

TABLE 2—(33 CFR 165.171)—Continued

Eliot Festival Day Fireworks .....	<p>43°47'44" N 070°07'27" W. 43°47'57" N 070°07'27" W.</p> <ul style="list-style-type: none"> <li>• Event Type: Fireworks Display.</li> <li>• Sponsor: Eliot Festival Day Committee.</li> <li>• Date: September 27, 2013.</li> <li>• Rain date: September 29, 2013.</li> <li>• Time: 8 p.m. to 10:30 p.m.</li> <li>• Location: In the vicinity of Eliot Town Boat Launch, Eliot, Maine in approximate position: 43°08'56" N, 070°49'52" W. (NAD 83).</li> </ul>
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For events where the date is different from the dates previously published for that event, new Temporary Rules may be issued to enforce limited access areas for the marine event. The Coast Guard may patrol each event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF-FM (156.8 MHz) by the call sign "PATCOM." Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the Captain of the Port, Sector Northern New England. For information about regulations and restrictions for waterway use during the effective periods of these events, please refer to 33 CFR 100.120 and 33 CFR 165.171.

This notice is issued under authority of 33 CFR 100.120, 33 CFR 165.171, and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: May 24, 2013.

**B.S. Gilda,**

*Captain, U. S. Coast Guard, Captain of the Port Sector Northern New England.*

[FR Doc. 2013-13907 Filed 6-11-13; 8:45 am]

BILLING CODE 9110-04-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2012-0921; FRL-9386-8]

**1,3-Propanediol; Exemptions 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 1,3-propanediol (CAS Reg. No. 504-63-2) when used as an inert ingredient solvent, co-solvent, diluent, or freeze-point depressant in pesticide formulations applied to growing crops and to raw agricultural crops 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. DuPont Tate & Lyle BioProducts submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance. These regulations eliminate the need to establish a maximum permissible level for residues of 1,3-propanediol.

**DATES:** This regulation is effective June 12, 2013. Objections and requests for hearings must be received on or before August 12, 2013, 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-2012-0921, 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), 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:** David Lieu, Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-0079; email address: [lieu.david@epa.gov](mailto:lieu.david@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://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). To access the OCSPP 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-2012-0921 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 August 12, 2013. 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-2012-0921, 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 January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8091) by DuPont Tate & Lyle BioProducts, LLC, 198 Blair Bend Dr., Loudon, TN 37774. The petition requested two exemptions from the requirement of a tolerance be established for residues of 1,3-propanediol (CAS Reg. No. 504-63-2) when used as an inert ingredient under 40 CFR 180.910 for its use as a solvent, co-solvent, diluent, or freeze-point depressant in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) for its use 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 DuPont Tate & Lyle BioProducts, 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 non-toxicity; 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 1,3-propanediol including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with 1,3-propanediol 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 1,3-propanediol 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.

The acute oral toxicity of 1,3-propanediol in rodents, expressed as an LD<sub>50</sub> ranges from 10,500 to 15,789 milligram/kilogram body weight (mg/kg bw). No acute dermal toxicity studies for 1,3-propanediol were available in the toxicity database. The acute inhalation toxicity of 1,3-propanediol in rats produced a LC<sub>50</sub> was > 5.0 mg/liter (L). It is minimally irritating to the eyes of rabbits. It is mildly irritating to the skin of rabbits. Dermal sensitization studies on guinea pigs showed that 1,3-propanediol is not a sensitizer.

In a 14-day inhalation toxicity study, three groups of 10 male CrI:CD (SD) IGS BR rats each were exposed by inhalation to either vapor only or a vapor/aerosol mixture of 1,3-propanediol in air at concentrations targeted to 60, 600, or 1,800 mg/meter cubed (m<sup>3</sup>) (0.06, 0.60,

or 1.80 mg/L) for 6 hours/day, 4 or 5 days/week for a total of 9 exposures. A procedural control group of 10 male rats were exposed simultaneously to air only. There were no clinical signs of toxicity, body weight effects, clinical chemistry parameters, hematology measurements, and histopathological findings. The NOAEL for repeated inhalation exposure to 1,3-propanediol in male rats was considered to be 1,800 mg/m<sup>3</sup> or 1.8 mg/L (the highest dose tested) and no LOAEL was identified.

In a 90-day oral toxicity study, 1,3-propanediol was administered to 10 Crl:CD®(SD)BR rats/sex/dose by gavage at dosages of 0, 100, 300, or 1,000 mg/kg/day. No treatment-related effects were observed on clinical signs, mortality, body weights and body weight gain, food consumption, ophthalmoscopic examination, sperm abnormalities, organ weights and macroscopic, and microscopic examinations at doses up to and including 1,000 mg/kg/day. The NOAEL for systemic toxicity of 1,3-propanediol administered orally via gavage to male and female rats for 91 or 92 consecutive days was 1,000 mg/kg/day (the highest dose tested) and no LOAEL was identified.

The mutagenic potential of 1,3-propanediol was evaluated in a bacterial reverse mutation test, an *in vitro* mammalian cell gene mutation test, an *in vitro* chromosome aberration assay, an *in vitro* mammalian cell chromosome aberration assay, and an *in vivo* mammalian erythrocyte micronucleus test. Although the *in vitro* mammalian cell chromosome aberration assay in the V79 Chinese hamster cell line indicated some chromosomal aberrations, the remainders of the studies including the *in vivo* mouse micronucleus assay were negative; therefore, there are no concerns for clastogenicity. Based on the results of these studies, 1,3-propanediol is not considered to be mutagenic.

No carcinogenicity studies on 1,3-propanediol were available in the toxicity database, however based on the lack of mutagenicity concerns, lack of any systemic toxicity at the limit dose, and lack of any structural alerts for carcinogenicity in the Derek analysis, there are no concerns for carcinogenicity for 1,3-propanediol.

In a developmental toxicity study, 1,3-propanediol was administered to 20 pregnant female Sprague-Dawley (Hag:SD) rats/dose by gavage in 0.8% aqueous hydroxypropyl-methylcellulose gel (with constant dose volume of 10 milliliter (mL)/kg bw) at dose levels of 0, 250, or 1,000 mg/kg bw/day on gestation days (GDs) 6 through 15. Dams

were sacrificed and necropsied on gestation day (GD) 20. There were no treatment-related effects on maternal survival, clinical signs, body weight, food consumption, or gross pathology. The maternal LOAEL is not identified, and the maternal NOAEL is greater than or equal to 1,000 mg/kg bw/day (the highest dose tested). There were no treatment-related effects on live litter size, fetal deaths, fetal weights, early or late resorptions, or the fetal sex ratio. The developmental LOAEL is not identified, and the developmental NOAEL is greater than or equal to 1,000 mg/kg bw/day (the highest dose tested).

There were no immunotoxicity or neurotoxicity studies on 1,3-propanediol available in the toxicity database. However, there was no evidence of clinical signs of neurotoxicity or immunotoxicity triggers in the available database up to the limit dose.

The proposed metabolic pathway for 1,3-propanediol follows that for other simple alcohols, where alcohol and aldehyde dehydrogenase enzymes sequentially break down this substance to aldehydes and acids used in intermediary metabolism. 1,3-propanediol is metabolized to 3-hydroxypropionaldehyde, malondialdehyde, or 3-hydroxypropionic acid, malonic semi-aldehyde, malonic acid, and ultimately, carbon dioxide and water.

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

There was no hazard identified in repeat dose toxicity and developmental studies with 1,3-propanediol at the limit dose of 1,000 mg/kg/day to either parental animals or their offspring. Based on the available mutagenicity studies, EPA concluded that 1,3-propanediol is not likely to be genotoxic. In addition, there were no structural alerts for carcinogenicity in the Derek analysis. Thus, due to its low potential hazard and lack of hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for 1,3-propanediol.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,3-propanediol, EPA considered exposure under the proposed exemptions from the requirement of a tolerance. Dietary exposure to 1,3-propanediol can occur eating food treated with pesticide formulation containing this inert

ingredient. In addition, dietary exposure to 1,3-propanediol could occur via residues from treated food contact surfaces. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment for 1,3-propanediol was not conducted.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to 1,3-propanediol 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 1,3-propanediol 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, and tables).

Residential (oral, dermal, and inhalation) exposure from food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils are possible. In addition, residential exposure through other potential agricultural uses is also possible. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for 1,3-propanediol was not 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 1,3-propanediol to share a common mechanism of toxicity with any other substances, and 1,3-propanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,3-propanediol 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 Web site at

<http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

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 toxicity database for 1,3-propanediol contains several acute and subchronic studies, mutagenic studies, and a developmental toxicity study. No hazard was identified based on those studies. The toxicity database does not contain a carcinogenicity study and an immunotoxicity study, but for the reasons stated in Unit IV.A., the Agency has concluded that there are no concerns for carcinogenicity or immunotoxicity for this chemical. No acute or subchronic neurotoxicity studies are available, but there were no clinical signs of neurotoxicity or any systemic toxicity observed with 1,3-propanediol in the available database at doses up to 1,000 mg/kg/day. No developmental or reproductive effects were seen in the available studies at doses of 1,3-propanediol up to and including 1,000 mg/kg/day. Thus, there is no residual uncertainty regarding prenatal and/or postnatal toxicity of 1,3-propanediol.

Based on this information, there is no concern at this time for increased sensitivity to infants and children to 1,3-propanediol when used as an inert ingredient in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and for food-contact surface sanitizing applications.

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

Taking into consideration all available information on 1,3-propanediol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 1,3-propanediol under reasonable foreseeable circumstances. Therefore, the establishment of exemptions from tolerance under 40 CFR 180.910 for residues of 1,3-propanediol when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) for residues of 1,3-propanediol when used as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, 1,3-propanediol is not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account chronic exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a chronic oral exposure was identified, and no chronic dietary endpoint was selected. Therefore, 1,3-propanediol is not expected to pose a chronic risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, 1,3-propanediol is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, 1,3-propanediol is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., 1,3-propanediol is not expected to pose a cancer risk to humans.

6. *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 1,3-propanediol residues.

#### V. Other Considerations

##### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing exemptions 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 FFDCA 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for 1,3-propanediol.

#### VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of 1,3-propanediol (CAS Reg. No. 504-63-2) under 40 CFR 180.910 when used as an inert ingredient (solvent, co-solvent, diluent, or freeze point depressant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) when used as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils.

#### VII. Statutory and Executive Order Reviews

This final rule 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 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 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 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: June 3, 2013.

**Lois 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, add to the table, after the entry "Propane," the following inert ingredient to read as follows:

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

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * * * *	* * * * *	* * * * *
1,3-Propanediol (CAS Reg. No. 504-63-2) .....	Solvent, co-solvent, diluent, or freeze-point depressant.	
* * * * *	* * * * *	* * * * *

■ 3. In § 180.940, add to the table in paragraph (a), after the entry "potassium iodide," the following inert ingredient 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-Propanediol .....	504-63-2 None.	
* * * * *	* * * * *	* * * * *

\* \* \* \* \*  
[FR Doc. 2013-13823 Filed 6-11-13; 8:45 am]  
BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2012-0264; FRL-9389-2]

**Bacillus pumilus Strain BU F-33; 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 *Bacillus pumilus* strain BU F-33 in or on all food commodities when applied to elicit induced systemic resistance in plants and used in accordance with label directions and good agricultural practices. Becker Underwood, Inc., submitted a petition to the 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 *Bacillus pumilus* strain BU F-33 under the FFDCA.

**DATES:** This regulation is effective June 12, 2013. Objections and requests for hearings must be received on or before August 12, 2013, 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-2012-0264, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency