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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8877–1]

Diethylene Glycol MonoEthyl Ether (DEGEE); 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 Diethylene Glycol MonoEthyl Ether (DEGEE) when used as an inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products, for preharvest use on growing crops and raw agricultural commodities, without limitation. Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DEGEE on growing crops and raw agricultural commodities.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0474. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Lisa Austin, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 305–7894; *e-mail address: austin.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0474 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 August 22, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2008–0474, 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 July 9, 2008 (73 FR 39291) (FRL–8371–2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 8E7355) by Huntsman, 10003 Woodloch Forest Drive, The Woodlands, TX 77380; Dow AgroSciences L.L.C., 9330 Zionsville Road, Indianapolis, Indiana 46268; Nufarm Americas Inc., 150 Harvester Drive, Suite 220, Burr Ridge, Illinois, 60527; BASF, 26 Davis Drive, Research Triangle Park, NC 27709; Stepan Company, 22 W. Frontage Road, Northfield, IL 60093; Loveland Products Inc., PO Box 1286, Greeley, CO 80632; and Rhodia Inc., CN 1500, Cranbury, New Jersey, 08512. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of DEGEE (CAS Reg. No. 111–90–0) when used as an inert ingredient, as a solvent, stabilizer and/or antifreeze

in pesticide formulations applied to growing crops and raw agricultural commodities pre-harvest without limitation. That notice referenced a summary of the petition prepared by Huntsman, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc., the petitioners, which is available in the docket, *http://www.regulations.gov.* The Agency received one comment in response to the notice of filing.

Currently, there is a tolerance exemption for DEGEE under 40 CFR 180.920 when it is used as a deactivator for formulations used before the crops emerge from the soil and stabilizer. This document provides an assessment of the risk to human health and the environment for DEGEE when used as a pesticide inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for DEGEE including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with DEGEE 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 DEGEE as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The following toxicity data on DEGEE were summarized from these sources, the World Health Organization (WHO), National Toxicology Program (NTP), Hazardous Substances Data Base (HSDB) and BIBRA Toxicology Advisory and Consulting (1976, 2003, respectively). DEGEE has low acute toxicity via oral and dermal routes. It is moderately irritating to the skin and is mildly irritating to the eye. It is not a skin sensitizer.

Several subchronic studies with DEGEE were available in rodents, ferrets and pigs. In rodents, toxicity was primarily manifested in the kidneys and liver. Increased kidney weights, tubular dilatation and centrilobular hepatocyte enlargement were seen at doses > 2,500 milligrams/kilogram/day (mg/kg/day). In ferrets, effects in the kidney were also observed. The concentrating power of the kidney was decreased and water intake was decreased at > 2.0 milliliter (mL)/kg/day (2,240 mg/kg/day). Kidney and liver effects were also observed in pigs. Kidney weights were increased, tubular hydropic degeneration and enlarged centrilobular and midzonal hepatocytes with pyknotic nuclei and fatty infiltration were observed at > 500 mg/kg/day.

A subchronic inhalation study with DEGEE in the rat was also available. No effects were observed at doses up to 1.1 milligrams/liter (mg/L) (approximately 314 mg/kg/day).

Several chronic carcinogenicity studies with DEGEE were available in rodents. However, these studies were conducted with a limited number of animals and doses and a complete histopathological examination was not performed. Due to these deficiencies, a definitive conclusion regarding carcinogenicity of DEGEE cannot be made on the basis of these studies. However, there were no obvious tumors detected in mice and rats.

Developmental studies with DEGEE in rodents were available for review. Fetal susceptibility was not observed in these studies. Parental (mortality and reduced body weight) and offspring (reduced mean pup birth weight) toxicity were observed in mice at the high dose (2,500 mg/kg/day). In a developmental toxicity study in rats via the dermal route of exposure, maternal toxicity was manifested as decreased body weight at 6,615 mg/kg/day. Developmental toxicity was not observed at this dose. In an inhalation developmental toxicity study in rats, maternal and developmental toxicity were not observed up to 100 parts per million (ppm) (approximately 31 mg/kg/day).

Two reproduction toxicity studies were available for review with DEGEE in rodents. One study in rats reported that increased urinary protein, bladder calculi, epithelial necrosis of the renal

tubules and cloudy swelling of hepatic tissue were observed in all animals at 920 mg/kg/day of DEGEE with less than 0.2% of ethylene glycol. The NOAEL in this study was 200 mg/kg/day. In another study in mice, offspring toxicity (decreased live pup weights, decreased absolute brain and liver weights) and parental toxicity (increase water intake and decreased body weight in males) occurred at 2,500 mg/kg/day. There were no effects on reproductive parameters in either study.

Several mutagenicity studies (Ames test, micronucleus assay and unscheduled DNA synthesis) with DEGEE were available for review. One Ames test reported ambiguous results, another reported positive results at high doses. However, *in vivo* assays (micronucleus and unscheduled DNA synthesis) reported negative results. Therefore, based on the weight of evidence, DEGEE is not considered mutagenic.

As noted, available long-term carcinogenicity studies were considered inadequate to fully assess DEGEE's potential to cause cancer; however, these studies in mice and rats do not report any tumors. DEGEE belongs to the glycol ether class of chemicals which include structurally similar chemicals ethylene glycol (EG) and diethylene glycol (DEG). EG and DEG have toxicities similar to DEGEE. Target organs of toxicity are the kidney and liver. There was no evidence of carcinogenicity in rats and mice when treated with EG (NTP). Bladder tumors were observed in rats treated with DEG at >1,500 mg/kg/day, however, these tumors were secondary to irritation from bladder stones. The resulting classification for EG and DEG was that they are not expected to pose a carcinogenic risk in humans. Therefore, the carcinogenicity data on EG and DEG were used to assess the cancer potential of DEGEE. Based on the lack of evidence of carcinogenicity potential for EG and DEG, lack of tumors in mice and rats with DEGEE, and the fact that DEGEE is not mutagenic, DEGEE is not expected to be carcinogenic to humans. Also, the established chronic reference dose/chronic population adjusted dose (cRfD/cPAD) (2.0 mg/kg/day) for DEGEE will be protective of effects leading to kidney damage and tumor formation seen at >1,500 mg/kg/day following DEG exposures.

Immunotoxicity studies for DEGEE were not available for review. However, DEGEE belongs to the glycol ethers class of chemicals. Immunotoxicity studies were available for ethylene glycol mono butyl ether (DEGBE), also a glycol ether differing in only one ethyl and butyl group from DEGEE. These data were used to assess the immunotoxic potential of DEGEE. Signs of potential immunotoxicity were not observed in any of the available studies for the surrogate chemical. Nor was there evidence of immunotoxicity potential in any of the studies submitted for DEGEE. Therefore, DEGEE is not expected to be immunotoxic.

Dermal absorption studies were available with DEGEE. In a study using human epidermal membranes, the absorption rate of DEGEE was 0.206 mg/cm^2/hr.

The available metabolism data in an adult human revealed that 68% of the administered dose of DEGEE was excreted in the urine as (2-ethoxy) acetic acid. In a metabolism study in the rabbit, oral or subcutaneous exposure to DEGEE resulted in the excretion of glucuronic acid in the urine; the major part of the dose was oxidized.

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 DEGEE used for human risk assessment is shown in the following table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DEGEE 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 general population including Females 13–50 years of age.	An acute endpoint was not identified in the database.		
Chronic dietary (All populations)	NOAEL = 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	Chronic RfD = 2.0 mg/kg/day cPAD = 2.0 mg/kg/day.	Reproduction Toxicity Study with chronic/ carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DEGEE 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
Incidental oral short-term (1 to 30 days).	NOAEL= 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 200 mg/kg/day ..... UF_A = 10x UF_H = 10 x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Dermal short-term (1 to 30 days) ..	NOAEL= 200 mg/kg/day (dermal absorption rate = 25%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Dermal intermediate-term (1 to 6 months).	NOAEL= 200 mg/kg/day (dermal absorption rate = 25% when appropriate). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Inhalation (1 to 6 months)	Inhalation (or oral) study NOAEL = 200 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Reproduction Toxicity Study with chronic/carcinogenicity measurements—rat LOAEL = 920 mg/kg bw/day, based on decreased growth, epithelial necrosis of renal tubules and cloudy swelling of hepatic tissue.
Cancer (Oral, dermal, inhalation) ..	Based on the lack of tumors in a study with DEGEE and carcinogenicity data available for the structurally similar chemicals, EG and DEG, and that DEGEE is not mutagenic, DEGEE is not expected to be carcinogenic to humans.		

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 (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effects attributable to a single exposure of DEGEE were seen in the toxicity databases. Therefore, an acute dietary exposure assessment for DEGEE 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 DEGEE. 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.* As discussed above, the Agency has not identified any concerns for carcinogenicity relating to DEGEE, and, therefore, a dietary exposure assessment to assess cancer risk is unnecessary.

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 DEGEE, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

DEGEE 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 DEGEE as inert ingredients. 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 DEGEE in pesticide formulations (Outdoor Scenarios) and DEGEE in disinfectant-type uses (Indoor Scenarios). The Agency is not aware of any use of DEGEE in hard surface cleaning products. However, this scenario was used for this assessment considering wide use of DEGEE in other products. Therefore, the Agency assessed the disinfectant-type products containing DEGEE using exposure scenarios used by the Antimicrobials Division in EPA's Office of Pesticide Programs to represent worst-case residential handler exposure. 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.

In addition to pesticidal uses for DEGEE, there are non-pesticidal uses for DEGEE. However, dermal and inhalation exposure are expected to be negligible; therefore, a quantitative exposure assessment was not conducted.

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 DEGEE to share a common mechanism of toxicity with any other substances, and DEGEE does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that DEGEE does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to

evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fetal susceptibility was not observed in the developmental toxicity studies with DEGEE in the mouse. Developmental studies were available via the oral (mice), dermal (rats) and inhalation (rats) routes of exposure in rodents. Following oral exposure to DEGEE, maternal (mortality and reduced body weight) and offspring (reduced mean pup birth weight) toxicity were observed in mice at the high dose (2,500 mg/kg/day). Following dermal exposure to DEGEE, maternal toxicity was manifested as decreased body weight at 6,615 mg/kg/day in rats. Developmental toxicity was not observed at this dose. Following inhalation exposure to DEGEE, maternal and developmental toxicity were not observed up to 100 ppm (approximately 31 mg/kg/day) in rats. A developmental toxicity study in rabbits is not available in the database. However, the concern for the lack of this study is low because toxicity was observed near the limit dose in the developmental and reproduction studies in rodents (>920 mg/kg/day).

Evidence of increased fetal susceptibility was observed in a reproduction toxicity study in the mice. Offspring toxicity was manifested as decreased adjusted live pup weight and absolute brain weights and increased liver weights in the absence of parental toxicity. There is no concern for this increased susceptibility in mice because these pup effects were observed at a dose 2.5 times above the limit dose of 1,000 mg/kg/day and a clear NOAEL was established in the study. It is unclear if there is fetal susceptibility in the reproduction toxicity study in rats. In this study, it was stated that increased urinary protein, bladder calculi, epithelial necrosis of the renal tubules and cloudy swelling of hepatic tissue were observed in all animals at 920 mg/kg/day (NOAEL 200 mg/kg/day). It is not clear whether all animals referred in the study include both the parental and F1 animals or not. However, in any case the concern for fetal susceptibility is low because the aforementioned effects occured near the limit dose and the cRfD (2.0 mg/kg/day) will be protective of these effects.

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 DEGEE is adequate for FQPA assessment. The following acceptable studies are available: Developmental and reproduction toxicity studies in mice and rats, subchronic and mutagenicity studies. A 2-generation reproduction toxicity study where tumors were evaluated is available. Also, chronic/carcinogenicity studies are available on a surrogate chemical, ethylene glycol. A developmental toxicity study in rabbits is not available in the database. However, the concern for the lack of this study is low because toxicity was observed at or above the limit dose in the developmental and reproduction studies in rodents.

ii. Signs of neurotoxicity were not observed in a reproduction toxicity study in rats. Decreased absolute brain weights were observed in the offspring at 2,500 mg/kg/day. However, a developmental neurotoxicity study is not required because decreased brain weights were observed above the limit dose (1,000 mg/kg/day), the effect occurred in the presence of maternal toxicity and the cRfD (2.0 mg/kg/day) will be protective of this effect. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence that DEGEE results in increased fetal susceptibility in the multi-generation reproduction study in the mouse. However, the concern for fetal susceptibility is low because the effects seen in the offspring (adjusted live pup weight and absolute brain weights and increased liver weights) occur at 2,500 mg/kg/day (2.5times the limit dose), the effects occur in the absence of maternal toxicity, a clear NOAEL (1,250 mg/kg/day) was established and the cRfD (2.0 mg/kg/day) will be protective of these effects.

iv. Immunotoxicity studies for DEGEE were not available for review. However, DEGEE belongs to the glycol ethers class of chemicals. Immunotoxicity studies were available for ethylene glycol monobutyl ether, also a glycol ether. This data were used to assess the immunotoxic potential of DEGEE. Signs of potential immunotoxicity were not observed in any of the available studies for the surrogate chemical. Nor was there evidence of immunotoxicity potential in any of the studies submitted for DEGEE. Therefore, DEGEE is not expected to be immunotoxic.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to DEGEE 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 DEGEE.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, DEGEE 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 DEGEE from food and water will utilize 0.10% of the cPAD for the general U.S. population and 0.31% 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 DEGEE 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).

DEGEE 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 DEGEE.

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 264 for both adult males and females, respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 228 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 DEGEE 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).

DEGEE 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 DEGEE.

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 777 for adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from homeowner mixer/loader/applicators using a trigger sprayer with a 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 267 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 DEGEE is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* DEGEE is not expected to pose a carcinogenic risk in humans based on the discussion in Unit IV.A.

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 DEGEE 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

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

The Codex has not established a MRL for DEGEE.

C. Response to Comments

The comment was received from private citizens who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for DEGEE (CAS Reg. No. 111–90–0) when used as an inert ingredient (as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation) in pesticide formulations applied to growing crops and raw agricultural commodities pre-harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such,

the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 10, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

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

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* * *
Diethylene Glycol MonoEthyl Ether (CAS Reg. No. 111–90–0).	Without limitation	Solvent, stabilizer and/or antifreeze.
* * *	* *	* * *

[FR Doc. 2011–15266 Filed 6–21–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0517; FRL–8876–2]

C_9 Rich Aromatic Hydrocarbons, $C_{10–11}$ Rich Aromatic Hydrocarbons, and $C_{11–12}$ Rich Aromatic Hydrocarbons; 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 C_9 rich aromatic hydrocarbons; $C_{10–11}$ rich aromatic hydrocarbons; and $C_{11–12}$ rich aromatic hydrocarbons, when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. ExxonMobil Chemical Company 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 C_9 rich aromatic hydrocarbons, $C_{10–11}$ rich aromatic hydrocarbons, and $C_{11–12}$ rich aromatic hydrocarbons.

DATES: This regulation is effective June 22, 2011. Objections and requests for hearings must be received on or before August 22, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2011–0517. 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: