

(NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: July 28, 2009.
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:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * *	* * * * *	* * * * *
Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether (CAS Reg. No. 69029–39–6)	Limited to herbicide formulations only, and to no more than 30% by weight in herbicide formulations intended for application to turf	Surfactants, related adjuvants of surfactants
* * *	* * * * *	* * * * *

[FR Doc. E9–18717 Filed 8–4–09; 8:45 am]
 BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0490; FRL–8428–5]

Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the sodium and ammonium naphthalenesulfonate formaldehyde condensates, herein referred to in this document as the SANFCs, when used as inert ingredients in pesticide formulations applied to growing crops under 40 CFR 180.920. The Joint Inerts Task Force (JITF), Cluster Support Team Number 11 and Akzo Nobel Surface Chemistry, LLC, submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of the SANFCs.

DATES: This regulation is effective August 5, 2009. Objections and requests for hearings must be received on or before October 5, 2009, 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–2009–0490. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. 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: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8811; e-mail address: leifer.kerry@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 those engaged in the following activities:

- 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 to provide 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**.

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also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0490 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 as required by 40 CFR part 178 on or before October 5, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0490, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

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II. Background

In the **Federal Register** of March 4, 2009 (74 FR 9397) (FRL-8401-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C.

346a(d)(3), announcing the filing of a pesticide petition (PP 9E7516) by The Joint Inerts Task Force (JITF), Cluster Support Team Number 11 (CST 11), c/o CropLife America, 1156 15th Street, NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of sodium and ammonium naphthalenesulfonate formaldehyde condensates. That notice referenced a summary of the petition prepared by the JITF, CST 11, the petitioner, which is available to the public in the docket, <http://www.regulations.gov>. Docket ID number EPA-HQ-OPP-2009-0043 was established for the petition. There were no comments received in response to the notice of filing.

In the **Federal Register** of March 25, 2009 (74 FR 12856) (FRL-8399-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7405) by Akzo Nobel Surface Chemistry, LLC, 525 West Van Buren Street, Chicago, IL 60607-3823. The petition requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts. That notice referenced a summary of the petition prepared by Akzo Nobel Surface Chemistry, LLC, the petitioner, which is available to the public in the docket, <http://www.regulations.gov>. Docket ID number EPA-HQ-OPP-2008-0822 was established for the petition. There were no comments received in response to the notice of filing.

These two petitions are grouped because they fall under the same general chemical description criteria.

These petitions were submitted in response to a final rule published August 9, 2006 (71 FR 45415) (FRL-8084-1) in which the Agency revoked, under section 408(e)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the existing exemptions from the requirement of a tolerance for residues of certain inert ingredients because of insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009, by a final rule published in the **Federal Register** of August 4, 2008 to allow for data to be submitted to support the establishment of tolerance exemptions for these inert

ingredients prior to the effective date of the tolerance exemption revocation.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA 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.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data

and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for exemption from the requirement of a tolerance for residues of the SANFCs when used as inert ingredients in pesticide formulations applied to growing crops. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database for the SANFC inerts is adequate to support their use as inert ingredients in pesticide formulations. The existing toxicology database for the SANFC consists of two OPPTS Harmonized Guideline 870.3650 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats), and several studies from the scientific literature on acute toxicity and mutagenicity.

The available toxicity data indicates that SANFC has low acute oral and inhalation toxicity. SANFC was not mutagenic in an Ames test. In a repeated 28–42 day OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental toxicity screening with the representative test compound, naphthalenesulfonic acid, sodium salt polymer with formaldehyde (CAS 9084–06–4), there was no evidence of increased susceptibility. Parental toxicity manifested as decrements in body-weight gain in both sexes at the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)). No developmental or reproductive effects were observed at doses of 100, 300, and 1,000 mg/kg/day. In an OPPTS Harmonized Guideline 870.3650 study submitted by Akzo Nobel Chemistry, LLC, no systemic toxicity was observed at doses up to and including 456 mg/kg/day. (The highest dose tested). There was no evidence of potential neurotoxicity or immunotoxicity in the adult animal in the OPPTS Harmonized Guideline 870.3650 study at the limit dose of 1,000 mg/kg/day. There is no evidence that the SANFCs are carcinogenic. There are no chronic data available on the SANFC surfactants;

however, no structural alerts for cancer were identified in a qualitative structure activity relationship (SAR) database, DEREK Version 11. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds. The higher molecular weight polymeric SANFC surfactants (MW>1,000) are not expected to be readily absorbed or metabolized, and should thus be rapidly excreted (likely in the feces) unchanged. Additionally, lower molecular microsome cytochrome P–450 oxygenases may hydroxylate the naphthalene ring and/or methylene bridge to produce alternative metabolites that should also be readily conjugated and excreted. Furthermore, these compounds are formaldehyde condensates and do not contain free formaldehyde. Therefore, formaldehyde is not a residue of concern. In summary, due to the low hazard potential for these inert compounds, a quantitative risk assessment is not required for the SANFC inerts.

Specific information on the studies received are included in the Agency's Human Health Risk Assessment which can be found at <http://www.regulations.gov> in document Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFCs - JITF CST 11 Inert Ingredients). "Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations," pages 6–8 and pages 11–14 in docket ID number EPA–HQ–OPP–2009–0043 and also in document "Mono-, Di-, and Trimethylnaphthalenesulfonic Acids and Naphthalenesulfonic Acids Formaldehyde Condensates, Ammonium and Sodium Salts: Review of Toxicological Studies in Support of an Exemption from the Requirement of a Tolerance (40 CFR 180.920 and 40 CFR 180.910) When Used as Inert Ingredients in Pesticide Formulations" in docket ID number EPA–HQ–OPP–2008–0822.

B. Toxicity Endpoint Selection and FQPA Considerations

There was no significant hazard identified in the OPPTS Harmonized Guideline 870.3650 study at the limit dose of 1,000 mg/kg/day to either parental animals or their offspring. Thus, due to their low potential hazard and the lack of a hazard endpoint, it was determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for the SANFCs. The

Agency notes that there was no evidence of neurotoxicity or increased susceptibility to the offspring of rats following prenatal or postnatal exposure in the OPPTS Harmonized Guideline 870.3650 studies. Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to the SANFCs when used as inert ingredients in pesticide formulations applied to growing crops and a safety factor analysis has not been used to assess risk. For the same reason, EPA has determined that an additional safety factor is not needed to protect the safety of infants and children.

C. Aggregate Exposures

In examining aggregate exposure, section 408 of 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).

The SANFC inerts are used as dispersants, defoamers and emulsifiers in pesticide formulations. These surfactants have a wide range of industrial uses as well as serve as emulsifiers in personal care products and in food contact packaging.

The residues of concern are for the parent compound only. Considering the large size and polarity of the SANFC molecules, it is unlikely that they would be readily absorbed by livestock or taken up by plants for further metabolism.

No hazard was identified for the acute and chronic dietary assessment (food and drinking water), or for the short-, intermediate-, and long-term residential assessments, and therefore no quantitative aggregate risk assessments were performed.

D. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

EPA has not found the SANFCs to share a common mechanism of toxicity with any other substances, and SANFCs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has

assumed that SANFCs do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

E. Determination of Safety

Based on all available information, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to residues of the SANFCs when used as inert ingredients in pesticide formulations applied to growing crops.

V. Other Considerations

A. 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.

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for the SANFCs nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of the sodium and ammonium naphthalenesulfonate formaldehyde condensates, under the tolerance expression mono-, di-, and trimethylnaphthalenesulfonic acids and naphthalenesulfonic acids formaldehyde condensates, ammonium and sodium salts, when used as inert ingredients in pesticide formulations applied to growing crops under 40 CFR 180.920.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: July 29, 2009.

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 pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert Ingredients	Limits	Uses
* * * *	*	Surfactants, related adjuvants of surfactants
* * * *	*	

[FR Doc. E9-18725 Filed 8-4-09; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0042; FRL-8424-4]

Methyl Poly(Oxyethylene) C_8-C_{18} Alkylammonium Chlorides; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of methyl poly(oxyethylene) C_8-C_{18} alkylammonium chlorides where the poly(oxyethylene) content is $n=2-15$ and where C_8-C_{18} alkyl is linear and may be saturated or unsaturated, herein referred to in this document as methyl poly(oxyethylene) C_8-C_{18} alkylammonium chlorides (MPOACs), when used as an inert ingredient in pesticide formulations for pre-harvest uses under 40 CFR 180.920 at a maximum of 10% by weight in herbicide formulations and 5% by weight in all other formulations. The Joint Inerts Task Force (JITF), Cluster Support Team (CST No. 7), submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of MPOACs.

DATES: This regulation is effective August 5, 2009. Objections and requests for hearings must be received on or before October 5, 2009, 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-2009-0042. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. 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

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