

Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: July 14, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. Section 180.1298 is added to subpart D to read as follows:

§ 180.1298 *Trichoderma hamatum* isolate 382; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Trichoderma hamatum* isolate 382 in or on all food commodities when applied as a fungicide and used in accordance with good agricultural practices.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0138; FRL-8825-6]

2-Propanol, 1,1',1''-nitrotriois-; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-Propanol, 1,1',1''-nitrotriois- (TIPA) (CAS No. 122-20-3) when used as an inert ingredient for use as a neutralizer on growing crops and raw agricultural commodities pre- and post-harvest. Dow AgroSciences, LLC 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 TIPA.

DATES: This regulation is effective July 23, 2010. Objections and requests for hearings must be received on or before September 21, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2009-0138. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7894; e-mail address: austin.lisa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at <http://www.gpoaccess.gov/ecfr>. To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/oppts> and select "Test Methods and Guidelines."

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0138 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 September 21, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2009-0138, 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 April 8, 2009 (74 FR 15971) (FRL-8407-4), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7504) by Dow AgroSciences, LLC, 9330 Zionsville Rd, Indianapolis, IN, 46268. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of TIPA (CAS No. 122-20-3) when used as an inert ingredient for use as a neutralizer in pesticide formulations applied to growing crops and raw agricultural commodities pre- and post-harvest. That notice referenced a summary of the petition prepared by Dow AgroSciences, LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

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

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

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

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in section 408(c)(2)(B) of FFDCA, 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 TIPA including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with TIPA 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 TIPA 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.

TIPA has low acute toxicity via the oral and dermal routes. It is moderately irritating to the skin and severely irritating to the eye. It is not a skin sensitizer.

A subchronic study was available in the dog. Following subchronic exposure to TIPA to dogs via the diet, no treatment related effects were noted up to the highest dose tested (288 milligrams/kilograms/day (mg/kg/day)).

A developmental study was available for review (rat) on the surrogate chemical, diisopropanolamine (DIPA). In this study maternal and offspring toxicity were not observed at the highest dose tested (1,000 mg/kg/day).

In a 1-generation reproduction toxicity study in rats with TIPA, no adverse clinical, histological, or reproductive effects were observed at the highest dose tested (M/F: 609/700 mg/kg/day).

Three mutagenicity studies (Ames test, mammalian gene mutation, and chromosome aberration) with TIPA were available for review. The results for these studies were negative.

TIPA is not expected to be carcinogenic since there were no triggers for carcinogenicity in the published study and a lack of systemic toxicity in the 1-generation reproduction study in rats as well as a negative response for mutagenicity. Also, TIPA is not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65.

Metabolism studies demonstrated that TIPA was rapidly and extensively absorbed with a minimum of 83% oral absorption. Virtually the entire absorbed dose was rapidly excreted primarily as unchanged TIPA in the urine of treated rats.

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 TIPA used for human risk assessment is shown in the Table below. The 90-day toxicity study in the dog was selected for all exposure scenarios

and durations for this risk assessment. The rationale for selecting this study is as follows. There was no toxicity observed at the highest dose (272 mg/kg/day) tested in the 90-day dog study. Toxicity was not observed in the 1-generation reproduction toxicity study in the rat at 609 mg/kg/day, the highest dose tested. In a 14-day toxicity study via drinking water, the NOAEL was 1,200 mg/kg/day. Although, the 30-day toxicity study via drinking water in the rat has a NOAEL of 140 mg/kg/day, there is no detail provided for microscopic findings in various organs. In addition, these findings were not reproduced in the 1-generation reproduction toxicity study in the rat. Therefore, less confidence was placed on the 30-day toxicity study in the rat. Finally, based on an EPA retrospective analysis, it was concluded that the 90-day toxicity and the 1-year toxicity studies in the dog are comparable. Therefore, based on the overall weight of evidence, the toxicity study in the dog provided a good basis for establishing the chronic reference dose (cRfD).

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TIPA FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	An acute endpoint was not identified in the database.		
Acute dietary (General population including infants and children)	An acute endpoint was not identified in the database.		
Chronic dietary (All populations)	NOAEL = 272 mg/kg/day UFA = 10x UFH = 10x FQPA SF = 1x	Chronic RfD = 2.72 mg/kg/day cPAD = 2.72 mg/kg/day	90-Day Oral Toxicity-Dog LOAEL = was not established.
Incidental oral short-term (1 to 30 days)	NOAEL = 272 mg/kg/day UFA = 10x UFH = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity-Dog LOAEL = was not established.
Incidental oral intermediate-term (1 to 6 months)	NOAEL = 272 mg/kg/day UFA = 10x UFH = 10x FQPA SF = 1x	LOC for MOE = 100	90 Day Oral Toxicity-Dog LOAEL = was not established.
Dermal short-term (1 to 30 days)	Dermal (or oral) study NOAEL = 272 mg/kg/day (dermal absorption rate = 100%) UFA = 10x UFH = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity-Dog LOAEL = was not established.
Dermal intermediate-term (1 to 6 months)	Dermal (or oral) study NOAEL = 272 mg/kg/day (dermal absorption rate = 100% when appropriate) UFA = 10x UFH = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity-Dog LOAEL = was not established.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR TIPA FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Inhalation short-term (1 to 30 days)	Inhalation (or oral) study NOAEL = 272 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity-Dog LOAEL = was not established.
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL = 272 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity-Dog LOAEL = was not established.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic based on no evidence of increased liver foci in rats and negative genotoxicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose. LOC = level of concern.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effects attributable to a single exposure of TIPA were seen in the toxicity databases. Therefore, an acute dietary risk assessment for TIPA is not necessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used food consumption information from the U.S. 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 TIPA. 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 levels 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 percent 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.

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 percent 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.* TIPA is not expected to be carcinogenic since there were no triggers for carcinogenicity in the published study and a lack of systemic toxicity in the 1-generation

reproduction study in rats as well as a negative response for mutagenicity. Since the Agency has not identified any concerns for carcinogenicity relating to TIPA, a cancer dietary exposure assessment was not performed.

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 TIPA, a conservative drinking water concentration value of 100 parts per billion 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).

TIPA may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure. A screening level residential exposure and risk assessment was completed for products containing TIPA as inert ingredients. The TIPA inerts may be present in consumer personal (care) products and cosmetics (at concentrations up to 1%). The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing TIPA in pesticide formulations (outdoor scenarios) and TIPA in disinfectant-type uses (indoor 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 TIPA to share a common mechanism of toxicity with any other substances, and TIPA does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that TIPA 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 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.* Fetal susceptibility was not observed in either the developmental study with DIPA or the one generation reproduction study with TIPA in the rat. There were no toxic effects observed in parents nor offspring in either study at the highest doses tested, 1,000 and 700 mg/kg/day, respectively. A developmental toxicity study in rabbits is not available in the database. However, the concern for the lack of this study is low because no systemic toxicity was observed at the limit dose in the developmental and reproduction studies in rats (700 mg/kg/day). Also, other studies in the database such as the 90-day toxicity study in the dog and the 14-day toxicity study via drinking water in the rat do not show significant systemic toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for TIPA is adequate.

ii. There is no indication that TIPA is a neurotoxic or immunotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that DIPA or TIPA result in increased susceptibility in *in utero* rats in the prenatal developmental studies or in young rats in the 1-generation reproduction study, respectively.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on the assumptions of 100% crop treated and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to TIPA in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by TIPA.

E. Aggregate Risks and Determination of Safety

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, TIPA 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 TIPA from food and water will utilize 22.9% of the cPAD for children 1 to 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 TIPA 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).

TIPA 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 TIPA.

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 679 for both adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from indoor hand wiping with a high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 337 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for TIPA is a MOE of 100 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).

TIPA 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 TIPA.

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 1,114 for adult males and females. Adult residential exposure includes high end post application dermal exposure from contact with treated lawns. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 387 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). Because EPA's level of concern for TIPA is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* TIPA is not expected to be carcinogenic since there were no triggers for carcinogenicity in the published study and a lack of systemic toxicity in the 1-generation reproduction study in rats as well as a negative response for mutagenicity.

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 TIPA residues.

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 2-Propanol, 1,1',1''-nitrotris- nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for TIPA (CAS No. 122-20-3) when used as an inert ingredient (used as a neutralizer) in pesticide formulations applied to growing crops and raw agricultural commodities pre- and post-harvest without limitation.

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) (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 7, 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 the table in § 180.910, add alphabetically an entry for the following inert ingredient to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
2-Propanol, 1,1',1''-nitritoltris- (CAS No. 122–20–3)	without limitation	neutralizer

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–R03–SFUND–2010–0436; FRL–9177–8]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Letterkenny Army Depot Southeastern (SE) Area and Letterkenny Army Depot Property Disposal Office (PDO) Area Superfund Sites

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region III is publishing a direct final Notice of Deletion of portions of the Letterkenny Army Depot Southeastern (SE) Area and Letterkenny Army Depot Property Disposal Office (PDO) Area (Sites), located in Chambersburg, PA, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final partial deletion is being published by EPA with the concurrence of the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), because EPA has determined that all appropriate response actions at these identified parcels under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, this partial deletion does not

preclude future actions under Superfund.

This partial deletion pertains to the soil and groundwater of parcels 24, 27, 28, 2–53, 2–53L, 2–54, 2–54L, 2–70, 2–70L, 3–89, 3–90, and 3–91. All other parcels within the site boundaries of Letterkenny Army Depot SE and PDO Areas will remain on the NPL and are not being considered for deletion as part of this action.

DATES: This direct final partial deletion is effective September 21, 2010 unless EPA receives adverse comments by August 23, 2010. If adverse comments are received, EPA will publish a timely withdrawal of the direct final partial deletion in the **Federal Register** informing the public that the partial deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID no. EPA–R03–SFUND–2010–0436, by one of the following methods:

- <http://www.regulations.gov>. Follow on-line instructions for submitting comments.
- *E-mail:* hoover.gerald@epa.gov.
- *Fax:* (215) 814–3025, Attn: Gerald Hoover.
- *Mail or Hand Delivery to:* U.S. Environmental Protection Agency, Region III, Attn: Gerald Hoover (3HS11), 1650 Arch Street, Philadelphia, PA 19103–2029. Phone: (215) 814–2077. Business Hours: Mon. thru Fri.—9 a.m. to 4 p.m.

Instructions: Direct your comments to Docket ID no. EPA–R03–SFUND–2010–0436. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you

consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or at:

U.S. EPA Region III, Library, 2nd Floor, 1650 Arch Street, Philadelphia, PA, 19103–2029. Phone: (215) 814–5254. Business Hours: Mon. thru Fri.—8 a.m. to 5 p.m.

Letterkenny Army Depot, Building 14, Chambersburg, PA 17201–4150. POC: Bryan Hoke. Phone: 717–267–9836.