ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0697; FRL–9949–11]

Monoethanolamine; 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 monoethanolamine (CAS Reg. No. 141–43–5) when used as an inert ingredient (solvent) in pesticides applied to growing crops and raw agricultural commodities after harvest limited to a maximum concentration of 3.35% by weight in the pesticide formulation. Technology Sciences Group Inc., on behalf of Doosan Corporation, 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 monoethanolamine when used in accordance with the approved concentrations.

DATES: This regulation is effective April 12, 2017. Objections and requests for hearings must be received on or before June 12, 2017, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0697, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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–2015–0697 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 June 12, 2017. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0697, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of November 23, 2015 (80 FR 72941) (FRL–9936–73), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10839) by Technology Sciences Group Inc. (1150 18th Street NW., Suite 1000, Washington, DC 20036) on behalf of Doosan Corporation (864 B/5F, Aict, 864–1, lui-dong, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443–284, Republic of Korea). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of monoethanolamine (CAS Reg. No. 141–43–5) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Technology Sciences Group Inc. on behalf of Doosan Corporation, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of monoethanolamine to 3.35% by weight in pesticide formulations. The reason for this change is explained in Unit V.B. below.

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 FFDCA section 408(c)(2)(A), 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 monoethanolamine including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with monoethanolamine 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 monoethanolamine as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral and dermal toxicities are low in rats and rabbits for monoethanolamine. The lethal dose (LD_{50}s) are >1,000 milligram/kilogram (mg/kg) in acute oral and dermal studies in the rat and rabbit, respectively. Monoethanolamine is irritating to the skin at 1%, very irritating at >1% and corrosive at 10% in the rabbit. It is corrosive to the eyes in rabbits. Acute inhalation toxicity is low; the LD_{50} is >1.3 milligram/liter. It is not a dermal sensitizer in the guinea pig maximization test or in the mouse local lymph node assay.

Subchronic exposure to rats administered monoethanolamine via the diet causes increases liver and kidney weights at 640 mg/kg/day. The NOAEL is 320 mg/kg/day.

Monoethanolamine did not cause developmental nor maternal effects up to 450 mg/kg/day, the highest dose tested, in a developmental toxicity study via gavage in rats.

In developmental studies via dermal exposure, maternal toxicity (irritation, necrosis, scabbing and scar formation) is observed in rats at 225 mg/kg/day. Developmental toxicity in rats is not observed at 225 mg/kg/day, the highest dose tested. In rabbits, maternal toxicity (skin irritation, necrosis, scabbing and scar formation) and developmental toxicity (reduced body weight) are observed at 75 mg/kg/day. The NOAEL is 25 mg/kg/day.

Parental, reproduction and offspring toxicities are observed at the limit dose, 1,000 mg/kg/day. Toxicity is manifested as decreased sperm head count in the cauda epididymidis; decreased absolute and relative weight of epididymides, cauda epididymidis and prostate; fewer implantation sites; higher post-implantation loss; and smaller litters in F0 and/or F1 animals. The parental, reproduction and offspring NOAELs are 300 mg/kg/day.

A chronic study conducted with a mixture containing 22% monoethanolamine is available in the dog. Monoethanolamine administered via the diet did not cause adverse effects up to 97.5 mg/kg/day (adjusted dose, 21.45 mg/kg/day, the highest dose tested.

Carcinogenicity studies with monoethanolamine are not available. However, a Derek Nexus structural alert analysis was conducted with monoethanolamine and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, monoethanolamine is not expected to be carcinogenic.

Monoethanolamine is negative in an Ames test, chromosomal aberrations, sister chromosome exchange and micronucleus assay and chromosomal aberration test. It is weakly positive in the micronucleus assay. However, based on the overall weight of evidence, monoethanolamine is not considered mutagenic.

Monoethanolamine administered as a vapor or liquid aerosol for 28 days causes severe lesions in the larynx, minimal to mild lesions in the nasal cavity, and minimal to mild signs of irritation in the trachea and bronchiolar epithelia at 50 mg/cubic meter (m^3) (15.5 mg/kg/day). The NOAEL is 10 mg/m^3 (3.1 mg/kg/day).

Clinical signs of neurotoxicity were observed in dogs and rats via oral and inhalation routes exposure. In an inhalation toxicity study conducted in 1960, initial excitation followed by central nervous system depression was observed in dogs exposed to continuous vapors at 12–26 parts per million (ppm) for 24 hours/day, 7 days/week for 90 days. However, these observations in dogs are considered due to the exposure regime rather than neurotoxic effects. In the same study, rats continuously exposed to 5 ppm of monoethanolamine displayed lethargy after 2 to 3 weeks of exposure. However, a more recent guideline study showed that rats exposed to monoethanolamine via

inhalation for 28-days did not show central nervous system excitation, depression or lethargy. In this study, salivation was the only effect observed that suggested potential neurotoxicity but was not considered a neurotoxic effect because it is likely due to the severely irritating properties of monoethanolamine as it enters the nasal pharynx region. In a developmental toxicity study in rats, lethargy, decreased response to light cage ''tap'', increased activity and agitation were observed at 500 mg/kg/day. Conversely, these effects were not reproduced in an OECD guideline 2-generation reproductive toxicity study at doses up to 1,000 mg/kg/day. In another study, rats administered a single dose monoethanolamine via intraperitoneal injection experienced a reduction in brain (16.5%) and red blood cell (24.8%) cholinesterase levels when compared to controls. In the same study, acetylcholinesterase activity was inhibited in isolated rat brain homogenate following exposure to 3665 microgram/milliliter (ug/ml) 2-aminoethanolamine. However, the effects in both studies are seen at doses (>3320 mg/kg) well above the limit dose, 1,000 mg/kg/day. Based on the overall weight of evidence from the available studies, EPA concluded that monoethanolamine is not neurotoxic.

Immunotoxicity studies are not available for review. However, evidence of immunotoxicity is not observed in the submitted studies.

Monoethanolamine is rapidly absorbed and metabolized. Following dermal or oral exposure, it is metabolized to acetaldehyde and ammonia. The reaction is catalyzed by ethanolamine deaminase and further degrade to CO_2 via the formation of ethanolamine-O-phosphate. In rats, the liver was the most active site of metabolism. Monoethanolamine in the liver is methylated to choline and converted to serine which in turn is made into hepatic proteins. In mice, urinary metabolites are urea and glycine, along with smaller concentrations of serine, monoethanolamine, choline and uric acid. Similarly, in rats, urinary metabolites include urea, hippuric acid and uric acid. Dermal absorption is estimated to be 60%.

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 monoethanolamine used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MONOETHANOLAMINE 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 and General population including infants and children).	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations)	NOAEL = 300 mg/kg/day. UF_A = 10x ..... UF_H = 10x. FQPA SF = 1x.	Chronic RfD = 3.00 mg/kg/day. cPAD = 3.00 mg/kg/day.	Two-generation Reproduction Toxicity Study-Rat LOAEL = 1,000 mg/kg/day based on decreased sperm head count in the cauda epididymidis; decreased absolute and relative weight of epididymides, cauda epididymidis and prostate; fewer implantation sites; higher post-implantation loss; and smaller litters in F1 and F2
Incidental oral short-term (1 to 30 days).	NOAEL = 300 mg/kg/day. UF_A = 10x ..... UF_H = 10x. FQPA SF = 1x.	LOC for MOE = 100	Two-generation Reproduction Toxicity Study-Rat LOAEL = 1,000 mg/kg/day based on decreased sperm head count in the cauda epididymidis; decreased absolute and relative weight of epididymides, cauda epididymidis and prostate; fewer implantation sites; higher post-implantation loss; and smaller litters in F1 and F2
Incidental oral intermediate-term (1 to 6 months).	NOAEL = 300 mg/kg/day.	LOC for MOE = 100	Two-generation Reproduction Toxicity Study-Rat

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MONOETHANOLAMINE 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
	UF_A = 10x		LOAEL = 1,000 mg/kg/day based on decreased sperm head count in the cauda epididymidis; decreased absolute and relative weight of epididymides, cauda epididymidis and prostate; fewer implantation sites; higher post-implantation loss; and smaller litters in F1 and F2
	UF_H = 10x. FQPA SF = 1x.		
Dermal short-term (1 to 30 days).	NOAEL = 25 mg/kg/day.	LOC for MOE = 100	Developmental Toxicity Study-Dermal-Rabbit
	UF_A = 10x		LOAEL = 75 mg/kg/day based on skin irritation, progressing from erythema to necrosis, scabbing and scar formation.
	UF_H = 10x. FQPA SF = 1x.		
Dermal intermediate-term (1 to 6 months).	NOAEL = 25 mg/kg/day.	LOC for MOE = 100	Developmental Toxicity Study-Dermal-Rabbit
	UF_A = 10x		LOAEL = 75 mg/kg/day based on skin irritation, progressing from erythema to necrosis, scabbing and scar formation.
	UF_H = 10x. FQPA SF = 1x.		
Inhalation short-term (1 to 30 days).	Inhalation (or oral) study NOAEL= 10 mg/m^3 (equivalent to 3.1 mg/kg/day (inhalation absorption rate = 100%).	LOC for MOE = 100	28 Day Inhalation Toxicity Study-Rat
	UF_A = 10x		LOAEL = 50 mg/m^3 (equivalent to 15.5 mg/kg/day) based on local effects in the larynx, trachea and lungs.
	UF_H = 10x. FQPA SF = 1x.		
Inhalation intermediate-(1 to 6 months).	Inhalation (or oral) study NOAEL= 10 mg/m^3 (equivalent to 3.1 mg/kg/day (inhalation absorption rate = 100%).	LOC for MOE = 100	28 Day Inhalation Toxicity Study-Rat
	UF_A = 10x		LOAEL = 50 mg/m^3 (equivalent to 15.5 mg/kg/day) based on local effects in the larynx, trachea and lungs.
	UF_H = 10x. FQPA SF = 1x.		
Cancer (Oral, dermal, inhalation).	Based on a Derek structural alert analysis and the lack of mutagenicity, monoethanolamine is considered not likely to be carcinogenic.		

C. Exposure Assessment

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

Dietary exposure (food and drinking water) to monoethanolamine can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of monoethanolamine are seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™, Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for monoethanolamine. 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. One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 3.35% by weight in pesticide formulations. 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.

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 monoethanolamine, a conservative drinking water concentration value of

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

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

Monoethanolamine may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. For residential handlers, the Agency assumed handlers may receive short-term dermal and inhalation exposure to monoethanolamine from formulations containing the inert ingredient in outdoor and indoor scenarios. Intermediate-term or long-term exposure is not expected because applications are not expected to occur daily or for more than 30 days. For post-application exposures to monoethanolamine in pesticide formulations, the Agency assumed short-term dermal exposures to adults from use on treated lawns and indoor surfaces and short-term and intermediate-term dermal and oral exposures to children from treated lawns, soils, and indoor surfaces. Since monoethanolamine is not expected to be used as an inert ingredient in pesticide aerosol products such as total release insecticide foggers, and given the fact that monoethanolamine has a low vapor pressure (<1 mm Hg), it is not expected to volatilize in indoor environments; therefore, post-application inhalation exposure is not expected. A conservative residential exposure and risk assessment was completed for pesticide products containing monoethanolamine as inert ingredients.

Monoethanolamine is also present in cosmetics. Although the Agency does not have data with which to quantitatively assess exposures that result from these non-pesticidal (*i.e.,* cosmetic) uses of monoethanolamine, the Agency expects that the exposures to amounts of monoethanolamine that might result from these uses are markedly less than the conservative estimates of residential exposures resulting from pesticide use and will not add any meaningful exposure to the Agency's assessments of residential exposure from pesticide use. This is based on the typical reported concentration ranges for monoethanolamine in cosmetics, pesticidal products and the specific use patterns and anticipated likely exposure levels, including the fact that cosmetics products with monoethanolamine are designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. Therefore, the Agency believes that any contribution to aggregate exposure from these non-pesticidal uses is likely to be negligible and therefore, the assessments of exposures due to pesticide uses are protective of non-pesticidal exposures.

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 monoethanolamine to share a common mechanism of toxicity with any other substances, and monoethanolamine does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that monoethanolamine 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

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.

The toxicity database for monoethanolamine contains a subchronic, developmental, two-generation reproduction, chronic and mutagenicity studies. There is no indication of immunotoxicity in the available studies; therefore, there is no need to require an immunotoxicity study. Fetal susceptibility is not observed in the developmental or reproduction toxicity studies in rats. Reproduction toxicity (decreased sperm head count in the cauda epididymidis; decreased absolute and relative weight of epididymides, cauda epididymidis and prostate; fewer implantation sites; higher post-implantation loss) is observed at the limit dose (1,000 mg/kg/day) only. Fetal toxicity (reduced body weight) is observed in the developmental toxicity study via the dermal route of exposure in the rabbits. However, the effect occurs in the presence of maternal toxicity (skin irritation, necrosis, scabbing and scar formation). As described in detail above, signs of potential neurotoxicity are observed in dogs and rats when exposed to monoethanolamine via inhalation and intraperitoneally. However, based on the overall weight of evidence from the available studies, EPA concluded that monoethanolamine is not neurotoxic. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated, tolerance-level residues, conservative drinking water modeling numbers, and a conservative assessment of potential residential exposure for infants and children. Based on the adequacy of the toxicity, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x.

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.

2. *Chronic risk.* Using the exposure assumptions described in this unit for

chronic exposure, EPA has concluded that chronic exposure to monoethanolamine from food and water will utilize 1.7% of the cPAD for children 1–2 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).

Monoethanolamine may be used as an inert ingredient in pesticide products 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 monoethanolamine. Using the exposure assumptions described above, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in MOEs of 182 for both adult males and females. Adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden 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 400 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.

Monoethanolamine is also present in some cosmetics, intended for discontinuous, brief use, followed by thorough rinsing from the surface of the skin. In the absence of actual residential exposure data resulting from such uses, the Agency considered information on the typical concentrations of monoethanolamine in cosmetics as well as typical use and likely exposures. Based on that review, the Agency believes the contribution from non-pesticidal (*i.e.,* cosmetic) sources of monoethanolamine is likely to be insignificant compared to the exposures conservatively estimated to occur as a result of the use of monoethanolamine as an inert ingredient in pesticide formulations and that the assessments of aggregate exposures due to pesticide uses more than adequately protect for exposure from non-pesticidal uses.

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).

Monoethanolamine may be used as an inert ingredient in pesticide products 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 monoethanolamine. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 1310 for adult males and females. Adult residential exposure combines liquids/trigger sprayer/home garden 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 742 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, this MOE is not of concern.

Monoethanolamine is also present cosmetics. In the absence of actual residential exposure data resulting from such uses, the Agency considered information on the typical concentrations of monoethanolamine in cosmetics as well as typical use and likely exposures. Based on that review, the Agency believes the contribution from non-pesticidal sources of monoethanolamine is likely to be negligible and that the assessments of aggregate exposures due to pesticide uses more than adequately protect for exposure from non-pesticidal uses.

5. *Aggregate cancer risk for U.S. population.* Based on a DEREK structural alert analysis, the lack of mutagenicity and the lack of specific organ toxicity in the chronic toxicity study, monoethanolamine is not expected to pose a cancer risk to humans.

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 monoethanolamine.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of monoethanolamine in or on any food commodities. EPA is establishing a limitation on the amount of monoethanolamine that may be used in pesticide formulations applied to growing crops. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops for sale or distribution that exceeds 3.35% by weight of monoethanolamine.

B. Revisions to Petitioned-For Tolerances

Based upon an evaluation of the data included in the petition, EPA is establishing an exemption from the requirement of a tolerance for residues of monoethanolamine when used in pesticide formulations as an inert ingredient (solvent/co-solvent), not to exceed 3.35% by weight of the formulation, instead of the unlimited use requested. Because unlimited use of monoethanolamine resulted in aggregate risks of concern, the EPA is establishing a 3.35% limitation by weight of formulation to support the safety finding of this tolerance exemption. The concern for unlimited use of this inert ingredient is documented on page 5 of the Agency's risk assessment document ''Monoethanolamine; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations,'' which can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2015–0697.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of monoethanolamine (CAS Reg. No. 141–43–5) when used as an inert ingredient (solvent/co-solvent) at a maximum concentration of 3.35% by weight in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes an exemption to the requirement for a tolerance under FFDCA section 408(d) 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 FFDCA section 408(d), 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 action 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 FFDCA section 408(n)(4). 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 the rule in the **Federal Register**. This action 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: March 7, 2017.

Michael Goodis,

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 § 180.910, add alphabetically the inert ingredient to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Monoethanolamine (CAS Reg. No. 141–43–5)	Not to exceed 3.35% by weight in pesticide formulation	Solvent.
* * *	* *	* *

[FR Doc. 2017–07130 Filed 4–11–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[CDC Docket No. CDC–2016–0045]

RIN 0920–AA64

Possession, Use, and Transfer of Select Agents and Toxins—Addition of *Bacillus cereus* Biovar *anthracis* to the HHS List of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Interim rule; adoption as final and response to public comments.

SUMMARY: On September 14, 2016, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) published in the **Federal Register** (81 FR 63138) an interim final rule and request for comments which added *Bacillus cereus* Biovar *anthracis* to the list of HHS select agents and toxins as a Tier 1 select agent. CDC received two comments, both of which supported the rule change.

DATES: Effective April 12, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel Edwin, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–A46, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: Effective on October 14, 2016, *Bacillus cereus* Biovar *anthracis* was added to the list of HHS select agents and toxins as a Tier 1 select agent (81 FR 63138, September 14, 2016). In the interim final rule, HHS/CDC invited comments on the following questions:

(1) Are there other virulent (pBCXO1+ and pBCXO2+) strains of *Bacillus* species that should also be regulated?

(2) What is the impact of designating *B. cereus* Biovar *anthracis* as a Tier 1 select agent?

The comment period ended November 14, 2016.

We received two comments, both of which supported adding *B. cereus* Biovar *anthracis* to the list of HHS select agents and toxins. While both commenters supported the addition, one commented that the regulation of *B. cereus* Biovar *anthracis* will ''restrict the ability of future laboratories and organizations to test for and analyze possible pBXO1 and pBXO2 isolates.'' The commenter further argued that