<table>
<thead>
<tr>
<th>Subpart</th>
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<tr>
<td>YY</td>
<td>Source Categories: Generic MACT.</td>
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<tr>
<td>CCC</td>
<td>Steel Pickling—HCl Process Facilities and Hydrochloric Acid Regeneration Plants.</td>
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<tr>
<td>DDD</td>
<td>Mineral Wood Production.</td>
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<td>EEE</td>
<td>Hazardous Waste Cumbustors.</td>
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<td>Pharmaceuticals Production.</td>
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<td>HHH</td>
<td>Natural Gas Transmission and Storage Facilities.</td>
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<tr>
<td>III</td>
<td>Flexible Polyurethane Foam Production.</td>
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<td>Polymers and Resins IV.</td>
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<td>Portland Cement Manufacturing.</td>
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<td>Pesticide Active Ingredient Production.</td>
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<td>Wood Fiberglass Manufacturing.</td>
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<td>Polyether Polysilicon Production.</td>
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<td>Primary Lead Smelting.</td>
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<tr>
<td>XXX</td>
<td>Ferroalloys Production: Ferromanganese &amp; Silicomanganese.</td>
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</table>

**Note to paragraph [a](47):** Dates in parenthesis indicate the effective date of the federal rules that have been adopted by and delegated to the state or local air pollution control agency. Therefore, any amendments made to these delegated rules after this effective date are not delegated to the agency.

**BILLING CODE 6560-50-P**

### ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 180**

**[OPP–300971; FRL–6490–8]**

**RIN 2070–AB78**

**Polyoxyethylated Sorbitol Fatty Acid Esters; Tolerance Exemption**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement for a tolerance for residues of the polymers polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanolic and/or alkenolic fatty acids C₆ through C₂₂ with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight of 1,300 when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals.

**DATES:** This regulation is effective February 28, 2000. Objections and requests for hearings, identified by docket control number OPP–300971, must be received by EPA on or before April 28, 2000.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–
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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of This Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select “Laws and Regulations” and then look up the entry for this document under the “Federal Register—Environmental Documents.” You can also go directly to the Federal Register listings at http://www.epa.gov/fedregstr/.

2. In person. The Agency has established an official record for this action under docket control number OPP–300971. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the Federal Register of February 24, 1999 (64 FR 4751) (FRL–6058–9), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (9E5063) by Unigema (formerly known as ICI Surfactants), 3411 Silverside Road, Wilmington, DE 19803–8340. This notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001 (c) and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanolic or and/or alkenol fatty acids balanced through C22 with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum MW of 1,300.

Section 408(c)(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(c)(2)(A)(ii) 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) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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.”

This includes food, drinking water, 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. Risk Assessment and Statutory Findings

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 section 408(b)(2)(D) of 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers that should present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b). The following exclusion criteria for identifying these low risk polymers are described in 40 CFR 723.250(d).

1. The polymers, polyoxyethylated sorbitol fatty acid esters, are not cationic polymers nor are reasonably anticipated to become cationic polymers in a natural aquatic environment.
2. The polymers do contain as an integral part of their composition the atomic elements carbon, hydrogen, and oxygen.
3. The polymers do not contain as an integral part of their composition, except as impurities, any element other than those listed in 40 CFR 723.250(d).
4. The polymers are neither designed nor can be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymers are manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. The polymers are not water absorbing polymers with a number average MW greater than or equal to 10,000 daltons. Additionally, the polymers, polyoxyethylated sorbitol fatty acid esters also meet as required the following exemption criteria specified in 40 CFR 723.250(e).
7. The polymers’ number average MW are greater than 1,000 and less than 10,000 daltons. The polymers contain less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymers do not contain any reactive functional groups.

Thus, polyoxyethylated sorbitol fatty acid esters meet all the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the above criteria, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to polyoxyethylated sorbitol fatty acid esters.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that polyoxyethylated sorbitol fatty acid esters could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of polyoxyethylated sorbitol fatty acid esters are greater than 1,000 and less than 10,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since polyoxyethylated sorbitol fatty acid esters conform to the criteria that identify a low risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. Since the Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to polyoxyethylated sorbitol fatty acid esters, a tolerance is not necessary.

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.” The Agency has not made any conclusions as to whether or not polyoxyethylated sorbitol fatty acid esters share a common mechanism of toxicity with any other chemicals. However, polyoxyethylated sorbitol fatty acid esters conforms to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of polyoxyethylated sorbitol fatty acid esters.

VIII. Determination of Safety 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of polyoxyethylated sorbitol fatty acid esters, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that polyoxyethylated sorbitol fatty acid esters are an endocrine disruptor.

B. Existing Exemptions from a Tolerance

Currently, an Exemption from the Requirement of a Tolerance is established in 40 CFR 180.1001 in the table in paragraph (d) inert ingredients in pesticide formulations applied to growing crops only. The exemption reads as follows:

Polyoxyethylated Sorbitol Fatty Acid Esters; the polyoxyethylated sorbitol solution containing up to 15% water is reacted with fatty acids limited to C_{12}, C_{14}, C_{16}, and C_{18} containing minor amounts of associated fatty acids; the poly (oxyethylene) content averages 30 moles.

C. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for polyoxyethylated sorbitol fatty acid esters nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusion

Accordingly, EPA finds that exempting polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkenic acid and/or alkenic fatty acids C_{n} through C_{22} with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum MW of 1,300 from
the requirement of a tolerance will be safe.

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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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 406(d), as was provided in the old FFDCA sections 408 and 409. 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 control provided in this unit and in 40 CFR part 180. You must also mail the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it “Tolerance Petition Fees.”

EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. Copies for the Docket. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300971, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp.dockets@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 file format 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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). 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 prior consultation as specified by Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled Public Services to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or require 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 FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. 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. 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 FFDCA section 408(n)(4).

XIII. Submission to Congress and the Comptroller General

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 rule in the Federal Register. This 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.


James Jones,
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), 346(a) and 371.

2. In § 180.1001 the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient and by deleting the entire entry for “Polyoxyethylated Sorbitol Fatty Acid Esters” in paragraph (d) to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

(c) * * * * *

Polyoxyethylated sorbitol fatty acid esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanolic and/or alkenolic fatty acids C8 through C22 with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight (in amu) of 1,300.

* * * * *

Inert ingredients

Limits

Uses

* * * * *

Dispersants, emulsifiers, surfactants, related adjuvants of surfactants.

Polyoxyethylated Sorbitol Fatty Acid Esters; the sorbitol solution containing up to 15% water is reacted with 20–50 moles of ethylene oxide and aliphatic alkanolic and/or alkenolic fatty acids C8 through C22 with minor amounts of associated fatty acids; the resulting polyoxyethylene sorbitol ester having a minimum molecular weight (in amu) of 1,300.

* * * * *

Inert ingredients

Limits

Uses

* * * * *

Dispersants, emulsifiers, surfactants, related adjuvants of surfactants.

[FR Doc. 00–4660 Filed 2–25–00; 8:45 am]

BILLING CODE 6560–50–F
SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of a range of polymers α-alkyl (C_{12}–C_{15})-ω-hydroxypropoxy (oxypropylene) poly (oxyethylene) copolymers (where the poly(oxypropylene) content is 3–60 moles and the poly(oxyethylene) content is 5–80 moles) also known as ethoxylated propoxylated C_{12}–C_{15} alcohols, CAS Reg. No. 68551–13–3 when used as an inert ingredient (surfactant) in or on growing crops, when applied to raw agricultural commodities after harvest, or to animals. Omnichem S. A. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) and the Food Quality Protection Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (PP BE4950) by Omnichem S. A., Industrial Research, and Development Laboratory, P.O. Box 36, Avenue de triomphe, 1270 Brussels, Belgium. This notice included a summary of the petition prepared by the petitioner. The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of α-alkyl (C_{12}–C_{15})-ω-hydroxypropoxy (oxypropylene) poly (oxyethylene) copolymers (where the poly (oxypropylene) content is 3–60 moles and the poly (oxyethylene) content is 5–80 moles) also known as ethoxylated propoxylated C_{12}–C_{15} alcohols, CAS Reg. No. 68551–13–3.

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 the table could also be affected. For example, the North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under “FOR FURTHER INFORMATION CONTACT.”

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

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II. Background and Statutory Findings

In the Federal Register of May 26, 1999 (64 FR 28480) (FRL–6081–3), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FDFCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (PP BE4950) by Omnichem S. A., Industrial Research Park, 1348 Louvain-La-Neuve, Belgium. This notice included a summary of the petition prepared by the petitioner. The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of α-alkyl (C_{12}–C_{15})-ω-hydroxypropoxy (oxypropylene) poly (oxyethylene) copolymers (where the poly (oxypropylene) content is 3–60 moles and the poly (oxyethylene) content is 5–80 moles, CAS Reg. No. 68551–13–3). After publication of the Federal Register notice, Omnichem informed the Agency that their summary contained an error and that the exemption from the requirement of a tolerance should have requested C_{12}–C_{15} not C_{12}–C_{15}. Since the desired C range is less than the range in the notice of filing, and there were no comments received in response to the notice, the Agency will establish the exemption from the requirement of a tolerance for the C_{12}–C_{15} range.

Section 408(c)(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(c)(2)(A)(ii) 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...”