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

■ 2. In §180.910, the table is amended by adding alphabetically the following inert ingredients to read as follows:

§ 180.910 N-alkyl (C8-C18) primary amines and accetate salts; Exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
N-alkyl (C8-C18) primary amines and their acetate salts where the alkyl group is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 61790-57-6, 61790-58-7, 61790-59-8, 61790-60-1, 61788-46-3, 61790-33-8, 68155-38-4)	Concentration in formulated end-use products not to exceed 10% by weight in herbicide products, 4% by weight in insecticide products, and 4% by weight in fungicide products.	Surfactants, related adjuvants of surfactants
* * *	* * *	*

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

§ 180.930 N-alkyl (C8-C18) primary amines and accetate salts; Exemption from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
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* * *	* * *	*

[FR Doc. 2010–20300 Filed 8–17–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8838–9]

Diethylene Glycol (DEG); 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 (DEG) (CAS No. 111–46–6) when used as an inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations without limitation, under 40 CFR 180.920, for use on growing crops and raw agricultural commodities pre-harvest 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 DEG.

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0474. 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 cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS 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–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 October 18, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–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 39289) (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, Dow AgroSciences L.L.C., Nufarm Americas Inc., BASF, Stepan Company, Loveland Products Inc., and Rhodia Inc. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of DEG (CAS No. 111–46–6) when used as an inert ingredient for use as a solvent, stabilizer and/or antifreeze without limitation in pesticide formulations applied to use on growing crops and raw agricultural commodities pre-harvest. 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. The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of FFDCA, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

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

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

Consistent with section 408(c)(2)(A) of FFDCA, and the factors specified in FFDCA section 408(c)(2)(B), EPA has

reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for DEG including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with DEG 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 DEG 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.

DEG has low acute toxicity via the oral route in animals. It has low acute toxicity via the dermal route. Data were not available regarding dermal irritation and sensitization. Data on humans show that the probable LD_{50} of DEG is approximately 0.5-5 gram/kilogram (g/kg) and that it is not irritating to the eyes or skin. However, a man developed allergic dermatitis 2–4 weeks after smoking cigarettes containing DEG. He also had a local reaction in a 24 hours covered patch test with DEG.

In subchronic oral studies in animals, the kidney, liver and hematopoietic systems were most often the target organs. In subchronic studies, males were more susceptible to kidney toxicity. Kidney lesions occurred in the range of 100 to 180 milligrams/kilograms/day (mg/kg/day) and were manifested as tubular damage. DEG caused increased size and hydropic changes in the liver and oxalate crystals were found in the urinary bladder and kidney at >100 mg/kg/day. The NOAEL for DEG in the subchronic rat study was 50 mg/kg/day, based on increased urinary oxalate at 100 mg/kg/day. Some subchronic studies available in the literature show kidney toxicity at very high doses. In addition, kidney toxicity was only evident at very high doses in chronic studies.

Several developmental studies in rodents were available for review. In these studies, maternal and developmental toxicity occurred at doses (> 1,118 mg/kg/day) that were above the limit dose of 1,000 mg/kg/day. Two reproduction toxicity studies in rodents were available for review. Again, maternal and offspring toxicity was observed at high doses (> 1,500 mg/kg/day).

Several mutagenicity studies (Ames test and chromosome aberration) with DEG were available for review. The TA104 strain was slightly positive in one assay with metabolic activity. All *in vivo* assays were negative. Therefore, based on the overall weight of evidence, DEG is not considered mutagenic.

In chronic oral studies, the kidney, liver and hematopoietic systems were most often the target organs. In chronic studies, kidney neuropathy occurred at dosages of greater than 920 mg/kg/day and was manifested as epithelial necrosis of the renal tubules. Bladder tumors were observed at > 1,500 mg/kg/day; however, these tumors were associated with irritation from bladder stones. The physiochemical properties of DEG cause crystal formation and deposition in the kidneys which leads to irritation, stone formation, kidney damage and tumor formation. Therefore, protecting from crystal formation would be protective of subsequent kidney damage and tumor formation. Also, a Soviet study reported no evidence of cancer in a group of 90 workers exposed to DEG for 1 to 9 years. In addition, DEG is not listed as a carcinogen byAmerican Conference of Industrial Hygienist,(ACGIH), International Agency for Research on Cancer (IARC), National Toxicology Program,(NTP) or California Proposition 65.

Metabolism studies demonstrated that DEG was rapidly absorbed and primarily excreted via the urine.

B. Toxicological Points of Departure/Levels of Concern

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

The available toxicity studies suggest that the DEG manifested toxicity appears to occur following high repeated doses. In developmental toxicity study in rats, mice and rabbits, the clear NOAELs were observed at doses 559 mg/kg/day and above. In reproduction studies in mice and rats, the lowest NOAEL was 300 mg/kg/day (highest dose tested) and one study in mice had a NOAEL of 610 mg/kg/day with a LOAEL of 3,060 mg/kg/day. The NOAEL for carcinogenicity studies in rats was 1,000 mg/kg/day and above. One chronic toxicity study in rats had a LOAEL of 1,000 mg/kg/day. The subchronic studies gave confounding results in terms of NOAEL for the study. In a subchronic study in rats (feeding), the reported NOAEL was 400 mg/kg/day and the second study in rats reported the NOAEL of 50 mg/kg/day. However, in other studies reported in the literature, no overt toxicity was observed in 20 mice/sex maintained on a diet containing 5.2 g/kg bw/day for 15 to 18 weeks. Kidney and liver damage occurred in rabbits given DEG by gavage or in drinking water at about 15 gram/kilograms bodyweight/day (g/kg bw/day) for up to 28 days, and also in guinea-pigs, cats and dogs subjected to similar exposures. Based on the overall weight of evidence from all studies, a NOAEL of 100 mg/kg/day is considered protective for DEG-mediated toxicity for estimating risk via all routes of exposure. In the absence of inhalation studies, 100% inhalation is assumed. The dermal absorption factor of 25% was estimated based on dermal absorption of structurally similar compound for converting oral to dermal equivalent dose.

Bladder tumors were observed following treatment with DEG at doses > 1,500 mg/kg/day. However, these tumors appear to be secondary to irritation and regenerative proliferation associated with the formation of urinary tract crystals/calculi. This is commonly seen for bladder carcinogenesis in rodents for non-genotoxic chemicals of the sulfonamide class. Since DEG presents no concern for mutagenicity and based on knowledge about other chemicals, EPA considers DEG as not

likely to be a human carcinogen. The cRfD (1.0 mg/kg/day) was established based on these precursor effects observed at >300 mg/kg/day. Therefore, the cRfD is considered adequately protective of any cancer or pre-cancerous effects seen in the carcinogenicity studies.

C. Exposure Assessment

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

i. *Acute exposure.* No adverse effects attributable to a single exposure of DEG were seen in the toxicity databases. Therefore, an acute dietary risk assessment for DEG 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 DEG. 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 in this unit, the Agency has not identified any concerns for carcinogenicity relating to DEG, 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 DEG, 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).

The term "'residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). DEG 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 DEG as inert ingredients. The DEG inerts may be present in consumer personal (care) products and cosmetics. 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 DEG in pesticide formulations (Outdoor Scenarios) and DEG in disinfectant-type uses (Indoor Scenarios). The Agency is not aware of any use of DEG in hard surface cleaning products. However, this scenario was used for this assessment considering wide use of DEG in other products. Therefore, the Agency assessed the disinfectant-type products containing DEG 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.

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 DEG to share a common mechanism of toxicity with any other substances, and DEG does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that DEG 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 Food Quality Protection Act (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*. There was no evidence of increased susceptibility of infants and children following prenatal exposure to DEG in mice, and rabbits. In mice and rabbits, the maternal or developmental toxicity were seen at or above the limit dose except in one study in mice where the maternal toxicity NOAEL was 559 mg/kg/day and developmental toxicity NOAEL was 2,759 mg/kg/day. In these studies with mice and rabbits, developmental effects were observed in the presence of maternal toxicity or at a dose above the dose that produced maternal toxicity. There was some evidence of increased susceptibility in the rat developmental toxicity study. In the rat developmental toxicity study, the maternal NOAEL was 4,472 mg/kg/day and the developmental NOAEL was 1,178 mg/kg/day. However, the concern for this increased susceptibility was low since the skeletal variations were seen at dose level above the limit dose.

Several reproduction studies are available in the database. The effects seen in these studies are characterized as high dose effects. There was no evidence of increased susceptibility of infants and children following prenatal and postnatal exposure to DEG in mice and rats except in one study in mice. In one reproduction study in mice (drinking water), the NOAEL for developmental toxicity was 610 mg/kg/day and the LOAEL was 3,060 mg/kg/day. The maternal toxicity NOAEL in the mice reproduction was 2,060 mg/kg/day. The reproduction study in mice suggest some evidence of increased susceptibility, however, the concern is low because the developmental effects were seen at 3 times higher dose than the limit dose of 1,000 mg/kg/day. Overall, based on available data in mice, rats and rabbits, the concern for isolated susceptibility is low because the increased susceptibility was seen at or above the limit dose and they were not reproduced in other studies conducted in same species.

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 DEG is adequate. The following acceptable studies are available: Developmental toxicity studies in mice, rats and rabbits, reproduction study in mice and rats and subchronic and chronic studies including carcinogenicity studies and mutagenicity studies.

ii. Clinical signs of neurotoxicity were reported in acute studies conducted at very high doses. However, no significant clinical signs were observed in repeated dose studies and no increased susceptibility was seen in the available developmental or reproduction studies at doses below the limit dose of 1,000 mg/kg/day. Based on overall weight of evidence, EPA concluded that the developmental neurotoxicity is not required.

iii. There was no evidence of increased susceptibility of infants and children following prenatal exposure to DEG in mice, and rabbits.

The developmental study in the rat and reproduction study in mice suggest some evidence of increased susceptibility of infants and children, however, the concern is low because the developmental effects were seen at higher doses than the limit dose of 1,000 mg/kg/day and there is a clear NOAEL established in these studies. Overall, based on available data in mice, rats and rabbits, the concern for isolated susceptibility is low because the increased susceptibility was seen at or above the limit dose and they were not reproduced in other studies conducted in same species.

iv. Signs of potential immunotoxicity were not observed in any of the submitted studies.

v. 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 DEG 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 DEG.

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, DEG 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 DEG from food and water will utilize 0.62% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

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).

DEG 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 DEG.

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 132 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 114 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, 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).

DEG 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 DEG.

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 388 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 133 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 DEG is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. DEG 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 DEG 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 DEG nor have any CODEX Maximum Residue Levels been established for any food crops at this time.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for DEG (Cas No. 111–46–6) 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 the requirement of 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 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) (Public Law 104–4).

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

VIII. Congressional Review Act

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

a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 6, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

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

PART 180—[AMENDED]

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

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

■ 2. In §180.920, in the table, add alphabetically the following inert ingredient to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Diethylene Glycol (CAS No. 111–46–6)	Without limitation	Solvent, stabilizer and/or anti-freeze
* * *	* *	* *

[FR Doc. 2010–20318 Filed 8–17–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0541; FRL–8841–1]

Mancozeb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mancozeb in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action establishes a time-limited tolerance for residues of mancozeb in or on walnuts in response to the approval of a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing the use of mancozeb on walnuts to control walnut blight. This regulation establishes a maximum permissible level of residues of mancozeb in walnuts. The time-limited tolerance on walnuts expires and is revoked on December 31, 2013. Also, this action revises the introductory text of paragraphs (a) and (b).

DATES: This regulation is effective August 18, 2010. Objections and requests for hearings must be received on or before October 18, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0541. 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: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703)308–9367; e-mail address: *ertman.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 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–2005–0541 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 18, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. 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–2005–0541, 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),