List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 20, 2018.

Alexandra Dapolito Dunn,

Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart EE—New Hampshire

■ 2. Amend § 52.1520 by:

■ a. In paragraph (c), amend the table by revising the entry ''Env–A 900''; and

■ b. In paragraph (d), amend the table by:

■ i. Removing the two entries entitled ''Sturm, Ruger & Company''; and

■ ii. Adding a new entry entitled ''Sturm Ruger & Company'' at the end of the table.

The revisions and additions read as follows:

§ 52.1520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED NEW HAMPSHIRE REGULATIONS

State citation	Title/subject	State effective date	EPA approval date [1]	Explanations
*	*	*	*	*
Env–A 900	Owner or Operator Obligations	7/18/2015	3/30/2018, [Insert **Federal Register** citation].	Approved sections Env–A 901 through 911, except for the following sections withdrawn by the State and which are not part of the approved SIP: Env–A 907.01(d) and (e); 907.02(a)(1), (d)(1) a. and c., (d)(2), and (e); 907.03; 911.04(b) and (c); 911.05.
*	*	*	*	*

[1] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

(d) * * *

EPA-APPROVED NEW HAMPSHIRE SOURCE SPECIFIC REQUIREMENTS

Name of source	Permit No.	State effective date	EPA approval date [2]	Additional explanations/§ 52.1535 citation
*	*	*	*	*
Sturm Ruger & Company.	ARD–03–001	2/2/2017	3/30/2018, [Insert **Federal Register** citation].	VOC RACT Order, as amended February 2, 2017, except sections D.1, and introductory clauses to sections D.2, D.3.b, D.5.a.i and b.i.

[2] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

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[FR Doc. 2018–06381 Filed 3–29–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0660, EPA–HQ–OPP–2015–0720, EPA–HQ–OPP–2015–0723; FRL–9974–70]

N,N-Dimethyl 9-Decenamide; N,N-Dimethyldodecanamide; N,N-Dimethyltetradecanamide; 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 *N,N*-dimethyl 9-decenamide (CAS Reg No. 1356964–77–6); *N,N*-dimethyldodecanamide (CAS Reg No. 3007–53–2); and *N,N*-dimethyltetradecanamide (CAS Reg No. 3015–65–4) when used as inert ingredients (surfactant, solvent) on growing crops and raw agricultural commodities after harvest, with a limitation that the concentration of the inert ingredient is at a concentration not

to exceed 20% by weight in a pesticide formulation. Technology Sciences Group on behalf of Stepan Company 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 *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide when used in accordance with the established limitations.

DATES: This regulation is effective March 30, 2018. Objections and requests for hearings must be received on or before May 29, 2018, 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–2015–0660, EPA–HQ–OPP–2015–0720 and EPA–HQ–OPP–2015–0723 are available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0660, EPA–HQ–OPP–2015–0720 and EPA–HQ–OPP–2015–0723 are 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 May 29, 2018. 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–2015–0660, EPA–HQ–OPP–2015–0720 and EPA–HQ–OPP–2015–0723 are, by one of the following methods:

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

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

II. Petition for Exemption

In the **Federal Register** of November 23, 2015 (80 FR 72941) (FRL–9936–73), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of pesticide petitions IN–10791, IN–10805, and IN–10806 by Technology Sciences Group, (1150 18th Street NW, Suite 1000 Washington, DC 20036) on behalf of Stepan Company (22 West Frontage Road, Northfield, Illinois 60093). The petitions requested that 40 CFR 180.910 be amended by establishing exemptions from the requirement of a tolerance for residues of *N,N*-dimethyl 9-decenamide (CAS Reg No. 1356964–77–6) (IN–10791); *N,N*-dimethyldodecanamide (CAS Reg No. 3007–53–2) (IN–10806); and *N,N*-dimethyltetradecanamide (CAS Reg No. 3015–65–4) (IN–10805) when used as inert ingredients (surfactant/solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. That document referenced summaries of the petitions prepared by Technology Sciences Group on behalf of Stepan Company, the petitioner, which are available in the corresponding dockets, *http://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.C.

Based upon review of the data supporting the petitions, EPA has limited the maximum concentration of *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide to not more than 20% by weight in pesticide formulations. The reason for this change is explained in Unit V.B. below.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing

agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide 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 *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide and *N,N*-dimethyltetradecanamide 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.

N,N-dimethyl 9-decenamide is very similar in structure to *N,N*-dimethyldecanamide (differing only in the presence of a single double bond), and to *N,N*-dimethyloctanamide (differeing only in alkyl group carbon chain length and the presence of a terminal double bond). *N,N*-dimethyldodecanamide is very similar in structure to *N,N*-dimethyldecanamide and *N,N*-dimethyloctanamide, differing only in alkyl group carbon chain length. Similarly, *N,N*-dimethyltetradecanamide is very similar in structure to *N,N*-dimethyldecanamide and *N,N*-dimethyloctanamide, differing only in alkyl group carbon chain length. Based upon these close structural similarities, *N,N*-dimethyldecanamide and *N,N*-dimethyloctanamide are considered suitable surrogates to characterize toxicity due to exposure to *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide.

N,N-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide are not sensitizers. Based on the acute toxicity data on surrogate chemicals *N,N*-dimethyldecanamide and *N,N*-dimethyloctanamide, they are expected to be of low oral acute toxicity; the lethal dose, (LD_{50}) in rats is 1,770 milligrams/kilogram (mg/kg). The acute dermal LD_{50} is greater than 400 mg/kg and the acute inhalation lethal concentration, LC_{50} is greater than 3.55 milligrams/liter (mg/L). They are expected to be a severe irritant to the skin and corrosive to the eyes.

Following subchronic exposure in the diet of the rat, toxicity is manifested as an increased incidence of basophilic regenerative tubules in the renal cortex as well as a slight increase in the amount of protein excreted in the urine at 10,000 parts per million (ppm) (787.6 mg/kg/day). The no-observed-adverse effect level (NOAEL) is 2,000 ppm (136.8 mg/kg/day). In the 6-weeks toxicity study in dogs via gavage, decreased food consumption was seen at 1,000 mg/kg/day, the highest dose tested. The NOAEL was 500 mg/kg/day.

No fetal susceptibility is observed in developmental studies in rats or rabbits. In rats, maternal and developmental toxicity are observed at 450 mg/kg/day. In rats, maternal toxicity is manifested as clinical signs, food consumption and increased post-implantation loss. Developmental toxicity is manifested as decreased fetal body weight and increased incidence of skeletal malformations/variations. In the rabbit, neither maternal nor developmental toxicity is observed at dose levels up to 1,000 mg/kg/day.

In a 5-day repeat dose inhalation toxicity study in rats (nose only, 6-hour exposure per day), marginally reduced body weight gains and goblet cell hyperplasia in the nasal and paranasal cavities were seen at 521.2 mg/m^3 (approximately 426.8 mg/kg/day), the highest dose tested. The NOAEL is 111.2 mg/m^3).

N,N-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide are negative for gene mutations and clastogenicity in the Ames test and the micronucleus assay, respectively.

A Derek Nexus structural alert analysis was conducted with *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide are not expected to be carcinogenic.

No neurotoxicity or immunotoxicity studies are available for review with *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide. However, evidence of potential neurotoxicity or immunotoxicity was not observed in the submitted studies.

Based on the chemical structure and known mammalian enzymatic activities, *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide are expected to undergo carboxyamide hydrolysis by amidase enzymes that have broad substrate specificity, resulting in the corresponding carboxylic acid with a fatty acid structure.

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.*

The chronic reference dose (cRfD) as well as all dermal exposure scenarios, was based on the 90-day toxicity study in the rat. In this study, the LOAEL was 10,000 ppm (equivalent to 787.6 mg/kg/day) based on an increased incidence of basophilic regenerative tubules in the renal cortex as well as a slight increase in the amount of protein excreted in the urine. The NOAEL was 2,000 ppm (equivalent to 136.8 mg/kg/day). 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 additional uncertainty factor was reduced to 3x to account for extrapolation from subchronic to chronic exposures scenarios because the kidney effects were reversible and observed in male rats only. Additionally, in the dog following 6 weeks of oral exposure, no signs of toxicity were observed up to 500 mg/kg/day and the only sign of toxicity (decreased food consumption) was observed at the limit dose of 1,000 mg/kg/day. The 5-day inhalation toxicity study in rats was not selected for inhalation exposure assessment because oral end point and inhalation end points yielded comparable NOAEL. In addition, the nasal effects seen in this study is primarily due to irritation and marginally decreased in reduced body weight would have observed in the oral study. A dermal absorption factor of 85% was applied based on a dermal penetration study in rats and an *in vitro* dermal absorption study with human skin. The default value of 100% absorption was used for the inhalation absorption factor. The resultant chronic population adjusted dose (cPAD) is 0.456 mg/kg/day. The MOEs for short-term and intermediate-term occupational and residential exposures are 100.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide in food as follows:

Dietary exposure (food and drinking water) to *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide can occur following ingestion of foods with residues from treated crops. Because no adverse effects attributable to a single exposure of *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; or *N,N*-dimethyltetradecanamide 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 *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; or *N,N*-dimethyltetradecanamide. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. One hundred percent crop treated was assumed, default processing factors, and tolerance-level residues for all foods and use limitations of not more than 20% 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 *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide, 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).

N,N-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide may be used as 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 a conservative assessment of potential residential exposure by assessing *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios). The Agency's assessment of

adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger sprayer/home garden and indoor hard surface, wiping with a high-end post application dermal exposure from contact with treated lawns. The Agency's assessment of children's residential exposure includes total post-application exposures associated with total exposures associated with contact with treated lawns and surfaces (dermal and hand-to-mouth exposures).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of 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 *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide to share a common mechanism of toxicity with any other substances, and *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (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.

2. *Prenatal and postnatal sensitivity.* The toxicity database for *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide contains subchronic and developmental toxicity studies conducted with surrogate chemicals. Increased fetal susceptibility is not observed in either of the developmental toxicity studies in rats or rabbits. In rats, maternal (clinical signs, food consumption and increased post-implantation loss) and developmental (fetal body weight, increased incidence of skeletal malformations/variations) toxicity were observed at 450 mg/kg/day. In the rabbit, neither maternal nor developmental toxicity was observed up to 1,000 mg/kg/day. Reproduction toxicity studies were not available; however, increased post-implantation loss is observed at 450 mg/kg/day in the developmental toxicity study in rats. The established cRfD will be protective of the observed effect. In addition, the Agency used conservative exposure estimates, with 100 percent crop treated, tolerance-level residues, conservative drinking water modeling numbers, and a conservative assessment of potential residential exposure for infants and children. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment, and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x for short and intermediate-term exposure and 3 x for chronic exposure assessment.

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, *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide are 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 *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide from food and water will utilize 62.3% 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).

N,N-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide may be used as inert ingredients in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide.

Using the exposure assumptions described above for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 680 for both adult males and females. EPA has concluded the combined short-term aggregated food, water, and residential pesticide exposures result in an aggregate MOE of 359 for children. Because EPA's level of concern for *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; and *N,N*-dimethyltetradecanamide 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).

N,N-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide may be used as inert ingredients in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to *N,N*-dimethyl 9-decenamide, *N,N*-

dimethyldodecanamide, and *N,N*-dimethyltetradecanamide.

Using the exposure assumptions described above for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1475 for adult males and females. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 394 for children. Because EPA's level of concern for *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of structural alerts in a DEREK structural alert analysis and the lack of mutagenicity, *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide 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 *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide and *N,N*-dimethyltetradecanamide in or on any food commodities. EPA is establishing limitations on the amount of *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide and *N,N*-dimethyltetradecanamide that may be used in pesticide formulations applied to growing crops. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq*. EPA will not register any pesticide formulation for use on growing crops or raw agricultural commodities after harvest for sale or distribution that exceeds 20% by weight of *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide unless additional data are submitted that demonstrate a higher concentration would be safe.

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 *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide,and *N,N*-dimethyltetradecanamide when used in pesticide formulations as inert ingredients (surfactant/solvent), not to exceed 20% by weight of the formulation, instead of the unlimited use requested. Because unlimited use of *N,N*-dimethyl 9-decenamide; *N,N*-dimethyldodecanamide; or *N,N*-dimethyltetradecanamide resulted in aggregate risks of concern, EPA is establishing a 20% limitation in formulation to support the safety finding of these tolerance exemptions. The concern for unlimited use of theses inert ingredients is documented on page 4 of the Agency's risk assessment documents ''*N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations,'' which can be found at *http://www.regulations.gov in in docket ID number* EPA–HQ–OPP–2015–0660, EPA–HQ–OPP–2015–0720 and EPA–HQ–OPP–2015–0723, respectively.

C. Response to Comments

The comment was received from a private citizen who opposed the authorization to sell any pesticide that leaves a residue on food. The Agency recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute. EPA has evaluated all the available data and concluded that there is a reasonable certainty of no harm from the limited use of *N,N*-dimethyl 9-decenamide, *N,N*-dimethyldodecanamide, and *N,N*-dimethyltetradecanamide as inert ingredients in pesticide formulations. The commenter has not provided any information supporting a conclusion that such exposure will not be safe.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues of *N,N*-dimethyl 9-decenamide (CAS Reg No. 1356964–77–6), *N,N*-dimethyldodecanamide (CAS Reg No. 3007–53–2), and N,N-dimethyltetradecanamide (CAS Reg No. 3015–65–4) when used as inert ingredients (surfactant, solvent) at a maximum concentration not to exceed 20% by weight in any pesticide formulation applied to growing crops or raw agricultural commodities after harvest.

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); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress

in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 12, 2018.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the inert ingredients 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
* * *	* * *	*
N,N-Dimethyl 9-decenamide (CAS Reg. No. 1356964–77–6).	Not to exceed 20% by weight of pesticide formulation ..	Surfactant, solvent
N,N-Dimethyldodecanamide (CAS Reg. No. 3007–53–2)	Not to exceed 20% by weight of pesticide formulation ..	Surfactant, solvent
* * *	* * *	*
N,N-Dimethyltetradecanamide (CAS Reg. No. 3015–65–4).	Not to exceed 20% by weight of pesticide formulation ..	Surfactant, solvent
* * *	* * *	*

[FR Doc. 2018–06108 Filed 3–29–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6078–N]

Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items; Update to the Master List of Items Frequently Subject to Unnecessary Utilization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Master list deletions.

SUMMARY: This document announces the deletion of four Healthcare Common Procedure Coding System (HCPCS) codes from the Master List of Items Frequently Subject to Unnecessary Utilization that could be potentially subject to Prior Authorization as a condition of payment.

DATES: This action is applicable on April 30, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the December 30, 2015 final rule (80 FR 81674) titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,'' we implemented section 1834(a)(15) of the Social Security Act (the Act) by establishing an initial Master List (called the Master List of Items Frequently Subject to Unnecessary Utilization) of certain DMEPOS that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization and by establishing a prior authorization process for these items. The Master List includes items that meet the following criteria:

- Appear on the DMEPOS Fee Schedule list.
- Have an average purchase fee of $1,000 or greater (adjusted annually for inflation) or an average monthly rental fee schedule of $100 or greater (adjusted annually for inflation). (These dollar amounts are referred to as the ''payment threshold''.)
- Meet either of the following criteria:

++ Identified in a Government Accountability Office (GAO) or Department of Health and Human Services Office of Inspector General (OIG) report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.

++ Listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s).

The rule described the maintenance process of the Master List as follows:

- The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the ''payment threshold'' are added to the list when