



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0461; FRL-9385-9]

Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate; 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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate (1174627-68-9) when used as an inert ingredient solvent in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. SciReg, Inc. (12733 Director's Loop, Woodbridge, VA 22192), on behalf of Rhodia Inc. (CN 7500, 8 Cedar Brook Drive, Cranbury, NJ 08512-7500) 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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate.

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-2012-0461. All documents in the docket 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), EPA West 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: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5533; email address: dow.mark@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://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

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

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0461 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-2012-0461, 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., N.W., 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 August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8010) by SciReg, Inc. (12733 Director's Loop, Woodbridge, VA 22192), on behalf of Rhodia Inc. (CN 7500, 8 Cedar Brook Drive, Cranbury, NJ 08512-7500). The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate (1174627-68-9) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (40 CFR 180.910). That document referenced a summary of the petition prepared by SciReg, Inc. (12733 Director's Loop, Woodbridge,

VA 22192), on behalf of Rhodia Inc. (CN 7500, 8 Cedar Brook Drive, Cranbury, NJ 08512-7500), the petitioner, which is available in the docket, <http://www.regulations.gov>.

There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

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

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of 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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate 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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate 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.

Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is not acutely toxic *via* the oral or dermal routes of exposure. It is not a primary eye irritant, a primary skin irritant, or a dermal sensitizer. A repeat dose reproduction/developmental toxicity study showed no treatment-related effects on mating or fertility. There were no treatment-related effects on gestation, litter size, litter growth, and development as compared to controls. There was no evidence of any toxicity in the parameters evaluated in this study. The NOAEL for systemic toxicity was considered to be 1,000 milligram/kilograms body weight/day (mg/kg bw/day), the highest dose tested; a LOAEL was not observed in this study. A Bacterial Reverse Mutation Assay with *Salmonella typhimurium* concluded methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate did not induce mutagenic activity. A Gene Mutation Assay with Chinese hamster cells showed no reproducible dose-dependent increase in gene mutation frequency. A Chromosome Aberration Test with Human Lymphocytes *in vitro* showed no signs of cells carrying structural chromosomal aberrations. There was no evidence of an increase in polyploidy metaphases after

treatment with methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate. A Mammalian Erythrocyte Micronucleus Test with mice revealed no statistically significant decreases in the PCE/NCE ratio therefore, methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate, is considered to be negative for genotoxicity. Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate, is considered non-mutagenic, there are no known data that directly suggest that methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is carcinogenic. Based on the absence any toxicity at the limit dose, lack of mutagenicity concerns, and lack of carcinogenicity triggers in the Derek analysis, EPA concluded that methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is unlikely to pose a cancer risk at anticipated human exposures. Neurotoxicity was not observed in a reproduction/developmental toxicity screening study in rats, where neurotoxic parameters were evaluated. Immunotoxicity studies were not available for review. However, signs of immunotoxicity were not observed in any of the submitted studies.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate has a very low overall toxicity. The NOAEL is 1,000 mg/kg bw/day (limit dose). Since signs of toxicity were not observed at the limit dose, an endpoint of concern for risk assessment purposes was not identified. Therefore, since no endpoint of concern was identified for the acute, and chronic dietary exposure assessments, and short-, and intermediate-term dermal, and inhalation exposure assessments, a quantitative risk assessment for methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate in food as follows: Dietary exposure to methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate can occur from eating food treated with pesticide formulations containing this inert ingredient. In addition, food can pick up residues of methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate that has been used in pesticide formulations applied to treat food contact surfaces, thus resulting in indirect exposure. However, since an endpoint of concern for risk assessment was not identified, a quantitative dietary exposure assessment for methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate was not conducted.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate can occur by drinking water that has been contaminated by run-off from a pesticide treated area, and from antimicrobial formulations used in food-contact surface sanitizing solutions. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment from drinking water for methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate was not conducted.

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).

Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate may be used in inert ingredients in pesticide products that are registered for specific uses that may result in both indoor and outdoor residential exposures. However, since there are no toxicological

effects of concern occurring below the limit dose of 1,000 mg/kg bw/day, it is not necessary to conduct quantitative assessments of residential (non-occupational) exposures and risks. There are no dermal or inhalation toxicological endpoints of concern to the Agency, therefore, quantitative assessments have not been conducted.

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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate to share a common mechanism of toxicity with any other substances, and methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity, and the completeness of the database on toxicity and exposure, unless EPA determines, based on reliable data that a

different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) safety factor. 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 qualitative or quantitative susceptibility of infants and children in the available database.

3. *Conclusion.* As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. The available toxicity studies suggest low toxicity of methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate. The toxicity database for methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate contains acute oral, dermal and inhalation toxicity studies; skin, eye, and sensitization studies; mutagenicity studies (gene mutation, chromosomal aberrations assay), including *in vivo* micronucleus assay; and reproduction/developmental toxicity screening study in the rat. There is no indication based upon the available data that methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is a neurotoxic or immunotoxic chemical, or results in increased qualitative or quantitative susceptibility in infants or children. Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to this chemical when used as inert ingredient in pesticides formulations.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate when used as an inert ingredient, specifically as a solvent, in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest, is safe under FFDCA section 408.

1. *Aggregate cancer risk for U.S. population.* For the reasons stated in Unit IV.A, methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate is not expected to pose a cancer risk to humans.

2. *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 methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate residues when used as an inert ingredient in pesticide formulations under 40 CFR 180.910.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate.

(1174627-68-9) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under FFDC 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 tolerance 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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 20, 2013

Lois A. Rossi,
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, alphabetically add the following 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
* * *	* *	* *
Methyl 5-(dimethylamino)-2-methyl-5-oxopentanoate (1174627-68-9)		Solvent
* * *	* *	* *

[FR Doc. 2013-12457 Filed 05/28/2013 at 8:45 am; Publication Date: 05/29/2013]