EPA-approved or conditionally approved are listed along with any limitations on their approval. Examples of EPA-approved documents and materials associated with the SIP include, but are not limited to: SIP Narratives; Particulate Matter Plans; Carbon Monoxide Plans; Ozone Plans; Maintenance plans; Vehicle Inspection and Maintenance (I/M) SIPs; Emissions Inventories; Monitoring Networks; State Statutes submitted for the purposes of demonstrating legal authority; Part D nonattainment area plans; Attainment demonstrations; Transportation control measures (TCMs); Committal measures; Contingency Measures; Non-regulatory and Non-TCM Control Measures; 15% Rate of Progress Plans; Emergency episode plans; and Visibility plans. As stated above, the "non-regulatory" documents are available for public inspection at the appropriate EPA Regional Office.

V. Background

A. Relationship of National Ambient Air Quality Standards (NAAQS) to SIPs

EPA has established primary and secondary National Ambient Air Quality Standards (NAAQS) for six criteria pollutants, which are widespread common pollutants known to be harmful to human health and welfare. The criteria pollutants are: Carbon monoxide; lead; nitrogen oxides; ozone; particulate matter; and sulfur dioxide. See 40 CFR part 50 for a technical description of how the levels of these standards are measured and attained. State Implementation Plans provide for implementation, maintenance, and enforcement of the NAAQS in each State. Areas within each State that are designated nonattainment are subject to additional planning and control requirements. Accordingly, different regulations or programs in the SIP will apply to different areas. EPA lists the designation of each area at 40 CFR part 81.

B. What is a State Implementation Plan?

The State Implementation Plan is a plan for each State that identifies how that State will attain and/or maintain the primary and secondary National Ambient Air Quality Standards (NAAQS) set forth in section 109 of the Clean Air Act and 40 Code of Federal Regulations 50.4 through 50.12 and which includes Federally-enforceable requirements. Each State is required to have a SIP which contains control measures and strategies which demonstrate how each area will attain and maintain the NAAQS. These plans are developed through a public process, formally adopted by the State, and submitted by the Governor's designee to EPA. The Clean Air Act requires EPA to review each plan and any plan revisions and to approve the plan or plan revisions if consistent with the Clean Air Act.

SIP requirements applicable to all areas are provided in section 110. Part D of title I of the Clean Air Act specifies additional requirements applicable to nonattainment areas. Section 110 and part D describe the elements of a SIP and include, among other things, emission inventories, a monitoring network, an air quality analysis, modeling, attainment demonstrations, enforcement mechanisms, and regulations which have been adopted by the State to attain or maintain NAAQS. EPA has adopted regulatory requirements which spell out the procedures for preparing, adopting and submitting SIPs and SIP revisions; these are codified in 40 CFR part 51.

EPA's action on each State's SIP is promulgated in 40 CFR part 52. The first section in the subpart in 40 CFR part 52 for each State is generally the "Identification of plan" section which provides chronological development of the State SIP. Alternatively, if the state has undergone the new Incorporation by Reference formatting process (*see* 62 FR 27968; May 22, 1997), the identification of plan section identifies the State-submitted rules and plan elements that have been Federally approved. The goal of the State-by-State SIP compilation is to identify those rules under the "Identification of plan" section which are currently Federally-enforceable. In addition, some of the SIP compilations may include control strategies, such as transportation control measures, local ordinances, State statutes, and emission inventories. Some of the SIP compilations may not identify these other Federally-enforceable elements.

The contents of a typical SIP fall into three categories: (1) State-adopted control measures which consist of either rules/regulations or source-specific requirements (*e.g.,* orders and consent decrees); (2) State-submitted "non-regulatory" components (*e.g.,* attainment plans, rate of progress plans, emission inventories, transportation control measures, statutes demonstrating legal authority, monitoring networks, etc.); and (3) additional requirements promulgated by EPA (in the absence of a commensurate State provision) to satisfy a mandatory section 110 or part D (Clean Air Act) requirement.

C. What does it mean to be federally-enforceable?

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, EPA is authorized to take enforcement action against violators. Citizens also have legal recourse to address violations as described in section 304 of the Clean Air Act.

When States submit their most current State regulations for inclusion into Federally-enforceable SIPs, EPA begins its review as soon as possible. Until EPA approves a submittal by rulemaking action, State-submitted regulations will be State-enforceable only. Therefore, State-enforceable SIPs may exist that differ from Federally-enforceable SIPs. As EPA approves these State-submitted regulations, the regional offices will continue to update the SIP compilations to include these applicable requirements.

Dated: November 17, 2010.

Lisa P. Jackson,

Administrator.

[FR Doc. 2010–29640 Filed 11–23–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0130; FRL–8851–8]

N,N,N′,N″,-Tetrakis-(2-Hydroxypropyl) Ethylenediamine (NTHE); 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,N,N′,N″,-Tetrakis-(2-Hydroxypropyl) Ethylenediamine (NTHE; CAS no. 102–60–3) when used as an inert ingredient stabilizer for formulation for pre- and post-harvest uses under 40 CFR 180.910 and application to animals under 40 CFR 180.930, at a maximum concentration of 20% by weight in pesticide formulations. The Joint Inerts Task Force (JITF), Cluster Support Team Number 15 (CST 15) EPA Company No. 84947 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 NTHE.

DATES: This regulation is effective November 24, 2010. Objections and requests for hearings must be received on or before January 24, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see* also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0130. 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 site at *http://www.gpoaccess.gov/ecfr.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0130 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 January 24, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0130, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of March 24, 2010 (75 FR 14156) (FRL–8815–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP #0E7683) by The Joint Inerts Task Force (JITF), Cluster Support Team Number 15 (CST 15) EPA Company No. 84947, c/o CropLife America, 1156 15th St., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of NTHE (102–60–3) when used as an inert ingredient stabilizer for formulation in pesticide formulations applied to pre- and post-harvest uses and application to animals at a maximum concentration of 20% by weight in pesticide formulations. That notice referenced a summary of the petition prepared by the Joint Inerts Task Force (JITF), Cluster Support Team Number 15 (CST 15) EPA Company No. 84947, the petitioner, which is available in the docket, *http://www.regulations.gov*. The Agency received one comment in response to the notice of filing. The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

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 NTHE including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with NTHE 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 NTHE 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 existing toxicology database for NTHE consists of one OPPTS Harmonized Guideline 870.3650 (combined repeated dose toxicity study with the reproduction/developmental screening study in rats), a 90-day toxicity study in rats, and several studies in the scientific literature on acute oral toxicity and mutagenicity.

The available toxicity data indicates that NTHE has low acute oral toxicity. NTHE was not mutagenic in an Ames test. In the OPPTS Harmonized Guideline 870.3650 rat reproductive/developmental toxicity screening study, there was no evidence of increased susceptibility. Parental toxicity manifested as microscopic brain lesions at 1000 mg/kg/day (the highest dose tested). No developmental or reproductive effects were observed at doses of 100, 300, and 1000 mg/kg/day. There is no evidence of increased susceptibility to the offspring of rats following prenatal and post-natal exposure in the OPPTS Harmonized Guideline 870.3650 study. There were no offspring effects at any dose level up to the limit dose (1000 mg/kg/day).

In addition, in a 90-day dietary study in rats (1956), where the NOAEL was set at 600–900 mg/kg/day (1% in diet), based on body-weight gain effects at 3% and 5% in the diet and a slightly greater incidence of borderline abnormalities of the liver of questionable significance, there are no other repeat dose toxicity data available. The NOAEL from the OPPTS Harmonized Guideline 870.3650 study (300 mg/kg/day) is protective of any potential liver toxicity.

However, there is suggestive evidence of adverse neurotoxic effects in the adult animal in the OPPTS Harmonized Guideline 870.3650 study at the limit dose of 1000 mg/kg/day. These effects manifested as different sized vacuoles in the choroid plexus epithelial cells (some were signet-ring shaped) of the lateral ventricles of the brain in all high-dose parental male and female rats. None of the low- or mid-dose or control animals showed a similar change.

Pharmacokinetics in rats indicates that, following oral dosing, NTHE is poorly absorbed and rapidly excreted in the urine, mainly unchanged (92%–96%). None of the hypothetical metabolites, such as keto- or N-dealkylated derivatives, were observed. The calculated bioavailability factor (F = 0.018) revealed that less than 2% of the orally administered dose of NTHE is absorbed through the stomach and intestine. The half-life for elimination is 82 minutes (in non-diabetic rats) as a first order process.

There are no chronic toxicity studies available for NTHE. The Agency used a qualitative structure activity relationship (SAR) database, DEREK 11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts were identified. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds.

Specific information on the studies received and the nature of the adverse effects caused by NTHE, as well as, the NOAEL and the lowest-observed adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "N,N,N′,N″,-Tetrakis-(2-Hydroxypropyl) Ethylenediamine (NTHE—JITF CST 15 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations" at pp. 7–11 and 31–34 in docket ID number EPA–HQ–OPP–2009–0130.

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.*

A summary of the toxicological endpoints for NTHE used for human risk assessment is discussed in Unit IV.B. of the final rule published in the **Federal Register** of July 29, 2009 (74 FR 37568) (FRL–8429–3).

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effects attributable to a single exposure of NTHE was seen in the toxicity databases; therefore, an acute exposure assessment for NTHE is not necessary.

ii. *Chronic exposure.* 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). As to residue levels in food, no residue data were submitted for NTHE. 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. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

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

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient. In the case of NTHE, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of NTHE that may be in formulations (no more than 20% by weight in pesticide formulations) and assumed that NTHE is present at the maximum limitation rather than at equal quantities with the active ingredient. This remains a very conservative assumption because surfactants are generally used at levels far below this percentage.

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

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

iii. *Cancer.* The Agency used a qualitative SAR database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified. NTHE is not expected to be carcinogenic. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for NTHE. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for NTHE, 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).

A screening level residential exposure and risk assessment was completed for

products containing NTHE as an inert ingredient. In this assessment, representative scenarios, based on end-use product application methods and labeled application rates, were selected. The Agency did not identify any products intended for use on pets or home cleaning products that contain NTHE. For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation exposure for outdoor scenarios with high exposure potential (*i.e.,* exposure scenarios with high end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing. Similarly, residential post application oral exposure assessments were also performed utilizing high end outdoor exposure scenarios. 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 NTHE to share a common mechanism of toxicity with any other substances, and NTHE does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that NTHE does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

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.* The existing toxicology database for NTHE consists of one OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study with the reproduction/developmental screening study in rats, and several studies in the scientific literature on acute oral toxicity and mutagenicity.

In the case of NTHE, there was no increased susceptibility to the offspring of rats following pre- and post-natal (PND 0–4) exposure in the OPPTS Harmonized Guideline 870.3650 study (gavage dosing of males for 28 days, females for 46 days). There were no offspring effects at any dose level up to the limit dose (1,000 mg/kg/day) where maternal/paternal toxicity was manifested as microscopic lesions in the brain at 1,000 mg/kg/day. Although the parental NOAEL selected as the point of departure for the chronic dietary, incidental oral, and inhalation risk assessments is protective of the adult animal, the particular findings in the parental animals lead to uncertainties for the offspring. There is a concern for neurodevelopment since this is not addressed in the OPPTS Harmonized Guideline 870.3650 screening study.

3. *Conclusion.* Despite the fact that no quantitative or qualitative increased susceptibility to offspring was seen in the OPPTS Harmonized Guideline 870.3650 combined repeated dose toxicity study and the conservative exposure assessment, EPA has determined that the FQPA SF cannot be reduced because of the neurotoxic effects seen in the OPPTS Harmonized Guideline 870.3650 reproductive/developmental study and the absence of standard neurotoxicity and developmental studies. EPA considered the following factors in determining that a 10X FQPA SF should be retained:

In the OPPTS Harmonized Guideline 870.3650 study in rats there is some evidence of neurotoxicity in the adult animals in the OPPTS Harmonized Guideline 870.3650 reproductive/developmental study, which occurred only at the highest dose tested of 1,000 mg/kg/day. The vacuoles in the choroid plexus epithelial cells of the lateral ventricles of the brain were of different size, and some of the epithelial cells were signet-ring shaped. None of the other dose groups (100 and 300 mg/kg/day) showed a similar change. These results indicate a potential concern for effects on neurodevelopment at high doses following repeat exposure. Given that neither neurotoxicity nor standard developmental toxicity studies are available on NTHE, retention of the FQPA Safety Factor is appropriate.

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, NTHE is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to NTHE from food and water will utilize 84% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of NTHE is not expected.

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).

NTHE is currently used as an inert ingredient in pesticide products that are 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 NTHE.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 4,800 and 5,000 for adult males and females, respectively. Adult

residential exposure includes high-end inhalation handler exposure from outdoor uses. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 1,100 for children. Children's residential exposure includes incidental oral exposure from treated turf. Because EPA's level of concern for NTHE is a MOE of 1,000 or below, 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).

NTHE is currently used as an inert ingredient in pesticide products that are 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 NTHE.

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 4,800 and 5,100, for adult males and females, respectively. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 1,200 for children. Children's residential exposure includes incidental oral exposure from treated turf. Because EPA's level of concern for NTHE is a MOE of 1,000 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has not identified any concerns for carcinogenicity relating to NTHE.

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 NTHE residues.

V. Other Considerations

A. Analytical Enforcement Methodology

EPA is establishing a limitation on the amount of NTHE that may be used in pesticide formulations applied to growing crops and raw agricultural commodities. 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 such pesticide for sale or distribution that contains greater than 20% of NTHE by weight in the pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for NTHE.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 and 40 CFR 180.930 for NTHE (102–60–3) when used as an inert ingredient (stabilizer for formulation) in pesticide formulations applied to pre- and post-harvest uses and application to animals at a maximum concentration of 20% by weight in pesticide formulations.

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 FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

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

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 16, 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 § 180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
N,N,N′,N″,-tetrakis-(2-hydroxypropyl) ethylenediamine (102–60–3).	Concentration in formulated end-use products not to exceed 20% by weight in pesticide formulations.	Stabilizer for formulation.
* * *	* * *	*

■ 3. In § 180.930, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
N,N,N′,N″,-tetrakis-(2-hydroxypropyl) ethylenediamine (102–60–3).	Concentration in formulated end-use products not to exceed 20% by weight in pesticide formulations.	Stabilizer for formulation.
* * *	* * *	*

[FR Doc. 2010–29647 Filed 11–23–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0061; FRL–8852–2]

Polyoxyalkylated Glycerol Fatty Acid Esters; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of polyoxyalkylated glycerol fatty acid esters; the mono-, di-, or triglyceride mixtures of C_8 through C_{22}, primarily C_8 through C_{18} saturated and unsaturated, fatty acids containing up to 15% water by weight reacted with a minimum of three moles of either ethylene oxide or propylene oxide, also known as polyoxyalkylated glycerol fatty acid esters, when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Croda Inc., 315 Cherry Lane, Wilmington, DE submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polyoxyalkylated glycerol fatty acid esters; the mono-, di-, or triglyceride mixtures of C_8 through C_{22}, primarily C_8 through C_{18} saturated and unsaturated, fatty acids containing up to 15% water by weight reacted with a minimum of three moles of either ethylene oxide or propylene oxide, also known as polyoxyalkylated glycerol fatty acid esters, when used as an inert ingredient in a pesticide chemical formulation on food or feed commodities.

DATES: This regulation is effective November 24, 2010. Objections and requests for hearings must be received on or before January 24, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (*see also* Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0661. 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: Kerry Leifer, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–8811; *e-mail address: leifer.kerry@epa.gov*.

SUPPLEMENTARY INFORMATION: