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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0201; FRL-9997-14]

C_1-C_4 Linear and Branched Chain Alkyl D-Glucitol Dianhydro Alkyl Ethers; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of pesticide inert ingredients within the C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers (AD-GDAE) cluster. These exemptions are being established with the following terms: when used as an inert ingredient (solvent, co-solvent, viscosity modifier and adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest, on animals, and in antimicrobial formulations applied to food-contact surfaces in public-eating places, dairy-processing equipment, and food-processing equipment, and utensils, and in antimicrobial formulations used for dairy processing equipment, and food-processing equipment and utensils. Exponent, Inc., on behalf of Croda, 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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster when used in accordance with the terms of these exemptions.

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-2018-0201, 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. 0The 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 L. 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-2018-0201 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-2018-0201, 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 October 18, 2018 (83 FR 52787) (FRL-9984-21), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11109) by Exponent, Inc. (1150 Connecticut Ave, Suite 1100, NW, Washington, D.C. 20036), on behalf of Croda, Inc. (315 Cherry Lane New Castle, DE 19720). The petition requested that 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of C1-C4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers (C1-C4 Linear and Branched Chain AD-GDAE) cluster—d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-(CAS Reg. No. 5306-85-4); d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-ethyl- (CAS Reg. No. 30915-81-2); d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-propyl) (CAS Reg. No. 107644-13-3); d-glucitol, 1,4:3,6-dianhydro-2,5-bis-O-(1-methylethyl)-,(iso-propyl diether) (CAS Reg. No. 103594-41-8); d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-butyl- (CAS Reg. No. 103594-42-9); d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-, (CAS Reg. No. not assigned); and d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned) when used as an inert ingredient (solvent, co-solvent, viscosity modifier and adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40

CFR 180.910, applied in or on animals under 40 CFR 180.930, in antimicrobial formulations used in food-contact surfaces in public-eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a) and in antimicrobial formulations used for dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(b). That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of Croda, Inc., the petitioner, which is available in the docket, *http://www.regulations.gov*. Although one comment was submitted in response to the relating to notice of filing regarding the use of pesticides generally, it was not specific to tolerances or this rulemaking.

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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 seven compounds included in the cluster are C_1-C_4 linear and branched chain glucitol, 1,4:3,6-dianhydro ether congeners of isosorbide, which is described as a fused ring furo[3,2-b]furan, d-glucitol heterocycle. These chemicals are similar in structure and are expected to be similar in regard to toxicity profile. Therefore, d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- was selected as a suitable analogue to represent toxicity due to exposure to the seven compounds included in the cluster and all toxicological studies were conducted with d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-.

The acute oral and dermal toxicities are low in rats and rabbits, respectively. C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers are not irritating to the skin or eyes in the rabbit. Acute inhalation and sensitization studies are not available for review.

New Zealand white rabbits exposed for 8 days via gavage to doses as high as 300 mg/kg/day of d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- do not exhibit adverse effects. No adverse effects are observed up to 375 mg/kg/day in rats following 13 weeks of exposure via gavage to d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-. Conversely, adverse effects are observed in the dog following 13 weeks of exposure via capsule to d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-. Decreased mean body weight, body weight gain, food consumption, changes in clinical biochemistry, lower levels of red blood cells (RBCs), hemoglobin and hematocrit and

decreased relative liver weights are observed in dogs at 700 mg/kg/day. The no-observed-adverse-effect level (NOAEL) is 100 mg/kg/day.

No fetal susceptibility is observed in the developmental toxicity studies in rats and rabbits. Developmental studies with d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-in the rat and rabbit show no maternal or developmental adverse effects up to 375 and 300 mg/kg/day, respectively, the highest doses tested. No reproduction toxicity studies are available for review, however, no evidence of toxicity to reproductive organs is observed in the 13-week oral toxicity studies in the rat or dog up to 375 and 700 mg/kg/day, respectively.

The Ames test and chromosomal aberrations assay in human lymphocytes are negative. Therefore, d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- is not considered mutagenic.

D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- is not expected to be carcinogenic based on a Derek Nexus structural alert analysis. No structural alerts for carcinogenicity or mutagenicity are indicated in the analysis.

Neurotoxicity and immunotoxicity studies are not available for review. However, no evidence of neurotoxicity and immunotoxicity is observed in the submitted studies.

Metabolism studies are not available for the C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster. However, based on the classical metabolic pathways for the alkyl and aryl etherases, it is expected that the C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster would be metabolized to monoethers, isosorbide (the common and major metabolite), and sorbitol.

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*.

The 13-week oral toxicity study in dogs is selected for the chronic dietary exposure scenario as well as intermediate-term incidental oral, dermal and inhalation exposure scenarios. The NOAEL is 100 mg/kg/day, and the LOAEL is 700 mg/kg/day based on decreased mean body weight, body weight gain and food consumption, changes in clinical biochemistry, lower levels of RBCs, hemoglobin and hematocrit and decreased relative liver weights. This represents the lowest NOAEL in the database in the most sensitive species. The developmental studies in rats and rabbits are selected for short-term exposure scenarios. These studies are considered co-critical, the NOAEL is 300 mg/kg/day, the highest dose tested. The standard inter- and intra-species uncertainty factors of 10x are applied; as discussed below in Unit IV.D., the Agency applied a 1x Food Quality Protection Act (FQPA) Safety Factor (SF). The default factor of 100% is applied for the dermal absorption rate and the inhalation absorption rate.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster, EPA considered

exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster in food as follows:

No adverse effects attributable to a single exposure of endpoint was identified for d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-; therefore, an acute dietary exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. 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.

In the dietary exposure assessment, the Agency assumed 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 (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain residues of the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant

exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

To assess dietary exposure due to its use in antimicrobial products, EPA calculated the daily dietary dose (DDD) and the estimated daily intake (EDI) as described in the Food Drug Administration (FDA) model. The assessment considered: application rates, residual solution or quantity of solution remaining on the treated surface without rinsing with potable water, surface area of the treated surface which comes into contact with food, pesticide migration fraction, and body weight. These assumptions are based on FDA guidelines (2003). Dietary exposures due to antimicrobial uses are aggregated with the aforementioned dietary exposures.

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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers, 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).

The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure. A conservative residential exposure and risk assessments were completed for pesticide products containing d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- as inert ingredients. The Agency assessed pesticide products containing d-glucitol, 1,4:3,6-dianhydro-

2,5-di-O-methyl- using exposure scenarios (treated lawns, mopping, wiping and aerosol spray) to represent conservative residential handler exposure. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled: ''JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA-HQ-OPP-2008-0710.

D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- is also present in some anti-acne and anti-aging topically applied pharmaceuticals products. The typical use levels of d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- in these products are limited to less than 5.44% to 15% weight/weight (w/w). These products are used sparingly and applied selectively to limited areas of the skin.

The Agency does not have sufficient data to quantitatively assess exposures to d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- that result from these non-pesticidal uses. However, the Agency believes the assessments of exposures due to pesticide uses are protective of these non-pesticidal uses. Based on the available data on the typical reported concentration ranges of d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- topically applied pharmaceuticals as well as the specific use and limited exposures resulting from such uses, the Agency anticipates that exposures to d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- that might result from anti-acne and anti-aging topically applied pharmaceutical products uses are likely to be markedly less than the conservatively-estimated exposures resulting from pesticide use. Therefore, the Agency believes that any contribution to the estimated pesticide exposure resulting from topically applied pharmaceuticals products is likely to be insignificant in comparison to the estimates for

exposure from pesticide use and these exposures have not been aggregated with other non-residential exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster to share a common mechanism of toxicity with any other substances, and C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 SF. In applying this provision, EPA either retains the default value of 10x, or uses a

different additional safety factor when reliable data available to EPA support the choice of a different factor.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x for the chronic dietary assessment for the following reasons. The toxicity database for C1-C4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster contains subchronic, developmental and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Fetal susceptibility is not observed in developmental toxicity studies in the rat and rabbit. No maternal or developmental toxicity is observed in either study up to 300 mg/kg/day. A reproduction toxicity is not available; however, reproduction parameters were not affected in the submitted studies at doses as high as 375 and 700 mg/kg/day in the rat and dog, respectively. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x.

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, C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster from food and water will utilize 70.6% 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).

C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster.

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 148 for adult males and females. Adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, aerosol spray with a high-end post application dermal exposure from contact with treated lawns. The combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 122 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern

for C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster is an MOE of less than 100, 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).

C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 434 for adult males and females. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. The combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 125 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern for C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster is an MOE of less than 100, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on a DEREK structural alert analysis, the lack of mutagenicity, and the lack of specific organ toxicity in the chronic toxicity study, C1-C4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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 C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster 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, exemptions from the requirement of a tolerance are established for residues of the following seven compounds within the C1-C4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers (AD-GDAE) cluster: (1) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- (CAS Reg. No. 5306-85-4); (2) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-ethyl- (CAS Reg. No. 30915-81-2); (3) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-propyl) (CAS Reg. No.107644-13-3); (4) d-glucitol, 1,4:3,6-dianhydro-2,5-bis-O-(1-methylethyl)-,(iso-propyl diether) (CAS Reg. No. 103594-41-8); (5) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-butyl- (CAS Reg. No. 103594-42-9); (6) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-, (CAS Reg. No. not assigned); and (7) d-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned) when used as an inert ingredient (solvent, co-solvent, viscosity modifier and adjuvant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910; applied in or on animals under 40 CFR 180.930; when used in antimicrobial formulations applied to food-contact surfaces in public-eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a) limited to 500 ppm; and in

antimicrobial formulations used for dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(b) limited to 1,000 ppm.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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 under 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section

408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: August 8, 2019

Michael Goodis,

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 §180.910, add alphabetically the following inert ingredients to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl- (CAS Reg. No. 5306-85-4); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-ethyl- (CAS Reg. No. 30915-81-2); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-propyl) (CAS Reg. No.107644-13-3); D-glucitol, 1,4:3,6-dianhydro-2,5-bis-O-(1-methylethyl)-,(iso-propyl diether) (CAS Reg. No. 103594-41-8); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-butyl- (CAS Reg. No. 103594-42-9); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-, (CAS Reg. No. not assigned); and D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned)		solvent, co-solvent, viscosity modifier, and adjuvant
* * * * * * *		

3. In §180.930, add alphabetically the following inert ingredients 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
* * * * * * *		
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-methyl-(CAS Reg. No. 5306-85-4); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-ethyl- (CAS Reg. No. 30915-81-2); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-propyl) (CAS Reg. No.107644-13-3); D-glucitol, 1,4:3,6-dianhydro-2,5-bis-O-(1-methylethyl)-,(iso-propyl diether) (CAS Reg. No. 103594-41-8); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-butyl- (CAS Reg. No. 103594-42-9); D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-, (CAS Reg. No. not assigned); and D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned)		solvent, co-solvent, viscosity modifier, and adjuvant
* * * * * * *		

4. In §180.940, add alphabetically the following inert ingredients to the tables in paragraphs (a) and (b) to read as follows:

§ 180. 940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * * * *		
C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster	5306-85-4; 30915-81-2; 107644-13-3; 103594-41-8;	When ready for use, the end-use concentration is not to

	103594-42-9	exceed 500 ppm
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-,	None	
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned)	None	
* * * * * * *		

(b) * * *

Pesticide Chemical	CAS Reg. No.	Limits
* * * * * * *		
C_1-C_4 linear and branched chain alkyl d-glucitol dianhydro alkyl ethers cluster	5306-85-4; 30915-81-2; 107644-13-3; 103594-41-8; 103594-42-9	When ready for use, the end-use concentration is not to exceed 1,000 ppm
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(1-methylpropyl)-,	None	
D-glucitol, 1,4:3,6-dianhydro-2,5-di-O-(2-methylpropyl)-, (CAS Reg. No. not assigned)	None	
* * * * * * *		

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[FR Doc. 2019-17993 Filed: 8/20/2019 8:45 am; Publication Date: 8/21/2019]