Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)  

700 Special Standards  

707 Periodicals  

6.0 Qualification Categories  

6.1 General Publications  

6.1.2 Circulation Standards  

General publications must meet these circulation standards:  

6.4 Requester Publications  

6.4.2 Circulation Standards  

Requester publications must meet these circulation standards:  

6.5 Electronic Copies  

Copies of Periodicals publications distributed through email or by accessing a password protected Web site may be counted toward an approved or pending general or requester publication’s eligibility for Periodicals prices. The following conditions additionally apply:  

b. Electronic copies of a Periodicals publication for which access is offered free in conjunction with printed copies of the same issues may not be counted when determining total circulation for the publication.  

c. At least 40% of the total circulation of each issue must consist of printed copies distributed to paying subscribers or requesters, as applicable. Up to 10% of the distributed copies used to qualify or remain eligible for Periodicals prices may be copies that are paid or requested to be sent electronically.  

d. If less than 60% of a Periodicals publication’s total circulation consists of printed copies distributed to paying subscribers or requesters, as applicable, annual Postal eligibility audits must be conducted by a certified audit bureau.  

6.6 through 6.7 and add new 6.5 as follows:  

[Revise item b as follows:]  

b. Subscription copies of the publications that are paid for or promised to be paid for, including those at or below a nominal price, may be included in the determination of whether the 50% request requirement is met. (For explanation of how electronic copies may be included, see 6.5.)  

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.  

Stanley F. Mires,  
Attorney, Legal Policy and Legislative Advice.  

ENVIRONMENTAL PROTECTION AGENCY  

40 CFR Part 180  

[FR Doc. 2012–11107 Filed 5–8–12; 8:45 am]  

BILLING CODE 7710–12–P  

ENVIRONMENTAL PROTECTION AGENCY  

40 CFR Part 180  


α-(P-Nonylphenol)-ω-hydroxypropoxy(oxyethylene) Sulfate and Phosphate Esters; 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 α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters and α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts.  

DATES: This regulation is effective May 9, 2012. Objections and requests for hearings must be received on or before July 9, 2012, 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–2011–0526. 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; email 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:

- 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 access to other related information?


C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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–2011–0526, by one of the following methods:

- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays).

Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background

In the Federal Register of August 26, 2011 (76 FR 53372) (FRL–8884–9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7860) by Joint Inerts Task Force, Cluster Support Team 9, c/o CropLife America, 1156 15th St. NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters and α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts when used as inert ingredients at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and to animals. That notice referenced a summary of the petition prepared by JTFF, CST 9, the petitioner, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Previously, in the Federal Register of May 17, 2010 (75 FR 27434) (FRL–8826–3), EPA established a time-limited tolerance exemption for α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters and α-(p-nonylphenol)-ω-hydroxypropoxy(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts (herein referred to in this document as nonylphenol ethoxylate phosphate and sulfate derivatives or NPEPSDs) with an expiration date of May 17, 2012. The 2-year time limitation was established for two purposes:

1. To provide time for the development and submission of confirmatory toxicity data to address equivocal results in the available genotoxicity studies conducted on NPEPSDs (as described in Unit IV of the May 17, 2010 final rule); and

2. To provide additional time, should the initial testing not confirm EPA’s conclusion regarding the lack of a cancer concern, for registrants to attain EPA approval of registration amendments for reformulation of their pesticide products to remove NPEPSDs and to replace existing products with reformulated products.

In establishing the time-limited tolerance exemption for NPEPSDs, EPA stated that if the submitted data confirmed its conclusion regarding a lack of cancer concern, the Agency intended to remove the expiration date from the tolerance exemption prior to expiration of the exemption.

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 non-toxicity; 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(c)(2)(A)(i) of 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 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 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 the requirement of a 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 FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 NPEPSDs including exposure resulting from the exemption established by this action.

In the Federal Register of May 17, 2010, EPA issued a final rule establishing an exemption from the requirement of a tolerance for residues of NPEPSDs when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 with an expiration date of May 17, 2012. EPA has determined that establishing an exemption from the requirement of a tolerance for residues of NPEPSDs when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest will not significantly change the risk assessments the Agency relied on to support the May 17, 2010, tolerance action, as explained in this unit.

As part of the Agency’s conduct of the risk assessment in support of the May 17, 2010, tolerance action, it was determined that there were no acute, chronic, short- or intermediate-term aggregate risks of concern. With regards to aggregate cancer risk, the assessment concluded that based on a weight of the evidence consideration of the available data, the Agency believed that cancer risks would be negligible. However, due to the equivocal findings in the mutagenicity data base, the Agency asked for confirmatory data. Specifically, EPA recommended that supporters of the NPEPSD tolerance exemption perform the following studies for confirmatory purposes:


A bone marrow assay (OCSSP Harmonized Guideline 870.5395—Mammalian erythrocyte micronucleus test).

Since in vivo mutagenicity studies such as the bone marrow assay are generally regarded as more definitive than in vitro studies, and a negative result in the bone marrow test may outweigh whatever results are found in the Ames test and mouse lymphoma assay, supporters of the NPEPSD tolerance exemption were given the option of conducting the mammalian erythrocyte micronucleus test in lieu of the two in vitro mutagenicity studies. If those data did not confirm EPA’s cancer conclusion, then EPA would need 2-year cancer bioassays in the mouse and rat (OCSSP Harmonized Guideline 870.4200—Carcinogenicity (mouse) and OCSSP Harmonized Guideline 870.4300—Combined Chronic Toxicity/Carcinogenicity (rat)) to make a safety finding in support of the tolerance exemption.

In response to the May 17, 2010, final rule, the JTI, CST 9 conducted an in vivo Mouse Bone Marrow Erythrocyte Micronucleus Test Following Oral Administration (Harmonized Test Guideline 870.5395) of two representative test compounds, poly(oxy-1,2-ethanediyl)-α-[p-nonylphenyl]-ω-hydroxy], branched, phosphates (CAS Reg. No. 68412–53–3) and poly(oxy-1,2-ethanediyl)-ω-sulfo-α-[nonylphenoxy], sodium salt (CAS Reg. No. 9014–90–8). These data were submitted to the Agency on November 12, 2010 (MRID 48293401 and 48293402).

The data were evaluated by EPA and it was determined that the test substances did not induce numerical or structural chromosomal damage, providing further confirmation that NPEPSDs are not of concern for aggregate cancer risk. Further details of this evaluation can be found at http://www.regulations.gov in the document “Nonylphenol Ethoxylates and Their Phosphate and Sulfate Derivatives (JITF CST 9 Inert Ingredients)-Review of Confirmatory Mutagenicity Toxicity Data” in docket ID number EPA–HQ–OPP–2011–0526.


Therefore, based on this information and the findings in the final rule published in the Federal Register of May 17, 2010, 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 NPEPSD residues.

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

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards wherever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that...
VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of \( \alpha \)-(p-nonylphenol)-\( \alpha \)-hydroxypropyloxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts of the phosphate esters and \( \alpha \)-(p-nonylphenol)-\( \alpha \)-hydroxypropyloxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts when used as an inert ingredient at levels not to exceed 7% in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and in pesticide formulations applied to animals under 40 CFR 180.930.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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). 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 FFDCA section 408(d), 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 FFDCA section 408(n)(4). As such, the Agency has determined that this action will 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) (Pub. L. 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, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.


G. Jeffery Herndon,
Acting 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:


2. Section 180.910 is amended by revising the following entries in the table of inert ingredients to read as follows:

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

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \alpha )-(p-Nonylphenol)-( \alpha )-hydroxypropyloxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts the nonyl group is propylene trimer isomer and the poly(oxyethylene) content averages 4 moles (CAS Reg. Nos. 9014–90–8, 9051–57–4, 9081–17–8, 68649–55–8, 68891–33–8).</td>
<td>Not to exceed 7% of pesticide formulation.</td>
<td>Surfactants, related adjuvants of surfactants.</td>
</tr>
</tbody>
</table>
Inert ingredients | Limits | Uses
--- | --- | ---

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

3. Section 180.930 is amended by revising the following entries in the table of inert ingredients to read as follows:

Inert ingredients | Limits | Uses
--- | --- | ---

B. How can I get electronic access to other related information?