

proposed rule is not subject to any of these requirements.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511)

This rule will not impose additional information collection requirements on the public.

Executive Order 13132, “Federalism”

We have examined the impact of the rule under Executive Order 13132, and it does not have policies that have federalism implications that would 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. Therefore, consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

■ Accordingly, 32 CFR part 199 is amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Section 199.17 is amended by revising the second sentence of paragraph (a)(3), redesignating paragraph (v) as paragraph (w), and by adding a new paragraph (v) to read as follows:

§ 199.17 TRICARE program

* * * * *

(a) * * *

(3) * * * Its geographical applicability is to all 50 states (except as modified for the state of Alaska under paragraph (v) of this section) and the District of Columbia. * * *

* * * * *

(v) *Administration of the TRICARE program in the state of Alaska.* In view of the unique geographical and environmental characteristics impacting the delivery of health care in the state of Alaska, administration of the TRICARE program in the state of Alaska will not include financial underwriting of the delivery of health care by a TRICARE contractor. All other provisions of this section shall apply to administration of the TRICARE program in the state of Alaska as they apply to

the other 49 states and the District of Columbia.

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Dated: August 10, 2010.

Patricia L. Toppings,
OSD Federal Register Liaison Officer,
Department of Defense.

[FR Doc. 2010–20391 Filed 8–17–10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 3 and 165

[Docket No. USCG–2010–0351]

RIN 1625–ZA25

Navigation and Navigable Waters; Technical, Organizational, and Conforming Amendments, Sector Columbia River; Correction

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard published in the *Federal Register* of August 11, 2010, a document concerning non-substantive changes to Title 33 Parts 3 and 165 of the Code of Federal Regulations. That publication contained several errors regarding the name of the Sector that was being disestablished and one being established in its place. In addition, there was an error in amendatory instruction 5. This document corrects these errors.

DATES: This correction is effective August 18, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lt. Matthew Jones, Coast Guard; telephone 206–220–7110, e-mail *Matthew.m.jones@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: In FR doc 2010–19754 appearing on page 48564 in the issue of Wednesday, August 11, 2010, the following corrections are made:

1. In the document heading on page 48564, correct the subject heading to read “Navigation and Navigable Waters; Technical, Organizational, and Conforming Amendments, Sector Columbia River.”

2. On page 48564, in the first column, revise the summary section to read as follows:

“This rule makes non-substantive changes throughout our regulations. The

purpose of this rule is to make conforming amendments and technical corrections to reflect the combination and renaming of Sector Portland and Group/Air Station Astoria to Sector Columbia River as part of the Coast Guard reorganization.”

3. On page 48564, in the second column, revise the discussion of rule section to read as follows:

“This rule revises 33 CFR parts 3 and 165 to reflect changes in Coast Guard internal organizational structure. Sector Portland and Group/Air Station Astoria have been disestablished and Sector Columbia River has been established in their place. The new Sector begins operations on August 23, 2010. This rule revises 33 CFR parts 3 and 165 to reflect the Sector Columbia River and Captain of the Port Zone name change in current regulations. This rule is a technical revision reflecting changes in agency procedure and organization, and does not indicate new authorities nor create any substantive requirements.”

4. On page 48565, in the third column, revise amendatory instruction number 5 to read as follows:

“In § 165.1312(b), remove the phrase “Coast Guard Captain of the Port, Portland” and add, in its place, the phrase “Captain of the Port Columbia River”.”

Dated: August 13, 2010.

Steve Venckus,
Chief, Office of Regulations and Administrative Law, United States Coast Guard.

[FR Doc. 2010–20509 Filed 8–17–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0601 and EPA–HQ–OPP–2008–0602; FRL–8836–3]

2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl; 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 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole (CAS Reg. No. 25973–55–1) and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl; (CAS Reg. No. 23328–53–2) when used as a ultraviolet (UV)

stabilizer at a maximum concentration of 0.6% in insecticide formulations applied pre-harvest to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch under 40 CFR 180.920. Ag-Chem Consulting on behalf of Caltex Inc. 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 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl.

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, 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-2008-0601 and EPA-HQ-OPP-2008-0602. 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: Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0851; e-mail address: sunderland.deirdre@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 cite at <http://www.gpoaccess.gov/ecfr>.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. 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-2008-0601 and EPA-HQ-OPP-2008-0602 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 October 18, 2010. 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 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 numbers EPA-HQ-OPP-2008-0601 and EPA-HQ-OPP-2008-0602, 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 December 3, 2008 (73 FR 73648) (FRL-8391-3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7362 and PP 8E7363) by, Ag-Chem Consulting, 12208 Quinque Lane, Clifton, VA 21024 on behalf of Caltex Inc., 2 Market Street, Sydney, Australia. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole (CAS Reg. No. 25973-55-1) and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl; (CAS Reg. No. 23328-53-2) when used as an inert ingredient as an ultraviolet (UV) stabilizers at a maximum concentration of 0.6% in insecticide formulations applied to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch. That notice referenced a summary of the petition prepared by Ag-Chem Consulting on behalf of Caltex Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own):

Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that

occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The petition provided evidence that Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl is structurally and toxicologically similar to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole. The Agency agrees that data on 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole would represent a worst case scenario for Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl and has, therefore, been used when determining risk associated with the use of both of these chemicals.

Acute studies with 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole revealed low acute toxicity with an oral LD₅₀ >2325 mg/kg. Acute inhalation and dermal studies resulted in LC₅₀ >1,420 mg/m³ and LD₅₀ >2,000 mg/kg,

respectively for analog chemicals. Skin irritation studies with 2-(2'-hydroxy-5'-methylphenyl) benzotriazole (CAS Reg. No. 2440-22-4), an analog chemical, on rats and mice showed no local irritation and no systemic toxicity. 2-(2'-hydroxy-5'-methylphenyl) benzotriazole was found to be slightly irritating to rabbit eyes. Skin sensitization studies with 2-(2'-hydroxy-5'-methylphenyl) benzotriazole in guinea pigs showed skin sensitization; however, studies conducted on humans showed no sensitization.

A 90-day toxicity study in Wistar rats administered 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole through the diet. Thyroid, liver, kidney, spleen, and testes weights were increased in higher exposure groups. The primary target organ was the liver which showed microscopic changes and a greenish-drab discoloration at higher dose levels. Reproductive organs were not evaluated microscopically. Pigmentation was also seen in the proximal tubular cells of females. No mortality was observed. The no-observed-adverse-effect-level (NOAEL) of 20 mg/kg/day is based on liver and kidney effects seen at the lowest-observed-adverse-effect-level (LOAEL) of 40 mg/kg/day.

In a 90-day dog study, Beagles were administered 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole via the diet. Animals in the high-dose group showed decreases in body weight and food consumption, and changes in blood chemistry. Males showed decreases in testes, prostate, and epididymal weights (≥120 mg/kg/day) and females showed decreases in uterus weight (≥60 mg/kg/day). One male dog in the highest dose group died. Histopathologic effects were noted in the liver (the primary target organ), kidney, and testes (≥60 mg/kg/day) groups along with atrophy of uterus, abnormal spermiogenesis, and atrophy of the prostate. Liver damage was observed in a few dogs. The NOAEL was 30 mg/kg/day based on body weight, liver, and kidney effects seen at the LOAEL of 60 mg/kg/day.

Developmental studies have been conducted on two structurally similar chemicals. Rats and mice received the test substance containing 2-(2'-hydroxy-5'-methylphenyl) benzotriazole (CAS Reg. No. 2440-22-4) on days 6-15 of gestation. No maternal toxicity was evident and the rates of implantation and embryotoxicity were not affected by treatment. No teratogenic effects were observed. The NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day (highest dose tested) in mice and rats. A second developmental rat study showed no maternal toxicity at any dose tested for 2-(2H-Benzotriazol-2-yl)-4,6-

bis(1-methyl-1-phenylethyl) phenol (CAS Reg. No. 70321-86-7). A significant reduction in fetal body weight and an increased delay of skeletal maturation was observed in the 1,000 mg/kg/day dose group. However, there were no similar effects in the high dose group indicating that these effects may be "incidental". An omphalocele was seen in one fetus in the high dose group. The maternal toxicity NOAEL was 3,000 mg/kg/day (highest dose tested). A developmental toxicity NOAEL of 1,000 mg/kg/day was chosen based on the omphalocele seen at the LOAEL of 3,000 mg/kg/day.

All genetic toxicity tests (in vitro and in vivo) conducted indicated that this group of chemicals are not mutagenic and will not undergo chromosomal aberrations. No evidence of carcinogenicity was observed in rats when 142 mg/kg/day of 2-(2'-hydroxy-5'-methylphenyl) benzotriazole (CAS Reg. No. 2440-22-4) was administered in the diet for 104 weeks. Negative finding were also seen in rats and mice given up to 62 mg/kg/day for 24 months. No clinical signs of neurotoxicity were seen in any of the repeat dose studies. Therefore, 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl are not expected to be neurotoxic.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level — generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) — and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a

complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

The point of departure for risk assessment for all durations and routes of exposure was from the 90-day toxicity study in rats. The NOAEL was 20 mg/kg/day and the LOAEL was 40 mg/kg/day based on increases in liver, kidney, spleen, and testes weights. Although the chronic point of departure was selected from a subchronic study, longer-term studies are available that shows the lack of toxicity even at higher doses (NOAEL higher than 60 mg/kg/day in carcinogenicity studies on a structurally similar chemical). No additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure. A 1,000 fold uncertainty factor was used for the chronic exposure (10X interspecies extrapolation, 10X for intraspecies variability and 10X FQPA factor for the lack of reproduction studies). The NOAEL of 20 mg/kg/day was used for all exposure duration via dermal and inhalation routes of exposure. The residential, occupational and aggregate level of concern (LOC) is for MOEs that are less than 1,000 and is based on 10X interspecies extrapolation, 10X for intraspecies variability and 10X FQPA factor for the lack of reproduction studies. Dermal absorption is estimated to be 10% based on SAR analysis. A 100% inhalation is assumed.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl in food as follows:

In conducting the chronic dietary exposure assessment, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. The Agency

believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

In the case of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl that may be in formulations (no more than 0.6% by weight in pesticide products applied to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch) and assumed that the 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl are present at the maximum limitation rather than at equal quantities with the active ingredient.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential uses of these chemicals are extremely limited. However, in order to account for all of the current and unanticipated potential residential uses of these chemicals various exposure models were employed. The

Agency believes that the scenarios assessed represent highly conservative worst-case short and intermediate term exposures and risks to residential handlers and those experiencing post-application exposure resulting from the use of indoor and outdoor pesticide product containing these inert ingredients in residential environments. Based on the use pattern the chronic exposure is not anticipated. Therefore, the risk from the chronic residential exposure was not assessed.

Further details of this residential exposure and risk analysis can be found at <http://www.regulations.gov> in the memorandum entitled "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA-HQ-OPP-2008-0710).

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

EPA has not found 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl share a common mechanism of toxicity with any other substances, and 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* 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.

2. *Prenatal and postnatal sensitivity.* Developmental studies have been conducted on two structurally similar chemicals. In one study, no maternal toxicity was evident and the rates of implantation and embryotoxicity were not affected by treatment. No teratogenic effects were observed; however, the study does not specify what developmental endpoints were examined. The NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day (highest dose tested). There was no evidence of increased susceptibility in this developmental toxicity study in rats and mice.

In a second study, no maternal toxicity was observed at any dose tested. The maternal toxicity NOAEL was 3,000 mg/kg/day. The developmental NOAEL was 1,000 mg/kg/day based on omphalocele seen in the one fetus in the high dose group (LOAEL 3,000 mg/kg/day). The data suggest evidence of increased susceptibility in this developmental toxicity study in rats. However, there is a low concern for this susceptibility because this effect (omphalocele) was seen at a very high dose of 3,000 mg/kg/day and only in one fetus. In addition, the study did not provide historical controls that would assist in making determination whether this effect is treatment related or not.

The dietary assessment includes estimates using highly conservative model assumptions. In addition, the drinking water assessment was conducted using the highly conservative value of 100 ppb. These model estimates are highly conservative so as to not underestimate the risk.

3. *Conclusion.* EPA has determined that it does not have reliable data to vary from the default FQPA safety factor of 10X. EPA considered the following factors:

i. The database for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl is incomplete. EPA lacks a 2-generation reproductive study or any study measuring reproductive performance parameters in male and female rats. EPA also does not have an

immunotoxicity study. In a 90-day toxicity study in rats, slight increases in spleen weights without histopathological findings was observed at the highest dose tested (80 mg/kg/day). There was no other evidence of immunotoxicity in the database.

ii. No clinical signs of neurotoxicity were seen in any of the repeat dose studies. Therefore, 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl are not expected to be neurotoxic.

iii. As discussed above, there is low concern for increased sensitivity in the young from exposure to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl.

iv. The dietary assessment includes estimates using highly conservative model assumptions. In addition, the drinking water assessment was conducted using the highly conservative value of 100 ppb. Finally, the model estimates for residential exposure are highly conservative so as to not underestimate the risk. Of principal concern to EPA is the lack of a 2-generation reproductive study or any other study measuring reproductive performance parameters in male and female rats.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure and the use limitation described previously in Unit C, the EPA has concluded that chronic exposure to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl)

benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl from food and water will be 0.3% of the cPAD for US populations and 2.8 % for non-nursing infants, the population group receiving the greatest exposure. Based on its use pattern, chronic residential exposure is not anticipated. Therefore, chronic residential exposure to residues of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl were not assessed.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl could potentially be used as an inert ingredient in pesticide products that may be registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl.

Using the exposure assumptions described in this unit for short-term exposures and the use limitation described previously in Unit C, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 7,100 for adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer in home gardens with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 10,000 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). The EPA's level of concern for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl is for MOEs that are lower than 1,000; therefore, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl could potentially be used as inert ingredients in pesticide products that may be registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 55,000 for adult males and 54,000 for adult females. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate term aggregated food, water, and residential exposures result in an aggregate MOE of 16,000 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). The level of concern is for MOEs that are lower than 1,000; therefore, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl are not expected to be carcinogenic since there was no evidence of carcinogenicity in the available studies.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole or Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl in or on any food commodities. EPA is establishing a limitation on the amount of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole and Phenol, 2-(2H-

benzotriazole-2-yl)-6-dodecyl-4-methyl that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution that contains greater than 0.6% of 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole or Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl by weight in the pesticide formulation.

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole or Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl nor have any CODEX Maximum Residue Levels (MRLs) 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 180.920 for 2-(2'-hydroxy-3', 5'-di-tert-amylphenyl) benzotriazole (CAS Reg. No. 25973-55-1) and Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl; (CAS Reg. No. 23328-53-2) when used as an inert ingredient [as an ultraviolet (UV) stabilizers at a maximum concentration of 0.6%] in insecticide formulations applied to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch.

VII. 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, 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 FFDCFA, 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(m)(4) of FFDCFA. 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).

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: August 9, 2010.

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 ingredients to read as follows:

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

* * * * *

| Inert ingredients | Limits | Uses |
|---|---|-----------------------------|
| 2-(2'-hydroxy-3',5'-di-tert-amylphenyl) benzotriazole (CAS Reg. No. 25973-55-1) | maximum concentration of 0.6% in insecticide formulations applied to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch | Ultraviolet (UV) stabilizer |
| Phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl; (CAS Reg. No. 23328-53-2) | maximum concentration of 0.6% in insecticide formulations applied to adzuki beans, canola, chickpeas, cotton, faba beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch | Ultraviolet (UV) stabilizer |

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[FR Doc. 2010-20299 Filed 8-17-10; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[EPA-HQ-OPP-2009-0046; FRL-8836-4]

N-alkyl (C8-C18) Primary Amines and Acetate Salts; Exemption from the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of N-alkyl (C8-C18) primary amines and acetate salts where the alkyl group is linear and may be saturated and/or unsaturated, herein referred to in this document as NAPAAS, when used as a surfactant and related adjuvants of surfactants for pre-harvest and post-harvest uses under 40 CFR 180.910 and application to animals under 40 CFR 180.930 at a maximum concentration in formulated end-use products of 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products. The Joint Inerts Task Force (JITF), Cluster Support Team Number 25 submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of NAPAAS.

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, 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-2009-0046. 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: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7894; e-mail address: austin.lisa@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 cite at <http://www.gpoaccess.gov/ecfr>. To access the Harmonized Test Guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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. 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-2009-0046 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 October 18, 2010. 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 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-2009-0046, 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 February 4, 2010, (75 FR 5793) (FRL-8807-5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 9E7627) by The JITF, Cluster Support Team 25 (CST 25), c/o CropLife