TABLE 9—ADDITIONAL REGULATIONS APPROVED FOR THE SPOKANE REGIONAL CLEAN AIR AGENCY (SRCAA) JURISDICTION

[Applicable in Spokane County, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
Spokane Regional Clean Air Agency Regulations				
Regulation I—Article VI—Emissions Prohibited				
6.05	Particulate Matter and Preventing Particulate Matter from Becoming Airborne.	04/10/04	04/12/16 [Insert **Federal Register** citation].	Except 6.05(A).
6.14	Standards for Control of Particulate Matter on Paved Surfaces.	06/03/07	04/12/16 [Insert **Federal Register** citation].	
6.15	Standards for Control of Particulate Matter on Unpaved Roads.	06/03/07	04/12/16 [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * * (e) * * *

TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP Provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
*	*	*	*	*
Particulate Matter (PM_{10}) 2nd 10-Year Limited Maintenance Plan.	Spokane	1/4/16	4/12/16 [Insert **Federal Register** citation].	

[FR Doc. 2016–08272 Filed 4–11–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0449; FRL–9944–11]

1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl] propoxy]-; 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl] propoxy]- (CAS Reg. No. 70280–68–1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 5% by weight. Exponent, on behalf of ISK Biosciences 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl] propoxy]-.

DATES: This regulation is effective April 12, 2016. Objections and requests for hearings must be received on or before June 13, 2016, 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–2014–0449, 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: Susan Lewis, 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 Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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–2014–0449 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 June 13, 2016. 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–2014–0449, 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 April 6, 2015 (80 FR 18327) (FRL–9924–00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10699) by Exponent, on behalf of ISK Biosciences, 7470 Auburn Road, Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280–68–1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 10% in formulation. That document referenced a summary of the petition prepared by Exponent, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the limitation on the maximum concentration in the pesticide formulation from 10% to 5%. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document, ''1,2-Propanediol, 3-[3-[1,3,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-; Human health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920'' in docket ID number EPA–HQ–OPP–2014–0449.

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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-

[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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.

There is currently limited data available for 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-. The Agency received three studies specifically testing 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-: acute oral toxicity, acute dermal toxicity, and an Ames assay. Those studies showed that 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- was non-toxic via acute oral and acute dermal exposures and was negative for mutagenicity. To assess the remaining potential toxicity of 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, the Agency relied on data for a suitable cluster of structurally related linear short chain siloxane (Si-2 to Si-5) compounds. Based on the similar structures and physicochemical properties of these compounds to 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, which primarily differ only in the number of siloxane units, the Agency has determined that the toxicological properties of these compounds is representative of the toxicity of 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-. The Agency has also determined that these data adequately address the physicochemical, mammalian metabolism, mammalian toxicological, and environmental fate endpoints of 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-.

Oral repeat dose toxicity studies are available for structurally similar linear short chain siloxane chemicals, for durations ranging from 28 days up to one year in rats, rabbits, and dogs. The lowest NOAELs were in the 25 milligram/kilogram/day (mg/kg/day) range for two 28-day oral repeat dose rat studies and a 90-day dog study. LOAELs for these studies were based mainly on liver effects which were present in all of these studies.

Dermal repeated dose toxicity studies are available for two of the structurally similar linear short chain siloxane compounds. A 28-day dermal toxicity study in rats and rabbits showed no adverse effects up to limit dose of 1,000 mg/kg/day. The NOAEL was 1,000 mg/kg/day; the highest dose tested in both studies.

Inhalation repeated dose toxicity studies are available for three of the structurally similar linear short chain siloxane compounds. Both 28-day and 90-day rat inhalation studies are available as well as a one-year chronic inhalation study. The lowest inhalation NOAEL was 3.9 milligrams per Liter (mg/L) in a 90-day study, equivalent to a dose of greater than 1,000 mg/kg/day, a limit dose value.

A carcinogenicity study is available on one structurally-related short chain siloxane compound. An increase incidence of Leydig cell tumors (LCTs) in males was observed at all doses. However, due to the high background incidence of LCTs in Fischer 344 rats, this effect has been determined to not be treatment-related. Renal tubular adenomas and carcinomas were also observed in the study but are attributable to male rat specific alpha-2µ-globulin mediated nephrotoxicity and therefore not relevant to cancer risk concerns in humans. Genotoxicity studies on 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- and structurally-related compounds were negative for genotoxic effects. A DEREK (structure-activity modeling) analysis was conducted and identified no structural alerts for possible carcinogenicity among the linear short chain siloxane compounds. Therefore, based on the lack of human-relevant carcinogenicity in the available study, and the results of the genotoxicity studies and DEREK analysis, 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- is not expected to be carcinogenic.

Reproductive and developmental toxicity studies with linear short chain siloxane compounds demonstrated no adverse effects at doses at or below limit dose levels. No evidence of immunotoxicity or neuro toxicity at doses below the limit dose was observed in the available studies for the structurally related linear short chain siloxane (Si-2 to Si-5) compounds at up to limit dose levels.

There are currently no publically-available metabolism studies for 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, however, the expected mammalian metabolic pathways which may be involved in the degradation of 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- include a combination of ether hydrolysis followed by ß-oxidation of the carbon chain followed by methyl oxidation of the silyl methyl groups. Methyl oxidation would result in the formation of a mixture of primary and alcohol metabolites. The more polar primary alcohol functionalities can both be conjugated and excreted directly or further oxidized to form a mixture of more polar carboxylic acid metabolites that are readily conjugated and excreted.

Specific information on the studies received and the nature of the adverse effects caused by 1,2-propanediol,3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- as well as the NOAEL and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document, ''1,2-Propanediol,3-[3-[1,3,3,3-tetraamethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920'' in docket ID number EPA–HQ–OPP–2014–0449.

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 the NOAEL and the LOAEL are identified. 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- used for human risk assessment is shown in Table 1 of this unit.

The 28-day studies in rats the NOAEL was 25 mg/kg/day with a LOAEL of 250 mg/kg/day based on based on increases in absolute liver weights, hepatocellular hypertrophy and protoporphyrin accumulation with associated bile duct proliferation and periportal chronic inflammation. A 90-day dog study had a NOAEL of 24 mg/kg/day with a LOAEL of 77 mg/kg/day based on increased relative liver weight in females and lower relative testes weight in males with slight testicular atrophy or hypoplasia in males. A NOAEL of 25 mg/kg/day was selected for use as the endpoint for dietary exposure in this risk assessment. An additional uncertainty factor of 3X was applied for the use of shorter term study for a chronic risk assessment.

Dermal and inhalation exposure endpoints were not selected as there were no adverse effects observed up to limit dose levels in both rat and rabbit dermal and inhalation toxicity studies.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 1,2-PROPANEDIOL, 3-[3-[1, 3, 3, 3-TETRAMETHYL-1-[(TRIMETHYLSILYL)OXY]-1-DISILOXYANYL] PROPOXY]- FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations)	NOAEL= 25 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 3x	Chronic RfD = 0.08 mg/kg/day ..... cPAD = 0.08 mg/kg/day	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Incidental oral short-term (1 to 30 days).	NOAEL= 25 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 25 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 3x	LOC for MOE = 300	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Cancer (Oral, dermal, inhalation) ..	Not likely to be carcinogenic to humans based on the lack of increased incidence of tumor formation compared to controls in the 1-year carcinogenicity study, lack of mutagenicity, and no structural alerts for genotoxicity or carcinogenicity identified in a qualitative structure activity relationship (SAR) database, DEREK.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- in food as follows:

i. *Acute Exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM–FCID), Version 3.16, EPA, which includes 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. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on 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. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4):

Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-, a conservative drinking water concentration value of 100 parts per billion (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).

Residential use patterns are possible for pesticide products containing 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-. Residential exposure could occur via the dermal and inhalation routes of exposure. However, there are no concerns for dermal or inhalation exposure because no effects were seen in dermal or inhalation toxicity studies up to the limit dose. Incidental oral exposure for children is possible either by hand-to-mouth or object-to-mouth ingestion resulting from contact with treated surfaces.

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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- to share a common mechanism of toxicity with any other substances, and 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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 Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA 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.* Although some adverse reproductive effects were observed in the inhalation developmental/reproductive toxicity studies, these effects were at dose levels far in excess of the clear NOAEL established in the oral reproductive and developmental screening study and the regulatory doses used in the risk assessment were selected to be protective of these effects.

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 3x to account for the use of a subchronic study to derive a chronic reference dose. That decision is also based on the following findings:

i. Although only limited data on 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is available, the Agency has reliable data based on the structurally related linear short chain siloxane (Si-2 to Si-5) compounds to adequately characterize the toxicity and assess the risk from dietary exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-.

ii. There is no indication that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is a neurotoxic chemical at doses below the limit dose and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no indication that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is a immunotoxic chemical and there is no need for a immunotoxicity study or additional UFs to account for immunotoxicity.

iv. As discussed in Unit IV.D.2., there is no need to retain the FQPA 10x to address any concern for potential increased susceptibility in infants and children from prenatal or postnatal exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on a highly conservative model that assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has residues of inert ingredient equivalent to the residue level of the highest established tolerance for an active ingredient on a given commodity. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-.

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, 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- from food and water will utilize 88.3% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in this unit regarding residential use patterns, chronic residential exposure to residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is not expected.

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).

1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- may be used as an inert ingredient in pesticide products that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Although short-term residential exposure is possible, there was no endpoint of concern identified in both dermal and inhalation toxicity studies. However the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures for children. EPA has concluded the combined short-term aggregated food, water, and residential exposures results in an aggregate MOE of 334 for children. Children's aggregate MOE combines average food and water exposure from the chronic dietary exposure with residential exposure associated with contact with treated lawns (hand-to-mouth + object-to-mouth). As the level of concern is for MOEs that are lower than 300, 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).

1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- may be used as an inert ingredient in pesticide products that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Although intermediate-term residential exposure is possible, there was no endpoint of concern identified in both dermal and inhalation toxicity. However the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures for children. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures results in an aggregate MOE of 342 for children. Children's aggregate MOE combines average food and water exposure from the chronic dietary exposure with residential exposure associated with contact with treated lawns (hand-to-mouth + object-to-mouth). As the level of concern is for MOEs that are lower than 300, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., EPA does not expect 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- 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 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The 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 for sale or distribution for use on growing crops with concentrations of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- exceeding 5% by weight of the formulation.

B. Revisions to Petitioned-For Tolerances

Based upon an evaluation of the data included in the petition, EPA is establishing an exemption from the requirement of a tolerance for residues of 1,2-propanediol 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- when used in pesticide formulations as an inert ingredient (antifoaming agent), not to exceed 5% by weight of the formulation, instead of the 10% limit requested. The basis for this revision can be found at *http://www.regulations.gov* in document, ''1,2-Propanediol,3-[3-[1,3,3,3-tetraamethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920'' in docket ID number EPA–HQ–OPP–2014–0449.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280–68–1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 5% by weight in formulation.

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). 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: March 31, 2016.

G. Jeffrey Herndon,

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 § 180.920, add alphabetically the inert ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * *	* *	*
1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280–68–1).	Not to exceed 5% by weight of pesticide formulation.	Antifoaming agent.
* * * *	* *	*

[FR Doc. 2016–08282 Filed 4–11–16; 8:45 am]

BILLING CODE 6560–50–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

40 CFR Part 1800

[Docket Number: 104122016–1111–01]

RESTORE Act Spill Impact Component Allocation

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice of effective date of final rule.

SUMMARY: This document confirms that on April 4, 2016, the United States District Court for the Eastern District of Louisiana entered a consent decree (Consent Decree) among the United States; the states of Alabama, Florida, Louisiana, Mississippi and Texas; and BP Exploration and Production Inc. with respect to the civil penalty and natural resource damages in case number MDL No. 2179. The Gulf Coast Ecosystem Restoration Council (Council) regulation (Spill Impact Regulation) that implements the Spill Impact Component Allocation of the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act) is effective as of the date of publication of this document.

DATES: The Spill Impact Regulation is effective on April 12, 2016.

FOR FURTHER INFORMATION CONTACT: Will Spoon at (504) 239–9814.

SUPPLEMENTARY INFORMATION:

Background

On December 15, 2015, the Council published the Spill Impact Regulation in the **Federal Register** (80 FR 77580), to be effective on the date that the Council publishes this document in the **Federal Register** confirming that the United States District Court for the Eastern District of Louisiana has entered the Consent Decree.

On April 4, 2016, the United States District Court for the Eastern District of Louisiana entered the Consent Decree. The Council confirms such entry by publication of this document, and the Spill Impact Regulation is therefore effective.

For more information on the Spill Impact Regulation, please see the final rule (80 FR 77580, December 15, 2015).

Procedural Requirements

Regulatory Planning and Review (Executive Orders 12866 and 13563)

As an independent Federal entity that is comprised, in part, of the Secretaries of the Departments of the Interior, Agriculture, Commerce and Homeland Security; the Secretary of the Army; and the Administrator of Environmental Protection Agency, the requirements of Executive Orders 12866 and 13563 do not apply to this document.