this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: August 17, 2005.

Stephen S. Tuber,

Acting Regional Administrator, Region VIII.

■ 40 CFR part 52 is amended to read as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart TT—UTAH

■ 2. Section 52.2320 is amended by adding paragraph (c)(61) to read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

(61) Revisions to the Utah State Implementation Plan, Section IX, Part C.8, ''Carbon Monoxide Maintenance Provisions for Ogden,'' as submitted by the Governor on November 29, 2004; revisions to UAC R307–110–12, ''Section IX, Control Measures for Area and Point Sources, Part C, Carbon Monoxide,'' as submitted by the Governor on November 29, 2004; revisions to the Utah State Implementation Plan, Section X, ''Vehicle Inspection and Maintenance Program, Part E, Weber County,'' as submitted by the Governor on November 29, 2004; and revisions to UAC R307–110–35, ''Section X, Vehicle Inspection and Maintenance Program, Part E, Weber County,'' as submitted by the Governor on November 29, 2004.

(i) Incorporation by reference.

(A) UAC R307–110–12, as adopted by the Utah Air Quality Board on November 3, 2004, effective January 4, 2005. This incorporation by reference of UAC R307–110–12 only extends to the following Utah SIP provisions and excludes any other provisions that UAC R307–110–12 incorporates by reference:

Section IX, Part C.8, ''Carbon Monoxide Maintenance Provisions for Ogden,'' adopted by the Utah Air Quality Board on November 3, 2004, effective January 4, 2005.

(B) UAC R307–110–35, ''Section X, Vehicle Inspection and Maintenance Program, Part E, Weber County,'' as adopted by the Utah Air Quality Board on November 3, 2004, effective November 4, 2004.

(ii) Additional Materials

(A) A July 28, 2005 letter from Jan Miller, Utah Department of Environmental Quality, to Kerri Fiedler, EPA Region VIII, to address typographical errors in the November 29, 2004 submittal.

(B) An August 2, 2005 letter from Richard Sprott, Utah Department of Environmental Quality, to Gary House, Weber-Morgan Board of Health, addressing limits on Weber County authority to revise vehicle emission cutpoints.

[FR Doc. 05–18232 Filed 9–13–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0166; FRL–7729–6]

Ethylhexyl Glucopyranosides; Exemption 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 [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl when used as inert ingredients in or on growing crops. Akzo Nobel Surface Chemistry LLC 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 these two ethylhexyl glucopyranoside chemicals.

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–2002–0166. 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 August 7, 2002 (67 FR 51260) (FRL–7190–4), 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 7E4807) by Akzo Nobel Surface Chemistry LLC, 200 South Riverside Plaza, Chicago, IL 60606. The petition requested that 40 CFR 180.1001(d) now redesignated as 40 CFR 180.920 (April 28, 2004, 69 FR 23113, FRL–7335–4) be amended by establishing an exemption from the requirement of a tolerance for residues of 2-ethylhexyl glucopyranoside when used as an inert ingredient (surfactant) in pesticide products applied to growing crops only. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

During its evaluation of the information submitted by Akzo Nobel, the Agency determined that the actual 2-ethylhexyl glucopyranosides to be considered under PP 7E4807 are: [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5)and [alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0).

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 nature of the toxic effects caused by [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl are discussed in this unit.

The test substance for all of the studies submitted by the petitioner for review and evaluation was identified as a mixture of [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl. Thus, both chemicals were in the test substance.

A. Acute Toxicity

The Agency's review of the following five acute toxicity studies and the toxicity category classification, are shown in Table 1. Toxicity Category I is indicative of very high acute toxicity. Toxicity Category IV is the Agency's lowest rating of acute toxicity.

TABLE 1.—ACUTE TOXICITY STUDIES

Study/Species	Results	Toxicity Category
Acute oral toxicity/rat	Lethal Dose (LD_{50} > 2,000 milligrams/kilogram (mg/kg) and <5,000 mg/kg (males and females)	III
Acute dermal toxicity/rat	LD_{50} > 2380 mg/kg (males and females)	IV
Primary eye irritation/rabbit	Corrosive	I
Primary dermal irritation/rabbit	Not irritating	IV
Dermal sensitization/guinea pig	Weak dermal sensitizer	N/A

B. Mutagenicity

A *Salmonella*/microsome reverse gene mutation assay (Ames Test) and an *in vitro* mammalian cytogenetics assay were reviewed for the Agency by the Department of Energy's Oakridge National Laboratory (ORNL), and the results of their review are presented in Table 2.

TABLE 2.—MUTAGENICITY STUDIES

Type of Study	Results
Salmonella/microsome reverse gene mutation assay (Ames Test)	Negative. No increase in the mean number of revertants per plate with or without S9-mix, in any tester strain either assay.
In vitro mammalian cytogenetics assay	Negative with and without activation.

C. Repeated Dose Toxicity

The repeated dose toxicity of 2-ethylhexylglucoside was investigated in a 28–day oral (gavage) toxicity study in rats, which was also reviewed by ORNL. Sprague-Dawley rats, were administered doses of 0, 15, 150, or 750 mg/kg/day. The NOAEL (no observed adverse effect level) was determined to be 150 mg/kg/day in females. The LOAEL (lowest observed adverse effect level) in females was 750 mg/kg/day in females due to decreased food consumption and an associated, statistically significant reduction in overall body weight gain (80% of weight gain of the control group). The NOAEL in males is equal to or greater than 750 mg/kg/day (highest dose tested - (HDT)). A LOAEL in males could not be determined, but would be greater than 750 mg/kg/day. The reduction in body weights and overall body weight gains in the high-dose females is likely representative of an adverse effect of the chemicals, and not related to a palatability problem, as the mode of administration was gavage.

D. Reproductive Toxicity

A recently conducted one-generation reproduction toxicity study of the two chemicals was reviewed by ORNL. The test substance was administered by oral gavage to Wistar rats at doses of 0, 15, 150, or 750 mg/kg/day. The premating period of exposure to the test substance was ten weeks for the males and two weeks for the females. Eight treatment related mortalities (four males and four females) occurred in the F0 parental generation at the HDT, 750 mg/kg/day. In addition, statistically significant decreases in body weights and food consumption of the F0 high-dose males and females were observed during the premating period. Clinical signs that were increased in parental animals at the 750 mg/kg/day dose level included brown staining of the head, back, neck, and/or genital region, rales, and hunched posture (females only). Postmortem examinations did not reveal any biologically significant abnormalities. The parental systemic toxicity NOAEL is 150 mg/kg/day. The parental toxicity LOAEL is 750 mg/kg/day based on statistically significant decreases in body weights and decreases in food consumption of the F0 males and females, increased mortality, and clinical signs.

There were no treatment-related effects on health, viability, body weight, and sex ratios of the F1 offspring. The offspring systemic toxicity NOAEL would be equal to or greater than 750 mg/kg/day. A LOAEL is not identified but would be greater than 750 mg/kg/day. Mating performance and fertility of males and females of the F0 parental generation were not adversely affected. The NOAEL for reproductive toxicity is equal to or greater than 750 mg/kg/day (HDT). A LOAEL is not identified but would be greater than 750 mg/kg/day.

E. 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. For [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl, the long chain alcohol formed via hydrolysis would be 2-ethylhexanol.

F. Toxicity of 2-EthylHexanol

Since 2-ethylhexanol is the alcohol formed via hydrolysis, toxicity studies performed using 2-ethylhexanol as the test substance can be used to further understand the toxicity of [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl.

Under a Toxic Substances Control Act (TSCA) test rule, toxicity studies performed using 2-ethylhexanol were submitted to the Agency's Office of Pollution Prevention and Toxics (OPPT). Reviews of two carcinogenicity studies (mouse and rat) and a dermal developmental toxicity study are posted on the Agency's website (see *http://www.epa.gov/opptintr/chemtest/ethylhex.htm*). The conclusions of the Agency's reviewers were that 2-ethylhexanol is not carcinogenic in the mouse under the conditions of the study, and that there is no evidence of carcinogenicity in the rat at any dose level tested. In the developmental toxicity study there was no evidence of developmental toxicity at any dose level. The dermal developmental NOAEL is therefore equal to or greater than the HDT, 3.0 milliliter (mL)/kg/day or 2,520 mg/kg/day. Maternal effects (reduced weight gain) were noted at the 3.0 mL/kg/day dose level. Exfoliation occurred at the application site at the 1.0 mL/kg/day dose level. The maternal NOAEL is 0.3 mL/kg/day or 252 mg/kg/day.

G. Conclusions

Acute toxicity studies on a mixture of [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl indicate that these two chemicals are of low acute oral and dermal toxicity, are a non-irritant to the skin, but a weak sensitizer. The chemicals are severe eye irritants.

Metabolism studies on structurally-related chemicals indicate that the body can effectively metabolize these two chemicals to water-soluble substances (predominantly sugar and 2-ethylhexanol) that are readily excreted from the body.

A predominant effect in both the repeated dose toxicity study and the one-generation reproductive toxicity study is decreased weight gain at the 750 mg/kg/day dose level. Considering both of these studies, the NOAEL for [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl is 150 mg/kg/day. In the one-generation reproductive study using [alpha]-D-

glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl as the test substance, both the offspring systemic toxicity NOAEL and the NOAEL for reproductive toxicity is equal to or greater than 750 mg/kg/day (HDT).

[alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl were not mutagenic in either of the two mutagenicity assays.

Given the relationship of 2-ethylhexanol as a metabolite of the mammalian body's metabolism of these two chemicals, data on 2-ethylhexanol can be used to judge that [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl are not carcinogens or developmentally toxic.

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 [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl.

2. *Drinking water exposure*. EPA has estimated the fate and biodegradation properties of the larger of the two ethylhexyl glucosides that are the subject of this final rule using EPI-Suite and the PBT profiler. Screening-level tools such as EPI-Suite and the PBT profiler are deliberately designed to be easy-to-use, fast, and conservative in nature. (see *http://pbtprofiler.net* and *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 the ethylhexyl glucosides are soluble in water, but are expected to degrade rapidly in the environment. Degradation begins within a matter of hours or days, with these primary degradation products including glucose and 2-ethylhexanol which will continue to degrade. Ultimate degradation (to carbon dioxide and water) occurs in days to weeks. These glucoside chemicals 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. Migration to ground water drinking water sources is possible, but will be limited by the rapid primary degradation.

Based on the available modeling (EPI-Suite models and the PBT profiler), the Agency judges that it is very unlikely that these glucosides 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 [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl in sources of drinking water is very unlikely.

B. Other Non-Occupational Exposure

Chemicals such as [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl are used in dishwashing detergents, cleaning products and degreasers. A typical concentration in such a product would be less than 15%.

VI. Cumulative Effects

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

Unlike other pesticide chemicals 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 as to [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl and any other substances. [alpha]-D-Glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl 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 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. [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl are readily metabolized in the mammalian body to sugars and 2-ethylhexanol. Information on the metabolite 2-ethylhexanol indicates that there is no increased susceptibility. In the reproductive study conducted using [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl

both the offspring systemic toxicity NOAEL and the NOAEL for reproductive toxicity is equal to or greater than 750 mg/kg/day (HDT). Given the parental NOAEL of 150 mg/kg/day, there is no increased susceptibility. A safety factor analysis has not been used to assess the risk of [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl. 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 on [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl, and on their metabolite 2-ethylhexanol, and on the modeled exposure levels which are well-below any dose level at which an adverse effect is expected, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5) and [alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0). EPA finds that establishing exemptions from the requirement of a tolerance for [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5)and [alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0) 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 alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl 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 alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- and [alpha]-D-glucopyranoside, 2-ethylhexyl nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusions

Accordingly, two exemptions from the requirement for a tolerance are established for [alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5) and [alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0).

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–2002–0166 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 14 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–2002–0166, 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 § 180.920 the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.920 Inert ingredients used preharvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * *	*	* *
[alpha]-D-glucopyranoside, 2-ethylhexyl 6-O-[alpha]-D glucopyranosyl- (CAS Reg. No. 330980–61–5)	.....	Surfactant
* * * *	*	* *
[alpha]-D-glucopyranoside, 2-ethylhexyl (CAS Reg. No. 125590–73–0)	.....	Surfactant
* * * *	*	* *

* * * * *

[FR Doc. 05–18244 Filed 9–13–05; 8:45 am]
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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