

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: April 25, 2016.

**Susan Lewis,**

*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 § 180.515, the table in paragraph (a) is revised to read as follows:

#### § 180.515 Carfentrazone-ethyl; tolerance for residues.

(a) \* \* \*

Commodity	Parts per million
Acerola .....	0.10
Almond, hulls .....	0.20
Animal feed, nongrass, crop group 18, forage .....	2.0
Animal feed, nongrass, crop group 18, hay .....	5.0
Animal feed, nongrass, crop group 18, seed .....	15.0
Artichoke, globe .....	0.10
Asparagus .....	0.10
Atemoya .....	0.10
Avocado .....	0.10
Banana .....	0.10
Berry, low growing, subgroup 13–07G .....	0.10
Birida .....	0.10
Bushberry subgroup 13–07B .....	0.10
Cacao bean, bean .....	0.10
Cactus .....	0.10
Caneberry subgroup 13A <sup>1</sup> .....	0.1
Caneberry subgroup 13–07A .....	0.10
Canistel .....	0.10
Cattle, fat .....	0.10
Cattle, meat .....	0.10
Cattle, meat byproducts .....	0.10
Cherimoya .....	0.10
Coffee, bean, green .....	0.10
Cotton, gin byproducts .....	10
Cotton, hulls <sup>1</sup> .....	0.60
Cotton, meal <sup>1</sup> .....	0.35
Cotton, refined oil <sup>1</sup> .....	1.0
Cottonseed subgroup 20C .....	0.20
Custard apple .....	0.10
Date, dried fruit .....	0.10
Feijoa .....	0.10
Fig .....	0.10

Commodity	Parts per million	Commodity	Parts per million
Fish .....	0.30	Stevia .....	0.10
Fruit, citrus, group 10–10 .....	0.10	Strawberrypear .....	0.10
Fruit, pome, group 11–10 .....	0.10	Sugar apple .....	0.10
Fruit, small vine climbing, subgroup 13–07F, except Fuzzy kiwifruit .....	0.10	Sugarcane .....	0.15
Fruit, stone, group 12–12 .....	0.10	Sunflower, subgroup 20B .....	0.10
Goat, fat .....	0.10	Tea, dried .....	0.10
Goat, meat .....	0.10	Teff, forage .....	1.0
Goat, meat byproducts .....	0.10	Teff, grain .....	0.25
Grain, aspirated grain fractions ..	1.8	Teff, hay .....	0.30
Grain, cereal, group 15 (except rice grain and sorghum grain) ..	0.10	Teff, straw .....	3.0
Grain, cereal, group 16, forage ..	1.0	Ti, leaves .....	0.10
Grain, cereal, group 16, hay .....	0.30	Ti, roots .....	0.10
Grain, cereal, group 16, stover ..	0.80	Vanilla .....	0.10
Grain, cereal, group 16, straw ....	3.0	Vegetable, brassica, leafy, group 5 .....	0.10
Grass, forage .....	5.0	Vegetable, bulb, group 3–07 .....	0.10
Grass, hay .....	8.0	Vegetable, cucurbit, group 9 .....	0.10
Guava .....	0.10	Vegetable, foliage of legume, except soybean, subgroup 7A ....	0.10
Herbs and spices group 19 .....	2.0	Vegetable, fruiting, group 8–10 ..	0.10
Hog, fat .....	0.10	Vegetable, leafy, except brassica, group 4 .....	0.10
Hog, meat .....	0.10	Vegetable, leaves of root and tuber, group 2 .....	0.10
Hog, meat byproducts .....	0.10	Vegetable, legume, group 6 .....	0.10
Hop, dried cones .....	0.10	Vegetable, root and tuber, group 1 .....	0.10
Horse, fat .....	0.10	Wasaba, roots .....	0.10
Horse, meat .....	0.10	Wax jambu .....	0.10
Horse, meat byproducts .....	0.10		
Horseradish .....	0.10		
llama .....	0.10		
Jaboticaba .....	0.10		
Kava, roots .....	0.10		
Kiwifruit .....	0.10		
Longan .....	0.10		
Lychee .....	0.10		
Mango .....	0.10		
Milk .....	0.05		
Noni .....	0.10		
Nut, tree, group 14–12 .....	0.10		
Olive .....	0.10		
Palm heart .....	0.10		
Palm heart, leaves .....	0.10		
Papaya .....	0.10		
Passionfruit .....	0.10		
Pawpaw .....	0.10		
Peanut .....	0.10		
Peanut, hay .....	0.10		
Peppermint, tops .....	0.10		
Persimmon .....	0.10		
Pomegranate .....	0.10		
Poultry, meat byproducts .....	0.10		
Psyllium, seed .....	0.10		
Pulasan .....	0.10		
Quinoa, grain .....	0.10		
Rambutan .....	0.10		
Rapeseed, forage .....	0.10		
Rapeseed subgroup 20A .....	0.10		
Rice, grain .....	1.3		
Rice, straw <sup>1</sup> .....	1.0		
Sapodilla .....	0.10		
Sapote, black .....	0.10		
Sapote, mamey .....	0.10		
Sheep, fat .....	0.10		
Sheep, meat .....	0.10		
Sheep, meat byproducts .....	0.10		
Shellfish .....	0.30		
Sorghum, grain .....	0.25		
Soursop .....	0.10		
Soybean, seed .....	0.10		
Spanish lime .....	0.10		
Spearmint, tops .....	0.10		
Star apple .....	0.10		
Starfruit .....	0.10		

<sup>1</sup>Effective Date to be removed: May 18, 2016.

\* \* \* \* \*

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA–HQ–OPP–2015–0524; FRL–9944–10]

#### Propanamide, 2-hydroxy-N, N-dimethyl-; 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 propanamide, 2-hydroxy-N, N-dimethyl- (CAS Reg. No. 35123–06–9) when used as an inert ingredient (solvent/co-solvent) in pesticides applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 or in pesticides applied to animals under 40 CFR 180.930 limited to maximum concentration of 20% by weight in the pesticide formulation. Spring Trading Company, LLC on behalf of BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the

requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of propanamide, 2-hydroxy-*N*, *N*-dimethyl-.

**DATES:** This regulation is effective May 2, 2016. Objections and requests for hearings must be received on or before July 1, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0524, 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: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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-2015-0524 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 July 1, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0524, 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 September 9, 2015 (80 FR 54257) (FRL-9933-26), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide

petition (PP IN-10782) by Spring Trading Company, LLC (10805 W. Timberwagon Circle Spring, TX 77380) on behalf of BASF Corporation (100 Campus Drive, Florham Park, NJ 07932). The petition requested that 40 CFR 180.910 and 40 CFR 180.930 be amended by establishing exemptions from the requirement of a tolerance for residues of propanamide, 2-hydroxy-*N*, *N*-dimethyl- (CAS Reg. No. 35123-06-9) when used as an inert ingredient (solvent/co-solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest or in pesticides applied to animals, respectively. That document referenced a summary of the petition prepared by Spring Trading Company, 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.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of propanamide, 2-hydroxy-*N*, *N*-dimethyl to 20% by weight in pesticide formulations. The reasons for this change are explained in Unit V.B. below.

### **III. Inert Ingredient Definition**

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

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will

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

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

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for propanamide, 2-hydroxy-*N*, *N*-dimethyl- including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with propanamide, 2-hydroxy-*N*, *N*-dimethyl- 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 propanamide, 2-hydroxy-*N*, *N*-dimethyl- 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.

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- is of low acute oral, dermal and inhalation toxicity in rats; all lethal dose (LD)<sub>50</sub>s are greater than 1,000 mg/kg. Dermal irritation is not observed in rabbits. It is mildly irritating to the eyes of rabbits. It is not a dermal sensitizer in mice in the lymph node assay.

The toxicity studies summarized below were all conducted with propanamide, 2-hydroxy-*N*, *N*-dimethyl- except the chronic toxicity study. That study was conducted with *N*, *N*-dimethylacetamide, a structurally similar chemical. The only difference between the two chemicals is that *N*, *N*-dimethylacetamide is missing a hydroxyl group on a carbon atom. Both compounds are expected to undergo similar metabolism (in this case, *N*-oxidation) by cytochrome P450 enzymes and have similar toxicological profiles; therefore, the Agency has determined the data to be suitable for evaluating propanamide.

In rats, 90 days of oral exposure to propanamide, 2-hydroxy-*N*, *N*-dimethyl- results in increased cholesterol and triglyceride levels, increased liver weights and centrilobular hypertrophy at 1,000 milligrams/kilogram/day (mg/kg/day), the limit dose. The NOAEL is 500 mg/kg/day. Reproduction parameters, estrus cyclicity and sperm parameters were also evaluated in this study and were found to be unaffected at 1,000 mg/kg/day.

A developmental toxicity study in rats showed no maternal toxicity at 500 mg/kg/day, the highest dose tested. Quantitative fetal susceptibility was observed as reduced body weight in pups at 500 mg/kg/day. The developmental NOAEL was 200 mg/kg/day.

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- was not mutagenic in the Chinese hamster ovary (CHO) cells HGPRT locus gene mutation assay or the micronucleus test.

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- is not expected to be carcinogenic based on the absence of structural alerts using Deductive Estimation of Risk from Existing Knowledge (Derek) Nexus program and the lack of mutagenicity. It is not expected to be neurotoxic based on the functional observation battery or on motor activity in the 90-day oral toxicity study in rats.

Immunotoxicity studies for propanamide, 2-hydroxy-*N*, *N*-dimethyl- were not available for review. However, evidence of immunotoxicity was not observed in the submitted studies.

Chronic studies with propanamide, 2-hydroxy-*N*, *N*-dimethyl- are not available for review. However, a chronic study conducted for 12 months in rats treated with *N*, *N*-dimethylacetamide, a structurally similar chemical, was used as surrogate data. In this study toxicity manifested as reduced bodyweight was observed at 300 mg/kg/day. The NOAEL is 100 mg/kg/day.

#### 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 therefore an acute dietary assessment is not necessary. The chronic reference dose (cRfD) as well as the toxicity endpoint applicable to all exposure scenarios was based on the 12-month chronic toxicity study in rats. In this study, the NOAEL was 100 mg/kg/day based on reduced bodyweights at 300 mg/kg/day, the LOAEL. This represents the lowest NOAEL in the most sensitive species in the toxicity database. The standard uncertainty factors were applied to account for interspecies (10x) and intraspecies (10x) variations. The Food Quality Protection

Act Safety Factor (FQPA SF) was reduced to 1x. Default values of 100% absorption were used in dermal and inhalation toxicity endpoint selection.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propanamide, 2-hydroxy-*N*, *N*-dimethyl-, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from propanamide, 2-hydroxy-*N*, *N*-dimethyl- in food as follows:

Dietary exposure (food and drinking water) to propanamide, 2-hydroxy-*N*, *N*-dimethyl- can occur following ingestion of foods with residues from treated crops and animals. Because no adverse effects attributable to a single exposure of propanamide, 2-hydroxy-*N*, *N*-dimethyl- 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 propanamide, 2-hydroxy-*N*, *N*-dimethyl-. 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 (PCT) was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 20% 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

propanamide, 2-hydroxy-*N*, *N*-dimethyl-, 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).

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- 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 worst-case residential exposure by assessing propanamide, 2-hydroxy-*N*, *N*-dimethyl- in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios).

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 propanamide, 2-hydroxy-*N*, *N*-dimethyl- to share a common mechanism of toxicity with any other substances, and propanamide, 2-hydroxy-*N*, *N*-dimethyl- does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propanamide, 2-hydroxy-*N*, *N*-dimethyl- does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

### D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal

and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

The toxicity database for propanamide, 2-hydroxy-*N*, *N*-dimethyl- contains a subchronic, developmental, chronic and mutagenicity studies. There is no indication of neurotoxicity or immunotoxicity in the available studies; therefore, there is no need to require neurotoxicity or immunotoxicity studies. Quantitative fetal susceptibility was observed in the developmental study in rats. Fetal toxicity (reduced bodyweight) was observed at 500 mg/kg/day, the highest dose tested, while toxicity was not observed in maternal animals. The developmental NOAEL was 200 mg/kg/day. However, fetal effects are not of concern since the cRfD (1mg/kg/day) will be protective of effects seen at 500 mg/kg/day. In addition, the Agency used conservative exposure estimates, with 100 PCT, tolerance-level residues, conservative drinking water modeling numbers, and a worst-case assessment of potential residential exposure for infants and children. Based on the adequacy of the toxicity and exposure databases and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x.

### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified

and no acute dietary endpoint was selected.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to propanamide, 2-hydroxy-*N*, *N*-dimethyl- from food and water will utilize 28.4% 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).

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- may be used as an inert ingredient in pesticide products that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to propanamide, 2-hydroxy-*N*, *N*-dimethyl-. Using the exposure assumptions described above, EPA has concluded that the combined short-term aggregated food, water, and residential exposures result in MOEs of 115 for both adult males and females. Adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden with a high-end post-application dermal exposure from contact with treated lawns. Adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden with a high-end post-application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 154 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

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).

Propanamide, 2-hydroxy-*N*, *N*-dimethyl- may be used as an inert ingredient in pesticide products that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to propanamide,

2-hydroxy-*N*, *N*-dimethyl-. Using the exposure assumptions described above, EPA has concluded that the combined intermediate-term aggregated food, water, and residential exposures result in aggregate MOEs of 591 for adult males and females. Adult residential exposure combines indoor hard surface, wiping with a high-end post-application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 214 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on a DEREK structural alert analysis, the lack of mutagenicity and the lack of specific organ toxicity in the chronic toxicity study, propanamide, 2-hydroxy-*N*, *N*-dimethyl- 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 propanamide, 2-hydroxy-*N*, *N*-dimethyl-.

## 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 propanamide, 2-hydroxy-*N*, *N*-dimethyl- in or on any food commodities. EPA is establishing a limitation on the amount of propanamide, 2-hydroxy-*N*, *N*-dimethyl- that may be used in pesticide formulations applied to growing crops. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for use on growing crops for sale or distribution that exceeds 20% by weight of propanamide, 2-hydroxy-*N*, *N*-dimethyl-.

### B. Revisions to Petitioned-For Tolerance Exemptions

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 propanamide, 2-hydroxy-*N*, *N*-dimethyl when used in pesticide formulations as an inert ingredient (solvent/co-solvent), not to exceed 20% by weight of the formulation, instead of the unlimited use requested. When considering unlimited use resulted in aggregate risks of concern, the petitioner revised their request to seek a 20% limitation by weight of formulation. The basis for this revision can be found at <http://www.regulations.gov> in document "Propanamide, 2-hydroxy-*N*, *N*-dimethyl-; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption From the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations" in docket ID number EPA-HQ-OPP-2015-0524.

## VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of propanamide, 2-hydroxy-*N*, *N*-dimethyl- (Reg. No. 35123-06-9) when used as an inert ingredient (solvent/co-solvent) at a maximum concentration of 20% by weight in pesticide formulations applied to growing crops or raw agricultural commodities after harvest and under 40 CFR 180.930 when used in pesticide formulations applied to animals.

## VII. Statutory and Executive Order Reviews

This action establishes exemptions to the requirement for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority

Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the 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: April 21, 2016.  
**Daniel J. Rosenblatt,**  
*Acting 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	
*	*	*	*	*	*	*
Propanamide, 2-hydroxy- <i>N</i> , <i>N</i> -dimethyl- (CAS Reg. No. 35123–06–9)				Not to exceed 20% by weight in pesticide formulation.	Solvent/co-solvent.	
*	*	*	*	*	*	*

■ 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	
*	*	*	*	*	*	*
Propanamide, 2-hydroxy- <i>N</i> , <i>N</i> -dimethyl- (CAS Reg. No. 35123–06–9)				Not to exceed 20% by weight in pesticide formulation.	Solvent/co-solvent	
*	*	*	*	*	*	*