DELEGATION STATUS FOR NEW SOURCE PERFORMANCE STANDARDS FOR SHASTA COUNTY AIR QUALITY MANAGEMENT DISTRICT, SISKIYOU COUNTY AIR POLLUTION CONTROL DISTRICT, SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT, AND TEHAMA COUNTY AIR POLLUTION CONTROL DISTRICT—Continued

	Subpart	Air Pollution Control Agency			
		Shasta County AQMD	Siskiyou County APCD	South Coast AQMD	Tehama County APCD
BBB ...	Rubber Tire Manufacturing Industry	.....	X	X	.....
CCC ..	(Reserved)	.....	.....	.....	.....
DDD ..	Volatile Organic Compounds (VOC) Emissions from the Polymer Manufacturing Industry.	.....	.....	X	.....
EEE ...	(Reserved)	.....	.....	.....	.....
FFF ...	Flexible Vinyl and Urethane Coating and Printing	.....	.....	X	.....
GGG	Equipment Leaks of VOC in Petroleum Refineries	.....	.....	X	.....
GGGa	Equipment Leaks of VOC in Petroleum Refineries for Which Construction, Reconstruction, or Modification Commenced After November 7, 2006.	.....	.....	.....	.....
HHH ..	Synthetic Fiber Production Facilities	.....	.....	X	.....
III	Volatile Organic Compound (VOC) Emissions From the Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes.	.....	.....	X	.....
JJJ	Petroleum Dry Cleaners	.....	.....	X	.....
KKK ...	Equipment Leaks of VOC From Onshore Natural Gas Processing Plants	.....	.....	X	.....
LLL	Onshore Natural Gas Processing: SO2 Emissions	.....	.....	X	.....
MMM	(Reserved)	.....	.....	.....	.....
NNN ..	Volatile Organic Compound (VOC) Emissions From Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations.	.....	.....	X	.....
OOO	Nonmetallic Mineral Processing Plants	.....	.....	X	.....
PPP ...	Wool Fiberglass Insulation Manufacturing Plants	.....	.....	X	.....
QQQ	VOC Emissions From Petroleum Refinery Wastewater Systems	.....	X	X	.....
RRR ..	Volatile Organic Compound Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes.	.....	.....	X	.....
SSS ...	Magnetic Tape Coating Facilities	.....	X	X	.....
TTT ...	Industrial Surface Coating: Surface Coating of Plastic Parts for Business Machines.	.....	X	X	.....
UUU ..	Calciners and Dryers in Mineral Industries	.....	.....	X	.....
VVV ...	Polymeric Coating of Supporting Substrates Facilities	.....	.....	X	.....
WWW	Municipal Solid Waste Landfills	.....	.....	X	.....
AAAA	Small Municipal Waste Combustion Units for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commended After June 6, 2001.	X	X	X	.....
CCCC	Commercial and Industrial Solid Waste Incineration Units for Which Construction Is Commenced After November 30, 1999 or for Which Modification or Reconstruction Is Commenced on or After June 1, 2001.	.....	.....	X	.....
EEEE	Other Solid Waste Incineration Units for Which Construction is Commenced After December 9, 2004, or for Which Modification or Reconstruction is Commenced on or After June 16, 2006.	.....	.....	X	.....
GGGG	(Reserved)	.....	.....	.....	.....
IIII	Stationary Compression Ignition Internal Combustion Engines	.....	.....	X	.....
JJJJ ...	Stationary Spark Ignition Internal Combustion Engines	.....	.....	.....	.....
KKKK	Stationary Combustion Turbines	.....	.....	X	.....

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0474; FRL–8876–5]

Diethylene Glycol Mono Butyl Ether; 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 mono butyl ether (CAS Reg. No. 112–34–5) when used as a pesticide inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation under 40 CFR 180.920. 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 an establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of diethylene glycol mono butyl ether.

DATES: This regulation is effective June 29, 2011. Objections and requests for hearings must be received on or before August 29, 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.* To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–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 29, 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 diethylene glycol mono butyl ether (CAS Reg. No. 112–34–5) when used as an inert ingredient solvent, stabilizer and/or antifreeze without limitation in pesticide formulations applied to pre-harvest crops. 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., which is available in the docket, *http://www.regulations.gov.* The Agency received one comment in response to the notice of filing.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is

reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *.''

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

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

Diethylene glycol mono butyl ether (DEGBE) has low acute toxicity via the oral and dermal routes. It is a slightly irritating to the skin and moderately irritating to the eyes. It is a skin not a sensitizer.

Oral subchronic studies with DEGBE were available in the rat. In a study in F344 rats, toxicity was mainly manifested as an increase in creatinine levels at >51 mg/kg/day. Confidence in this study is low because of the high unexplained mortality. Also, in other studies in rats, toxicity was observed at doses >210 mg/kg/day. These effects included increased absolute relative liver weight; and hepatic cytochrome P450's and UGT levels; decreased total protein, cholesterol, and aspartate aminotransferase, very slight hepatocyte hypertrophy and increased individual hepatocyte degeneration in females only, decreased RBC count; hemoglobin (Hgb); and hematocrit (Hct) and increased absolute and relative kidney weights with an equivocal increase in minor histopathologic changes typical of early spontaneous nephropathy. In a well conducted 90-day toxicity study in rats via drinking water, rats were exposed to DEGBE at 0, 50, 250, or 1000 mg/kg/day. The NOAEL in this study was 250 mg/kg/day based on kidney, liver and blood effects seen at the LOAEL of 1000 mg/kg/day. In this study, no adverse treatment-related effects were observed on functional observational battery (FOB) parameters. Liver toxicity (including liver enzymes), kidney toxicity and blood parameters were affected at the limit dose of 1000 mg/kg/day.

There was one developmental toxicity study in Wistar rats conducted via the oral route of exposure. In this study, there were no maternal or developmental effects at doses up to 633 mg/kg/day. In a developmental toxicity study in mice via gavage, DEGBE did not produce any malformations at doses up to 2050 mg/kg/day. The maternal and developmental NOAEL in mice was 500 mg/kg/day. A developmental study in rabbits via the dermal route of exposure was available for review. In this study, maternal and developmental toxicity was not observed at doses up to 1000 mg/kg/day.

There were 2 oral reproduction toxicity studies in rats available for review. In both studies rats were exposed to DEGBE via gavage at doses of 0, 250, 500 or 1000 mg/kg/day. In one study fetal susceptibility was not observed. Maternal (mortality) and offspring (reduced mean pup weight) toxicity occurred at the same dose (1000 mg/kg/day). The maternal and developmental NOAELs in this study were 500 mg/kg/day. In a second study quantitative fetal susceptibility was observed. Parental toxicity was not observed at doses up to 1,000 mg/kg/day. Offspring toxicity (decreased bodyweight) was observed at 1000 mg/kg/day. The offspring NOAEL was 500 mg/kg/day. Reproductive toxicity was not observed in either study. A reproductive toxicity study in rats with exposure via the dermal route was also available for review. Parental, offspring and reproduction toxicity was not observed at doses up to 2000 mg/kg/day.

Dermal toxicity studies with DEGBE were available in the rat and rabbit. In a 13-week dermal toxicity study in the Sprague-Dawley (SD) rat, systemic toxicity was not observed at doses up to 2,000 mg/kg/day. In a separate 13-week dermal toxicity study in SD rats, the NOAEL was 580 mg/kg/day based on renal tubular epithelium degeneration seen at the LOAEL of 1900 mg/kg/day. In a neurotoxicity study via the dermal route of exposure, degeneration of the renal tubular epithelium was observed at 2000 mg/kg/day. The NOAEL was 600 mg/kg/day. No effects on FOB parameters, motor activity or neuropathology were observed at doses up to 2000 mg/kg/day following dermal treatment. No local or systemic effects were observed in the New Zealand white rabbit.

Several inhalation toxicity studies with DEGBE were available for review in rats. Perivascular and peribronchial infiltrate were observed in Wistar male and female rats and decreased spleen weights in males at doses > 100 mg/m3. In addition, liver toxicity, kidney toxicity and blood effects were identified as the target organs in inhalation studies.

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

Mutagenicity studies (Ames test, mammalian gene mutation, mouse lymphoma, chromosome aberration and unscheduled DNA synthesis) with DEGBE were available for review. All

the tests were negative with the exception of the mouse lymphoma assay in which cells were weakly positive in the absence of S–9, while it was negative in the presence of S–9.

Chronic and carcinogenicity studies were not available on DEGBE. However, DEGBE belongs to the glycol ether class of chemicals which include structurally similar chemicals ethylene glycol and diethylene glycol. Therefore, carcinogenicity data available on these chemicals were used to assess DEGBE's potential to cause cancer. Based on the lack of evidence of carcinogenicity potential for ethylene glycol and diethylene glycol and the lack of mutagenic concerns for DEGBE, it is not expected to be carcinogenic to humans.

Metabolism studies demonstrated that DEGBE was absorbed rapidly, metabolized and primarily eliminated via the urine. The major metabolite was identified as 2-(2-butoxyethoxy) acetic acid.

Specific information on the studies received and the nature of the adverse effects caused by the diethylene glycol mono butyl ether, as well as, the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document 042203, Diethylene glycol mono butyl ether; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations at pp. 6–21 and pp. 19–22 in EPA–HQ–OPP–2008–0474.

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 diethylene glycol mono butyl ether used for human risk assessment is shown in Table 1 of this unit.

No acute endpoint of concern for general population was identified in the available data base.

The 90 day oral toxicity study in rats via drinking water was selected to establish the chronic reference dose (cRfD). The NOAEL in this study was 250 mg/kg/day and the LOAEL was 1000 mg/kg/day based on kidney, liver, and blood effects. Although 51 mg/kg/day was the lowest LOAEL in the database, confidence in this study was low due to the observed unexplained mortality. A lower NOAEL (94 mg/kg/day) was also observed in a 30 day oral toxicity study in the rat. The LOAEL (210 mg/kg/day) was based on decreased water consumption, growth retardation, and abnormalities in various organs. However, there is more confidence in the 90 day oral toxicity study in rats because it is a more recent study, was well conducted, tested more animals, provided more detailed information, provided data on all parameters measured in the 30-day study, has a well established NOAEL (250 mg/kg/day) and none of the aforementioned effects were observed. Therefore, the point of departure of 250 mg/kg/day was selected to establish the cRfD.

The point of departure selected for the dermal exposure scenario is from the 13 week neurotoxicity screening battery in rats. The NOAEL in this study was 600 mg/kg/day and the LOAEL was 2,000 mg/kg/day based on mild degeneration of renal tubular epithelium in males. This endpoint and dose for dermal exposure assessment was further supported by a 90-day dermal toxicity study in rats with a NOAEL of 580 mg/kg/day based renal tubular degeneration seen at the LOAEL of 1900 mg/kg/day. For the inhalation scenarios, 94 mg/m3 (~27 mg/kg/day) from an inhalation toxicity study in Wistar rats was selected for the point of departure. Although, 39 mg/m3 (~11 mg/kg/day) from an inhalation toxicity study in F344 rats represents the lowest NOAEL in the database for this scenario it was not selected because the observed liver changes were minor and occurred at the high dose (117 mg/m3). In addition, the selected study was more recent and one would expect changes to occur in the liver since animals in this study were treated for a longer duration. However, liver toxicity was not observed in the selected study. Therefore, 94 mg/m3 (~27 mg/kg/day) was selected for the point of departure for all inhalation scenarios.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DIETHYLENE GLYCOL MONO BUTYL ETHER FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–50 years of age)	An acute endpoint was not identified in the database.		
Chronic dietary (All populations)	NOAEL= 250 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 2.5 mg/kg/day cPAD = 2.5 mg/kg/day	90 Day Oral Toxicity Study LOAEL = 1000 mg/kg/day based on kidney, liver, and blood effects.
Incidental oral short-term (1 to 30 days)	NOAEL= 250 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 00	90 Day Oral Toxicity Study LOAEL = 1000 mg/kg/day based on kidney, liver, and blood effects.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR DIETHYLENE GLYCOL MONO BUTYL ETHER 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 intermediate-term (1 to 6 months).	NOAEL= 250 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	90 Day Oral Toxicity Study LOAEL = 1000 mg/kg/day based on kidney, liver, and blood effects.
Dermal short-term (1 to 30 days)	NOAEL = 600 mg/kg/day (UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	13 week Neurotoxicity Screening Battery LOAEL = 2000 mg/kg/day based on [mild degeneration of renal tubular epithelium in males.
Dermal intermediate-term (1 to 6 months)	NOAEL = 600 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	13 week Neurotoxicity Screening Battery LOAEL = 2000 mg/kg/day based on mild degeneration of renal tubular epithelium in males.
Inhalation short-term (1 to 30 days)	NOAEL= 27 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	5 week Subchronic Inhalation Toxicity Study LOAEL was not established.
Inhalation (1 to 6 months)	NOAEL= 27 mg/kg/day (inhalation absorption rate = 100%) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	5 week Subchronic Inhalation Toxicity Study LOAEL was not established.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic based on lack of evidence of carcinogenicity in structurally similar chemicals, ethylene glycol and diethylene glycol and the lack of mutagenicity.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. 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 diethylene glycol mono butyl ether, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from diethylene glycol mono butyl ether in food as follows:

No acute endpoint of concern was identified in the database. Therefore, acute dietary risk assessment was not conducted.

i. Chronic exposure. In conducting the chronic dietary exposure assessments, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data were submitted for the diethylene glycol mono butyl ether. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

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

The Agency believes the assumptions used to estimate dietary exposures led 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 concentration of active ingredient in agricultural products is 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.

ii. Cancer. For the reasons discussed above, the Agency has not identified any concerns for carcinogenicity relating to diethylene glycol mono butyl ether. Accordingly, a dietary exposure assessment to evaluate cancer risk was not performed.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for diethylene glycol mono butyl ether, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

DEGBE 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 DEGBE as inert ingredients. The DEGBE inerts may be present in consumer personal (care) products and cosmetics (at concentrations up to 30%) (*http://hpd.nlm.nih.gov/index.htm*). The Agency conducted exposure assessments based on end-use product application methods and labeled application rates. The Agency conducted an assessment to represent worst-case residential exposure by assessing DEGBE in pesticide formulations used in crack and crevice applications. The Agency conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from DEGBE in pesticide formulations.

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 diethylene glycol mono butyl ether to share a common mechanism of toxicity with any other substances, and diethylene glycol mono butyl ether does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that diethylene glycol mono butyl ether 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 either of the developmental toxicity studies with rats or rabbits. There were no toxic effects observed in parents or offspring in either study at the highest doses tested, 633 and 1000 mg/kg/day, respectively. No developmental effects were observed in mice at doses up to 2050 mg/kg/day. In a reproduction toxicity study in the rat, quantitative fetal susceptibility was observed. Parental toxicity was not observed at doses up to 1,000 mg/kg/day. However, offspring toxicity (decreased bodyweight) occurred at 1000 mg/kg/day. There was a well established NOAEL in this study protecting fetuses. Therefore, the concern for increased fetal susceptibility is low and there are no residual concerns.

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 diethylene glycol mono butyl ether is adequate. The following acceptable studies are available:

Developmental toxicity in rodents (3 oral)
Developmental toxicity in rabbits (1 dermal)
Reproduction toxicity study in rats (2 oral, 1 dermal)

ii. Signs of neurotoxicity were not observed in the neurotoxicity screening battery administered via the dermal route. Nor were signs of neurotoxicity observed in a 90 day oral toxicity (drinking water) in rats. In addition, signs of neurotoxicity were not observed in any of the other submitted studies. Therefore, EPA concluded that the developmental neurotoxicity study is not required.

iii. Immunotoxicity studies for DEGBE were not available for review. However, DEGBE belongs to the glycol ethers class of chemicals. Immunotoxicity studies were available for ethylene glycol monobutyl ether, also a glycol ether differing only in one ethyl group. This data was used to assess the immunotoxic potential of DEGBE. Signs of potential immunotoxicity were not observed in any of the available studies with DEGBE and the surrogate chemical. Therefore, DEGBE is not expected to be immunotoxic.

iv. Evidence of increased susceptibility was observed in a reproduction toxicity study in the rat. However, the concern for this increased susceptibility was low because there was a well established NOAEL of 500 mg/kg/d in this study. Also, the established cRfD (250 mg/kg/day) is protective of the fetal effects.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using very conservative assumptions. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to DEGBE in drinking

water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by DEGBE.

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.* No adverse effects attributable to a single exposure of DEGBE were seen in the toxicity databases. Therefore, DEGBE 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 DEGBE from food and water will utilize 0.08% for the U.S. population and 0.25% of the cPAD for children 1–2 yrs 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).

DEGBE 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 DEGBE.

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 102 for both adult males and females respectively. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden use 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 163 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 DEGBE 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).

DEGBE 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 DEGBE.

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 550 for adult males and females. Adult residential exposure combines high end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden use 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 230 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 DEGBE is a MOE of 100 or below, these MOEs are not of concern.

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

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 DEGBE 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 an MRL for diethylene glycol mono butyl ether.

C. Response to Comments

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

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 920 for diethylene glycol mono butyl ether when used as an inert ingredient (pesticide inert ingredient as a solvent, stabilizer and/or antifreeze within pesticide formulations/products without limitation) in pesticide formulations applied to pre-harvest crops.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule

has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: June 20, 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 ingredients to read as follows:

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

Inert ingredients	Limits	Uses
* * *	* * *	* * *
Diethylene glycol mono butyl ether (CAS Reg. No. 112–34–5).	Without limitation	Pesticide inert ingredient as a solvent, stabilizer and/or antifreeze
* * *	* * *	* * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0980; FRL–8877–2]

Cloquintocet-mexyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the established tolerance expression for residues of cloquintocet-mexyl and its acid metabolite on wheat forage, wheat grain, wheat hay, and wheat straw to cover residues in or on these commodities when cloquintocet-mexyl is used as an inert ingredient (safener) in pesticide formulations containing the active ingredient, dicamba. BASF Corporation requested this tolerance amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 29, 2011. Objections and requests for hearings must be received on or before August 29, 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–2010–0980. 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.