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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0362; FRL–7729–7]

Alkyl (C_{10}–C_{16}) Polyglycosides; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes two exemptions from the requirement of a tolerance for residues of alkyl (C_{10}–C_{16}) polyglycosides also known as D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Cognis Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides.

DATES: This regulation is effective September 14, 2005. Objections and requests for hearings must be received on or before November 14, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2003–0362. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of December 10, 2003 (68 FR 68908) (FRL–7335–5), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 4E4332) by Cognis Corporation, 490 Este Avenue, Cincinnati, OH 45232. That notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of alkyl (C_{10}–C_{16}) polyglycosides or polyglucosides, also known as D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides (CAS Reg. No. 110615–47–9) when used as an inert ingredient in pesticide products. There were no comments received in response to the notice of filing.

The Agency has determined that the use of D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides (CAS Reg. No. 110615–47–9) in a pesticide product is as a surfactant.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the 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 the 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

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. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The information submitted by the petitioner for review and evaluation included information on toxicity studies performed on alkyl (C_8–C_{10}) polyglycosides, and alkyl (C_{12}–C_{14}) polyglycosides. The actual substance used for each test is noted below.

An alkyl polyglycoside is created by combining glucose and an alcohol. Alkyl (C_8–C_{10}) polyglycosides and alkyl (C_{12}–C_{14}) polyglycosides are structurally-related to the alkyl (C_{10}–C_{16}) polyglycosides also known as D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides that is the subject of this final rule. These chemicals differ from one another only in the length of the alkyl chain. Given these structural similarities, these chemicals have similar toxicological characteristics.

Two types of data were submitted by the petitioner: Publicly-available information from open literature and complete toxicity studies. The results of the existing reviews in the publicly-available information were extracted from the submitted article. The complete toxicity studies included two mutagenicity studies, a subchronic 90 day study, and a developmental study. These studies were reviewed by the Department of Energy's Oakridge National Laboratory (ORNL), and the results of their review are presented below, noted by an asterisk (*).

A. Acute Toxicity

TABLE 1.—ACUTE TOXICITY STUDIES

Study/Species	Test Substance	Results
Acute oral toxicity/rat	C_8–C_{14}	Lethal Dose $(LD)_{50}$ > 5,000 milligrams/kilogram (mg/kg)
Acute oral toxicity/rat	C_{12}–C_{14}	LD_{50} > 5,000 mg/kg
Acute oral toxicity/rat	C_{12}–C_{14}	LD_{50} > 2,000 mg/kg
Acute dermal toxicity/rabbit	C_8–C_{10}	LD_{50} > 2,000 mg/kg
Acute dermal toxicity/rabbit	C_{12}–C_{14}	LD_{50} > 2,000 mg/kg
Primary eye irritation/rabbit	C_8–C_{10}	No irritating effects
Primary eye irritation/rabbit	C_{12}–C_{14}	Irritating to the eye
Primary dermal irritation/rabbit	C_8–C_{10}	No irritating effects
Primary dermal irritation/rabbit	C_{12}–C_{14}	No irritating effects at concentrations of up to 30% Irritating to the skin at concentrations greater than 30% to 100%.
Dermal sensitization/guinea pig	C_8–C_{10}	Not a dermal sensitizer
Dermal sensitization/guinea pig	C_{12}–C_{14}	Not a dermal sensitizer

TABLE 2.—MUTAGENICITY STUDIES

Type of Study	Test Substance	Results
Salmonella/Escherichia reverse gene mutation assay (Ames Test)*	C_{12}–C_{14}	Negative. No evidence of induced mutant colonies over background.
Salmonella typhimurium reverse (Ames Test)	Not specified	Did not induce reverse mutations in the tested strains of *Salmonella typhimurium* either with or without metabolic activation.
In vitro cytogenetic test in Chinese hamster V79 lung fibroblast	Not specified	Considered to be non-mutagenic.
In vitro mammalian cytogenetics assay*	C_{12}–C_{14}	Negative with and without activation.

*B. Repeated Dose Toxicity**

In a 90–day rat oral (gavage) toxicity study, alkyl (C_{12}–C_{14}) polyglucosides was administered at dose levels of 0, 250, 500, or 1,000 mg/kg/day for 5 days/week. An additional high-dose group was treated and then had a treatment-free period of 27 days before sacrifice.

There were no treatment-related adverse effects on body weight, body

weight gain, food consumption, hematological or clinical chemistry parameters or organ weights in any group. Adverse treatment-related effects were limited to the forestomach in both males and females receiving 500 or 1,000 mg/kg/day. After 27 days, it was observed that forestomach effects were reversible following the cessation of treatment, but not during treatment. Under the conditions of the study, the NOAEL (no observed adverse effect level) for alkyl (C_{12}–C_{14}) polyglucosides is 250 mg/kg/day. The LOAEL (lowest observed adverse effect level) is 500 mg/kg/day based on acanthosis, subepithelial inflammatory edema, and hyperkeratosis (females only) of the forestomach, which did not resolve during the treatment period.

*C. Developmental Toxicity**

In a rat developmental toxicity study, alkyl (C_{12}–C_{14}) polyglucosides was administered by gavage at dose levels of 0, 100, 300, and 1,000 mg/kg/day on gestation days 6 to 15. No treatment related maternal deaths, clinical signs, or decreases in mean body weight, weight gain, corrected weight gain or gross lesions were observed in this study. The maternal NOAEL is equal to or greater than 1,000 mg/kg/day. A LOAEL was not determined, but would be greater than 1,000 mg/kg/day.

No treatment-related effects were observed on any cesarean section parameter. No treatment-related external abnormalities, visceral abnormalities or skeletal malformations/variations, including the number of ossification sites were observed at any dose. The developmental NOAEL is equal to or greater than 1,000 mg/kg/day. A LOAEL was not determined, but would be greater than 1,000 mg/kg/day.

D. Metabolism

The petitioner submitted an article from open literature on metabolism studies in mice conducted with the structurally-related chemicals (octyl β-D-glucoside, dodecyl β-D-maltoside, and hexadecyl β-D-glucoside). The radiolabeled test material consisted of octyl β-D-[U-^{14}C]glucoside, [l-^{14}C]dodecyl β-D-maltoside and [l-^{14}C]hexadecyl β-D-glucoside). The treated animals were sacrificed two hours following administration of the test material. Radioactivity analysis indicated that most radioactivity was found in the stomach, intestine, liver and kidneys. The test material was hydrolyzed to form sugar and long chain alcohols, which were then processed in the mammalian body's pathways for carbohydrate and lipid metabolism. Most metabolites were excreted via urine, and appeared to be water soluble.

E. Conclusions

Acute toxicity studies on various chain lengths of alkyl polyglucosides indicate that D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is likely to be of low acute oral and dermal toxicity. However, based on the surrogate data, D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is likely to be an eye and dermal irritant when used at higher concentrations.

Metabolism studies on structurally-related chemicals indicate that the body can effectively metabolize D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides to water-soluble substances (predominantly sugar and various alcohols) that are readily excreted from the body.

In a 90–day rat oral (gavage) toxicity study, using alkyl (C^{12}–C^{14}) polyglucosides, the NOAEL (no observed adverse effect level) for alkyl (C^{12}–C^{14}) polyglucosides is 250 mg/kg/day. In a rat developmental toxicity study using alkyl (C^{12}–C^{14}) polyglucosides, both the maternal and developmental NOAELs are equal to or greater than 1000 mg/kg/day.

Mutagenicity studies on various chain lengths of alkyl polyglucosides indicate that D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is not likely to be mutagenic based on the two mutagenicity assays reviewed by the Agency and the two mutagenicity assays described in open literature.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

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.

A. Dietary Exposure

1. *Food.* The Agency has developed a screening-level model for predicting dietary exposure to inert ingredients. The results of this model are considered to over-estimate exposure to an inert ingredient in a pesticide product. The modeled chronic dietary exposure for the US population is 0.12 mg/kg/day. This is well-below any dose level at which an adverse effect is expected from exposure to D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides.

2. *Drinking water exposure.* EPA has estimated the fate and biodegradation properties of D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides using EPI-Suite. Screening-level tools such as EPI-Suite are deliberately designed to be easy-to-use, fast, and conservative in nature. (see *http://www.epa.gov/opptintr/exposure/docs/episuite.htm*). If modeled estimates do not indicate a level of concern, then higher-tiered modeling or measured data may not be needed. The modeled estimates indicate that a chemical substance such as D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is expected to degrade rapidly in the environment. Degradation begins within a matter of hours or days, with these primary degradation products including glucose and various alcohols which will continue to degrade. Ultimate degradation (to carbon dioxide and water) occurs in days to weeks. These glycoside compounds are soluble, non-volatile, and mobile. Leaching to ground water is likely in highly porous soils, but mitigated in other soils due to the rapid biodegradation. Volatilization from surface waters is very low. Migration to ground water drinking water sources is possible, but will be limited by the rapid primary degradation.

Based on values estimated using the EPI-Suite model, it is very unlikely that D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides will reach either ground or surface water, or bioaccumulate in the environment. This conclusion is based on its rather rapid primary degradation (estimated to be hours to days), and ultimate biodegradation to carbon dioxide and water. Significant concentrations of D-glucopyranose, oligomeric, C_{10}–C_{16}-

alkyl glycosides in sources of drinking water is very unlikely.

B. Other Non-Occupational Exposure

Various alkyl polyglucosides are used in glass cleaners and other household cleaning products, as rinse aids in dish washers, and in cleaning products used by the food industry.

VI. Cumulative Effects

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides. D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides does not appear to produce any toxic metabolite produced by other substances and the overall toxicity of this compound is very low. For the purposes of this tolerance action, therefore, EPA has not assumed that D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA concluded that a different margin of safety will be safe for infants and children.

D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is of low acute toxicity, and is readily metabolized in the mammalian body. In a developmental toxicity study reviewed and evaluated by ORNL for EPA, the developmental NOAEL is equal to or greater than 1,000 mg/kg/day. Due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk of D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides. For the same reasons, the additional tenfold safety factor for the protection of infants and children is unnecessary.

VIII. Determination of Safety for U.S. Population, and Infants and Children

Based on the available toxicity data, EPA judges that D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides is a chemical of lower toxicity. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides (CAS Reg. No. 110615–47–9). EPA finds that establishing an exemption from the requirement of a tolerance for D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides (CAS Reg. No. 110615–47–9) will be safe for the general population including infants and children.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides for endocrine effects may be required.

B. Analytical Method(s)

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.

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Accordingly, an exemption from the requirement for a tolerance is established for D-glucopyranose, oligomeric, C_{10}–C_{16}-alkyl glycosides (CAS Reg. No. 110615-47-9).

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0362 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 14, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver

your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2003–0362, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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 of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 2, 2005.

Lois Rossi,

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 the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

* * *

Inert ingredients	Limits	Uses
* * * *	*	* *
D-glucopyranose, oligomeric, $C_{10–16}$-alkyl glycosides (CAS Reg. No. 110615–47–9)	.....	Surfactant
* * * *	*	* *

* * * * *

■ 3. In § 180.930 the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

* * *

Inert ingredients	Limits	Uses
* * * *	*	* *
D-glucopyranose, oligomeric, $C_{10–16}$-alkyl glycosides (CAS Reg. No. 110615–47–9)	.....	Surfactant
* * * *	*	* *

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[FR Doc. 05–18241 Filed 9–13–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–7968–3]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the Agency'') in determining which sites warrant further investigation. These further investigations will allow EPA to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds seven new sites to the General Superfund Section of the NPL.

DATES: The effective date for this amendment to the NCP shall be October 14, 2005.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see section II, ''Availability of Information to the Public'' in the ''Supplementary Information'' portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Terry Jeng, phone (703) 603–8852, State, Tribal and Site Identification Branch; Assessment and Remediation Division; Office of Superfund Remediation and Technology Innovation (mail code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW.; Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

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I. Background

A. What Are CERCLA and SARA?

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601–9675 (''CERCLA'' or ''the Act''), in response to the dangers of uncontrolled releases or threatened releases of hazardous substances, and releases or substantial threats of releases into the environment of any pollutant or contaminant which may present an