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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0853; FRL-9945-82]

Maleic Anhydride; 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 maleic anhydride (CAS Reg. No. 108-31-6) when used as an inert ingredient (stabilizer) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 3.5% by weight in the pesticide formulation. Exponent, on behalf of Cheminova A/S, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of maleic anhydride.

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-2014-0853, 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*.

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. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0853 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-2014-0853, 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 6, 2015 (80 FR 18327) (FRL-9924-00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP) IN-10771 by Exponent on behalf of Cheminova A/S, 1600 Wilson Boulevard, Suite 700, Arlington, VA 22209. The petition requested that 40 CFR 180.920 be amended by modifying an exemption from the requirement of a tolerance for residues of maleic anhydride (CAS Reg. No. 108-31-6) when used as an inert ingredient (stabilizer) in pesticide formulations applied to growing crops to allow for use at a maximum concentration not to exceed 5% in formulation. That document referenced a summary of the petition prepared by Exponent, 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 modified the limitation on the maximum concentration in pesticide formulation from 5% to 3.5%. This limitation is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document, Maleic Anhydride; 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 Products under 40 CFR 180.920, in docket ID number EPA-HQ-OPP-2014-0853.

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 maleic anhydride including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with maleic anhydride 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 maleic anhydride 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.

Maleic anhydride exhibits relatively low toxicity via oral and dermal routes of exposure. Maleic anhydride has been reported to be severely irritating to the skin and eyes of rabbits, dermally sensitizing to guinea pigs, and is a possible respiratory sensitizer.

In a six-month repeat dose inhalation study, CD rats, Engle hamsters, and Rhesus monkeys were exposed by inhalation (whole body) to 0, 1.1, 3.3 and 9.8 mg/m^3 (0, 0.3, 0.8, and 2.4 ppm) maleic anhydride for six months. Body weights were decreased in rats at 3.3 and 9.8 mg/m^3 (0.8, and 2.4 ppm) in the mid- and high-exposure groups at intervals during the study (<10%). However, at study termination, body weights were decreased only at the 9.8 mg/m^3 exposure group (6 – 8%). These decreases in the body weights are not considered as an adverse effect. All other effects were limited to the respiratory tract and eye. All of these effects were considered indicative of irritation and judged to be reversible. The NOAEL for irritation in this study was 3.3 mg/m^3 or 0.93 mg/kg/day based on localized eye/nasal irritation effects seen at the LOAEL of 9.8 mg/m^3. The NOAEL for systemic toxicity in rats, hamsters and monkeys is 9.8 mg/m^3, the highest dose tested.

In a 28-day inhalation study with maleic anhydride in Sprague-Dawley rats, evidence of nasal and ocular irritation (concentration-dependent) occurred at 12, 32 and 86 mg/m^3. Reduced body weight gain and food consumption as well as increased incidence of hemorrhagic lung foci occurred at 32 and 86 mg/m^3. The NOAEL for the systemic toxicity is 12 mg/m^3 (3 ppm) based on the reduced body weights and food consumption seen at the LOAEL of 32 mg/m^3.

In a 90-day oral (dietary) study in rats were fed in the diet 0, 100, 250, or 600 mg/kg/day maleic anhydride for 90 days. At 600 mg/kg/day, there was slight proteinuria in both sexes, increased relative liver weight in males, increased relative/absolute kidney weights in both sexes. Macroscopic and microscopic kidney changes, including nephrosis were seen in male rats at 100, 250, and 600 mg/kg/day. The LOAEL for this study is 100 mg/kg/day. In a separate study, rats were fed in the diet 0, 20, or 40 mg/kg /day maleic anhydride, seven days a week for 90 days. There were no treatment-related effects. The NOAEL for this study is 40 mg/kg/day.

In a 183-day oral (dietary) study in rats there were renal lesions and an increase in the absolute and relative liver and kidney weights at 250 mg/kg/day and 600 mg/kg/day. The LOAEL for this study is 250 mg/kg/day. A NOAEL was not established.

In a 2-year oral (dietary) study in rats only marginal toxicity was observed which was evidenced by small (<6%), but dose-related, decrease in body weights of rats. The LOAEL for this study is 32 mg/kg/day and the NOAEL for this study is 10 mg/kg/day.

In a 90-day dietary study in dogs, there were no treatment related effects observed at doses up to 60 mg/kg/day, the highest dose tested.

In an oral (gavage) developmental toxicity study in CD rats, no treatment related adverse effects were observed. The NOAEL for both maternal and developmental toxicity was 140 mg/kg/day, the highest dose tested.

In a 2-generation oral (gavage) reproductive toxicity study in rats, significant mortality occurred in the F_0 and F_1 parental animals and maleic anhydride was toxic to parental animals in all dose groups (20, 55 and 150 mg/kg/day of maleic anhydride). There was no significant reduction in the percentage of pregnant females or the percentage of fertile males. Adverse effects on litter size and on pup survival were observed at the dose of 55 mg/kg/day and above in the F_2 litters. Maleic anhydride was toxic to parental animals in all dose groups. For parental toxicity the LOAEL was 20 mg/kg/day. Although a NOAEL for parental toxicity was not established, the selected NOAEL (which is from the 2-year toxicity study in the rat) will be protective of the kidney and bladder effects seen at the lowest dose tested in this study, since the 2-year toxicity study examined those organs and found no effects. The NOAEL for offspring toxicity was 55 mg/kg/day based on decreased pup survival observed at 150 mg/kg/day.

Maleic anhydride was negative for mutagenicity or chromosomal aberrations in a battery of tests of genotoxicity including a bacterial gene mutation test, an *in vivo* mammalian chromosomal aberration test using rat bone marrow and an *in vitro* chromosomal test.

In the previously described 2-year dietary study, male and female rats were exposed to 0, 10, 32, or 100 mg/kg/day maleic anhydride in feed for two years. There were no increases in tumor incidence that were considered related to maleic anhydride exposure. Additionally in a two-year chronic feeding study on Osborne-Mendel rats fed 0, 0.5, 1.0 or 1.5% maleic acid in their diets for two years resulted in no treatment-related increases in tumors.

A 1-hour neurotoxicity inhalation study exposed rats to 0.72 mg/L of maleic acid which produced generalized inactivity, hyperpnea and sedation within 15 minutes of exposure. Gross necropsy revealed no significant findings. No neurotoxic effects have been reported in the other available studies.

No immunotoxicity studies on maleic anhydride or maleic acid were available in the database.

In a metabolism study, dogs were fed 60 mg/kg/day maleic anhydride for 90 days. Using a one compartment model, uptake rate and elimination rate constants were calculated as 3.49 x 10^{-3} per day and 8.32 x 10^{-2} per day, respectively. Based on this model, 99% of steady state was reached by day 55 of the study.

Maleic anhydride is readily hydrolyzed to maleic acid under aqueous conditions and is then hydroxylated to malic acid, which participates in the Krebs cycle or may be excreted unchanged or in conjugated form.

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*.

An acute effect was not found in the database for maleic anhdyride.

The 2-year oral toxicity study in rats was selected for dietary and dermal exposure scenarios (all non-acute durations) for this risk assessment. The NOAEL in this study was 10 mg/kg/day. The LOAEL was 32 mg/kg/day based on slight to marginal decreases in body weight. The rationale for selecting this study for the dietary is based on the fact that this study provided the lowest and most conservative toxicity endpoint in the most sensitive species for oral after a long-term exposure. No repeat dose dermal toxicity studies are available for maleic anhydride; the dermal risk assessment was conducted using the most sensitive conservative oral endpoint. An uncertainty factor of 100x was applied, 10x for interspecies variability and 10x for

intraspecies variability; the FQPA safety factor was reduced to 1x. No dermal absorption studies were available for maleic anhydride or maleic acid, therefore, a dermal absorption value was estimated using the ratio of an oral LD_{50} and a dermal LD_{50}. The two studies used were the oral rabbit LD_{50} of 875 mg/kg and the dermal rabbit LD_{50} of 2,620 mg/kg. The resulting estimated dermal absorption was 33%. Therefore, a dermal absorption factor of 33% will be used for dermal exposure scenarios.

The 6-month inhalation toxicity study in rats was selected for inhalation exposure scenarios (all durations) for this risk assessment. The NOAEL in this study was 3.3 mg/m^3 or 0.93 mg/kg/day based on localized eye/nasal irritation effects seen at the LOAEL of 9.8 mg/m^3. Since the major effect of maleic anhydride is irritation via inhalation, this endpoint is protective of any systemic toxicity seen at concentrations of 32 mg/m^3 and above seen in the 28-day inhalation toxicity study. An uncertainty factor of 100x was applied, 10x for interspecies variability and 10x for intraspecies variability. The FQPA safety factor was reduced to 1x.

C. Exposure Assessment

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

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for maleic anhydride therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM–FCID),

Version 3.16, EPA, which includes 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. 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 maleic anhydride, EPA made specific adjustments to the dietary exposure assessment to account for the use limitation of maleic anhydride (as an inert ingredient in pesticide formulations applied to apples with a minimum preharvest interval of 21 days and at maximum concentration of 3.5% by weight in all other 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 maleic anhydride, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic

dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

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

Maleic anhydride may be used as inert ingredient in pesticide products that are registered for specific uses that may result in indoor or outdoor residential inhalation and dermal exposures. A screening-level residential exposure and risk assessment was completed utilizing conservative residential exposure assumptions. The Agency assessed short- and intermediate-term dermal and inhalation exposures for residential handlers that would result from low pressure handwand, hose end sprayer and trigger sprayer for outdoor scenarios of each pesticide type, herbicide, insecticide and fungicide and mopping, wiping and aerosol sprays for indoor scenarios. The Agency assessed post-application short-term dermal exposure for children and adults as well as short-term hand-to-mouth exposure for children from contact with treated lawns.

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 maleic anhydride to share a common mechanism of toxicity with any other substances, and maleic anhydride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that maleic anhydride 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*. There is no evidence of increased quantitative or qualitative susceptibility of rat fetuses to the effects of maleic anhydride. In the 2-generation reproduction study, the LOAEL for parental toxicity was 20 mg/kg/day. No adverse effects on litter size or pup survival were noted at doses up to 55 mg/kg/day.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for maleic anhydride is adequate for characterizing the toxicity and assessing the risk from dietary exposure.

ii. There is no indication that maleic anhydride is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no indication that maleic anhydride is an immunotoxic chemical and there is no need for an immunotoxicity study or additional UFs to account for immunotoxicity.

iv. There is no evidence that maleic anhydride results in increased susceptibility in *in utero* in rats in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening studies and prenatal developmental studies.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on highly conservative model that assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has residues of inert ingredient equivalent to the residue level of the highest established tolerance for an active ingredient on a given commodity. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to maleic anhydride in drinking water. EPA used similarly conservative assumptions to assess post application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by maleic anhydride.

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, maleic anhydride 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 maleic anhydride from food and water will utilize 72.4% 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 maleic anhydride is not expected.

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).

Maleic anhydride may be used as an inert ingredient in pesticide products that are registered for use**s** 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 maleic anhydride.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 112 for adults and 105 for children. Because EPA's level of concern for maleic anhydride 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).

Maleic anhydride is currently used as an inert ingredient in pesticide products that are registered for use**s** 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 short-term residential exposures to maleic anhydride.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 178 for adults and 119 for children. Because EPA's level of concern for maleic anhydride is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population*. Based on the discussion in Unit IV.A., maleic anhydride is not expected to pose a cancer risk.

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 maleic anhydride residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of maleic anhydride that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption. The 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 for sale or distribution for use on growing crops with concentrations of maleic anhydride exceeding 3.5% by weight of the formulation.

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 maleic anhydride when used in pesticide formulations as an inert ingredient (stabilizer), not to exceed 3.5% by weight of the formulation, instead of the 5% limit requested. The basis for this revision can be found at

http://www.regulations.gov in document Maleic Anhydride; 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 Pre-harvest Pesticide Products under 40 CFR 180.920 in docket ID number EPA-HQ-OPP-2014-0853.

VI. Conclusions

Therefore, EPA is amending the existing exemption from the requirement of a tolerance under 40 CFR 180.920 for maleic anhydride (CAS Reg. No. 108-31-6). In addition to the existing limitation for use as an inert ingredient (stabilizer) in pesticide formulations applied to growing crops for use in pesticide formulations applied to apples with a minimum preharvest interval of 21 days, the Agency is extending the exemption for use in all pesticide formulations at a maximum concentration not to exceed 3.5% in the pesticide formulation. In order to clarify that this extension applies only to maleic anhydride, the Agency is separating the existing exemption for maleic anhydride from the existing maleic acid exemption.

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: May 6, 2016.

Daniel J. Rosenblatt,
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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:

i. Remove the existing entry for “Maleic acid and maleic anhydride” from the table.

ii. Add alphabetically the following entries “Maleic acid,” and “Maleic anhydride” to the table to read as follows:

§ 180.920 Inert ingredients used preharvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Maleic acid	For pesticide formulations applied to apples with a minimum preharvest interval of 21 days	Stabilizer
Maleic anhydride (CAS Reg. No. 108-31-6)	Not to exceed 3.5% in pesticide formulations; or for pesticide formulations applied to apples with a minimum preharvest interval of 21 days	Stabilizer
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