(iv) *Exempt records from other systems.* In addition, in the course of carrying out the overall purpose for this system, exempt records from other system of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

* * * * *

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27706 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0294; FRL–9226–01–OCSPP]

Various Fragrance Components; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of various fragrance components listed in unit II of this document when they are 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 with end-use concentration not to exceed 100 parts per million (ppm). Verto Solutions on behalf of The Clorox Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of such exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of various fragrance components.

DATES: This regulation is effective December 22, 2021. Objections and requests for hearings must be received on or before February 22, 2022, 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–2020–0294, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- 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, 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–2020–0294 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 February 22, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0294, 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/contacts.html.*

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 24, 2020 (85 FR 37807) (FRL–10010–82), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11016) by Verto Solutions on behalf of The Clorox Company, 4900 Johnson Dr., Pleasanton, CA 94588. The petition requested that 40 CFR 180.940(a) be amended by

establishing an exemption from the requirement of a tolerance for residues of δ-decalactone (CAS Reg. No. 705–86–2), γ-decalactone (CAS Reg. No. 706–14–9), dimethyl-1-octanol (CAS Reg. No. 106–21–8), 3,7, ethyl acetate (CAS Reg. No. 141–78–6), ethyl butyrate (CAS Reg. No. 105–54–4), ethyl decanoate (CAS Reg. No. 110–38–3); ethyl heptanoate (CAS Reg. No. 106–30–9), ethyl hexanoate (CAS Reg. No. 123–66–0), ethyl isobutyrate (CAS Reg. No. 97–62–1), ethyl laurate (CAS Reg. No. 106–33–2), ethyl octanoate (CAS Reg. No. 106–32–1), ethyl nonanoate (CAS Reg. No. 123–29–5), γ-heptalactone (CAS Reg. No. 105–21–5), γ-hexalactone (CAS Reg. No. 695–06–7), cis-3-hexenyl butyrate (CAS Reg. No. 16491–36–4), cis-3-hexenyl hexanoate (CAS Reg. No. 31501–11–8), 3-hexenyl 2-methylbutanoate (CAS Reg. No. 10094–41–4), hexyl butyrate (CAS Reg. No. 2639–63–6), hexyl hexanoate (CAS Reg. No. 6378–65–0), hexyl isobutyrate (CAS Reg. No. 2349–07–7), hexyl propionate (CAS Reg. No. 2445–76–3), hydroxynonanoic acid, δ-lactone (CAS Reg. No. 3301–94–8), 5-hydroxyundecanoic acid lactone (CAS Reg. No. 710–04–3), isoamyl acetate (CAS Reg. No. 123–92–2), isoamyl alcohol (CAS Reg. No. 123–51–3), isoamyl butyrate (CAS Reg. No. 106–27–4), isobutyl acetate (CAS Reg. No. 110–19–0), isobutyl isobutyrate (CAS Reg. No. 97–85–8), isopropyl 2-methylbutyrate (CAS Reg. No. 66576–71–4), Lavandin oil (Lavandula hybrida) (CAS Reg. No. 8022–15–9), linalool (CAS Reg. No. 78–70–6), linalyl acetate (CAS Reg. No.115–95–7), γ-nonalactone (CAS Reg. No. 104–61–0), γ-octalactone (CAS Reg. No. 104–50–7), ω-pentadecalactone (CAS Reg. No. 106–02–5), Petitgrain bigarade oil (CAS Reg. No. 8014–17–3), α-terpineol (CAS Reg. No. 98–55–5), terpinyl acetate (isomer mixture) (CAS Reg. No. 8007–35–0), Tetrahydrolinalool (CAS Reg. No. 78–69–3), γ-undecalactone (CAS Reg. No. 104–67–6), 10-undecen-1-yl acetate (CAS Reg. No. 112–19–6) 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 with end-use concentrations not to exceed 100 ppm. That document referenced a summary of the petition prepared by Verto Solutions on behalf of The Clorox Company, the petitioner, 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(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for various fragrance components including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 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 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 2018 proposed guidance document on the use of TTC in food safety assessment. This approach relies on the most recent evaluation of the literature on TTC as reviewed by EFSA and the World Health Organization (WHO) in 2016. 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 Nation's Food and Agriculture Organization and the World Health Organization, the former Scientific Committee on Food of the European Commission, the European Medicines Agency, and EFSA.

Thresholds of toxicological concern (TTC) are derived from a conservative and rigorous approach developed by

Munro and Kroes (Munro et al. 1996) 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 their structure using the Cramer classification scheme, *i.e.,* Cramer Class (Cramer et al. 1978), and NOEL (no-observed-effect-level), fifth percentile NOELs were established for each Cramer Class as ''Human Exposure Thresholds'' assuming a 60 kg human. These determined values were 30, 9, and 1.5 µg/kg/day for Cramer Class 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/pesticides/factsheets/riskassess.htm.*

The human exposure threshold value for threshold (*i.e.,* non-cancer) risks is based upon Cramer structural class. In the case of the fragrance components listed above, all the substances included are in the Cramer Class I category, which is defined as chemicals of simple structure and efficient modes of metabolism, suggesting low oral toxicity. The corresponding TTC value for substances in the Cramer Class I category is 30 µg/kg/day, which is based on a 5th percentile NOEL of 3 mg/kg/day.

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, 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. EPA assessed dietary exposures from various fragrance components 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 Food and Drug Administration (FDA) guidelines.

The dietary assessment for food contact sanitizer solutions showed that children 1 to 2 years old would be the highest exposed subgroup (48% of the chronic PAD (cPAD)). The general U.S. population resulted in 19% of the cPAD. Any percent cPAD exceeding 100% would be of concern.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for various fragrance components a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Various fragrance components 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 pesticide 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. The Agency's assessment of children's residential exposure includes total post-application exposures associated with total exposures associated with contact with treated indoor surfaces (dermal and hand-to-mouth exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not made a common mechanism of toxicity finding as to these fragrance chemicals listed in unit II and any other substances, and these fragrance chemicals do not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these fragrance chemicals listed in unit II have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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 analyzed by Munro et al. 1996 (which included developmental and reproductive toxicity studies), maternal and

developmental-specific 5th percentile NOAELs calculated by van Ravenzwaay et al. 2011 indicate low potential for offspring susceptibility, and the conservative assumptions made in the exposure assessment are unlikely 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 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 were selected for any of the fragrance components. Therefore, the fragrance components listed in Unit II 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 the fragrance components listed in Unit II from food and water will utilize 48% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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

The fragrance components listed in Unit II are currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 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 MOEs of 109 for both adult males and females. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 135 for children. Because EPA's level of concern for the fragrance components listed in Unit II of this document is an MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, the fragrance components listed in Unit II are not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for various fragrance components.

5. *Aggregate cancer risk for U.S. population.* No structural alerts for cancer that are relevant to humans were identified for the fragrance components listed in Unit II Therefore, there is low concern for genotoxicity/carcinogenicity in humans and 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 fragrances listed in unit II in or on any food commodities. EPA is establishing a limitation on the amount of the fragrances listed in unit II that may be used in pesticide formulations. This limitation 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 exceeds 100 ppm of any one of the fragrances listed in unit II in the final pesticide formulation.

B. International Residue Limits

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

The Codex has not established a MRL for the fragrance components listed in Unit II.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for δ-decalactone (CAS Reg. No. 705–86–2), γ-decalactone (CAS Reg. No. 706–14–9), dimethyl-1-octanol (CAS Reg. No. 106–21–8), 3,7, ethyl acetate (CAS Reg. No. 141–78–6), ethyl butyrate (CAS Reg. No. 105–54–4), ethyl decanoate (CAS Reg. No. 110–38–3); ethyl heptanoate (CAS Reg. No. 106–30–9), ethyl hexanoate (CAS Reg. No. 123–66–0), ethyl isobutyrate (CAS Reg. No. 97–62–1), ethyl laurate (CAS Reg. No. 106–33–2), ethyl octanoate (CAS Reg. No. 106–32–1), ethyl nonanoate (CAS Reg. No. 123–29–5), γ-heptalactone (CAS Reg. No. 105–21–5), γ-hexalactone (CAS Reg. No. 695–06–7), cis-3-hexenyl butyrate (CAS Reg. No. 16491–36–4), cis-3-hexenyl hexanoate (CAS Reg. No. 31501–11–8), 3-hexenyl 2-methylbutanoate (CAS Reg. No. 10094–41–4), hexyl butyrate (CAS Reg. No. 2639–63–6), hexyl hexanoate (CAS Reg. No. 6378–65–0), hexyl isobutyrate (CAS Reg. No. 2349–07–7), hexyl propionate (CAS Reg. No. 2445–76–3), hydroxynonanoic acid, δ-lactone (CAS Reg. No. 3301–94–8), 5-hydroxyundecanoic acid lactone (CAS Reg. No. 710–04–3), isoamyl acetate (CAS Reg. No. 123–92–2), isoamyl alcohol (CAS Reg. No. 123–51–3), isoamyl butyrate (CAS Reg. No. 106–27–

4), isobutyl acetate (CAS Reg. No. 110–19–0), isobutyl isobutyrate (CAS Reg. No. 97–85–8), isopropyl 2-methylbutyrate (CAS Reg. No. 66576–71–4), Lavandin oil (Lavandula hybrida) (CAS Reg. No. 8022–15–9), linalool (CAS Reg. No. 78–70–6), linalyl acetate (CAS Reg. No.115–95–7), γ-nonalactone (CAS Reg. No. 104–61–0), γ-octalactone (CAS Reg. No. 104–50–7), ω-pentadecalactone (CAS Reg. No. 106–02–5), Petitgrain bigarade oil (CAS Reg. No. 8014–17–3), α-terpineol (CAS Reg. No. 98–55–5), terpinyl acetate (isomer mixture) (CAS Reg. No. 8007–35–0), Tetrahydrolinalool (CAS Reg. No. 78–69–3), γ-undecalactone (CAS Reg. No. 104–67–6), 10-undecen-1-yl acetate (CAS Reg. No. 112–19–6) 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 and utensils with end-use concentration not to exceed 100 ppm.

VII. Statutory and Executive Order Reviews

This action establishes 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 tolerance 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: December 10, 2021.

Marietta Echeverria,

Acting 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. In § 180.940, amend the table in paragraph (a) by revising the heading and adding in alphabetical order the inert ingredients ''δ-decalactone'', ''γ-decalactone'', ''dimethyl-1-octanol'', ''3,7, ethyl acetate'', ''ethyl butyrate'', ''ethyl decanoate''; ''ethyl heptanoate'', ''ethyl hexanoate'', ''ethyl isobutyrate'', ''ethyl laurate'', ''ethyl octanoate'', ''ethyl nonanoate'', ''γ-heptalactone'', ''γ-hexalactone'', ''cis-3-hexenyl butyrate'', ''cis-3-hexenyl hexanoate'', ''3-hexenyl 2-methylbutanoate'', ''hexyl butyrate'', ''hexyl hexanoate'', ''hexyl isobutyrate'', ''hexyl propionate'', ''hydroxynonanoic acid, δ-lactone'', ''5-hydroxyundecanoic acid lactone'', ''isoamyl acetate'', ''isoamyl alcohol'', ''isoamyl butyrate'', ''isobutyl acetate'', ''isobutyl isobutyrate'', ''isopropyl 2-methylbutyrate'', ''Lavandin oil (Lavandula hybrida)'', ''linalool'', ''linalyl acetate'', ''γ-nonalactone'', ''γ-octalactone'', ''ω-pentadecalactone'', ''Petitgrain bigarade oil'', ''α-terpineol'', ''terpinyl acetate (isomer mixture)'', ''Tetrahydrolinalool'', ''γ-undecalactone'', and ''10-undecen-1-yl acetate'' to 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
*	*	* * * * *
δ-decalactone	705–86–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
γ-decalactone	706–14–9	When ready for use, the end-use concentration is not to exceed 100 ppm.

TABLE 1 TO PARAGRAPH (a)—Continued

Pesticide chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
3,7-dimethyl-1-octanol	106–21–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ethyl acetate	141–78–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl butyrate	105–54–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl decanoate	110–38–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl heptanoate	106–30–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl hexanoate	123–66–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl isobutyrate	97–62–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl laurate	106–33–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ethyl nonanoate	123–29–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
ethyl octanoate	106–32–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-heptalactone	105–21–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-hexalactone	695–06–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
cis-3-hexenyl butyrate	16491–36–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
cis-3-hexenyl hexanoate	31501–11–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
3-hexenyl 2-methylbutanoate	10094–41–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl butyrate	2639–63–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl hexanoate	6378–65–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl isobutyrate	2349–07–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
hexyl propionate	2445–76–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
hydroxynonanoic acid, δ-lactone	3301–94–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
5-hydroxyundecanoic acid lactone	710–04–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
isoamyl acetate	123–92–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
isoamyl alcohol	123–51–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
isoamyl butyrate	106–27–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
isobutyl acetate	110–19–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
isobutyl isobutyrate	97–85–8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
isopropyl 2-methylbutyrate	66576–71–4	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Lavandin oil (*Lavandula hybrida*)	8022–15–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
linalool	78–70–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
linalyl acetate	115–95–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-nonalactone	104–61–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-octalactone	104–50–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
ω-pentadecalactone	106–02–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Petitgrain bigarade oil	8014–17–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
α-terpineol	98–55–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
terpinyl acetate (isomer mixture)	8007–35–0	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
tetrahydrolinalool	78–69–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
γ-undecalactone	104–67–6	When ready for use, the end-use concentration is not to exceed 100 ppm.

TABLE 1 TO PARAGRAPH (a)—Continued

Pesticide chemical	CAS Reg. No.	Limits
* * *	* * *	* * *
10-undecen-1-yl acetate	112–19–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *

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[FR Doc. 2021–27580 Filed 12–21–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 483, 484, 488, 489, and 498

[CMS–1747–CN and CMS–5531–CN]

RINs 0938–AU37 and 0938–AU32

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the **Federal Register** on November 9, 2021 titled ''Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities''.

DATES: This correcting document is effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229, for home health payment inquiries.

Frank Whelan (410) 786–1302, for provider enrollment inquiries.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2021–23993 of November 9, 2021 (86 FR 62431), there were a number of technical errors that are identified and corrected in this correcting document. The provisions in this correction document are effective as if they had been included in the document that appeared in the November 9, 2021 **Federal Register**.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 62240, we inadvertently included a website address that is not related to Home Health Value Based Purchasing Model.

On pages 62250 and 62251, in our discussion of the functional impairment levels under the Patient-Driven Groupings Model (PDGM), we made typographical errors in an Outcome and Assessment Information Set (OASIS) item number.

On page 62251, we inadvertently omitted a note following the table titled ''Table 2: OASIS Points Table for those Items Associated with Increases Resource Use Using a Reduced Set of OASIS Items, CY 2020''.

B. Summary of Errors in the Regulations Text

On page 62419, in our amendatory instructions for § 424.525, we made an inadvertent error in specifying the revisions to § 424.525(a)(3).

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rulemaking in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this final rule correction does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements. This document corrects typographical and technical errors in the CY 2022 HH PPS final rule, but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this final rule correction is intended to ensure that the information in the CY 2022 HH PPS final rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that