■ 2. Add § 100.T11–084 to read as follows:

§ 100.T11–084 Special Local Regulation; Sail Grand Prix 2021 Race Event, San Francisco, CA.

(a) *Regulated areas.* The regulations in this section apply to all navigable waters of the San Francisco Bay, from surface to bottom, encompassed by a line connecting the following latitude and longitude points, beginning at 37°48′24.3″ N, 122°27′53.5″ W; thence to 37°49′15.6″ N, 122°27′58.1″ W; thence to 37°49′28.9″ N, 122°25′52.1″ W; thence to 37°49′7.5″ N, 122°25′13″ W; thence to 37°48′42″ N, 122°25′13″ W; thence to 37°48′26.9″ N, 122°26′50.5″ W and thence to the point of beginning.

(b) *Definitions.* As used in this section:

(1) *Designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer on a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the special local regulation in this section.

(2) *Zone ''A''* means the Official Practice Box Area. This zone will encompass all navigable waters of the San Francisco Bay, from surface to bottom, within the area formed by connecting the following latitude and longitude points in the following order: 37°48′24.3″ N, 122°27′53.5″ W; thence to 37°49′15.6″ N, 122°27′58.1″ W; thence to 37°49′28.9″ N, 122°25′52.1″ W; thence to 37°49′7.5″ N, 122°25′13″ W; thence to 37°48′42″ N, 122°25′13″ W; thence to 37°48′26.9″ N, 122°26′50.5″ W and thence to the point of beginning.

(3) *Zone ''B''* means the Official Race Box Area, which will be marked by 12 or more colored visual markers within the special regulation area designated in paragraph (a) of this section. The position of these markers will be specified via Broadcast Notice to Mariner at least three days prior to the event.

(4) *Zone ''C''* means the Spectator Area, which is within the special local regulation area designated in paragraph (a) of this section and outside of Zone ''B,'' the Official Race Box Area. Zone ''C'' will be defined by latitude and longitude points per Broadcast Notice to Mariners. Zone ''C'' will be further divided into three additional sub-areas: Zone ''C1 East,'' Zone ''C1 West,'' and Zone ''C2.'' Zone ''C1 East'' and Zone ''C1 West'' will be the general spectator area or areas marked by approximately four or more colored buoys that will be managed by marine event sponsor officials. Vessels shall not anchor within the confines of Zone ''C.''

(5) *Zone ''D''* means the No Loitering and Anchoring Area. This zone will allow vessels to transit in and out of marinas, piers, and vessel launch areas throughout the duration of the Sail Grand Prix. All vessels shall maintain headway and shall not loiter or anchor within the confines of Zone ''D.'' Mariners can transit Zone ''D'' during the Sail Grand Prix 2021 event, decreasing the impact of the special local regulation to the San Francisco waterfront.

(c) *Special local regulation.* The regulations in paragraphs (c)(1) through (5) of this section apply between noon and 5:30 p.m. on the Sail Grand Prix 2021 official practice and race days.

(1) Only support and race vessels will be authorized by the COTP or designated representative to enter Zone ''B'' during the race event. Vessel operators desiring to enter or operate within Zone ''A'' or Zone ''B'' must contact the COTP or a designated representative to obtain permission to do so. Persons and vessels may request permission to transit Zone ''A'' on VHF–23A.

(2) Spectator vessels in Zone ''C'' must maneuver as directed by the COTP or designated representative by a succession of sharp, short signals by whistle or horn, the hailed vessel must come to an immediate stop and comply with the lawful direction issued. Failure to comply with a lawful direction may result in additional operating restrictions, citation for failure to comply, or both.

(3) Spectator vessels in Zone ''C'' must operate at safe speeds, which will create minimal wake.

(4) Vessels in Zone ''D'' shall maintain headway and shall not loiter or anchor within the confines of Zone ''D.'' Vessels in Zone ''D'' must maneuver as directed by the COTP or designated representative.

(5) Rafting and anchoring of vessels is prohibited within Zones ''A,'' ''B,'' ''C,'' and ''D.''

(d) *Enforcement periods.* This section will be enforced for the official practices and race events from noon to 5:30 p.m. each day from March 24, 2022, through March 27, 2022. At least 24 hours in advance of the official practice and race events commencing on March 24, 2022, the COTP will notify the maritime community of periods during which the zones in paragraphs (b)(2) through (5) of this section will be enforced via Broadcast Notice to Mariners and in writing via the Coast Guard Boating Public Safety Notice.

Dated: March 11, 2022.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2022–05621 Filed 3–16–22; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0531; FRL–9608–01–OCSPP]

Zinc Stearate; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of zinc stearate (CAS No. 557–05–1) when used as an inert ingredient (lubricant) in pesticide formulations at rates of no more than 6 percent by weight of the formulation in pre- and post-harvest applications to crops. Pyxis Regulatory Consulting, Inc., on behalf of UPL NA Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of zinc stearate (CAS No. 557–05–1) on food or feed commodities when used in accordance with this exemption.

DATES: This regulation is effective March 17, 2022. Objections and requests for hearings must be received on or before May 16, 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–2020–0531, 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 open to visitors by appointment only. For the latest status information on EPA/DC services and 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:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0531 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 May 16, 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–2020–0531, 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 December 21, 2020 (85 FR 82998) (FRL–10016–93), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11376) filed by Pyxis Regulatory Consulting, Inc., on behalf of UPL NA Inc. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of zinc stearate (CAS No. 557–05–1) when used as an inert ingredient (lubricant) in fumigant pesticide formulations at rates of no more than 6 percent by weight of the formulation when applied pre-and post-harvest to crops. That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any substantive public comments.

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 the 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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that EPA has determined 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 it 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 an exemption 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 shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a 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 and considered its validity, completeness and reliability and the relationship of this information 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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to zinc stearate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with zinc stearate 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 zinc stearate 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 acute toxicity of zinc stearate to mammals is low. The acute oral LD_{50} (lethal dose) in rats is greater than 2,000 milligrams/kilogram (mg/kg). The acute dermal LD_{50} in rabbits is also greater than 2,000 mg/kg, and the acute inhalation LD_{50} in rats is greater than 200 mg/L. Zinc stearate is not an eye or a dermal irritant.

The repeated-dose toxicity for zinc stearate and the related compound calcium distearate in mammals is low. No adverse effects were observed in a 28-day rat study with zinc stearate, which also conducted a neurobehavioral evaluation. Also, no adverse effects were observed in a combined repeated dose with reproduction/developmental screening study in rats with calcium distearate.

No oral chronic or carcinogenicity studies are available for zinc stearate. However, there are no structural alerts for carcinogenicity for zinc stearate and there were no adverse effects observed in the available studies on related substances. There is also low concern for mutagenicity, based on negative results in an *in vitro* bacterial reverse mutation study on zinc stearate. No evidence of neurotoxicity or immunotoxicity was observed in the available studies.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoint of concern for zinc stearate were identified in the database.

C. Exposure Assessment

1. Dietary exposure. Although dietary exposure (food and drinking water) may occur from the proposed uses as well as existing pesticide inert uses (*e.g.,* flow control agent) and non-pesticide uses (*e.g.,* cosmetics, personal care, pharmaceuticals, plastics and coating additives) of zinc stearate, no endpoint of concern was identified. Therefore, an acute or chronic dietary exposure assessment is not necessary for zinc stearate.

2. Residential exposure. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure. Residential exposure to zinc stearate may occur from existing and proposed pesticide inert uses as well as from non-pesticide uses (cosmetics, personal care, pharmaceuticals, plastics and coating additives) that may be used in and around the home. However, based on the absence of a toxicological endpoint of concern, a quantitative assessment for residential exposure was not performed.

3. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption, 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.'' Based on the lack of toxicity in the available database, zinc stearate and its metabolites are not expected to share a common mechanism of toxicity with other substances. For the purposes of this action, therefore, EPA has assumed that zinc stearate does not have a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 unless EPA concludes that a different margin of safety will be safe for infants and children. Based on the low toxicity of zinc stearate in the available studies, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and therefore conducted a qualitative assessment of zinc stearate. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on zinc stearate, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to zinc stearate residues. Therefore, the establishment of an exemption from the requirement of a tolerance under 40 CFR 180.910 for residues of zinc stearate when used as an inert ingredient (lubricant) in pesticide formulations at rates of no more than 6 percent by weight of the formulation in pre- and post-harvest applications to crops is safe under FFDCA section 408.

VII. 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 zinc stearate in or on any food commodities. EPA is establishing a limitation on the amount of zinc stearate that may be used in pesticide formulations applied pre- or post-harvest. 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 6 percent zinc stearate by weight 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 has not established a MRL for zinc stearate.

VIII. Conclusion

Taking into consideration all available information on zinc stearate, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup,

including infants and children, will result from aggregate exposure to zinc stearate residues. Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for zinc stearate when used as an inert ingredient at no more than 6 percent by weight of the total pesticide formulation.

IX. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption 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).

X. 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: March 9, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, the EPA amends 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 § 180.910, amend Table 1 to 180.910 by adding, in alphabetical order, an entry for ''Zinc stearate (CAS Reg No. 557–05–1)'' to reads as follows:

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

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * *	* *	* *
Zinc stearate (CAS Reg No. 557–05–1)	Not to exceed 6 percent by weight of fumigant pesticide formulation.	Lubricant.
* * *	* *	* *

[FR Doc. 2022–05661 Filed 3–16–22; 8:45 am]

BILLING CODE 6560–50–P