TABLE 1 TO PARAGRAPH (a)—Continued

Commodity	Parts per million
* * * * *	
Dragon fruit	1.5
Fennel, Florence, fresh leaves and stalk	8
* * * * *	
Kohlrabi	2
Leaf petiole vegetable subgroup 22B	8
* * * * *	
Vegetable, *Brassica*, head and stem, group 5–16	2
Vegetable, leafy, group 4–16	10
* * * * *	

* * * * *

[FR Doc. 2021–07185 Filed 4–6–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0103; FRL–10015–73]

2,2-Dimethyl-1,3-dioxolane-4-methanol; 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 2,2-dimethyl-1,3-dioxolane-4-methanol (CAS Reg. No. 100–79–8) when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and in antimicrobial formulations applied to certain food-contact surfaces. SciReg. Inc., on behalf of Solvay USA, submitted a petition to EPA under section 346a of 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 2,2-dimethyl-1,3-dioxolane-4-methanol, when used in accordance with these exemptions.

DATES: This regulation is effective April 7, 2021. Objections and requests for hearings must be received on or before June 7, 2021, 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–2017–0103, 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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 Publishing 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–2017–0103 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 June 7, 2021. 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–2017–0103, 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 June 8, 2017 (82 FR 26642) (FRL–9961–14), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11024) by SciReg. Inc., 12733, Director's

Loop, Woodbridge, VA 22192, on behalf of Solvay USA, 504 Carnegie Center, Princeton, NJ 08540. The petition requested that 40 CFR 180.910 and 180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of 2,2-dimethyl-1,3-dioxolane-4-methanol (CAS Reg. No.100–79–8) when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest and in antimicrobial pesticide formulations (food-contact surface sanitizing solutions). That document referenced a summary of the petition prepared by SciReg, Inc., on behalf of Solvay USA 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.C.

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 2,2-dimethyl-1,3-dioxolane-4-methanol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 2,2-dimethyl-1,3-dioxolane-4-methanol 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 2,2-dimethyl-1,3-dioxolane-4-methanol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies 2,2-Dimethyl-1,3-dioxolane-4-methanol exhibits low levels of acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not irritating to the rabbit skin, the rabbit eye, and is not a dermal sensitizer. 2,2-Dimethyl-1,3-dioxolane-4-methanol is negative for genotoxic effects in a battery of genotoxicity assays. Based on a cancer expert prediction system (DEREK analysis), 2,2-dimethyl-1,3-dioxolane-4-methanol is unlikely to pose a carcinogenic risk to humans. 2,2-Dimethyl-1,3-dioxolane-4-methanol exhibits no adverse toxicological effects in a combined repeat dose oral toxicity study with the reproduction/developmental toxicity screening test in rats at doses equal to or exceeding the limit dose of 1,000 mg/kg/day.

B. Toxicological Points of Departure/Levels of Concern

Due to the lack of hazard associated with 2,2-dimethyl-1,3-dioxolane-4-methanol based on the available data, no points of departure were identified for assessing risk; therefore, a quantitative risk assessment was not conducted.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 2,2-dimethyl-1,3-dioxolane-4-methanol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2,2-dimethyl-1,3-dioxolane-4-methanol in food as follows:

Acute and chronic dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. Because no adverse effects attributable to a single or repeat exposures to 2,2-dimethyl-1,3-dioxolane-4-methanol were seen in the toxicity databases, quantitative dietary risk assessments are not appropriate. Due to the expected use of 2,2-dimethyl-1,3-dioxolane-4-methanol in pesticide formulations applied to growing crops and raw agricultural commodities post-harvest, and in antimicrobial products, it is reasonable to expect that there will be some exposure residues of 2,2-dimethyl-1,3-dioxolane-4-methanol in or on food from its use in pesticide products.

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).

It is possible that 2,2-dimethyl-1,3-dioxolane-4-methanol may be used as an inert ingredient in pesticide products that may result in residential exposures,

although no residential uses are currently proposed. A residential exposure assessment was not conducted because no endpoint of concern following a single or repeat dose exposure was identified in the available studies.

D. Safety Factor for Infants and Children

Because there are no threshold effects associated with 2,2-dimethyl-1,3-dioxolane-4-methanol, EPA conducted a qualitative assessment. As part of that 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. Based on an assessment of 2,2-dimethyl-1,3-dioxolane-4-methanol, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on 2,2-dimethyl-1,3-dioxolane-4-methanol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to 2,2-dimethyl-1,3-dioxolane-4-methanol under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 and 180.940 for residues of 2,2-dimethyl-1,3-dioxolane-4-methanol when used as an inert ingredient in pesticide formulations is safe under FFDCA.

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 limit.

B. Response to Comments

One commenter opposed a tolerance for residues of pesticides in or on food, although the commenter did not present any information that the Agency could take into account when making a determination about the safety of this pesticide. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance 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 these exemptions from the requirement of a tolerance are safe. The commenters have provided no information to indicate that 2,2-dimethyl-1,3-dioxolane-4-methanol is not safe.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910 and 180.940 for 2,2-dimethyl-1,3-dioxolane-4-methanol (CAS Reg. No 100–79–8) when used as an inert ingredient as solvent/cosolvent in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

VII. Statutory and Executive Order Reviews

This action establishes exemptions 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) 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 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).

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: November 20, 2020.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 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 § 180.910, amend table 1 by adding alphabetically the inert ingredient ''2,2-Dimethyl-1,3-dioxolane-4-methanol (CAS Reg. No.100–79–8)'' to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * * * *	*	*
2,2-Dimethyl-1,3-dioxolane-4-methanol (CAS Reg. No.100–79–8)		Solvent/cosolvent.
* * * * *	*	*

■ 3. In § 180.940, amend the table in paragraph (a) by adding alphabetically the inert ingredient ''2,2-Dimethyl-1,3-dioxolane-4-methanol'' to read as follows:

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

(a) * * *

* * * * *

TABLE 180.940(a)

Pesticide chemical	CAS Reg. No.	Limits
* * * * *	*	*
2,2-Dimethyl-1,3-dioxolane-4-methanol	100–79–8	
* * * * *	*	*

* * * * *

Editorial note: This document was received for publication by the Office of the Federal Register on April 1, 2021.

[FR Doc. 2021–07028 Filed 4–6–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0531; FRL–10017–27]

Penthiopyrad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of penthiopyrad in or on persimmon. Mitsui Chemicals Agro, Inc., c/o Landis International, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 7, 2021. Objections and requests for hearings must be received on or before June 7, 2021, 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–2019–0531, 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: Marietta Echeverria, 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 EPA's tolerance regulations at 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.*