



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1033; FRL-9968-30]

1,3-dibromo-5,5-dimethylhydantoin; 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 1,3-dibromo-5,5-dimethylhydantoin in or on food when used in antimicrobial pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and/or food processing equipment and utensils. In addition, this regulation establishes an exemption from the requirement of a tolerance for residues of 1,3-dibromo-5,5-dimethylhydantoin when used as an antimicrobial pesticide treatment solution. Albemarle Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting exemptions from the requirement of a tolerance for residues of 1,3-dibromo-5,5-dimethylhydantoin in end-use products applied to food contact surfaces and used for washing raw agricultural commodities. This regulation eliminates the need to establish a maximum permissible level of residues of 1,3-dibromo-5,5-dimethylhydantoin resulting from uses consistent with the terms of 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-2011-1033, 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: Steven H. Weiss, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 308-6411; email address: ADFRNotices@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.

- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.

- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.

- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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. To access the OSCPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

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-2011-1033 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-2011-1033, 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. Summary of Petitioned-For Exemption

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F7914) by Albemarle Corporation, 451 Florida Street, Baton Rouge, LA 70801. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of the antimicrobial 1,3-dibromo-5,5-dimethylhydantoin resulting from the use of this antimicrobial in food contact surface sanitizing solutions applied to food contact surfaces in public eating places, dairy processing equipment, and food-processing equipment and utensils at concentrations not to exceed 500 parts per million (ppm) of total bromine. The petition also requested establishment of an exemption from the requirement of a tolerance for residues of the antimicrobial 1,3-dibromo-5,5-dimethylhydantoin in or on all raw agricultural commodities resulting from the use of 1,3-dibromo-5,5-dimethylhydantoin as an antimicrobial treatment in solutions containing a diluted end-use concentration of all bromide-producing chemicals in the solution not to exceed 900 ppm of total bromine. That document referenced a summary of the petition prepared by Albemarle Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. 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 exemption is “safe.” Section 408(c)(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. Pursuant to FFDCA 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), which 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”

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 1,3-dibromo-5,5-dimethylhydantoin including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,3-dibromo-5,5-dimethylhydantoin follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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.

Exposures to 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) only occur during the mixing of the treatment solution. These exposures would only be associated with the occupational handling/applying when pouring and mixing with water. When mixed with water, DBDMH

rapidly hydrolyzes to 5,5-dimethylhydantion (DMH). DMH is stable in water and is the residue available for dietary exposure.

Most of the toxicology studies submitted to the Agency in support of registration of DBDMH were conducted on DMH (including subchronic oral toxicity in the rat and dog; subchronic dermal toxicity in the rat; chronic toxicity in the dog; combined chronic/oncogenicity in the rat and mouse; oncogenicity in the mouse; developmental toxicity in the rat and rabbit; 2-generation reproductive toxicity in the rat; genotoxicity battery; and general metabolism in the rat). These studies generally show lack of systemic toxicity up to the limit dose. No specific target organs were identified in adult animals tested. No developmental or maternal toxicity was observed. There was no evidence of carcinogenicity. There is also no indication of neurotoxicity or immunotoxicity in the database.

The formation of the bromide ion is also present during the degradation of DBDMH. Based on available data, the Agency has previously determined that bromine does not present adverse systemic effects and therefore no endpoints were identified. *See Bromine Final Registration Review Decision, Case 4015*, which is document number 10 in docket number EPA-HQ-OPP-2009-0167, in *www.regulations.gov*. Based on its previous assessment, which remains valid, the Agency has determined that there are no risks of concern from exposures to bromine.

Specific information on the studies received from the toxicity studies can be found at <http://www.regulations.gov> in document 1,3-dibromo-5,5-dimethylhydantoin (DBDMH), Human health and ecological risk assessment for the new use as a Fruit and Vegetable Wash and Food Contact Surface Sanitizer in docket ID number EPA-HQ-OPP-2011-1033.

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 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 Agency did not identify any toxicological points of departure because the available data indicate a lack of toxicity for DBDMH and its degradates (DMH and the bromide ion).

C. Exposure Assessment

1. *Dietary exposure from food uses and drinking water.* Based on the use patterns for DBDMH, residues of the degradate DMH may be present in or on food as a result of exposure to the substance in treatment solutions or on treated food contact surfaces. DMH residues are unlikely to be in drinking water because the product is intended to be used in treatment solutions in RAC treatment facilities and on food contact surfaces in public eating places or processing. Nevertheless, because of the lack of toxicological endpoints, quantitative dietary food and drinking water exposure and risk assessments were not conducted.

2. *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).

1,3-dibromo-5,5-dimethylhydantoin is not registered for use on any sites that would result in residential exposure. Further information regarding EPA standard assumptions and generic

inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

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 1,3-dibromo-5,5-dimethylhydantoin to share a common mechanism of toxicity with any other substances, and 1,3-dibromo-5,5-dimethylhydantoin does not appear to produce a toxic metabolite produced by other substances. Based on the lack of toxicity for DBDMH and its metabolites and degradates, therefore, EPA concludes that 1,3-dibromo-5,5-dimethylhydantoin 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 chemical, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children.

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

There are adequate pre-and/or post-natal toxicity studies for DMH that show no qualitative or quantitative susceptibility from exposure to DMH. As a result, the Agency has

conducted a qualitative assessment in which safety factors were not relevant. Moreover, because of the lack of any threshold effects, the requirement to retain an additional 10X safety factor does not apply.

E. Aggregate Risks and Determination of Safety

Based on the toxicological profile of DBDMH, EPA concludes that exposures to the antimicrobial 1,3-dibromo-5,5-dimethylhydantoin will not pose a risk under reasonably foreseeable circumstances. In order to use this substance as antimicrobial treatment in process water and as a food contact surface sanitizer, the substance must be mixed with water, necessarily resulting in the conversion of DMDBH into DMH and bromine, for which the Agency has not identified any toxicological endpoints of concern. Therefore, the Agency concludes that reasonably foreseeable uses of this substance are safe. Accordingly, EPA finds that there is a reasonable certainty of no harm will result to the general population, or to infants and children from aggregate exposure to 1,3-dibromo-5,5-dimethylhydantoin residues.

IV. 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. Revisions to Petitioned-For Exemption

Although the petitioner requested exemptions for residues of 1,3-dibromo-5,5-dimethylhydantoin with limitations on the amount of DBDMH in sanitizing and antimicrobial treatment solutions, EPA is establishing exemptions, without the requested limitations, for residues of 1,3-dibromo-5,5-dimethylhydantoin, because of the lack of toxicity of DMDBH and its metabolites and degradates.

V. Conclusion

Therefore, exemptions from the requirement of a tolerance are established for residues of 1,3-dibromo-5,5-dimethylhydantoin as follows: when used in food contact surface sanitizing

solutions applied to food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils and when used as an antimicrobial treatment in solutions applied to raw agricultural commodities in treatment facilities.

VI. Statutory and Executive Order Reviews

This action establishes exemptions from tolerance under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCa section 408(d), such as the 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 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).

VII. 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: November 15, 2017.

Steven Weiss,
Acting Director, Antimicrobials 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 § 180.940, add alphabetically the pesticide chemical “1,3-dibromo-5,5-dimethylhydantoin” to the table in paragraph (a) to read as follows:

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

* * * * *

(a) * * *

Pesticide Chemical	CAS Reg. No.	Limits
	* * * * *	* * *
1,3-dibromo-5,5-dimethylhydantoin	77-48-5	None
	* * * * *	* * *

3. Add § 180.1346 to subpart D to read as follows:

§ 180.1346 1,3-Dibromo-5,5-Dimethylhydantoin; exemption from the requirement of a tolerance.

Residues of 1,3-dibromo-5,5-dimethylhydantoin, including its metabolites and degradates, resulting from the use of 1,3-dibromo-5,5-dimethylhydantoin in antimicrobial treatment solutions of raw agricultural commodities in treatment facilities are exempt from the requirement of a tolerance.

[FR Doc. 2017-25842 Filed: 12/4/2017 8:45 am; Publication Date: 12/5/2017]