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## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2016-0183; FRL-9947-45]**

### **Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate);**

### **Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes exemptions from the requirement of a tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683-19-8) under 40 CFR 180.910 and 180.930 when used as an inert ingredient (antioxidant/stabilizer) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum concentration of 5% by weight in the formulation and applied to animals at a maximum concentration of 3% by weight in the formulation, respectively. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of these exemptions from the requirement of a tolerance. These regulations eliminate the need to establish a maximum permissible level for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) for these uses.

**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-2016-0183, 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:** Susan Lewis, 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 FFDCFA 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-2016-0183 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-2016-0183, 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 April 25, 2016 (81 FR 24044) (FRL-9944-86), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10829) by BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932. The petition requested that 40 CFR 180.910 and 180.930 be amended by establishing an exemption from the requirement of a tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683-19-8) when used as an inert ingredient antioxidant/stabilizer in pesticide formulations applied to growing crops and raw agricultural commodities after harvest

under 40 CFR 180.910 at a maximum concentration of 5% by weight in the formulation; and applied to animals under 40 CFR 180.930 at a maximum concentration of 3% by weight in the formulation. That document referenced a summary of the petition prepared by Lewis & Harrison LLC on behalf of BASF 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.

### **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 FFDCFA 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 FFDCFA 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 pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) including exposure resulting from the

exemption established by this action. EPA's assessment of exposures and risks associated with pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 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. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate) has low acute toxicity via the oral, dermal, and inhalation routes of exposure. Pentaerythritol tetrakis 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate) is not irritating to the eyes and the skin. It is not a dermal sensitizer. In a subchronic study in dogs and a subchronic study in rats, effects were limited to decreases in body weight gain, food consumption, and thyroid weights in rats. No fetal toxicity was reported in developmental toxicity study in the rat. In a developmental toxicity study with mice, incompletely ossified sternbrae in the high-dose group was observed in the absence of maternal toxicity. In a rat 2-generation reproduction study, no adverse effects were observed at doses up to 1,000 milligrams/kilogram/day (mg/kg/day). There was no evidence of carcinogenic potential in a rat chronic toxicity/carcinogenicity study. Specific information on the studies received and the nature of the adverse effects caused by pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 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 “Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate) (CAS Reg. No. 6683-19-8); Human Health Risk Assessment and Ecological Effects Assessment to Support A Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient” at pages 10-15 in docket ID number EPA-HQ-OPP-2016-018.

*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>.

Based on the results of the available safety studies for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, the reference dose (RfD) for repeated oral, dermal, and inhalation exposures to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate is 1.35 mg/kg/day. The key study for deriving the RfD is the chronic toxicity study in rats. The NOAEL for in this study is 135 mg/kg/day based on decreases in body weight gain, food consumption, and thyroid weights in males at the LOAEL of 446 mg/kg/day. Applying an uncertainty factor of 100 for extrapolation from animal to human (interspecies variation) and potential variation in sensitivity among members of the human population (intraspecies sensitivity) results in the RfD of 1.35 mg/kg/day. The Food Quality Protection Act (FQPA) (Pub. L. 104-170) safety factor for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate is 1X. The resultant population adjusted dose (PAD) is 1.35 mg/kg/day. The margin of exposure (MOE) for residential exposure is 100 or greater and is based upon the NOAEL derived from the chronic oral toxicity study in rats (135 mg/kg/day) with an assumption of 10% dermal absorption (based on molecular weight and octanol-water partition coefficient) and inhalation toxicity being equivalent oral toxicity.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in food as follows:

An acute dietary risk assessment was not conducted because no endpoint of concern following a single exposure was identified in the available studies. A chronic

dietary exposure assessment was completed and performed using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate). In the absence of actual residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) 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 model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. 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 case of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) EPA made specific adjustments to the dietary exposure assessment to account for the use limitations of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a maximum concentration of % by weight in the pesticide formulation and as an inert ingredient in pesticide formulations applied to animals at a maximum concentration of 3% by weight in the pesticide formulation. Preharvest uses.

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 pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), 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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Based on the requested use of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate), the Agency does not expect non-occupational, non-dietary exposures. However, once approved, there is a potential for residential exposure from use as an inert ingredient in pesticide formulations used in residential settings. These residential exposures could occur by ingestion of materials to which pesticides containing of

pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) have been applied as well as dermal and inhalation exposures through the use of such products. These residential pesticide exposures are considered short-term and intermediate-term in nature.

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 pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) to share a common mechanism of toxicity with any other substances, and pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fetal susceptibility was not observed in the developmental toxicity study in mice. In a developmental toxicity study with rats, fetal effects (decreased ossification of the sternebrae) were observed without accompanying maternal toxicity at the high dose group of 500 mg/kg/day. There are no concerns for reproductive toxicity (no effects at up to the limit dose of 1,000 mg/kg/day were observed in a 2-generation reproductive toxicity study in rats).

3. *Conclusion.* EPA has determined that reliable data show the safety of infant 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 pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) includes a subchronic toxicity study, two developmental toxicity studies, a reproductive toxicity study, chronic/carcinogenicity studies, and several mutagenicity studies. No parental or offspring effects were observed in a 2-generation reproductive toxicity study in rats at dose levels up to 500 mg/kg/day, the highest dose tested. In a developmental study in mice, no fetal or maternal effects were observed at doses up to 1,000 mg/kg/day. In a developmental toxicity study in rats no maternal effects were observed at 500 mg/kg/day, the highest dose tested, however, fetal effects were observed, albeit only in the high dose test group of 500 mg/kg/day. Since a

clear NOAEL (150 mg/kg/day) for fetal effects was established in this study, no effects are observed in the mice developmental and rat reproductive toxicity study, and the selected point of departure for risk assessment purposes is based on dose levels below which effects are seen in the rat developmental toxicity study, there is no need for an additional UF to account for fetal susceptibility.

ii. There is no indication that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is a neurotoxic chemical. Although no neurotoxicity studies were available in the database, no clinical signs of neurotoxicity were observed in the available subchronic and chronic studies. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication that pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is an immunotoxic chemical. Although no immunotoxicity studies were available in the database, no signs of immunotoxicity were observed in the available studies. Therefore, there is no need for an immunotoxicity study or additional UFs to account for immunotoxicity.

iv. The dietary food exposure assessment utilizes 100% crop treated information for all commodities. By using these screening-level assessments, chronic exposures/risks will not be underestimated. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not

underestimate the exposure and risks posed by pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate).

#### *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, pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 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 pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) from food and water will utilize 26% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure based on the explanation in this unit, regarding residential use patterns, chronic

residential exposure to residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) is not expected.

3. *Short-term aggregate risk.* A short-term aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water; and short-term residential exposure. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) may be used as an inert ingredient in pesticide products that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. The Agency has concluded that the aggregate short-term MOEs for adult and children are above 100. Therefore there is no concern for short-term aggregate risk.

4. *Intermediate-term aggregate risk.* An intermediate-term aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water; and intermediate-term residential exposure. Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) may be used as an inert ingredient in pesticide products that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. The Agency has concluded that the aggregate intermediate-term MOEs for adult and children are above 100. Therefore there is no concern for intermediate term aggregate risk.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in an adequate rodent carcinogenicity studies, pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) 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 pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) residues.

## **V. Analytical Enforcement Methodology**

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) in or on any food commodities. EPA is establishing a limitation on the amount of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) that may be used in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals. Those 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 product applied to growing crops and raw agricultural commodities after harvest that contains pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) a concentration of more 5% by weight in the formulation; or any pesticide product applied applied to animals that contains pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) a concentration of more than 3% by weight in the formulation.

## **VI. Conclusions**

Therefore, exemptions from the requirement of a tolerance are established for residues of pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683-19-8) when used as an inert ingredient (antioxidant, stabilizer) in pesticide products as follows: under 40 CFR 180.910, at a concentration not to exceed 5% by weight of the formulation in pesticide formulations applied to growing crops and raw agricultural commodities and under 40 CFR 180.930 at a concentration not to exceed 3% by weight of the formulation in pesticide formulations applied to animals.

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

This action establishes exemptions from the requirement of a tolerance under FFDCFA 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 exemptions 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 13, 2016.

Daniel J. Rosenblatt,

*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
* * *	* *	* *
Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683-19-8)	Not to exceed 5% by weight of the pesticide formulation	Antioxidant, stabilizer
* * *	* *	* *

3. In §180.930, add alphabetically the inert ingredient to the table to read as follows:

**§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (CAS Reg. No. 6683-19-8)	Not to exceed 3% by weight of the pesticide formulation	Antioxidant, stabilizer
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[FR Doc. 2016-15613 Filed: 6/29/2016 8:45 am; Publication Date: 6/30/2016]