



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2019-0368; FRL-10006-98]**

### **Methyl Mercaptan; 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 mercaptan in or on all food commodities when methyl mercaptan is used as a gopher repellent in irrigation lines in accordance with label directions and good agricultural practices. Acqua Concepts, Inc. (d/b/a Ag Water Chemical) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of methyl mercaptan under FFDCA.

**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-2019-0368, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution

Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@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-2019-0368 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-2019-0368, 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. Background**

In the **Federal Register** of August 2, 2019 (84 FR 37818) (FRL-9996-78), EPA issued a notice pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance exemption petition (PP 8F8713) by Acqua Concepts, Inc. (d/b/a Ag Water Chemical), 2665 S. Chestnut, Fresno, CA 93725. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the gopher repellent methyl mercaptan in or on all food commodities that use irrigation lines treated with methyl mercaptan. That notice referenced a summary of the petition prepared by the petitioner Acqua Concepts, Inc. (d/b/a Ag Water Chemical) and available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

## **III. Final Rule**

### *A. EPA's safety determination*

Section 408(c)(2)(A)(i) of FFDCFA allows EPA to establish an exemption from the requirement of 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 FFDCFA 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. Pursuant to FFDCFA section

408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C) and (D), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance 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. . . .” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicology and exposure data on methyl mercaptan and considered their validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Methyl mercaptan, also known as methanethiol, is a naturally occurring compound. In its ambient state, it is a colorless gas that smells like rotten cabbage. At lower temperatures, it can also be expressed as a liquid. Methyl mercaptan is naturally found in the blood and brain of humans and other animals, as well as in plant tissues. It is excreted from the human and animal body in feces. It also occurs naturally in certain foods, such as vegetables and some nuts and cheeses, and, as such, is often consumed by humans.

Methyl mercaptan has several commercial uses. Due to its strong odor, it is commonly employed as a leak detector in natural gas lines. Methyl mercaptan is also used in the production of plastics to moderate the growth of free radical polymers. Most notably, methyl mercaptan is used as a Food and Drug Administration-approved food additive to impart an umami flavor and

to act as an adjuvant (21 CFR 172.515).

As a new biochemical pesticide, methyl mercaptan is intended for use as a gopher repellent in irrigation/chemigation lines (subterranean, surface drip, and micro irrigation systems). The repellent mode of action is due to its noxious, putrid odor. Methyl mercaptan is intended to be applied in trace amounts through irrigation/chemigation lines (subterranean, surface drip, and micro irrigation systems). No direct application to food is expected, but it is possible that some trace amounts of the active ingredient may be taken up into the plant.

Overall, methyl mercaptan is considered to be of low toxicity relative to its proposed pesticidal use. Based on the available information and the fact that humans have been exposed to methyl mercaptan in food and nonfood products, the compound is considered to have a history of safe natural exposure. With specific regard to human oral toxicity, EPA notes that the human digestive system is designed to accommodate methyl mercaptan in its digestive processes. Notably, significant levels of methyl mercaptan (in excess of 1,000 ppm) are naturally produced by microflora within the human intestine. Even so, only trivial amounts are absorbed into the body because methyl mercaptan is readily oxidized in the human colon.

Although the available data indicate moderate acute inhalation toxicity, EPA does not expect any consumer exposures due to the proposed use pattern in irrigation systems. In the 90-day inhalation toxicity study, no adverse effects were identified.

With regard to potential exposure from the use of methyl mercaptan as a pesticidal active ingredient, EPA determined that expected exposures will be minimal and dietary hazards negligible. Foremost, EPA does not anticipate any significant dietary exposure due to the physical properties of methyl mercaptan. One, methyl mercaptan, which presents as a gas at ambient temperatures, is highly volatile and dissipates rapidly in the atmosphere. Two, methyl

mercaptan is readily biodegradable in the soil.

Based primarily on negligible exposure levels and additionally on the active ingredient's volatility (short half-life), its biodegradability, its capacity to be metabolized by humans, its history of safe consumption in both naturally occurring foods (such as nuts and cheeses) and foods containing methyl mercaptan as a food additive, and its use as a food-grade compound in pesticide products, the remaining toxicology data requirements were waived and no points of departure were identified that would necessitate a quantitative dietary assessment of methyl mercaptan.

Therefore, due to the low toxicological profile of available methyl mercaptan, its long history of safe exposure, and the minimal dietary exposure anticipated from its use as an active ingredient, EPA determined that the pesticidal use of methyl mercaptan (as a gopher repellent) poses no significant dietary risk.

As part of its risk assessment for methyl mercaptan, EPA further considered the potential risks of residential exposures, aggregate exposures, and cumulative risk. Based on methyl mercaptan's low toxicity, anticipated negligible dietary exposure, and history of safe use in consumer products, no risks of concern have been identified relative to residential (non-occupational) pesticidal uses or any aggregate of exposures to products containing methyl mercaptan. At this time, no residential uses of methyl mercaptan are proposed. Similarly, no risks of concern were identified for cumulative exposures to methyl mercaptan, since no common mechanism of toxicity was identified for either methyl mercaptan or its metabolites.

Therefore, based on the expectation of negligible exposures and low toxicity, EPA determined that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to methyl mercaptan.

A summary of the data upon which EPA relied and its risk assessment based on those data can be found within the document entitled “Federal Food, Drug, and Cosmetic Act (FFDCA) Safety Determination for Methyl Mercaptan.” This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based on its safety determination, EPA is establishing an exemption from the requirement of a tolerance for residues of methyl mercaptan in or on all food commodities when methyl mercaptan is used as a gopher repellent in irrigation lines in accordance with label directions and good agricultural practices.

#### *B. Analytical enforcement methodology*

The analytical method “ASTM D 5504–12 using a gas chromatograph equipped with a sulfur chemiluminescence detector (SCD)” is available to EPA for the detection and measurement of the pesticide residues.

#### **IV. 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 EPA. 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, 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 exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (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. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA 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, EPA 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 (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require EPA’s consideration of voluntary consensus standards pursuant to section 12(d) of the National

Technology Transfer and Advancement Act (15 U.S.C. 272 note).

#### **V. Congressional Review Act (CRA)**

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

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

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

Dated: April 2, 2020.

**Richard Keigwin,**

*Director, 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. Add § 180.1375 to subpart D to read as follows:

**§180.1375 Methyl mercaptan; exemption from the requirement of a tolerance.**

Residues of methyl mercaptan are exempt from the requirement of a tolerance in or on all food commodities, when methyl mercaptan is used as a gopher repellent in irrigation lines in accordance with label directions and good agricultural practices.

[FR Doc. 2020-08964 Filed: 5/15/2020 8:45 am; Publication Date: 5/18/2020]