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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0138; FRL-9999-72]

Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)- ω-hydroxy-; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- (CAS Reg. No. 67674-67-3) when used as an inert ingredient (surfactant) applied to animals. Exponent, on behalf of LNouvel, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- when used in accordance with the terms of the exemption in EPA regulations.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0138, is available at *http://www.regulations.gov* or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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 Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0138 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. 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-2019-0138, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC),

(28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Petition for Exemption

In the **Federal Register** of May 13, 2019 (84 FR 20843) (FRL-9991-91), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11248) by Exponent, on behalf of LNouvel, Inc., 4657 Courtyard Trail, Plano, TX 75024-2114. The petition requested that 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy)disiloxanyl)propyl)-ω-hydroxy- (CAS Reg. No. 67674-67-3) when used as an inert ingredient in pesticide formulations applied to animals. That document referenced a summary of the petition prepared by Exponent, on behalf of LNouvel, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term

"inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to take into account the considerations set forth in section 408(b)(2)(C) and (D), when making this safety determination. 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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- 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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- 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.

Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy exhibits low levels of acute toxicity. Acute studies in rats showed oral LD_{50}

of >1,600 mg/kg. The dermal LD_{50} in rats was >3,200 mg/kg. No acute inhalation studies were available. Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is considered to be an eye irritant and a mild skin irritant. However, it was not found to be a dermal sensitizer.

Repeat dose studies on poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- are limited. In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats, effects seen at 1,000 mg/kg/day, the highest dose tested (i.e., 800 mg/kg/day to poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-) included decreased body weight, body weight gain, and food consumption and reduced body temperature in males. No developmental/reproductive adverse effect attributed to the test substance were observed in the study.

There is no evidence that exposure to poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- suppresses or otherwise harms immune function in humans. No signs of neurotoxicity were reported in acute or repeat-dose oral studies. There were also no signs of carcinogenicity in the database. Similarly, all tests were negative for genotoxicity and mutagenicity. The available data suggests that poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is not carcinogenic.

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 *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- used for human risk assessment are described in this unit. The Point of Departure (POD) for all durations of oral, dermal, and inhalation exposure is based on the NOAEL of 300 mg/kg/day and the LOAEL of 1,000 mg/kg/day based on decreased body weight, body weight gain, and food consumption and reduced body temperature in males from the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test. Once corrected for the percent inert ingredient in the test formulation, the NOAEL was 240 mg/kg/day and the LOAEL was 800 mg/kg/day poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-.

A 100-fold uncertainty factor was used (10X interspecies extrapolation, 10X for intraspecies variability, and 1X FQPA safety factor (SF)). The FQPA SF is reduced to 1X

because the reproductive and developmental toxicity database is complete and there is no evidence of increased risk to infants and children.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-, EPA considered exposure under the proposed exemption from the requirement of a tolerance as well as the existing tolerance exemption for this chemical. Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is currently approved as a food use inert ingredient under 40 CFR 180.910. EPA assessed dietary exposures from poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- in food as follows:

Because no acute endpoint of concern was identified, a quantitative acute dietary exposure assessment is unnecessary. In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM– FCID^{TM}, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The Inert Dietary Exposure Evaluation Model (I-DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a

person each day has tolerance-level residues. This model incorporates all current and proposed pesticidal food uses for this inert ingredient.

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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-, 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). A review of residential products containing this inert ingredient revealed that it is currently used in fungicides, herbicides, and insecticides applied to residential settings, mainly on lawns and turf. In an effort to assess exposure, the EPA has conducted a conservative screening-level assessment using high-end exposure scenarios for pesticidal use on lawns/turf. For each residential scenario, short-term exposure for both the handler (adult) and post-application exposure (adult and child) is expected. Based on the use pattern (e.g., pre- and post-harvest uses, use on lawns), intermediate-term and long-term pesticidal exposures from residential uses are not expected.

In addition to the proposed and current pesticidal uses of poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-, poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is

also used in various non-pesticidal products; however, quantifiable exposure data are not available for these exposure scenarios.

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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- to share a common mechanism of toxicity with any other substances, and poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website 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.

2. *Prenatal and postnatal sensitivity*. A combined repeated dose toxicity study with a reproduction/developmental toxicity screening test showed no effect on reproductive parameters of fertility in the absence of maternal toxicity.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is complete.

ii. There is no indication that poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- results in increased susceptibility in *in utero* rats in a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- in drinking water. EPA used similarly conservative assumptions

to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-.

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, poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is 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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- from food and water will utilize 29.4 % 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). Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy)

disiloxanyl) propyl)-ω-hydroxy- is 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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-.

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 390 for adults and 175 for children 1 to 2 years old. Because EPA's level of concern for poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A potential intermediate-term adverse effect was identified; however, poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is 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 poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-.

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity, poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy-residues.

V. Other Considerations

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.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.930 for poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- (CAS Reg. No. 67674-67-3) when used as an inert ingredient (surfactant) in pesticide formulations applied to animals.

VII. 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), nor is it considered a regulatory action for purposes of Executive Order 13771, entitled "reducing Regulations and Controlling Regulatory Costs (82 FR 9339, February 3, 2017). 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 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).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 13, 2019.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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

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

2. In §180.930, add alphabetically the inert ingredient "Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- (CAS Reg. No. 67674-67-3)" to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

***** ***** ***** ***** *****

Inert ingredients	Limits	Uses
* * * * * * *		
Poly(oxy-1,2-ethanediyl), α-(3-(1,3,3,3-tetramethyl-1-((trimethylsilyl) oxy) disiloxanyl) propyl)-ω-hydroxy- (CAS Reg. No. 67674-67-3)		Surfactant
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