Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the OW Docket Center. This Docket Facility is open from 8:30 a.m. until 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–2426, and the Docket address is OW Docket, EPA West, Room 3334, and 1301 Constitution Avenue, NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: Caroline Whitehead at U.S. EPA Headquarters, Office of Water (4305T), 1200 Pennsylvania Ave, NW., Washington, DC 20460 (telephone: 202–566–2907, fax: 202–566–0409 or e-mail: *whitehead.caroline@epa.gov*) or Denise Hakowski at U.S. EPA Region 3, (3WP30) 1650 Arch Street, Philadelphia, Pennsylvania 19103 (telephone: 215–814–5726, fax: 215–814–2318 or e-mail: *hakowski.denise@epa.gov*).

SUPPLEMENTARY INFORMATION:

I. Potentially Affected Entities

Citizens concerned with water quality in Pennsylvania may be interested in this rulemaking. Entities discharging pollutants to the surface waters of Pennsylvania could be indirectly affected by this rulemaking since water quality standards are used in determining National Pollutant Discharge Elimination System (NPDES) permit limits.

Categories and entities which may ultimately be affected include:

Category	Examples of potentially affected entities.
Industry	Industries discharging pollutants to surface waters in Pennsylvania.
Municipalities	Publicly-owned treatment works discharging pollutants to surface waters in Pennsylvania.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding NPDES-regulated entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action.

II. Today's Action

As EPA explained in its September 15, 2008 notices (73 FR 53140 and 73 FR 53178), EPA proposed to remove the federal regulation that made provisions of the federal antidegradation policy directly applicable in Pennsylvania. EPA proposed to remove the federal rule because Pennsylvania now has an EPA-approved antidegradation policy meeting the federal requirements at 40 CFR 131.12. Therefore, the federal antidegradation regulation promulgated by EPA for Pennsylvania is no longer needed. On September 15, EPA also published a direct final rule to remove the federal regulation at 40 CFR 131.32.

EPA has determined that additional opportunity for public comment would be beneficial. Therefore, EPA is withdrawing the direct final rule (73 FR 53140).

List of Subjects in 40 CFR Part 131

Environmental protection, Antidegradation, Water quality standards.

Dated: November 6, 2008.

Stephen L. Johnson,

Administrator.

■ Accordingly, the amendments to the rule published on September 15, 2008 (73 FR 53140) are withdrawn as of November 14, 2008.

[FR Doc. E8–26952 Filed 11–13–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0250; FRL–8362–4]

Inert Ingredient: Exemption from the Requirement of a Tolerance for (S,S)–Ethylenediaminedisuccinic Acid

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)–Ethylenediaminedisuccinic acid (CAS Reg. No. 20846–91–7) ((S,S)–EDDS) when used as an inert ingredient sequestrant or chelating agent in pesticide formulations applied to growing crops only under 40 CFR 180.920. Associated Octel Company, Limited, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of (S,S)–Ethylenediaminedisuccinic acid.

DATES: This regulation is effective November 14, 2008. Objections and requests for hearings must be received on or before January 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0250. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Karen Samek, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e–mail address: *samek.karen@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2008–0250 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 13, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0250, 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'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 and Statutory Findings

In the **Federal Register** of January 19, 2005 (70 FR 3026) (FRL–7690–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4E6818) by Associated Octel Company, Limited, P.O. Box 17, Oil Sites Road, Ellesmere Port, South Wirral L65 4HF, United Kingdom. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of (S,S)–Ethylenediaminedisuccinic acid (CAS Reg. No. 20846–91–7) when used as an inert ingredient sequestrant or chelating agent in pesticide formulations. That notice provided a summary of studies summated by the petitioner, Associated Octel Company, Limited. There were no comments received in response to the notice of filing. For ease of reading in this document, (S,S)–Ethylenediaminedisuccinic acid is referred to as (S,S)–EDDS.

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(c)(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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 nature of the toxic effects caused by (S,S)–EDDS are discussed in this unit.

The following provides a brief summary of the risk assessment and conclusions for the Agency's review of (S,S)–EDDS. The Agency's full decision document for this action is available in EPA's Electronic Docket at *http://www.regulations.gov* under docket number EPA–HQ–OPP–2007–0250.

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 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 LOAEL is 944.1 milligrams/kilograms, body weight/day (mg/kg bw/day) (16,000 ppm) (limit dose) based on reductions in body weight, body weight gain, feed consumption, and blood levels of zinc, iron, and copper, and the NOAEL is 551.1 mg/kg bw/day (8,000 ppm). The developmental toxicity LOAEL is 944.1

mg/kg bw/day (16,000 ppm) (limit dose) was manifested as 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 VII.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

There are no data provided on (S,S)–EDDS residues in food or on non-occupational exposures to (S,S)–EDDS. In the absence of actual residue data for (S,S)–EDDS, the Agency performed a dietary (food and drinking water) exposure assessment for (S,S)–EDDS in which it was assumed that (a) (S,S)–EDDS would be used as an inert ingredient in all food use pesticide formulations, applied to all crops; (b) one hundred percent of all food crops would be treated with pesticides containing (S,S)–EDDS; (c) (S,S)–EDDS residues would be present in all crops at levels equal to or exceeding the highest established tolerance levels for any pesticide active ingredient, and (d) (S,S)–EDDS would be present in all sources of drinking water at concentrations equal to the highest established standards for drinking water contaminants established by EPA.

This approach is highly conservative as it is extremely unlikely that (S,S)–EDDS would have such use as a pesticide product inert ingredient and be present in food commodities and drinking water at such high levels. In addition, this highly conservative exposure assessment is protective of any possible non-occupational exposures to (S,S)–EDDS as it results in exposure estimates orders of magnitude greater than the high-end exposure estimates for residential uses of pesticides routinely used by EPA.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the 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.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to (S,S)–EDDS and any other substances, and the chemical does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that (S,S)–EDDS has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. EPA concluded that the FQPA safety factor could be removed for (S,S)–EDDS for the following reasons:

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

2. EPA has low concern regarding the potential developmental effects of (S,S)–EDDS. 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 LOAEL is 944.1 mg/kg bw/day (16,000 ppm) (limit dose) based on reductions in body weight, body weight gain, feed consumption, and blood levels of zinc, iron, and copper, and the NOAEL is 551.1 mg/kg bw/day (8,000 ppm). The developmental toxicity LOAEL is 944.1 mg/kg bw/day (16,000 ppm) (limit dose) was manifested as 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 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. In the absence of actual exposure data on (S,S)–EDDS, a highly conservative exposure estimate was utilized thereby reducing uncertainty associated with exposures by infants and children to (S,S)– EDDS.

VII. Determination of Safety for U.S. Population, Infants, and Children

EPA determines whether pesticide chemical exposures are safe by comparing aggregate exposure estimates to the dose at which no adverse effects were seen in the most sensitive animal studies. In the case of (S,S)–EDDS, the estimated exposures are compared to a dose level equal of 551.1 mg/kg/day derived from the rat developmental toxicity study. Utilizing the highly conservative aggregate exposure assessment discussed in Unit IV of this document, EPA has concluded that aggregate exposures to (S,S)–EDDS 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 therefore, are below the level of concern for the entire U.S. population, including infants and children.

Based on this risk assessment, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to residues of (S,S)–EDDS. Accordingly, EPA finds that the tolerance exemption under 40 CFR 180.920 for residues of (S,S)–EDDS will be safe and is granting the requested tolerance exemption.

VIII. Other Considerations

A. Analytical Method

An analytical method is not required for enforcement purposes because the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Tolerances

There are no known international tolerances for residues of (S,S)–EDDS in food or animal feed.

IX. Statutory and Executive Order Reviews

This final rule establishes 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, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

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

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

X. 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: October 31, 2008.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, the table is amended by adding alphabetically the following inert ingredient to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	*	*
(S,S)–Ethylenediaminedisuccinic acid (CAS Reg. No. 20846–91–7)		Sequestrant or chelating agent
* * *	*	*

[FR Doc. E8–26973 Filed 11–13–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1161; FRL–8386–7]

Tetraconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of tetraconazole in or on grape. Interregional Research Project Number 4 (IR–4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 14, 2008. Objections and requests for hearings must be received on or before January 13, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1161. 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