* * * * *

[FR Doc. 2011–2408 Filed 2–3–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0181; FRL–8860–7]

n-Octyl Alcohol and n-Decyl Alcohol; 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 n-octyl alcohol (CAS Reg. No. 111–87–5); and n-decyl alcohol (CAS Reg. No. 112–30–1) when used as an inert ingredient (solvent or co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under EPA regulations. Technology Sciences Group Inc., on behalf of AMVAC, Chemical Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of n-octyl alcohol and n-decyl alcohol.

DATES: This regulation is effective February 4, 2011. Objections and requests for hearings must be received on or before April 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION** section).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0181. 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: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; e-mail address: *debesai.alganesh@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?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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–2010–0181 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0181, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *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. Petition for Exemption

In the **Federal Register** of March 24, 2010 (75 FR 14154) (FRL–8815–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7671) by AMVAC Chemical Corporation, 4695 MacArthur Court, Suit 1250, Newport Beach, CA 90660. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of n-octyl alcohol (CAS Reg. No. 111–87–5); and n-decyl alcohol (CAS Reg. No. 112–30–1) when used as inert ingredients (solvent or co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. That notice referenced a summary of the petition prepared by AMVAC Chemical Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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(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 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(c)(2)(A) of FFDCA, 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 n-octyl alcohol and n-decyl alcohol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with n-octyl alcohol and n-decyl alcohol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by n-octyl alcohol and n-decyl alcohol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The following provides a brief summary for the risk assessment and conclusions for the Agency's review for the aliphatic alcohols, which include n-octyl alcohol and n-decyl alcohol. The Agency's full decision document for this action is available in the Agency's electronic docket (*regulations.gov*) under the docket number EPA–HQ–OPP–2010–0181. Details regarding the Agency's findings with regards to human health and environmental fate and effects, are found in: "Aliphatic Alcohols: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document Reregistration Case Number 4004 (June 30, 2006). DP Barcode: 325712; PC Codes: 079029, 079038, 079059" (June 30, 2006), and "Ecological Risk Assessment Aliphatic Alcohols Considered in Registration Case 4004". These documents are available on the Agency's Web site in the EPA Docket at: *http://www.regulations.gov* (Docket ID EPA–HQ–2007–0134). Additional information on the use, physical/chemical properties, toxicological effects, and exposure profile of n-octyl and n-decyl alcohols can be found on the 2006 Agency's reassessment decision document for tolerance exemption at *http://www.epa.gov/opprd001/inerts/octyldecyl.pdf*.

Briefly, the available acute toxicity studies indicate the aliphatic alcohols are of low acute toxicity. Acute oral toxicity for n-octyl alcohol was 4,135 milligrams/kilogram (mg/kg) and for n-decyl alcohol was 9,800 mg/kg. Acute inhalation studies with the rat resulted in LC_{50} estimates above the limit concentration of 2 milligrams per Liter (mg/L). Eye irritation studies with undiluted test compound resulted in severe and sometimes non-reversible eye damage. Dermal irritation studies revealed slight to moderate irritation in rabbits. The aliphatic alcohols generally did not produce sensitization in guinea pigs.

A 90-day dermal toxicity study in rats with fatty alcohol blend (56.7% decanol, 42.7% octanol) at dose levels of 0, 100, 300, or 1,000 mg/kg resulted in severe irritation at the application site. Severe irritation including fissuring of the skin occurred in 40% of the animals at 100 mg/kg/day and 80% of the animals at the limit dose. Slight changes in hematology, clinical chemistry, and organ weights were noted at the limit dose of 1,000 mg/kg/day. The systemic toxicity NOAEL in the 90-day dermal study was 300 mg/kg/day based on changes in clinical chemistry and hematological parameters, and organ weight changes seen at the LOAEL of 1,000 mg/kg/day. No systemic or developmental toxicity was observed in the developmental toxicity studies in rats via the inhalation with n-decyl alcohol at the maximum attainable vapor concentration (100 mg/cubic meter (m^3)) approximately equivalent to 30 mg/kg/day. Similarly, no maternal or developmental toxicity was seen in an oral (gavage) developmental toxicity study in rats with fatty alcohol blend at doses up to 1,000 mg/kg/day. Aliphatic alcohols gave a negative response for mutagenicity in the available studies. No long term studies or carcinogenicity studies are available in the database via oral routes of exposure. However, as a class, the straight chain aliphatic alcohols are not considered carcinogenic. In addition, the Agency used a qualitative structure activity relationship (QSAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified.

No neurotoxicity studies are available in the database. The clinical signs suggestive of neurotoxicity were observed following a single high bolus dose and/or repeated high bolus doses. These signs were transient and considered due to bolus dosing.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to n-octyl and n-decyl alcohol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from n-octy and n-decyl alcohol in food as follows:

i. *Acute exposure.* No adverse effects attributable to a single exposure of n-octyl alcohol and n-dectyl alcohol were seen in the available toxicity studies. Therefore, an acute dietary risk assessment for n-octyl and n-decyl alcohol was not conducted.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for n-octyl and n-decyl alcohol. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather, there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, and then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically 1 to 2 orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

iii. *Cancer.* The Agency used a qualitative structure activity relationship (QSAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. Therefore, a quantitative dietary exposure assessment was not conducted for the purpose of evaluating cancer risk.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and or PCT information in the dietary assessment for n-octyl and n-decyl alcohol. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Due to the low hazard profile and lack of endpoint selection for the dermal route of exposure, no post application dermal risk was assessed.

4. *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 n-octyl and n-decyl alcohols to share a common mechanism of toxicity with any other substances, and does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that n-octyl and n-decyl alcohol 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 Web site at *http://www.epa.gov/pesticides/cumulative*.

C. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. EPA has determind that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. The decision is based on the following findings:

1. The database on n-octyl alcohol and n-decyl alcohol is considered adequate for FQPA assessment. The database includes two developmental toxicity studies in rats via oral route of exposure, one developmental toxicity study in rats via inhalation routes and one Organization of Economic Development (OECD) 422 study (reproductive and developmental screening study) in rats. In addition, there are a 90-day dermal toxicity study in rats and several mutagenicity studies.

2. There is no evidence of increased susceptibility of infants and children from exposure to low chain aliphatic alcohols. In developmental toxicity studies in rats via the oral route, no developmental toxicity was seen at doses 1,000 mg/kg/day and above. No developmental or systemic toxicity was seen in the developmental toxicity study in rats via the inhalation route of exposure. No evidence of fetal or systemic toxicity was seen at doses up to 2,000 mg/kg/day in the OECD 422 study in rats.

3. There is no indication in the database that n-octyl and n-decyl alcohols are neurotoxic chemicals except when administered in high bolus doses. Therefore, there is no need for a developmental neurotoxicity study. There is no indication of immunotoxicity in the available database; therefore, an immunotoxicity study is not required.

4. There are no long-term studies in the database but there are no concerns for the lack of such data because the available studies indicate that no systemic toxicity was seen at the limit dose or above except in one developmental gavage study in rats in which the salivation was seen at the high dose of 1,000 mg/kg/day. This effect is considered to be due to bolus gavage dosing. This study and endpoint was used for the chronic reference dose (RfD), therefore, providing conservative estimates.

5. There are no residual uncertainties identified in the exposure databases. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children. The dietary exposure assessments are considered to be highly conservative as they are based on the use of the highest tolerance level from the surrogate pesticides for every food and 100% crop treated is assumed for all crops. EPA also made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to n-octyl alcohol and n-decyl alcohol in drinking water. These assessments will not underestimate the exposure and risks posed by both alcohols. Based on the above considerations; EPA has reduced the FQPA factor to 1X.

D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate point of departures (PODs) to ensure that an adequate margin of exposure (MOE) exists.

1. *Acute aggregate (food and drinking water) risk.* No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, n-octyl alcohol and n-decyl alcohol are not expected to pose an acute risk.

2. *Chronic aggregate (food and drinking water) risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure, the chronic dietary exposure from food and water to n-octyl alcohol and n-decyl alcohol is 5.1% of the cPAD for the U.S. population and 16.6% of the cPAD for children 1–2 years old, the most highly exposed population subgroup. The chronic dietary exposure estimates for food and drinking water are below the Agency's level of concern (<100% cPAD) for the U.S. population and all population subgroups.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- term quantitative aggregate risk assessment was not conducted because there is low hazard via the oral, dermal and inhalation routes of exposure. The endpoint of concern for the chronic RfD was based on the conservative NOAEL of 375 mg/kg/day. This NOAEL was based on salivation seen at the LOAEL of 1,000 mg/kg/day in a developmental toxicity study in rats. The dietary exposure from food and water is estimated to be 5.1% of the cPAD. The short-term residential exposure is not expected to be 95% of the cPAD because dermal and inhalation exposures are not likely to be significant since the alcohols will be readily volatized and dissipated in the environment. Therefore, aggregate short-term exposure does not pose a risk concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Intermediate-term quantitative aggregate risk assessment was not conducted because there is low hazard via the oral, dermal and inhalation routes of exposure. The endpoint of concern for the chronic RfD was based on the conservative NOAEL of 375 mg/kg/day. This NOAEL was based on salivation seen at the LOAEL of 1,000 mg/kg/day in a developmental toxicity study in rats. The dietary exposure from food and water is estimated to be 5.1% of the cPAD. The intermediate-term residential exposure is not expected to be 95% of the cPAD because dermal and inhalation exposure are not likely to be significant since the alcohols will be readily volatized and dissipated in the environment. Therefore quantitative short-term residential exposure assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to n-octyl alcohol and n-decyl alcohol.

6. *Determination of safety.* Based on these risk assessments, 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 n-octyl alcohol and n-decyl alcohol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residue of n-octyl alcohol and n-decyl alcohol in or any food commodities.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever 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 U.N. 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 EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for n-octyl and n-decyl alcohol.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for of n-octyl alcohol (CAS Reg. No. 111–87–5); and n-decyl alcohol (CAS Reg. No. 112–30–1) when used as an inert ingredient (solvent or co-solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.910.

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 exemptions 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) (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, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 24, 2011.

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 § 180.910, the table is amended by adding alphabetically two new inert ingredients to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
n-Decyl alcohol (CAS Reg. No. 112–30–1)		Solvent or co-solvent.
* * * * * * *		
n-Octyl alcohol (CAS Reg. No. 111–87–5)		Solvent or co-solvent.
* * * * * * *		

* * * * *

§ 180.920 [Amended]

■ 3. Section 180.920 is amended by removing from the table the entries for "n-Decyl alcohol" and "n-Octyl alcohol".

[FR Doc. 2011–2398 Filed 2–3–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0733; FRL–8860–6]

(S,S)-Ethylenediamine Disuccinic Acid Trisodium Salt; 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 (S,S)-ethylenediamine disuccinic acid trisodium salt (CAS Reg. No. 178949–82–1) when used as an inert ingredient (sequestrant or chelating agent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest under EPA regulations. Innospec Limited submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of (S,S)-ethylenediamine disuccinic acid trisodium salt.

DATES: This regulation is effective February 4, 2011. Objections and requests for hearings must be received on or before April 5, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION** section).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0733. 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: Alganesh Debesai, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8353; e-mail address: *debesai.alganesh@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?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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–2010–0733 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 5, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0733, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *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. Petition for Exemption

In the **Federal Register** of September 23, 2010 (75 FR 57942) (FRL–8845–4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 0E7753) by Innospec Limited, c/o Walter G. Talarek, PC, 1008 Riva Ridge Drive, Great Falls, VA 22066–1620. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of (S,S)-ethylenediamine disuccinic acid trisodium salt (CAS Reg. No. 178949–82–1) when used as an inert ingredient as sequestrant or chelating agent in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. That notice referenced a summary of the petition