infants and children and the exposure assumptions utilized in the risk assessment of the fragrance components are highly conservative (protective). These assessments will not underestimate the exposure and risks posed by these fragrance components and no additional safety factor is needed for assessing risk to infants and

*E. Aggregate Risks and Determination of Safety*

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, the fragrance components 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 each of the fragrance components listed in Unit II. from food and water will utilize 23% of the safe exposure level for the U.S. population and all subpopulations.

3. *From non-dietary exposure.* The fragrance components listed in Unit II. may be utilized in antimicrobial pesticide products with uses that could result in residential exposure such as hard surface cleaning products. For residential handler exposure, the Agency assumed that most residential use will result in short-term (1 to 30 days) dermal and inhalation exposures.

The Agency assumed that post-application exposure in residential settings is expected to be short-term in duration only but antimicrobial products used as cleaning agents may be used in facilities where cleaning activities can occur on an intermediate-term basis. Therefore, these post-application scenarios were included in the intermediate-term aggregate assessment. The scenarios evaluated were short- and intermediate term post-application dermal and inhalation (indoor), short- and intermediate-term incidental oral ingestion from treated indoor surfaces (hand-to-mouth vinyl/hard surfaces).

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/science/residential-exposure-sop.html.*

4. *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).

These fragrance components may be utilized as inert ingredients in pesticide formulations registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to the fragrance components listed in Unit II.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate exposures for each of the individual fragrance components listed in Unit II. do not exceed 24% of the safe exposure level (i.e., a level equivalent to a PAD or RfD) and therefore are not of concern.

5. *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).

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate exposures that do not exceed 24% of the safe exposure level for each of the fragrance components listed in Unit II. and not of concern.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of structural alerts for carcinogenicity and the lack of exceedance of the chronic TTC value, the fragrance components listed in Unit II. are not expected to pose a cancer risk to humans.

7. *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 each of the fragrance components listed in Unit II. Therefore EPA is proposing to exempt from the requirement of a tolerance under 40 CFR 180.940(a) the residues of acetaldehyde, acetic acid, allyl cyclohexyl propionate, butryic acid, butyl alcohol, citral, citronellol, citronellyl acetate, β-damascone, (Z)-, decanal, (E)-4-decenal, decanoic acid, 1-decanol, 2,6-dimethyl-5-heptanal, 2-dodecanol, (2E)-, d-limonene, ethyl 2-methylbutyrate, (E)-geraniol, (E)-geraniol acetate, heptanal), heptanoic acid, heptyl alcohol, hexanal, hexanoic acid, (Z)-3-hexenol, (Z)-3-hexenol acetate, hexyl acetate, hexyl alcohol, lauric acid, lauric aldehyde, lauryl alcohol), methyl-α-ionone, 3-methyl-2-butenyl acetate, 2-methylundecanal, myristaldehyde, myristic acid, neryl acetate, n-hexanol, nonanal, nonanoic acid, nonyl alcohol, octanal, octanoic acid, 1-octanol, palmitic acid, propionic acid, stearic acid, 2-tridecanal, 3,5,5-trimethylhexanal, undecanal, undecyl alcohol, valeraldehyde, and valeric acid.

## IV. 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. The use limitation of 100 ppm will be enforced through the pesticide registration process under the FIFRA, 7 U.S.C. 136 et seq. EPA will not register any food-contact use antimicrobial pesticide for sale or distribution containing any of the fragrance components listed in Unit II. at concentrations exceeding 100 ppm.

## V. Conclusion

An exemption from the requirement for a tolerance is proposed for residues of acetaldehyde, acetic acid, allyl cyclohexyl propionate, butryic acid, butyl alcohol, citral, citronellol, citronellyl acetate, β-damascone, (Z)-, decanal, (E)-4-decenal, decanoic acid, 1-decanol, 2,6-dimethyl-5-heptanal, 2-dodecanol, (2E)-, d-limonene, ethyl 2-methylbutyrate, (E)-geraniol, (E)-geraniol acetate, heptanal), heptanoic acid, heptyl alcohol, hexanal, hexanoic acid, (Z)-3-hexenol, (Z)-3-hexenol acetate, hexyl acetate, hexyl alcohol, lauric acid, lauric aldehyde, lauryl alcohol), methyl-α-ionone, 3-methyl-2-butenyl acetate, 2-methylundecanal, myristaldehyde, myristic acid, neryl acetate, n-hexanol, nonanal, nonanoic acid, nonyl alcohol, octanal, octanoic acid, 1-octanol, palmitic acid, propionic acid, stearic acid, 2-tridecanal, 3,5,5-trimethylhexanal, undecanal, undecyl alcohol, valeraldehyde, and valeric acid when used as inert ingredients (fragrance components) in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at end-use concentrations not to exceed 100 ppm.

## VI. Statutory and Executive Order Reviews

This document proposes to establish exemptions from tolerances under FFDCA section 408(d). 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 proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or 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.*). 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); or OMB review or any Agency action under Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). 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). The Agency hereby certifies under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishing an a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

## VII. References


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**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 14, 2014.

**Jack Housenger,**

*Director, Office of Pesticide Programs.*

Therefore, it is proposed that 40 CFR chapter I be 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 § 180.940, add alphabetically the following inert ingredients to the table in paragraph (a) to read as follows:

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

(a) * * *

| Pesticide chemical | CAS Reg. No. | Limits |
|---|---|---|
| Acetaldehyde | 75–07–0 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Acetic acid | 64–19–7 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| Allyl cyclohexyl propionate | 2705–87–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| Butryic acid | 107–92–6 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Butyl alcohol | 71–36–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Citral | 5392–40–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Citronellol | 106–22–9 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Citronellyl acetate | 150–84–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| β-Damascone, (Z)- | 23726–92–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Decanal | 112–31–2 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| (E)-4-Decenal | 65405–70–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Decanoic acid | 334–48–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| 1-Decanol | 112–30–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| 2,6-Dimethyl-5-heptanal | 106–72–9 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| 2-Dodecanol, (2E)- | 20407–84–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| Ethyl 2-methylbutyrate | 452–79–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * * * | * |
| (E)-Geraniol | 106–24–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| (E)-Geraniol acetate | 105–87–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Heptanal | 111–71–7 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Heptanoic acid | 111–14–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Heptyl alcohol | 111–70–6 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Hexanal | 66–25–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Hexanoic acid | 142–62–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| n-Hexanol | 111–27–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| (Z)-3-Hexenol | 928–96–1 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| (Z)-3-Hexenol acetate | 3681–71–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Hexyl acetate | 142–92–7 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Hexyl alcohol | 111–27–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |

| Pesticide chemical | CAS Reg. No. | Limits |
|---|---|---|
| * * * | * | * * * * |
| Lauric acid | 143–07–7 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Lauric aldehyde | 112–54–9 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Lauryl alcohol | 112–53–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| d-Limonene | 5989–27–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Methyl-α-ionone | 127–42–4 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| 3-Methyl-2-butenyl acetate | 1191–16–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| 2-Methylundecanal | 110–41–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Myristaldehyde | 124–25–4 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Myristic acid | 544–63–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Neryl acetate | 141–12–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Nonanal | 124–19–6 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Nonanoic acid | 112–05–0 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Nonyl alcohol | 143–08–8 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Octanal | 124–13–0 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Octanoic acid | 124–07–2 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| 1-Octanol | 111–87–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Palmitic acid | 57–10–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Propionic acid | 79–09–4 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| Stearic acid | 57–11–4 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |
| 2-Tridecanal | 7774–82–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| 3,5,5-Trimethylhexanal | 5435–64–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Undecanal | 112–44–7 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Undecyl alcohol | 112–42–5 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Valeraldehyde | 110–62–3 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| Valeric acid | 109–52–4 | When ready for use, the end-use concentration is not to exceed 100 ppm. |
| * * * | * | * * * * |

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