



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2016-0507; FRL-9963-58]**

### **Beta cyclodextrin, methyl ethers; 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 beta cyclodextrin, methyl ethers (CAS Reg. No. 128446-36-6) when used as an inert ingredient (stabilizer and solvent) in pesticide formulations applied to growing crops pre-harvest limited to a maximum concentration of 40% by weight in the pesticide formulation. Lewis and Harrison, LLC, on behalf of Wacker Chemie AG 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 beta cyclodextrin, methyl ethers that result from applications of pesticides consistent with the conditions in EPA regulations.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-2016-0507, 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](mailto: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](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-2016-0507 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 *[insert date 60 days after date of*

*publication in the **Federal Register***]. 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-2016-0507, 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 February 7, 2017 (82 FR 9555) (FRL-9956-86), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN-10964) by Lewis and Harrison, LLC (122 C St, NW, Suite 505, Washington, DC 20001), on behalf of Wacker Chemie AG (Hanns-Seidel-Platz 4, D-81737 Munich, Germany). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of beta cyclodextrin, methyl ethers (CAS Reg. No. 128446-36-6) when used as an inert ingredient (stabilizer/solvent) in pesticide formulations applied to growing crops pre-harvest, limited to 40% by weight in the pesticide formulation. That document referenced a summary of the petition prepared by Lewis and Harrison, LLC, on behalf of Wacker Chemie AG, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

The Agency is establishing an exemption from the requirement of a tolerance as requested, but is using the chemical abstract index name “beta- cyclodextrin, methyl ethers”, the assigned formal name rather than “methyl-beta-cyclodextrin”, the common name.

### **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 beta cyclodextrin, methyl ethers including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with beta cyclodextrin, methyl ethers 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 beta cyclodextrin, methyl ethers 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.

All studies are conducted with beta cyclodextrin, methyl ethers except the developmental/reproduction toxicity studies which are conducted with beta-cyclodextrin ( $\beta$ -CD) and 2-hydroxypropyl-beta-cyclodextrin (HP- $\beta$ -CD). These chemicals are structurally similar to beta cyclodextrin, methyl ethers and are considered suitable surrogates. A quantitative structural-activity relationship (QSAR) analysis demonstrates that results are nearly identical for these chemicals; therefore, data from the developmental/reproduction toxicity studies conducted with  $\beta$ -CD and HP- $\beta$ -CD are used to assess potential developmental/reproduction toxicity from beta cyclodextrin, methyl ethers exposure.

The acute oral toxicity is low in rats and mice for beta cyclodextrin, methyl ethers. The lethal dose (LD<sub>50</sub>) is >8000 milligrams/kilogram (mg/kg) in acute oral toxicity studies in the rat and mouse. Beta cyclodextrin, methyl ethers is not irritating to the skin in the rabbit. It is moderately irritating to the eyes in rabbits. Acute inhalation toxicity is low; the lethal concentration (LC<sub>50</sub>) is >2.95 milligram/liter (mg/L) (equivalent to 398 mg/kg). Beta cyclodextrin, methyl ethers is not a dermal sensitizer in the guinea pig maximization test.

Beta cyclodextrin, methyl ethers administered via the diet for 28 days causes tubular degeneration of the renal cortex at 1,000 milligrams/kilogram/day (mg/kg/day). The no-observed-adverse-effect level (NOAEL) is 300 mg/kg/day.

No fetal susceptibility was observed in any of the developmental and reproduction toxicity studies. Following oral administration of beta-cyclodextrin in rats and rabbits, no developmental toxicity was observed at doses as high as 5,000 mg/kg/day and 600 mg/kg/day, respectively. No maternal toxicity was observed at doses as high as 2,500 mg/kg/day and 600 mg/kg/day in rats and rabbits, respectively. Similarly, no developmental or maternal toxicity was observed in rats following oral exposure to doses of 2-hydroxypropyl-beta-cyclodextrin as high as 5,000 mg/kg/day and in rabbits following oral exposure to doses as high as 500 mg/kg/day. Following intravenous administration of 2-hydroxypropyl-beta-cyclodextrin to rats, slight maternal toxicity was observed at 400 mg/kg/day (with a NOAEL at 100 mg/kg/day), but no developmental toxicity was observed. No maternal or developmental toxicity was observed in rabbits exposed to doses of 2-hydroxypropyl-beta-cyclodextrin at 400 mg/kg/day, the highest dose tested. In the three-generation reproduction toxicity study in rats, no effects were observed in parental or offspring animals at doses up to 1,099 mg/kg/day beta-cyclodextrin. No reproduction effects were observed up to 2,277 mg/kg/day.

Beta cyclodextrin, methyl ethers administered for 26 weeks via gavage causes tubular vacuolation in the kidney at 500 mg/kg/day. The NOAEL is 100 mg/kg/day. The chronic reference dose (cRfD) is based on this study.

Carcinogenicity studies with beta cyclodextrin, methyl ethers are not available; however, a Deductive Estimation of Risk from Existing Knowledge (Derek) Nexus structural alert analysis was conducted with beta cyclodextrin, methyl ethers and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, beta cyclodextrin, methyl ethers is not expected to be carcinogenic.

All available mutagenicity studies (Ames tests, gene mutation, chromosomal aberrations, unscheduled DNA synthesis and micronucleus tests) were negative; therefore, beta cyclodextrin, methyl ethers is not mutagenic.

Although neurotoxicity and immunotoxicity studies are not available for review, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

Beta cyclodextrin, methyl ethers is not metabolized and very little is absorbed. Following oral exposure, it is mostly excreted in the feces and 0.92% is excreted in the urine. 0.97-0.92 % of an orally administered dose is absorbed. A distribution study shows that beta cyclodextrin, methyl ethers is found along the gastrointestinal tract, in the kidney and bladder. Dermal absorption is estimated to be 0.4% in 126 hours in rats.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of

exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for beta cyclodextrin, methyl ethers used for human risk assessment is shown in Table 1 of this unit.

**Table 1.--Summary of Toxicological Doses and Endpoints for Beta Cyclodextrin, Methyl Ethers for Use in Human Risk Assessment**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute dietary  (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 = 100 mg/kg/day $UF_A = 10x$  $UF_H = 10x$  FQPA SF = 1x	Chronic RfD = 1.00 mg/kg/day   cPAD = 1.00 mg/kg/day	26-week Oral Toxicity Study-Rat  LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Incidental oral short-term  (1 to 30 days)	NOAEL= 300 mg/kg/day $UF_A = 10x$  $UF_H = 10x$	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat  LOAEL = 1000 mg/kg/day based on

	FQPA SF = 1x		tubular vacuolation in the kidneys.
Incidental oral intermediate-term (1 to 6 months)	NOAEL = 100 mg/kg/day UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	26-week Oral Toxicity Study-Rat  LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Dermal short-term (1 to 30 days)	NOAEL = 300 mg/kg/day (dermal absorption rate = 0.4 %) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat  LOAEL = 1000 mg/kg/day based on tubular vacuolation in the kidneys.
Dermal intermediate-term (1 to 6 months)	NOAEL = 100 mg/kg/day (dermal absorption rate = 0.4 %) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	26-week Oral Toxicity Study-Rat  LOAEL = 500 mg/kg/day based on tubular degeneration in the kidneys.
Inhalation short-term (1 to 30 days)	NOAEL = 300 mg/kg/day (inhalation absorption rate = 100%) UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	LOC for MOE = 100	28-Day Oral Toxicity Study-Rat  LOAEL = 1000 mg/kg/day based on tubular vacuolation in the kidneys.
Inhalation intermediate-term	NOAEL = 100 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100	26-week Oral Toxicity Study-Rat  LOAEL = 500

(1 to 6 months)	$UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x		mg/kg/day based on tubular degeneration in the kidneys.
Cancer (Oral, dermal, inhalation)	Based on a Derek structural alert analysis and the lack of mutagenicity, beta cyclodextrin, methyl ethers is considered not likely to be carcinogenic.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_{DB}$  = to account for the absence of data or other data deficiency.  $UF_H$  = 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.

### C. Exposure Assessment

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

- i. Dietary exposure (food and drinking water) to beta cyclodextrin, methyl ethers can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of beta cyclodextrin, methyl ethers 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 beta cyclodextrin, methyl ethers. 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 40% 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 beta cyclodextrin, methyl ethers, 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).

Beta cyclodextrin, methyl ethers may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. The Agency conducted an assessment to represent conservative residential exposure by assessing beta cyclodextrin, methyl ethers in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios). The Agency’s assessment of adult residential exposure combines high end dermal and inhalation handler exposure from liquids/backpack sprayer/home garden with a high end post application dermal exposure from contact with treated lawns. The Agency’s assessment of children’s residential exposure includes total post-application exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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 beta cyclodextrin, methyl ethers to share a common mechanism of toxicity with any other substances, and beta cyclodextrin, methyl ethers does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that beta cyclodextrin, methyl ethers does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

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

2. *Prenatal and postnatal sensitivity.* The toxicity database for beta cyclodextrin, methyl ethers contains developmental and 3-generation reproduction toxicity studies conducted with surrogate chemicals. Increased fetal susceptibility is not observed in any of the studies: the only fetal effects observed (slight embryotoxicity following oral

exposure in developmental toxicity study in rabbits to 2-hydroxypropyl-beta-cyclodextrin at doses of 1,000 mg/kg/day) occurred in the presence of slight maternal toxicity (NOAEL of 500 mg/kg/day). In other studies involving oral exposure to beta-cyclodextrin and to 2-hydroxypropyl-beta-cyclodextrin in rats and rabbits, no adverse effects of statistical significance were observed in fetuses. In the three-generation reproduction toxicity study in rats, no effects were observed in parental or offspring animals at doses up to 1,099 mg/kg/day beta-cyclodextrin. No reproduction effects were observed up to 2,277 mg/kg/day.

3. *Conclusion.* The toxicity database for beta cyclodextrin, methyl ethers contains subchronic, developmental, 3-generation reproduction toxicity and mutagenicity studies. Although there are no neurotoxicity or immunotoxicity studies, there is no need to retain the FQPA 10X safety factor because there is no indication of potential neurotoxicity or immunotoxicity in the available studies. Also, there is no need to retain the FQPA 10X safety factor for lack of an inhalation study because baseline inhalation margin of exposure (MOE) ranges from 86000-1400000 and more than adequately surpass the Agency's level of concern of MOEs<100 or MOEs<1,000 if an additional 10X were applied. 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 database and 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. Therefore, beta cyclodextrin, methyl ethers 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 beta cyclodextrin, methyl ethers from food and water will utilize 56.6 % 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).

Beta cyclodextrin, methyl ethers may be 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 beta cyclodextrin, methyl ethers.

Using the exposure assumptions described above for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1910 for both adult males and females respectively. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 500 for children. Because EPA's level of concern for beta cyclodextrin, methyl ethers 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).

Beta cyclodextrin, methyl ethers may be 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 beta cyclodextrin, methyl ethers.

Using the exposure assumptions described above for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 650 for adult males and females. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 170 for children. Because EPA's level of

concern for beta cyclodextrin, methyl ethers is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of structural alerts in a DEREK structural alert analysis and the lack of mutagenicity, beta cyclodextrin, methyl ethers 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 beta cyclodextrin, methyl ethers residues.

## **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 beta cyclodextrin, methyl ethers in or on any food commodities. EPA is establishing limitations on the amount of beta cyclodextrin, methyl ethers that may be used in pesticide formulations applied to growing crops. These limitations 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 pre-harvest for sale or distribution that exceeds 40% by weight of beta cyclodextrin, methyl ethers unless additional data are submitted.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for beta cyclodextrin, methyl ethers (CAS Reg. No. 128446-36-6) when used as an inert ingredient (stabilizer and solvent) in pesticides applied to growing crops pre-harvest limited to a maximum concentration of 40% by weight in the pesticide formulation.

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of 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: June 22, 2017.

Michael L. Goodis, P.E.

*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, add alphabetically the entry “Beta Cyclodextrin, Methyl Ethers” to the table to read as follows:

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

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Beta Cyclodextrin, Methyl Ethers (CAS Reg. No. 128446-36-6)	40% by weight	Stabilizer and solvent
* * *	* *	* *