EPA-APPROVED IOWA NONREGULATORY PROVISIONS—Continued

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
(25) Letter Pertaining to NO_X Rules and Analysis Which Certifies the Material Was Adopted by the State on October 17, 1990.	Statewide	11/8/90	2/13/91, 56 FR 5757.	
(26) SO_2 Plan	Clinton	3/13/91	11/1/91, 56 FR 56158.	
(27) Letter Withdrawing Variance Provisions.	Polk County	10/23/91	11/29/91, 56 FR 60924.	Correction notice published 1/26/93.
(28) Letter Concerning Open Burning Exemptions.	Statewide	10/3/91	1/22/92, 57 FR 2472.	
(29) Compliance Sampling Manual	Statewide	1/5/93	5/12/93, 58 FR 27939.	
(30) Small Business Assistance Plan.	Statewide	12/22/92	9/27/93, 58 FR 50266.	
(31) Voluntary Operating Permit Program.	Statewide	12/8/94 2/16/96 2/27/96	4/30/96, 61 FR 18958.	
(32) SO_2 Plan	Muscatine	6/19/96 5/21/97	12/1/97, 62 FR 63454.	
(33) SO_2 Maintenance Plan	Muscatine	4/25/97	3/19/98, 63 FR 13343.	
(34) SO_2 Control Plan	Cedar Rapids	9/11/98	3/11/99, 64 FR 12090.	
(35) PM_{10} Control Plan	Buffalo, Iowa	10/1/98	3/18/99, 64 FR 13346.	
(36) CAA 110(a)(2)(D)(i) SIP—Interstate Transport.	Statewide	11/22/06	3/8/07, 72 FR 10380.	
(37) SO_2 Maintenance Plan for the Second 10-year Period.	Muscatine	4/5/07	8/1/07; 72 FR 41900.	
(38) CAA 110(a)(1) and (2)—Ozone Infrastructure SIP.	Statewide	6/15/07	3/04/08; 73 FR 11554.	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0130; FRL–8429–3]

N,N,N′,N″,-Tetrakis-(2-Hydroxypropyl) Ethylenediamine; 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) when used as an inert ingredient for pre-harvest uses under 40 CFR 180.920 at a maximum of 20% by weight in pesticide formulations. The Joint Inerts Task Force (JITF), Cluster Support Team Number 15 (CST 15), 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 NTHE.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

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

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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be

affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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. 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 requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, 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. Background

In the **Federal Register** of April 15, 2009 (74 FR 17487) (FRL–8409-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7531) by JITF, CST 15, c/o CropLife America, 1156 15th St., NW., Suite 400, Washington, DC 20005. The petition requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of the inert ingredient NTHE. That notice referenced a summary of the petition prepared by JITF, CST 15, the petitioner, which is available to the public in the docket, *http://www.regulations.gov*.

The Agency received only one comment in response to the notice of filing. One 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 FFDCA section 408, 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 that statute.

Based upon review of the data supporting the petition, EPA has modified the exemption requested by limiting NTHE to a maximum of 20% by weight in pesticide formulations. This limitation is based on the Agency's risk assessment which 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* in docket ID number EPA–HQ–OPP–2009–0130.

This petition was submitted in response to a final rule published in the **Federal Register** issue of August 9, 2006, (71 FR 45415) (FRL–8084–1) in which the Agency revoked, under FFDCA section 408(e)(1), the existing exemptions from the requirement of a tolerance for residues of certain inert ingredients because of insufficient data to make the determination of safety required by FFDCA section 408(b)(2). The expiration date for the tolerance exemptions subject to revocation was August 9, 2008, which was later extended to August 9, 2009 by a final rule published in the **Federal Register** of August 4, 2008 (73 FR 45312) (FRL–8372–7) to allow for data to be submitted to support the establishment of tolerance exemptions for these inert ingredients prior to the effective date of the tolerance exemption revocation.

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(b)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 the petitioned-for exemption from the requirement of a tolerance for residues of NTHE provided that the concentration of NTHE inerts is limited to no more than 20% by weight in pesticide formulations. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The 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 1,000 milligrams/kilograms/day (mg/kg/day) (the highest dose tested). No developmental or reproductive effects were observed at doses of 100, 300, and 1,000 mg/kg/day. There is no evidence of increased susceptibility to the offspring of rats following prenatal and postnatal exposure in the OPPTS Harmonized Guideline 870.3650 study. There were no offspring effects at any dose level up to the limit dose (1,000 mg/kg/day). In addition, in a 90–day dietary study in rats (1956), where the no-observed-adverse-effect-level (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 1,000 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 indicate 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 Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a benchmark dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-, intermediate-, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the level of concern (LOC).

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 greater than that 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 health risk assessment is shown in Table 1 of this unit.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/Scenario	POD and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations)	No appropriate endpoint was identified for acute dietary assessment. The brain lesions observed following repeat dosing at the limit dose would not be expected to occur following a single exposure.		
Chronic dietary (all populations)	NOAEL= 300 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X	Chronic RfD = 3 mg/kg/day cPAD = 3 mg/kg/day	OPPTS Harmonized Guideline 870.3650 reproduction/developmental screen in rats LOAEL = 1,000 mg/kg/day, based on microscopic lesions (vacuoles in choroid plexus epithelial cells of the lateral ventricles) of the brain in all high-dose animals (both sexes).
Short-Term (1–30 days) Incidental Oral and Inhalation	NOAEL= 300 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X Inhalation hazard assumed to be equivalent to oral hazard	Residential LOC for MOE = 1,000	OPPTS Harmonized Guideline 870.3650 reproduction/developmental screen in rats LOAEL = 1,000 mg/kg/day, based on microscopic lesions (vacuoles in choroid plexus epithelial cells of the lateral ventricles) of the brain in all high-dose animals (both sexes).
Intermediate- and Long-Term (1–6 months and >6 months) Incidental Oral and Inhalation	Oral NOAEL = 300 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 10X Inhalation hazard assumed to be equivalent to oral hazard	Residential LOC for MOE = 1,000	OPPTS Harmonized Guideline 870.3650 reproduction/developmental screen in rats LOAEL = 1,000 mg/kg/day, based on microscopic lesions (vacuoles in choroid plexus epithelial cells of the lateral ventricles) of the brain in all high-dose animals (both sexes).
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment. Based on SAR analysis, NTHE is not expected to be carcinogenic.		

Point of departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed-adverse-effect-level. LOAEL = lowest-observed-adverse-effect-level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a=acute, c=chronic). FQPA SF = Food Quality Protection Act of 1996 Safety Factor. RfD = reference dose. MOE = margin of exposure. LOC = level of concern. SAR = structure activity relationship.

C. Exposure Assessment

Limited information is available on the metabolism and environmental degradation of this compound. The Agency has considered the chemical structure, the submitted physicochemical data, as well as SAR information, to determine the residues of concern for this inert ingredient.

A rat metabolism study showed little absorption, with most of the parent compound excreted unchanged in the urine. Although data on plant metabolism and environmental degradation are not available, any postulated metabolites as a result of dealkylation are likely to be highly water soluble (like the parent) and are not likely to be more toxic than the parent compound. Therefore, a risk assessment based on the toxicity data for the parent compound is not likely to underestimate risk.

Available data indicate that oral absorption of NTHE is low, and dermal absorption is expected to be very low. Low dermal absorption is expected based on its physicochemical properties. Therefore, it is concluded that quantification of dermal risk is not necessary for NTHE.

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to NTHE, EPA considered exposure under the petitioned-for 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 is 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*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for NTHE in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of NTHE. Further information regarding EPA drinking water models used in the pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

A screening level drinking water analysis, based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) was performed to calculate the estimated drinking water concentrations (EDWCs) of NTHE. Modeling runs on four surrogate inert ingredients using a range of physical chemical properties that would bracket those of NTHE were conducted. Modeled acute drinking water values ranged from 0.001 part per billion (ppb) to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in the 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. 11–12 and 36–38 in docket ID number EPA–HQ–OPP–2009–0130.

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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). NTHE may be used as inert ingredients in pesticide products that are registered for specific uses that may result in outdoor residential exposures.

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 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 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 SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF 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 postnatal (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 POD 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 reproduction/developmental 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. A 10X FQPA SF is retained for the following reason:

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 SF is appropriate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest-safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases 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 POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*.There was no hazard attributable to a single exposure seen in the toxicity database for NTHE. Therefore, NTHE is not expected to pose an acute risk.

2. *Chronic risk*. A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for chronic exposure and the use limitations of not more than 20% by weight in pesticide formulations, the chronic dietary exposure from food and water to NTHE is 26% of the cPAD for the U.S. population and 84% of the cPAD for children 1–2 years old, the most highly exposed population subgroup.

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 used as an inert ingredient in pesticide products that are currently 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, EPA has concluded that the combined short-term aggregated 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. As the LOC is for MOEs that are lower than 1,000, 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 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, EPA has concluded that the combined intermediate-term aggregated 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. As the LOC is for MOEs that are lower than 1,000, 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 residues of NTHE.

V. Other Considerations

A. Analytical Enforcement Methodology

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

B. International Residue Limits

The Agency is not aware of any country requiring a tolerance for NTHE nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues.of *N*,*N*,*N*′,*N*″,-tetrakis-(2-hydroxypropyl) ethylenediamine when used as an inert ingredient for pre-harvest uses under 40 CFR 180.920 at a maximum of 20% by weight in pesticide formulations.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances 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) (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: July 21, 2009.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

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

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

* * * * *

Inert Ingredients	Limits	Uses
*	* * * *	
N,*N*,*N*′,*N*″,-tetrakis-(2-hydroxypropyl) ethylenediamine (CAS Reg. No. 102–60–3).	Concentration in formulated end-use products not to exceed 20% by weight in pesticide formulations.	Stabilizer for formulation
*	* * * *	

[FR Doc. E9–17945 Filed 7–28–09; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0131; FRL–8424–6]

Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of alkyl alcohol alkoxylate phosphate derivatives when used as inert ingredients in growing crops under 40 CFR 180.920 and for residues of alkyl alcohol alkoxylate sulfate derivatives when used as inert ingredients in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals under 40 CFR 180.910 and 40 CFR 180.930. The Joint Inerts Task Force (JITF), Cluster Support Team Number 2 (CST 2) 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 alkyl alcohol alkoxylate phosphate and sulfate derivatives.

DATES: This regulation is effective July 29, 2009. Objections and requests for hearings must be received on or before September 28, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0131. 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:

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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

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. 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–2009–0131 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before September 28, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0131, 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. Background

In the **Federal Register** of April 15, 2009 (74 FR 17487) (FRL–8409–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E7533) by JITF, CST 2, c/o CropLife America, 1156 15th St., NW., Suite 400, Washington, DC 20005, The petition requested that 40 CFR 180.910, 40 CFR 180.920, and 40 CFR 180.930 be amended by establishing exemptions from the