defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: May 12, 2005.

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. Section 180.557 is amended by adding text to paragraph (b) to read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide tetraconazole 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy) propyl]-1H-1,2,4-triazole in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Egg	0.03	12/31/09
Poultry, fat	0.004	12/31/09
Poultry, liver	0.03	12/31/09
Poultry, meat	0.0003	12/31/09
Poultry, meat byproduct, except liver	0.002	12/31/09
Soybean, seed	0.05	12/31/09

* * * * *

[FR Doc. 05–10765 Filed 5–31–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0028; FRL–7713–2]

3-Hexen-1-ol, (3Z)-; 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 cis -3-hexen-1-ol also known as leaf alcohol or 3-hexen-1-ol, (3Z)- (CAS Reg. No. 928–96–1) when used as an inert ingredient - an odorant or alerting agent in certain pesticide formulations. Syngenta Crop Protection, Inc. 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 cis -3-hexen-1-ol.

DATES: This regulation is effective June 1, 2005. Objections and requests for hearings must be received on or before August 1, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0028. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number:

(703) 305–6304; e-mail address: *boyle.kathryn@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 Documents and Other Related Information?

In addition to using EDOCKET at (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of July 16, 2003 (68 FR 42035) (FRL–7316–2), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 3E6589) by Syngenta Crop Protection, Inc, Box 18300, Greensboro, NC 27419.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of cis -3-hexen-1-ol which is also known as leaf alcohol or 3-hexen-1-ol, (3Z)- (CAS Reg. No. 928–96–1). That notice included a summary of the petition prepared by Syngenta Crop Protection, Inc. The notice specifically requested a limited inert ingredient use pattern for cis -3-hexen-1-ol. The petitioner intends to use the cis-3-hexen-1-ol as an odorant or alerting agent to warn pesticide handlers that a pesticide formulation had been or is being used. Syngenta, in that Notice, described their intent to use cis -3-hexen-1-ol in pesticide formulations containing the active ingredient paraquat dichloride and at a concentration not to exceed 4 grams/liter (g/L) in the formulated pesticide product.

One comment was received in response to the notice of filing. The Agency's response to this comment is in Unit X.E.

Section 408(b)(2)(A)(i) of the 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 the 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 the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . . ''

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

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. Physical/Chemical Properties

Consistent with section 408(b)(2)(D) of the 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. The physical/chemical properties of cis-3-hexen-1-ol are given in this unit.

Cis-3-Hexen-1-ol is a six carbon unsaturated alcohol with a molecular formula of $C_6H_{12}O$ and a structural formula of $CH_3CH_2CHCHCH_2CH_2OH$. It is a colorless liquid with a pine needle or grassy odor. Cis-3-Hexen-1-ol is also referred to as leaf alcohol, because of its presence in the fragrance released by green leaves. The vapor pressure of cis-3-hexen-1-ol is estimated as 0.86 millimeter (mm) mercury (Hg). It's solubility in water is greater than 10 g/L at 25°C.

V. Toxicity Profile

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 cis-3-hexen-1-ol are discussed in this unit.

A. Structure Activity Relationship Assessment

For cis-3-hexen-1-ol, toxicity was assessed, in part, by a process called structure-activity relationship (SAR). In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

For cis-3-hexen-1-ol the conclusions of the team performing the SAR assessment are as follows: Cis-3-hexen-1-ol is absorbed via all routes of exposure. There is concern for irritation to all tissues and neurotoxicity based on solvent properties of the material. A concern for liver toxicity based on cis-

3-hexen-1-ol's structural relationship to several long chain alcohols was noted. Various concerns based on the 98–day drinking water study (discussed below) are also noted. The overall rating for human health is low-moderate concern.

Cis-3-Hexen-1-ol is not structurally related to any known mutagens, carcinogens or developmental/reproductive toxicants. The SAR did note a concern for solvent neurotoxicity, i.e., neurotoxic effects that can occur due to ''high'' and/or ''prolonged'' dermal and inhalation exposures to organic solvents. It should be noted that the indication of concerns for solvent-type neurotoxicity in the SAR assessment does not necessarily indicate chemical-specific concerns. By including this statement, those performing the assessment are acknowledging that the chemical is a member of a class of chemicals that can exhibit solvent neurotoxicity.

B. Metabolism of cis-3-Hexen-1-ol

The metabolism of alcohols such as cis-3-hexen-1-ol in the mammalian body is well-understood. The mammalian body would effectively metabolize the alcohol to the corresponding aldehyde, which would then be metabolized to the corresponding carboxylic acid. The mammalian body has well-understood pathways for metabolism of carboxylic acids to carbon dioxide and water.

C. Review of Data from Open Literature

1. *Acute toxicity*. As shown in the following Table, rat and mouse lethal dose $(LD)_{50}$ values range from 7.0 to 10.1 g/kilogram (kg).

ACUTE TOXICITY OF CIS-3-HEXEN-1-OL

Species	Route	Sex	LD_{50} (95% C.I.) (g/kg)
Rat	Oral	Male (M) Female (F)	10.1 (8.4-12.1) 7.3 (5.6-9.5)
Mice	Oral	Male Female	7.0 (5.0-9.6) 7.2 (5.8-9.3)

Signs of toxicity in these oral studies included ataxia, lethargy and comatose-like state. Dermal LD_{50} values of greater than 5,000 milligrams (mg)/kg have been reported for rabbits. No irritation was associated with a 24-hour dermal application of neat (undiluted) cis-3-hexen-1-ol with an occlusive dressing to either intact or abraded rabbit skin. Similarly, human subjects exhibited no signs or symptoms of irritation following a 48-hour dermal exposure to 4% cis-3-hexen-1-ol (in petrolatum) under an occlusive patch. In maximization tests using human volunteers, there was no evidence of sensitization.

2. *Subchronic toxicity*. In a 98–day drinking water study, 15 male and 15 female weanling rats were given cis-3-hexen-1-ol in drinking water at concentration levels of 0, 310, 1,250, or 5,000 parts per million (ppm). The dose levels were calculated as 0, 30, 127, or 410 mg/kg/day (males); and 0, 42, 168, or 721 mg/kg/day (females). There were no effects on food consumption or body weight gain, and no indications of clinical toxicity. Reduced water intake was recorded for high-dose males, which was attributed to reduced palatability. Evidence of a renal effect was observed in high-dose males as shown by increased relative kidney weights and increased specific gravity of urine following water loading challenge. There were also increases in adrenal weights at the high-dose level. High-dose females exhibited transitory anemia (reduced hemoglobin concentration) during the 6th week of treatment. The 1,250 ppm or 127/168 mg/kg/day (M/F) is considered a no observed adverse effect level (NOAEL). The lowest observed adverse effect level (LOAEL) of 5,000 ppm is based on effects to the kidneys, blood and adrenal glands.

D. Conclusions

The mammalian body effectively metabolizes alcohols such as cis-3-hexen-1-ol to the corresponding aldehyde and then to the corresponding carboxylic acid.

The SAR assessment did not identify any concerns for mutagenicity, carcinogenicity or developmental/reproductive toxicity. One of the concerns identified was for possible solvent neurotoxicity. Solvent neurotoxicity concerns usually stem from dermal and inhalation exposures. Exposures generally need to be ''high'' and/or ''prolonged'' for these solvent toxicity effects to occur. Also, for acute exposures, such effects, generally, are reversible. Concerns are for occupational exposures since the potential for day in/day out exposure can occur in the workplace. Such concerns are addressed through product labeling and the use of protective equipment such as gloves and respirators.

Another SAR concern is for irritation to all tissues. However, acute dermal skin irritation and sensitization studies indicate no evidence of sensitization or irritation.

Alcohols, in general, are considered to be hepatotoxic, i.e. impacting the liver. However, the target organs in the 98 day drinking water study were the kidneys, blood and adrenal glands. And, the reduced hemoglobin concentration was transitory, that is, the test animals recovered during the study.

Thus, the mammalian body can effectively metabolize cis-3-hexen-1-ol. It is not acutely toxic. The SAR assessment did not identify any concerns for mutagenicity, carcinogenicity or developmental/reproductive toxicity. The NOAEL in the 98–day drinking water study is 127/168 mg/kg/day (M/F).

The petitioner has proposed to limit the use of cis-3-hexen-1-ol to a concentration not to exceed 4 g/L in the formulated pesticide product. This is equivalent to 0.4%. At this low percentage in the formulated product, the residues from the use of cis-3-hexen-1-ol as an inert ingredient, an odorant or alerting agent, will be much lower than the level at which an adverse effect could occur.

VI. Aggregate Exposures

In examining aggregate exposure, section 408 of the 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).

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.

A. Dietary Exposure

1. *Food*. Cis-3-Hexen-1-ol is naturally-occurring in common food sources such as green leafy vegetables. In fact, low molecular weight alcohols, aldehydes, and acids such as cis-3-hexen-1-ol are ubiquitous in nature, in our foods as the flavors and fragrances which give foods their distinctive tastes. Such chemicals have been detected (at low levels) in almost every known fruit and vegetable. Given the natural occurrence, there is a background (naturally occurring) level of exposure to cis-3-hexen-1-ol, that cannot be regulated and cannot be decreased.

Cis-3-Hexen-1-ol is also used as a direct food additive, a flavoring, under 21 CFR 172.515: Synthetic Flavoring Substances and Adjuvants. In its 1999 evaluation (Food Additives Series 42; see *http://www.inchem.org/documents/jecfa/jecmono/v042je16.htm*.) of the safety of various linear and branched-chain aliphatic, unsaturated chemicals used as flavoring substances, the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Expert Committee on Food Additives estimated the per capita intake of cis-3-hexen-1-ol when used as a food additive. In Europe, the estimate is 71 micrograms (ug)/kg/day. In the US, the estimate is 18 ug/kg/day, or 0.018 mg/kg/day.

Exposure resulting from the use of cis-3-hexen-1-ol at less than 0.4% in the formulated product is anticipated to be much smaller than the naturally occurring background level of exposure, or exposure from its use as a flavoring agent.

2. *Drinking water exposure*. The SAR assessment also estimated the fate properties of cis-3-hexen-1-ol. Based on these properties, the team performing the SAR judged that the potential for cis-3-hexen-1-ol to migrate to ground water as very small. The estimated water solubility of cis-3-hexen-1-ol is greater than 10 g/L. However, based on cis-3-hexen-1-ol's vapor pressure of 0.86 mm Hg, the Agency modeled a volatilization half-life of 39 hours in rivers and 21 days in lakes. Primary biodegradation begins rapidly, within days, as the cis-3-hexen-1-ol is degraded to other chemicals. Based on biodegradation models and on the Agency's professional judgement, cis-3-hexen-1-ol is completely biodegraded to water and carbon dioxide in days to weeks. Given the lack of migration to ground water, the rapid biodegradation (i.e. lack of persistence), and the volatilization of cis-3-hexen-1-ol, significant concentrations of cis-3-hexen-1-ol are very unlikely in sources of drinking water.

B. Other Non-Occupational Exposure

Cis-3-Hexen-1-ol has been used since the 1940s in soaps, detergents, and personal care products. Because it constitutes such a low percentage of the formulation, exposure is likely to be minimal.

Cis-3-Hexen-1-ol is released to the atmosphere from deciduous, coniferous, and herbaceous vegetation, and also agricultural crops. These naturally-occurring emissions vary according to the season, and the maturity of the vegetation, which would include growth stages such as flowering. Again, this is a background (naturally occurring) level of exposure to cis-3-hexen-1-ol, that cannot be regulated and cannot be decreased.

VII. Cumulative Effects

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

Unlike other pesticide chemicals 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 cis-3-hexen-1-ol and any other substances, and cis-3-hexen-1-ol 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 cis-3-hexen-1-ol 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VIII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. 3-Hexen-1-ol, (3Z)- which is also known as cis -3-hexen-1-ol or leaf alcohol (CAS Reg. No. 928-96-1) is naturally-occurring in both the human diet and in the atmosphere. The SAR assessment did not indicate any concerns for developmental or reproductive toxicity. Exposure resulting from the use of 3-hexen-1-ol, (3Z)- at less than 0.4% in the formulated product is anticipated to be much smaller than the naturally occurring background level of exposure. Given the available information on toxicity and exposure, EPA has not used a safety factor analysis to assess the risk of 3-hexen-1-ol, (3Z)-. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Determination of Safety for U.S. Population and Infants and Children

Based on the available information on toxicity and exposure (including the limitation on the amount of 3-hexen-1-ol, (3Z)- that can be used in a pesticide formulation), EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of 3-hexen-1-ol, (3Z)- (CAS Reg. No. 928–96–1). EPA finds that establishing an exemption from the requirement of a tolerance for 3-hexen-1-ol, (3Z)- (CAS Reg. No. 928–96–1) will be safe for the general population including infants and children.

X. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . . '' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this

program, further testing of products containing 3-hexen-1-ol, (3Z)- for endocrine effects may be required.

B. Analytical Method(s)

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

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for 3-hexen-1-ol, (3Z)-.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for 3-hexen-1-ol, (3Z)- nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

E. Public Comment

One comment was received from a private citizen requesting that all pesticides be banned. The Agency understands the commentor's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, under the existing legal framework provided by section 408 of the FFDCA EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The commentor has not provided the Agency with a specific rationale or additional information pertaining to the legal standards in FFDCA section 408 for opposing the establishment of a tolerance exemption for 3-hexen-1-ol, (3Z)-. In the absence of any additional information of a factual nature, the Agency can not effectively respond to the commentor's disagreement with the Agency's decision.

XI. Conclusions

Accordingly, an exemption from the requirement for a tolerance is established for 3-hexen-1-ol, (3Z)- (CAS Reg. No. 928–96–1) with the limitation that not more than 0.4% may be used in the pesticide formulation.

XII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the 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. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0028 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 August 1, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0028, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XIII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this 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). 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.*, or 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). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications '' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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: May 20, 2005.

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 to read as follows:

§ 180.910 Exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * *	*	* *
3-hexen-1-ol, (3Z)- (CAS Reg. No. 928-96-1)	not more than 0.4% of the pesticide formulation.	odorant, alerting agent
* * * *	*	* *

* * * * *

[FR Doc. 05–10846 Filed 5–31–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0115; FRL–7712–1]

Two Isopropylamine Salts of Alkyl C_4 and Alkyl C_{8-10} Ethoxyphosphate esters; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes two exemptions from the requirement of a tolerance for residues of 2-propanamine, compound with α-phosphono- ω -butoxypoly (oxy-1,2-ethanediyl) (2:1) and 2-propanamine, compounds with polyethylene glycol dihydrogen phosphate C_{8-10}- alkyl ether (2:1), referred to as 2 isopropylamine salts of alkyl C_4 and alkyl C_{8-10} ethoxyphosphate esters, when used as inert ingredients (emulsifier, solvent and cosolvent) in pesticide formulations applied only to growing crops. Rhodia, Inc, CN 7500, Cranbury, NJ 08512–7500, 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 these two chemicals.

DATES: This regulation is effective June 1, 2005. Objections and requests for hearings must be received on or before August 1, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0115. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8033; e-mail address: *campbell.princess@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**.

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B. How Can I Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of March 17, 1999 (64 FR 13195) (FRL–6065–5) EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 8E4990 and 8E4956) by Rhodia Inc, CN 7500, Cranbury, NJ 08512–7500.

The petitions requested that 40 CFR 180.1001(d) newly re-designated as 40 CFR 180.920 be amended to include exemptions from the requirement of a tolerance for residues of 2-Propanamine, compound with α-phosphono- ω-butoxypoly (oxy-1,2-ethanediyl) (2:1) (CAS Reg. No. 43140–31–2) and 2-Propanamine, compounds with polyethylene glycol dihydrogen phosphate C_{8-10}- alkyl ether (2:1) (CAS Reg. No. 431062–72–5). The 1999 notice included a summary of the petition prepared by the petitioner requesting, to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for these two chemicals when used as inert ingredients in pesticide formulations applied only to growing crops. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the 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 the 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 the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate