



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2019-0571; FRL-10010-64]**

### **Magnesium sulfate; 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 magnesium sulfate anhydrous (CAS Reg. No. 7487-88-9); magnesium sulfate monohydrate (CAS Reg. No. 14168-73-1); magnesium sulfate trihydrate (CAS Reg. No. 15320-30-6); magnesium sulfate tetrahydrate (CAS Reg. No. 24378-31-2); magnesium sulfate pentahydrate (CAS Reg. No. 15553-21-6); magnesium sulfate hexahydrate (CAS Reg. No. 17830-18-1); and magnesium sulfate heptahydrate (CAS Reg. No. 10034-99-8), collectively referred to as magnesium sulfate, when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 4400 parts per million (ppm). Ecolab, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance for magnesium sulfate. This regulation eliminates the need to establish a maximum permissible level for residues of magnesium sulfate when used in accordance with these exemptions.

**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-2019-0571, 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 note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://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](mailto:RDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

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

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

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCFA section 408(g), 21 U.S.C. 346a(g), 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-2019-0571 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-2019-0571, 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 February 4, 2020 (85 FR 6129) (FRL-10003-17), EPA issued a document pursuant to FFDCFA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11325) by Ecolab, Inc., 1 Ecolab Place, St. Paul, MN 55102. The petition requested that 40 CFR 180.940(a) be amended by establishing exemptions from the requirement of a tolerance for residues of magnesium sulfate when used as an inert ingredient at an upper limit of 4,400 ppm in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

That document referenced a summary of the petition prepared by Ecolab, Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.B.

### **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 the FFDCCA 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 exemption is “safe.” Section 408(c)(2)(A)(ii) of the FFDCCA defines “safe” to mean that EPA has determined 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 it does not include occupational exposure. Section 408(b)(2)(C) of FFDCCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption

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 harm 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 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 to magnesium sulfate, including exposure resulting from the exemptions established by this action. EPA's assessment of exposures and risks associated with magnesium sulfate follows.

#### *A. Toxicological Profile*

Magnesium and sulfate are both abundant in the natural environment and are necessary for human life. Magnesium sulfate is commonly found in food and water, including as a naturally occurring element or as an additive. EPA has evaluated the available toxicity data for magnesium sulfate 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 magnesium sulfate 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.

Available studies on magnesium sulfate include an oral toxicity study, a dermal irritation study, a dermal sensitization study, a combined oral repeat dose reproduction/developmental toxicity screening test, and a 1-year inhalation cancer study in rats. No adverse effects of treatment were seen at the highest dose tested in the repeat dose oral study in rats at the NOAEL of 450 mg/kg/day. In addition, there was no evidence of carcinogenicity or neuropathological changes or effects reported in any of the studies. Magnesium sulfate was also tested for genotoxic and/or mutagenic effects using bacterial reverse mutation tests and *in vitro* mammalian chromosome aberration tests. The agency does not believe magnesium sulfate will be carcinogenic or neurotoxic.

All studies showed low acute and repeat dose toxicity and no reproductive/developmental toxicity. The primary health effect associated with magnesium sulfate is an osmotic laxative effect at high doses. The laxative effect is transient, and recovery is rapid and is usually observed only when following acute exposures to high concentrations above the limit dose of 1,000 mg/kg/day.

#### *B. Toxicological Points of Departure/Levels of Concern*

No toxicological endpoint of concern for magnesium sulfate has been identified in the database.

#### *C. Exposure Assessment*

1. *Dietary exposure from food, feed uses, and drinking water.* In evaluating dietary exposure to magnesium sulfate, EPA considered exposure under the current and proposed exemption from the requirement of a tolerance. Magnesium sulfate is currently exempt from the requirement of a tolerance under 40 CFR 180.910 for use as an inert ingredient in pesticide formulations used pre- and post-harvest. Dietary exposure to magnesium sulfate may occur from eating foods treated with pesticide formulations containing this inert ingredient and drinking water containing runoff from soils containing the treated crops. In addition, magnesium sulfate is used as a food additive and a dietary supplement. However, no toxicological endpoint of concern was identified for magnesium sulfate and therefore, a quantitative assessment of dietary exposure is not necessary.

2. *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). Residential exposure to magnesium sulfate may occur based on its use as an inert ingredient in pesticide formulations registered for residential uses. Additional non-dietary exposure may occur from use of magnesium sulfate in pharmaceutical products and cosmetics. However, no toxicological endpoint of concern was identified for magnesium sulfate and therefore a quantitative residential exposure assessment for magnesium sulfate was not conducted.

3. *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 magnesium sulfate to share a common mechanism of toxicity with any other substances, and magnesium sulfate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that magnesium sulfate 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*

Section 408(b)(2)(C) of the FFDCA requires EPA to retain an additional tenfold margin of safety in the case of threshold effects 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. As noted in Unit IV.B., there is no indication of threshold effects being caused by magnesium sulfate. Therefore, this requirement does not apply to the present analysis. Moreover, due to the lack of any toxicological endpoints of concern, EPA conducted a qualitative assessment of magnesium sulfate, which does not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on magnesium sulfate, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to magnesium sulfate residues. Therefore, the establishment of exemptions from the requirement of a tolerance under 40 CFR 180.940(a) for residues of magnesium sulfate when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public

eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum end-use concentration of 4,400 ppm is safe under FFDCa section 408.

## **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. Response to Comments*

One comment was submitted generally opposing the establishment of these tolerance exemptions and chemical use overall. Although the Agency recognizes that some individuals believe that chemicals should be banned, the existing legal framework provided by section 408 of the FFDCa authorizes EPA to establish exemptions from the requirement of a tolerance when it determines that the exemption is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCa requires EPA to consider, EPA has determined that this exemption from the requirement of a tolerance is safe. The commenter provided no information to support a conclusion that the exemption was not safe.

## **VI. Conclusions**

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.940(a) for residues of magnesium sulfate anhydrous (CAS Reg. No. 7487-88-9); magnesium sulfate monohydrate (CAS Reg. No. 14168-73-1); magnesium sulfate trihydrate (CAS Reg. No. 15320-30-6); magnesium sulfate tetrahydrate (CAS Reg. No. 24378-31-2); magnesium sulfate pentahydrate (CAS Reg. No. 15553-21-6); magnesium sulfate hexahydrate (CAS Reg. No. 17830-18-1); and magnesium sulfate heptahydrate (CAS Reg. No. 10034-99-8) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public

eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 4,400 ppm.

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

This action establishes tolerance exemptions 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), nor is it considered a regulatory action under 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 exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

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

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

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

#### **VIII. Congressional Review Act**

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

#### **List of Subjects in 40 CFR Part 180**

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

Dated: June 22, 2020.

**Michael Goodis,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore for the reasons stated in the preamble, EPA amends 40 CFR chapter I as follows:

**PART 180-- TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

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

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

2. In §180.940, amend the table in paragraph (a) by adding, in alphabetical order, “Magnesium sulfate anhydrous”, “Magnesium sulfate heptahydrate”, “Magnesium sulfate hexahydrate”, “Magnesium sulfate monohydrate”, “Magnesium sulfate pentahydrate”, “Magnesium sulfate tetrahydrate”, and “Magnesium sulfate trihydrate” to read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

<b>Pesticide Chemical</b>	<b>CAS Reg. No.</b>	<b>Limits</b>
* *	* *	* * *
Magnesium sulfate anhydrous	7487-88-9	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate heptahydrate	10034-99-8	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate hexahydrate	7830-18-1	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate monohydrate	14168-73-1	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate pentahydrate	5553-21-6	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate tetrahydrate	24378-31-2	When ready for use, the end-use concentration is not to exceed 4400 ppm
Magnesium sulfate trihydrate	15320-30-6	When ready for use, the end-use concentration is not to exceed 4400 ppm
* *	* *	* * *

\* \* \* \* \*

[FR Doc. 2020-14401 Filed: 7/17/2020 8:45 am; Publication Date: 7/20/2020]