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**§ 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

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**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.

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**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](mailto: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

prepared by Innospec Limited, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. For ease of reading in this document, (S,S)-ethylenediamine disuccinic acid trisodium salt is referred to as (S,S)-EDDS trisodium salt.

### 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 no 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 and 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 (S,S)-EDDS trisodium salt including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with (S,S)-EDDS trisodium salt 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.

The Agency completed a risk assessment on October 28, 2008 for the approval of an exemption from the requirement of a tolerance under 40 CFR 180.920 for pre-harvest use for a substantially similar chemical, i.e., (S,S)-ethylenediamine disuccinic acid, (CAS Reg. No. 20846-91-7) which is referred to as (S,S)-EDDS. This risk assessment as well as data on another similar compound, ethylenediamine tetracetic acid (EDTA), was used to evaluate the current request for (S,S)-EDDS trisodium salt (CAS Reg. No. 178949-82-1) because it is likely that (S,S)-EDDS trisodium salt, EDTA, and (S,S)-EDDS readily disassociates in the body to their respective salts or acids and the active moiety ethylenediamine. Therefore, these toxicological data can be bridged.

Briefly, studies show that (S,S)-EDDS has low acute and subchronic toxicity, is a mild eye irritant, and is not a

dermal irritant or skin sensitizer. Based on the results of submitted mutagenicity studies, (S,S)-EDDS is not likely to be mutagenic. No carcinogenicity studies are available on (S,S)-EDDS, however, NTP tested trisodium EDTA in mice and rats and it showed no carcinogenic potential. Based on its similarity with EDTA and lack of mutagenicity, (S,S)-EDDS is not likely to be carcinogenic to humans at low doses. In addition, metabolism studies show that (S,S)-EDDS is poorly absorbed but rapidly excreted within 72 hours.

The (S,S)-EDDS studies indicate developmental toxicity only at high dosage levels that resulted in maternal toxicity (limit dose levels). In a developmental toxicity study in rats, the maternal toxicity low observed adverse effect level (LOAEL) is 944.1 milligrams/kilograms/body weight/day (mg/kg bw/day) (16,000 parts per million (ppm)) (limit dose) based on reductions in body weight, body weight gain, feed consumption, and blood levels of zinc, iron, and copper, and the no observed adverse effect level (NOAEL) is 551.1 mg/kg bw/day (8,000 ppm). The developmental toxicity LOAEL of 944.1 was based on an increase in fetal death, reduced fetal growth, and multiple developmental malformations and variations affecting almost all major organ systems and skeletal structures, and the NOAEL is 551.1 mg/kg bw/day (8,000 ppm). Therefore, the maternal and developmental NOAEL are both 551.1 mg/kg bw/day (8,000 ppm). The results of this dietary study indicate qualitative evidence of increased susceptibility; however, the concern for this increased susceptibility is low for the reasons discussed in Unit IV.D.

Specific information on the studies received and the nature of the adverse effects caused by (S,S)-EDDS as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in the document for Petition #4E6818 (S,S)-ethylenediaminedisuccinic acid (CAS Reg. No. 20846-91-7) for tolerance exemption under 40 CFR 180.920 under docket ID number EPA-HQ-OPP-2008-0250.

#### B. Toxicological Points of Departure/ Levels of Concern

Due to the low potential hazard of this chemical, quantitative dietary or occupational and residential exposure assessment is not necessary. However, EPA conducted quantitative chronic dietary assessment using the NOAEL of 551.0 mg/kg/day based on reductions in body weight, body weight gain, feed consumption seen at the LOAEL of 944

mg/kg/day observed in a developmental toxicity study in rats with uncertainty factor of 100 (10x for intraspecies variability and 10x for interspecies extrapolation). The Food Quality Protection Act (FQPA) safety factor (SF) was reduced to 1X.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses and drinking water.* Since toxicity effects were seen only at the limit dose for (S,S)-EDDS, a quantitative exposure assessment for (S,S)-EDDS trisodium salt is not needed. Any possible dietary exposure to (S,S)-EDDS trisodium salt from its use as an inert ingredient in pesticide products would be through consumption of food to which pesticide products containing it have been applied, although the rapid biodegradation properties will reduce the amount of (S,S)-EDDS trisodium salt that is available for uptake by plants. Run-off into surface water is not anticipated due to rapid biodegradation, and therefore, contributions of concern to drinking water are not expected.

To further support this conclusion, the Agency performed a dietary (food and drinking water) exposure assessment for (S,S)-EDDS trisodium salt using worst case assumptions as detailed below. This exposure assessment assumed that:

i. (S,S)-EDDS trisodium salt would be used as an inert ingredient in all food use pesticide formulations applied to all crops.

ii. One hundred percent of all food crops would be treated with pesticides containing (S,S)-EDDS trisodium salt.

iii. (S,S)-EDDS trisodium salt residues would be present in all crops at levels equal to or exceeding the highest established tolerance levels for any pesticide active ingredient for the use, and

iv. A conservative default value of 100 parts per billion (ppb) for the concentration of an inert ingredient in all sources of drinking water was used. This approach is highly conservative as it is extremely unlikely that (S,S)-EDDS trisodium salt would have such use as pesticide product inert ingredients and be present in food commodities and drinking water at such high levels.

EPA also considered whether it should quantitatively aggregate exposure to (S,S)-EDDS trisodium salt and EDTA (ethylenediamine tetraacetic acid) and its salts and S,S-ethylenediamine disuccinic acid (S,S-EDDS) in assessing risk. However, because these chemicals are chelating agents, it is not expected that more than one of these chemicals would be present in the same pesticide formulation.

Further, in quantitatively assessing risk, EPA has assumed that (S,S)-EDDS trisodium salt would be present in all foods and at extremely high values. Thus, EPA believes that its approach to aggregate exposure is conservative and health protective.

2. *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).

(S,S)-EDDS trisodium salt may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in both outdoor and indoor residential exposures. In addition, (S,S)-EDDS trisodium salt may be used in and around the home. Although dermal and inhalation exposures are possible from residential use of pesticide products containing this inert ingredient, negligible inhalation and dermal absorption is expected based on its low toxicity, poor absorption, and rapid biodegradation properties of the chemical and therefore, an aggregate risk assessment was not performed.

3. *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."

As explained above, EPA has based its assessment of the toxicity of (S,S)-EDDS trisodium salt on data on the toxicity of EDTA (ethylenediamine tetraacetic acid) and its salts and S,S-ethylenediamine disuccinic acid (S,S-EDDS). For the same reason, EPA believes that aggregate exposure to these compounds would have cumulative toxic effects. EPA's approach to aggregating exposures to these compounds is discussed in Unit IV.C.1.

EPA has not found (S,S)-EDDS trisodium salt to share a common mechanism of toxicity with any other substances, and (S,S)-EDDS trisodium salt does not appear to produce a toxic metabolite produced by any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that (S,S)-EDDS trisodium salt does not have a common mechanism of toxicity with any 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>.

However, these chemicals are chelating agents, therefore, it is not expected that all of these chemicals would be present in the same pesticide formulation. A quantitative aggregate exposure assessment was not performed for this class of chemicals since highly conservative dietary exposure assessments (food and water) for U.S. general population was less than 5% of the cPAD.

### D. 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 FQPA Safety Factor (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 determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

1. EPA has sufficient data to assess the toxicity of (S,S)-EDDS trisodium salt. Although the toxicological database on (S,S)-EDDS trisodium salt is limited, adequate long term studies are available on structurally related compounds such as (S,S)-EDDS calcium disodium EDTA, and trisodium EDTA. Based on the structural similarities in these compounds, EPA concluded the database for (S,S)-EDDS trisodium salt is adequate.

2. EPA has low concern regarding the potential developmental effects of (S,S)-EDDS trisodium salt. The (S,S)-EDDS studies indicate developmental toxicity only at high dosage levels that resulted in maternal toxicity (limit dose levels). In evidence of increased susceptibility; however, the concern for this increased susceptibility is low because:

i. Effects were seen only at the limit dose and in the presence of maternal toxicity.

ii. There is a well characterized NOAEL (551.1 mg/kg/day) protecting from these effects.

iii. The presence of zinc, iron and copper may have contributed to the observed developmental toxicity, since other chelating agents (such as EDTA) have been shown to impact zinc, iron, and copper levels and some of the developmental toxicity.

iv. The results were not reproduced in a concurrently conducted gavage study in rats at doses up to 1,000 mg/kg/day.

3. Neurotoxicity studies are not available in the database; however, there is no evidence of clinical signs of neurotoxicity in the available studies. Therefore, developmental neurotoxicity study is not required.

4. Immunotoxicity study is not available; however, there is no evidence of immune system involvement in the available studies.

5. In the absence of actual exposure data on (S,S)-EDDS trisodium salt, a highly conservative exposure estimate was utilized thereby reducing uncertainty associated with exposures by infants and children to (S,S)-EDDS trisodium salt.

#### *E. Aggregate Risks and Determination of Safety*

Considering the low toxicity, poor absorption, and rapid biodegradation properties of (S,S)-EDDS trisodium salt, residues of concern are not anticipated from dietary exposures (food and drinking water) or from residential exposures (inhalation and dermal). Utilizing a highly conservative aggregate exposure assessment, EPA has concluded that aggregate exposures to (S,S)-EDDS trisodium salt are more than three orders of magnitude less than the dose at which no adverse effects were seen in the most sensitive animal study and are therefore below the level of concern. In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to (S,S)-EDDS trisodium salt as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by the Office of Pesticide Programs. The Agency has not identified any concern for carcinogenicity related to (S,S)-EDDS trisodium salt.

Taking into consideration all available information on (S,S)-EDDS trisodium salt, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to (S,S)-EDDS trisodium salt under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for

residues of (S,S)-EDDS trisodium salt when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest is safe under FFDC section 408.

#### **V. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An analytical method is not needed for enforcement purposes since the Agency is not 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 (S,S)-EDDS trisodium salt nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

#### **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for (S,S)-EDDS 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.

#### **VII. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of FFDC 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 FFDC, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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 FFDC. 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 the following inert ingredient:

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

\* \* \* \* \*

Inert ingredients	Limits	Uses
(S,S)-Ethylenediamine disuccinic acid trisodium salt (CAS Reg. No. 178949-82-1).		Sequestrant or chelating agent.

[FR Doc. 2011-2399 Filed 2-3-11; 8:45 am]

**BILLING CODE 6560-50-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**46 CFR Part 401**

[Docket No. USCG-2010-0517]

RIN 1625-AB48

**Great Lakes Pilotage: 2011 Annual Review and Adjustment**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is increasing the rates for pilotage service on the Great Lakes to generate sufficient revenue to cover allowable expenses, target pilot compensation, and return on investment. This increase reflects a projected August 1, 2011, increase in benchmark contractual wages and benefits and an adjustment for deflation. This rule promotes the Coast Guard's strategic goal of maritime safety.

**DATES:** This final rule is effective August 1, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2010-0517 and are available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2010-0517 in the "Keyword" box, and then clicking "Search."

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Mr. Paul Wasserman, Chief, Great Lakes Pilotage Division, Commandant (CG-5522), Coast Guard; telephone 202-372-1535, or e-mail [Paul.M.Wasserman@uscg.mil](mailto:Paul.M.Wasserman@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

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**I. Abbreviations**

- AMOU American Maritime Officer Union
- CFR Code of Federal Regulations
- FR **Federal Register**
- GLPAC Great Lakes Pilotage Advisory Committee
- MISLE Marine Information for Safety, and Law Enforcement
- NAICS North American Industry Classification System
- NPRM Notice of Proposed Rulemaking
- NTTAA National Technology Transfer and Advancement Act
- U.S.C. United States Code

**II. Regulatory History**

On August 19, 2010, we published a notice of proposed rulemaking (NPRM) entitled "Great Lakes Pilotage Rates: 2011 Annual Review and Adjustment" in the **Federal Register** (75 FR 51191). We received three comments on the proposed rule. No public meeting was requested and none was held.

**III. Basis and Purpose**

The basis of this rulemaking is the Great Lakes Pilotage Act of 1960 ("the Act") (46 U.S.C. chapter 93), which requires vessels engaged in foreign trade to use U.S. registered pilots while transiting the St. Lawrence Seaway and the Great Lakes system. The Act also requires the Secretary of Homeland Security to "prescribe by regulation rates and charges for pilotage services, giving consideration to the public interest and the costs of providing the services." 46 U.S.C. 9303(f). The Secretary's duties and authority under the Act have been delegated to the Coast Guard, and Coast Guard regulations implementing the Act appear in parts 401 through 404 of Title 46, Code of Federal Regulations (CFR).

The Act requires annual pilotage rate reviews to be completed by March 1 of each year, with a "full ratemaking" to establish new base rates at least once every five years. The purpose of this rulemaking is to comply with 46 U.S.C. 9303(f) by applying the ratemaking methodology described in Appendix C to 46 CFR part 404, which will satisfy the requirement for the annual pilotage rate review for 2011.

**IV. Background**

The U.S. waters of the Great Lakes and the St. Lawrence Seaway are divided into three pilotage districts. Pilotage in each district is provided by an association certified by the Coast Guard Director of Great Lakes Pilotage to operate a pilotage pool. It is