



Federal Register

**Monday,
August 4, 2008**

Part III

Environmental Protection Agency

40 CFR Part 180

**Inert Ingredients; Extension of Effective
Date of Revocation of Certain Tolerance
Exemptions with Insufficient Data for
Reassessment; Final Rule**

**Pesticide Inert Ingredients: Status of
Revoked Tolerance Exemptions; Notice**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2006-0230; FRL-8372-7]

Inert Ingredients; Extension of Effective Date of Revocation of Certain Tolerance Exemptions with Insufficient Data for Reassessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This document moves the effective date of the revocation of certain inert ingredient tolerance exemptions with insufficient data for reassessment as set forth in the **Federal Register** on August 9, 2006 (71 FR 45415).

DATES: In the final rule published August 9, 2006 (71 FR 45421):

1. The effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.910: 2.a., c., i. through k., m. through o., s., t., w. through aa., and cc.

2. The effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.920: 3.a., b., e. through k., m. through p., s., y., z., bb., cc., ff., gg., ii., ll. through nn., and ss.

3. The effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.930: 4.b., c., d., f., l., n., o., s. through w., cc., and ee. through jj.

4. The effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.940: 5.a.i., ii., and 5.c.i., ii., iv., vii., and viii.

Objections and requests for hearings must be received on or before October 3, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0230. All documents in the docket are listed in the index for the docket. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP

Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Karen Angulo, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 306-0404; e-mail address: angulo.karen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit II. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background and Statutory Findings

A. Background.

In a final rule published in the **Federal Register** on August 9, 2006 (71 FR 45415) (FRL-8084-1), EPA revoked inert ingredient tolerance exemptions because insufficient data were available to the Agency to make the safety determination required by FFDCA section 408(c)(2). In reassessing the safety of the tolerance exemptions, EPA considered the validity, completeness, and reliability of the data that are available to the Agency [FFDCA section 408 (b)(2)(D)] and the available information concerning the special

susceptibility of infants and children (including developmental effects from in utero exposure) [FFDCA section 408 (b)(2)(C)]. EPA concluded it had insufficient data to make the safety finding of FFDCA section 408(c)(2) and revoked the inert ingredient tolerance exemptions identified in the final rule under 40 CFR 180.910, 180.920, 180.930, and 180.940, with the revocations effective on August 9, 2008.

EPA has received communications from pesticide registrants and inert ingredient manufacturers expressing interest in supporting certain inert ingredient tolerance exemptions that were revoked in the final rule of August 9, 2006. EPA developed voluntary guidance describing how interested parties could support these revoked tolerance exemptions, including consultations with the Agency about how they can demonstrate support, identifying test materials, and providing evidence that a laboratory has been hired to conduct the study. The voluntary guidance document, entitled "Guidance for Supporting the Inert Ingredients Subject to the Revocation Notice of August 9, 2006", is available on EPA's Web site at <http://www.epa.gov/oppr001/inerts/>.

In the interest of keeping the stakeholders informed about activities that may affect these revoked tolerance exemptions, EPA published the support status of each of the revoked tolerance exemptions in the **Federal Register** of November 2, 2007, (72 FR 62232) (FRL-8155-4), and indicated whether the Agency had received a demonstration of intent to support (such as described in the guidance document). Be advised that the information provided in today's notice or the November 2, 2007 (72 FR 62232) notice on the revoked inert ingredients does not guarantee or in any way bind the Agency to reinstate tolerance exemptions or establish new tolerance exemptions. EPA cannot guarantee that the parties will, in fact, submit any data at all. Additionally, it is possible that the data submitted to support a tolerance exemption may not support a safety finding under FFDCA section 408(c)(2). In these cases, the tolerance exemption will not be reinstated nor will a new one be established. It is important to note that several parties have indicated that they may want to support only a portion of a tolerance exemption expression that includes a range of chemicals. At this time, EPA does not know exactly what range of chemicals within a tolerance exemption will eventually be supported by data. Until the data are submitted and reviewed, EPA will not know what portion, if any, of a current tolerance

exemption can be reinstated. If the results of the data permit, a supported exemption may be reinstated in whole, or a new tolerance exemption may be established if only a part of a revoked exemption is supported by the data. EPA recommends that registrants relying on the continued existence of a particular tolerance exemption contact the chemical's supplier to confirm their plans for supporting the exemption.

B. Moving the Effective Date of the Revocation for Supported Tolerance Exemptions

EPA has received requests for an extension of the revocation date from pesticide registrants and inert ingredient manufacturers who have demonstrated their intent to support certain inert ingredient tolerance exemptions. For each of these supported tolerance exemptions, EPA has received data development plans and schedules with all data projected to be submitted by January 2009. EPA has determined that these parties have shown a good-faith effort to develop studies in a timely manner and have followed EPA's guidance (see guidance document) describing how interested parties can support the revoked tolerance exemptions. EPA recognizes that repeat-dose studies may take about a year to conduct, and this does not include any preliminary studies that often must be completed beforehand (e.g., range finding). EPA will then analyze the submitted data and develop risk assessments prior to making a safety finding and reinstatement determination. EPA, therefore, concludes that additional time is necessary for study generation and the development of EPA's risk assessments, and that the effective date of the revocation of the supported tolerance exemptions should be moved by one year to August 9, 2009.

In addition, two other revoked tolerance exemptions received an acceptable demonstration of support and the effective date of the revocation is now August 9, 2009. In the **Federal Register** on August 9, 2006 (71 FR 45415), the Agency revoked two inert ingredient tolerance exemptions with insufficient data under 40 CFR part 180. They were inadvertently removed from the CFR some time ago but are considered to be active tolerance exemptions subject to reassessment as required by the FFDCA section 408(q). The effective date of the revocation of the following two tolerance exemptions is now August 9, 2009: 1. § 180.910: "α-Alkyl(C₁₂-C₁₅)-ω-hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium,

potassium, sodium, and zinc salts; the poly(oxyethylene) content averages 3 moles.", and 2. § 180.930: "α-Alkyl (C₁₂-C₁₅)-ω-hydroxypoly(oxyethylene) sulfate and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the poly(oxyethylene) content averages 3 moles."

It is important to note that this action does not move the effective date of those tolerance exemptions revoked in the **Federal Register** on August 9, 2006 (71 FR 45415) for which there has been no expression of an intent to support. Elsewhere in this issue of the **Federal Register** is a document providing the revocation date of each of the inert ingredient tolerance exemptions revoked because of insufficient data on August 9, 2006. Tolerance exemptions with no expression of an intent to support are revoked as of August 9, 2008. All commodities containing residues of these revoked inert ingredients on food are adulterated under FFDCA 408 if the residues are the result of applications of pesticide products made after August 9, 2008. At this time, EPA is no longer accepting or processing applications for registrations for food-use products containing a tolerance exemption that expires on August 9, 2008 unless accompanied by a petition for a new tolerance or exemption under the Pesticide Registration Improvement Renewal Act (PRIA 2), together with all necessary supporting data. Registrants who submitted a registration application for a food-use formulation containing an inert ingredient with an expiring tolerance exemption may submit a new application for registration with only those inert ingredients that are approved for the label's use sites. If the registration application is subject to PRIA 2, including registration applications submitted under PRIA 2 that include a petition for a new or amended food-use inert ingredient, the following Web site provides useful information: http://www.epa.gov/pesticides/fees/questions/pria21day_wrksht.pdf. Currently approved food-use inert ingredient tolerance exemptions are found in 40 CFR part 180 (<http://www.epa.gov/opprd001/inerts/lists.html>). Contact EPA's Inert Ingredient Assessment Branch at inertsbranch@epa.gov for information about how to establish a new inert ingredient.

C. What is the Agency's Authority for Taking this Action?

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed

foods. Section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Without a tolerance or exemption, food containing pesticide residues is considered to be unsafe and therefore "adulterated" under FFDCA section 402(a), 21 U.S.C. 342(a). Such food may not be distributed in interstate commerce (21 U.S.C. 331(a)). For a food-use pesticide to be sold and distributed, the pesticide must not only have appropriate tolerances under FFDCA, but also must be registered under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*). Food-use pesticides not registered in the United States must have tolerances in order for commodities treated with those pesticides to be imported into the United States. Under FFDCA Section 408(e)(1)(B), 21 U.S.C. 346a(e)(1)(B), EPA may take action establishing, modifying, suspending or revoking a tolerance exemption.

III. Delayed Effective Date for Certain Tolerance Exemptions

The amendatory designations listed in this unit are reprinted from the final rule published in the **Federal Register** issue of August 9, 2006 (71 FR 45415) for the convenience of the user. The structure mirrors the amendatory designations in the original document. The asterisks represent those amendatory designations that go into effect August 9, 2008. The amendatory designations shown are those with the effective date delayed until August 9, 2009.

Section 180.910

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a. α-Alkyl (C₉-C₁₈)-ω-hydroxypoly(oxyethylene) with poly(oxyethylene) content of 2-30 moles.

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c. α-Alkyl (C₆-C₁₄)-ω-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 4-12 moles; average molecular weight (in amu) is approximately 635.

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i. Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.

j. α -Lauryl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.

k. α -Lauryl- ω -hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.

* * * * *

m. α -(*p*-Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles.

n. α -(*p*-Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.

o. Polyglyceryl phthalate ester of coconut oil fatty acids.

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s. Sodium diisobutylphenylsulfonate.

t. Sodium dodecylphenoxybenzenedisulfonate.

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w. Sodium monoalkyl and dialkyl (C_8 - C_{16}) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.

x. Sodium mono- and dimethylnaphthalenesulfonates, molecular weight (in amu) 245-260.

y. Sodium mono-, di-, and tributyl naphthalenesulfonates.

z. Sodium mono-, di-, and trisopropyl naphthalenesulfonate.

aa. Sodium *N*-oleoyl-*N*-methyltaurine.

* * * * *

cc. α -[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.

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Section 180.920

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a. α -Alkyl (C_{12} - C_{18})- ω -hydroxypoly(oxyethylene) copolymers with poly(oxypropylene); polyoxyethylene content averages 3-12

moles and polyoxypropylene content 2-9 moles.

b. α -Alkyl (C_{10} - C_{16})- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles.

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e. α -Alkyl (C_{12} - C_{18})- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content averages 13-17 moles and the oxypropylene content averages 2-6 moles.

f. α -Alkyl (C_{10} - C_{16})- ω -hydroxypoly(oxyethylene)poly(oxypropylene) mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the combined poly(oxyethylene) poly(oxypropylene) content averages 3-20 moles.

g. α -Alkyl (C_{12} - C_{18})- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-12 moles and the oxypropylene content is 3-7 moles.

h. α -Alkyl (C_{12} - C_{15})- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.

i. α -Alkyl (C_{21} - C_{71})- ω -hydroxypoly(oxyethylene) in which the poly(oxyethylene) content is 2 to 91 moles and molecular weight range from 390 to 5,000.

j. *n*-Alkyl(C_8 - C_{18})amine acetate.

k. Amine salts of alkyl (C_8 - C_{24}) benzenesulfonic acid (butylamine, dimethylaminopropylamine, mono- and diisopropylamine, mono-, di-, and triethanolamine).

* * * * *

m. *N,N*-Bis[α -ethyl- ω -hydroxypoly(oxyethylene) alkylamine; the poly(oxyethylene) content averages 3 moles; the alkyl groups (C_{14} - C_{18}) are derived from tallow, or from soybean or cottonseed oil acids.

n. *N,N*-Bis(2-hydroxyethyl)alkylamine, where the alkyl groups (C_8 - C_{18}) are derived from coconut, cottonseed, soya, or tallow acids.

o. *N,N*-Bis 2-(ω -hydroxypolyoxyethylene) ethyl) alkylamine; the reaction product of 1 mole *N,N*-bis(2-hydroxyethyl)alkylamine and 3-60

moles of ethylene oxide, where the alkyl group (C_8 - C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

p. *N,N*-Bis-2-(ω -hydroxypolyoxyethylene/polyoxypropylene) ethyl alkylamine; the reaction product of 1 mole of *N,N*-bis(2-hydroxyethyl alkylamine) and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C_8 - C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

* * * * *

s. α -(Di-*sec*-butyl)phenylpoly(oxypropylene) block polymer with poly(oxyethylene); the poly(oxypropylene) content averages 4 moles, the poly(oxyethylene) content averages 5 to 12 moles, the molecular.

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y. Linoleic diethanolamide (CAS Reg. No. 56863-02-6).

z. Methyl bis(2-hydroxyethyl)alkyl ammonium chloride, where the carbon chain (C_8 - C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

* * * * *

bb. Methylnaphthalenesulfonic acid—formaldehyde condensate, sodium salt.

cc. Methyl poly(oxyethylene) alkyl ammonium chloride, where the poly(oxyethylene) content is 3-15 moles and the alkyl group (C_8 - C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

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ff. Naphthalenesulfonic acid-formaldehyde condensate, ammonium and sodium salts.

gg. Partial sodium salt of *N*-lauryl- α -iminodipropionic acid.

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ii. Primary *n*-alkylamines, where the alkyl group (C_8 - C_{18}) is derived from coconut, cottonseed, soya, or tallow acids.

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ll. Sodium 1,4-dihexyl sulfosuccinate.

mm. Sodium 1,4-diisobutyl sulfosuccinate.

nn. Sodium 1,4-dipentyl sulfosuccinate.

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ss. *N,N,N',N'*-Tetrakis-(2-hydroxypropyl) ethylenediamine.

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Section 180.930

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b. α -Alkyl (C_{12} - C_{15})- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.

c. α -Alkyl (C_8 - C_{10}) hydroxypoly(oxypropylene) block

polymer with polyoxyethylene; polyoxypropylene content averages 3 moles and polyoxyethylene content averages 5-12 moles.

d. α -Alkyl (C₆-C₁₄)- ω -hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 7-9 moles; average molecular weight (in amu) approximately 635.

* * * * *

f. Amine salts of alkyl (C₈-C₂₄) benzenesulfonic acid (butylamine; dimethylamino propylamine; mono- and diisopropyl- amine; and mono-, di-, and triethanolamine).

* * * * *

l. Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.

* * * * *

n. α -Lauryl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.

o. α -Lauryl- ω -hydroxypoly(oxyethylene), sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.

* * * * *

s. Naphthalenesulfonic acid and its sodium salt.

t. α -(*p*-Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.

u. α -(*p*-Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.

v. α -(*p*-Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30-90 moles of ethylene oxide.

w. Polyglyceryl phthalate esters of coconut oil fatty acids.

* * * * *

cc. Sodium diisobutyl-naphthalenesulfonate.

* * * * *

ee. Sodium isopropyl-naphthalenesulfonate.

ff. Sodium monoalkyl and dialkyl (C₈-C₁₃) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.

gg. Sodium mono- and dimethylnaphthalenesulfonate, molecular weight (in amu) 245-260.

hh. Sodium mono-, di-, and tributyl-naphthalenesulfonates.

ii. Sodium *N*-oleoyl-*N*-methyl taurine.

jj. α -[*p*-(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p* (1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.

* * * * *

Paragraph (a) to Section 180.940

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i. α -Alkyl(C₁₀-C₁₄)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837.

ii. α -Alkyl(C₁₂-C₁₈)- ω hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120.

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Paragraph (c) to Section 180.940

* * * * *

i. α -Alkyl(C₁₀-C₁₄)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837.

ii. α -Alkyl(C₁₁-C₁₅)- ω -hydroxypoly(oxyethylene) with ethylene oxide content 9 to 13 moles.

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iv. α -Alkyl(C₁₂-C₁₈)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120.

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vii. Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives.

viii. Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives alkylated at 3% by weight with C₆-C₉ linear olefins.

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IV. Statutory and Executive Order Reviews

This rule changes the effective date of the revocation of certain tolerance exemptions under section 408(d) of FFDCA. The Office of Management and Budget (OMB) has exempted tolerance exemption 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 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).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have a significant negative economic impact on a substantial number of small entities. The factual basis for this certification is included in Unit II.B.8.

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 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 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.

List of Subjects in 40 CFR Part 180

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

Dated: July 23, 2008.

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.

§ 180.910 [Amended]

■ 2. In the final rule published August 9, 2006 (71 FR 45421), the effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.910: 2.a., c., i. through k., m. through o., s., t., w. through aa., and cc.

§ 180.920 [Amended]

■ 3. In the final rule published August 9, 2006 (71 FR 45421), the effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.920: 3.a., b., e. through k., m. through p., s., y., z., bb., cc., ff., gg., ii., ll. through nn., and ss.

§ 180.930 [Amended]

■ 4. In the final rule published August 9, 2006 (71 FR 45421), the effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments to § 180.930: 4.b., c., d., f., l., n., o., s. through w., cc., and ee. through jj.

§ 180.940 [Amended]

■ 5. In the final rule published August 9, 2006 (71 FR 45421), the effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments in paragraph (a) to § 180.940: 5.a.i. and ii.

■ 6. In the final rule published August 9, 2006 (71 FR 45421), the effective date is delayed from August 9, 2008, to August 9, 2009, for the following amendments in paragraph (c) to § 180.940: 5.c.i., ii., iv., vii. and viii.

[FR Doc. E8-17458 Filed 8-1-08; 8:45 am]

BILLING CODE 6560-50-S