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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0249; FRL-9942-43]

D-Glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives; 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives (CAS Reg. No. 1591782-62-5) when used as an inert ingredient (surfactant) applied to growing crops and raw agricultural commodities after harvest at a concentration not to exceed 40% by weight under 40 CFR 180.910. Keller & Heckman LLP on behalf of the Clariant Corporation 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives.

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-2015-0249, 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*.

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-2015-0249 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-2015-0249, 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 August 26, 2015 (80 FR 51762) (FRL-9931-74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10792) by Keller & Heckman LLP (1001 G Street, NW, Suite 500 West Washington, DC 20001), on behalf of the Clariant Corporation (4000 Monroe Road, Charlotte, NC 28205). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives (CAS Reg. No. 1591782-62-5) when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities at a concentration in formulations not to exceed 40% by weight. That document referenced a summary of the petition prepared by Keller & Heckman on behalf of the Clariant Corporation, 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(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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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.

D-Glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives exhibits low acute toxicity. The oral lethal dose $(LD)_{50}$ in the rat is 500 milligram/kilogram (mg/kg) and above. The dermal LD_{50} in rats and rabbits was determined to be > 2,000 mg/kg. The inhalation lethal concentration $(LC)_{50}$ value for Wistar rats is greater than 1 milligram per Liter (mg/L). A primary skin irritation test with the rabbit indicates it is not irritating to rabbit's skin. An eye irritation test with New Zealand white rabbits indicates it to be moderately irritating. Two skin sensitization tests with Hartley guinea pigs show it is not a sensitizer to the guinea pig.

A 28-day repeat dose oral toxicity study was conducted with Wistar rats. In this study, rats were treated via gavage with D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives at doses up to 500 milligram/kilogram/day (mg/kg/day). At the 500 mg/kg/day dose, mortality was observed as well as toxicity reflected as microscopic findings in the GI tract, trachea, lung, spleen and bone marrow. The NOAEL was 250 mg/kg/day.

In a reproduction/developmental toxicity screening test, rats were dosed for 54 days with D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives at doses up to 312.5 mg/kg/day. Neither parental, developmental nor reproduction toxicity was observed at 312.5 mg/kg/day, the highest dose tested (HDT).

A gene reverse mutation study with *Salmonella,* an *in vitro* mammalian cell gene mutation study with Chinese hamster V 79 cells, a mammalian micronucleus mutagenicity test of micronuclei in polychromatic erythrocytes in the mouse bone marrow, a mammalian micronucleus test with murine peripheral blood cells, a mutagenesis assay using L5178Y TK+/- mouse lymphoma cells, an *in vivo* rat bone marrow cytogenicity study all were negative for mutagenic and clastogenic effects.

There were no neurotoxicity data *per se* however there were no indications of neurotoxic effects in the functional observation battery in the 28-day oral toxicity study in the rat. In addition, the DEREK predictive modeling system did not identify any alerts for potential neurotoxicity.

There were no data regarding immunotoxicity. However evidence of potential immunotoxicity was observed in the 28-day oral toxicity study in the rat. In this study, atrophy is seen in the spleen and bone marrow at 500 mg/kg/day. These effects will be protected since the established chronic reference dose (cRfD) is 1.04 mg/kg/day.

There were no study data presented specifically addressing metabolism. Modeling data using the DEREK (Nexus) and METEOR modeling systems indicate 80% absorption via the gastrointestinal system and less than 1% via dermal absorption. The major route of excretion is via the urine.

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*.

An acute effect was not found in the database therefore an acute dietary assessment is not necessary. The reproduction/developmental toxicity screening study in the rat was selected for the toxicological endpoint for use in the chronic dietary risk assessment. In this study, no effects are observed up to 312.5 mg/kg/day. The standard uncertainty factors (100X) are applied for intra-and interspecies variation and an additional uncertainty factor (3X) is applied to account for extrapolation from subchronic to chronic exposures. EPA identified the uncertainty factor of 3X as protective rather than 10X is because there was no toxicity observed at doses up

to 312.5 mg/kg/day in an Organization for Economic Cooperation and Development (OECD) 422 study. Dermal and inhalation absorption are assumed to be 100%. For all short- and intermediate-term residential risk assessments, the toxicological endpoint selected for use in the assessment is taken from the reproduction/developmental toxicity screening study in the rat. In this study, no effects are observed up to 312.5 mg/kg/day. The level of concern for residential risk assessments is for MOEs of less than 300.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives, in food as follows: Dietary exposure (food and drinking water) to D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives can occur following ingestion of foods with residues from treated crops. An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model DEEM–FCID™, Version 3.16, 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 that 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.

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 D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives, 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).

D-Glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted an assessment to represent worst-case residential exposure by assessing D-glucitol, 1-deoxy-1-(methylamino)- N-C_{8-10} derivatives in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives to share a common mechanism of toxicity with any other substances, and D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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 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*. There is no evidence of increased susceptibility in the OECD 422 study based on lack of systemic toxicity in the maternal animals and offspring at doses up to 312.5 mg/kg/day; the HDT.

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. That decision is based on the following findings:

i. The toxicity database for D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives contains the following studies that are adequate to evaluate the potential toxicity of D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives for infants and children: The database contains a 28-day repeat dose oral toxicity study, a reproduction/developmental toxicity screening study and several mutagenicity studies.

ii. There were no neurotoxicity data *per se* however there were no indications of neurotoxic effects in the functional observation battery in the 28-day oral toxicity study in the rat.

iii. There were no data regarding immunotoxicity. However evidence of potential immunotoxicity was observed in the 28-day oral toxicity study in the rat. In this study, atrophy is seen in the spleen and bone marrow at 500 mg/kg/day. These effects will be protected since the established cRfD is 1.04 mg/kg/day.

iv. There was no evidence of increased susceptibility of infants and children in the OECD 422 study.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 percent crop treated (PCT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives

E. Aggregate Risks and Determination of Safety

Determination of safety section. 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, D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives from food and water will utilize 54.4% of the cPAD for children 1-2 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).

D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives may be used as inert ingredients in pesticide products 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives. Using the exposure assumptions described above, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in MOEs of 490 for both adult males and females respectively. Adult residential exposure combines high-end dermal and inhalation handler exposure from indoor hard surface, mopping, wiping and trigger-pump spray. As the level of concern is for MOEs that are lower than 300, this MOE is not of concern. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 420 for children As the level of concern is for MOEs that are lower than 300, this MOE is 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). D-Glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives may be used as inert ingredients in pesticide products 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 490 for adult males and females. Adult residential exposure combines indoor hard surface, wiping with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 300, this MOE is not of concern. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 420 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 300, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on a DEREK structural alert analysis and the lack of mutagenicity, D-Glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives 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 D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives in or on any food commodities. EPA is establishing a limitation on the amount of D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives that may be used in pesticide formulations applied to growing crops. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. EPA will not register any pesticide formulation for use on growing crops for sale or distribution that exceed 40% of D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for D-glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops and raw agricultural commodities at a concentration not to exceed 40% by weight.

VII. Statutory and Executive Order Reviews

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

Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 18, 2016.

Susan Lewis,

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 ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
*******		
D-Glucitol, 1-deoxy-1-(methylamino)-, N-C_{8-10} acyl derivatives (CAS Reg. No. 1591782-62-5)	Not more than 40% by weight in pesticide formulation	Surfactant
*******		

[FR Doc. 2016-04071 Filed: 2/25/2016 8:45 am; Publication Date: 2/26/2016]