ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0901; FRL–9394–5]

Propylene Glycol; 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 propylene glycol (CAS Reg. No. 57–55–6) when used as an inert ingredient in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under our regulations. Exponent on behalf of Ecolab, Inc. submitted a petition to EPA under 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 propylene glycol.

DATES: This regulation is effective August 9, 2013. Objections and requests for hearings must be received on or before October 8, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2012–0901. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; 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. Potentially affected entities may include, but are not limited to:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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–2012–0901 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 October 8, 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0901, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Exemption

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL–9375–4), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–10525) by Exponent®, 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036 on behalf of Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of propylene glycol (CAS Reg. No. 57–55–6) when used as an inert ingredient in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. That notice referenced a summary of the petition prepared by Ecolab, 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 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 propylene glycol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with propylene glycol 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 propylene glycol 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 propylene glycol is low propylene glycol did not cause dermal or eye irritation in rabbits. It was not a dermal sensitizer.

Propylene glycol administered via the oral route did not cause systemic toxicity in rats or dogs in studies conducted for up to 2 years at doses as high as 2,500 mg/kg/day. Neither maternal, developmental, offspring nor reproduction toxicity was observed at doses up to approximately 10,000 mg/kg/day in a teratology screening and a continuous breeding study in mice.

Also, dermal exposure to propylene glycol did not cause systemic toxicity nor increased skin tumor incidence at concentrations up to 100% (~100,000 mg/kg/day) propylene glycol in mice.

Propylene glycol was not mutagenic or genotoxic on the basis of a battery of studies that included the bacterial gene mutation assay using Salmonella typhimurium (AMES) in vitro assay, in vitro Chinese hamster ovary (CHO) mutation assay, Chinese hamster ovary (CHO) chromosomal aberration assays, and an in vitro sister chromatid exchange assay. In addition, EPA concluded that propylene glycol was negative for carcinogenicity in studies conducted up to the testing limit doses established by the Agency.

Although no neurotoxicity or immunotoxicity studies on propylene glycol are available, there is no evidence of neurotoxicity or immunotoxicity in the available studies.

Propylene glycol should be readily metabolized to lactic acid at the typical low-level exposures. At higher concentrations (absorbed doses), propylene glycol is primarily excreted unchanged in the urine.

B. Toxicological Points of Departure/Levels of Concern

EPA has concluded that there are no toxicity endpoints of concern for oral, dermal, or inhalation exposure to propylene glycol. This conclusion is based on the results of toxicity testing of propylene glycol at dose levels near or above testing limits (as established in the OPPTS 870 series harmonized test guidelines). Since signs of toxicity were not observed, a toxicological endpoint of concern for use in risk assessment was not identified. Therefore, EPA has determined that a quantitative risk assessment, which would use safety factors applied to a point of departure that is protective of an identified hazard endpoint, for propylene glycol is not appropriate.

C. Exposure Assessment

1. *Dietary exposure from food, feed, drinking water and non-dietary exposures.* In evaluating dietary exposure to propylene glycol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. For purposes of this action, EPA qualitatively assessed dietary and non-dietary exposures from propylene glycol as follows:

Dietary exposure (food and drinking water) could potentially occur from the use of propylene glycol as a food additive, from food packaging, from its use as an inert ingredient in pesticide formulations. In addition, dietary exposure to propylene glycol could occur as a result of contact with treated surfaces or food- or dairy-processing equipment or food utensils. Residential exposure could also potentially occur as a result of the use of propylene glycol in and around the home as a sanitizer, disinfectant, and pet treatment. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment for propylene glycol was not conducted.

2. *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 propylene glycol to share a common mechanism of toxicity with any other substances, and propylene glycol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propylene glycol 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 propylene glycol contains several acute, subchronic, and chronic, developmental, and reproductive toxicity studies, as well as carcinogenicity, mutagenicity, metabolism/pharmacokinetics, and dermal toxicity studies. No hazard was identified based on those studies. Although the toxicity database does not contain any neurotoxicity or immunotoxicity studies, no evidence of neurotoxicity or immunotoxicity effects was present in any of the available studies. Thus, there is no residual uncertainty regarding prenatal and/or postnatal toxicity of propylene glycol.

Based on this information, there is no concern at this time for increased sensitivity to infants and children to propylene glycol when used as an inert ingredient in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on propylene glycol, EPA concludes that there are no dietary or aggregate dietary/non-dietary risks of concern as a result of exposure to propylene glycol in food and water or from residential exposure. As discussed in this unit, EPA expects aggregate exposure to propylene glycol to pose no appreciable dietary risk given that the data show a lack of systemic toxicity at doses < 2500 mg/kg/day and a lack of any increased susceptibility of infants and children. Taking into consideration of all available information on propylene glycol, 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 propylene glycol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. 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 propylene glycol.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for propylene glycol (CAS Reg. No. 57–55–6) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

VII. Statutory and Executive Order Reviews

This final rule exempts certain pesticide residues 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 exemption 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) (Pub. L. 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: July 29, 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 § 180.940, the table in paragraph (a) is amended by adding, alphabetically, 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
* * * * *		
Propylene glycol	57–55–6	None.
* * * * *		

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[FR Doc. 2013–19025 Filed 8–8–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 27, and 101

[WT Docket Nos. 12–70 and 04–356; ET Docket No. 10–142; FCC 12–151]

Service Rules for Advanced Wireless Services in the 2000–2020 MHz and 2180–2200 MHz Bands, etc.

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with the Commission's Report and Order (R&O), Service Rules for Advanced Wireless Services in the 2000–2020 MHz and 2180–2200 MHz Bands, etc.

This notice is consistent with the *R&O,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: The amendments to §§ 1.949, 27.14, 27.17, 27.1131, 27.1134, 27.1136, 27.1166, 27.1168, 21.1170, 101.69, and 101.73(d) that appeared in the **Federal Register** at 78 FR 8229, February 5, 2013, are effective on August 9, 2013.

FOR FURTHER INFORMATION CONTACT: Kevin Holmes, Wireless Telecommunications Bureau, Broadband Division, at (202) 418–BITS or by email at *Kevin.Holmes@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on July 31, 2013, OMB approved, for a period of three years, the information collection requirements contained in the Commission's *R&O,* FCC 12–151, published at 78 FR 8229 on February 5, 2013. The OMB Control Number is 3060–1030. The Commission publishes this notice as an announcement of the effective date of the rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Judith B. Herman at (202) 418–0214 or via email at *Judith-B.Herman@fcc.gov.* Please include the OMB Control Number, 3060–1030, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on July 31, 2013, which contained new or modified information collection requirements, in 47 CFR 1.949, 27.14, 27.17, 27.1131, 27.1134, 27.1136, 27.1166, 27.1168, 21.1170, 101.69, and 101.73(d), which would not be effective until approved by the Office of Management and Budget. The information collection was adopted in the Report and Order in WT Docket Nos. 12–70 and 04–356; ET Docket No. 10–142, FCC 12–151, which appears at 78 FR 8229, February 5, 2013, adopts flexible use rules for 40 megahertz of spectrum in the 2 GHz band (2000–2020 MHz and 2180–2200 MHz) that would increase the nation's supply of spectrum for mobile broadband. Also, we adopted AWS–4 terrestrial service, technical, and licensing rules that generally follow the Commission's part 27 flexible use rules, modified as necessary to account for issues unique to the AWS–4 bands. First, we establish 2000–2020 MHz paired with 2180–2200 MHz as the AWS–4 band plan. In addition, we adopted appropriate technical rules for operations in the AWS–4 band. This includes rules governing the relationship of the AWS–4 band to other bands. Third, mindful that AWS–4 spectrum is now allocated on a co-primary basis for Mobile Satellite and for terrestrial Fixed and Mobile services and that MSS licensees already have authorizations to provide service in the band, we determined that the AWS–4 rules must provide for the protection of 2 GHz MSS systems from harmful interference caused by AWS–4 systems. Fourth, consistent with our determination below to grant AWS–4 terrestrial operating authority to the incumbent 2 GHz MSS licensees, we proposed to assign terrestrial rights by modifying the MSS operators' licenses pursuant to section 316 of the Communications Act. Fifth, we adopted performance requirements for the AWS–4 spectrum. Specifically, licensees of AWS–4 operating authority will be subject to build-out requirements that require a licensee to provide terrestrial signal coverage and offer terrestrial service to at least 40 percent of its total terrestrial license areas' population within four years, and to at least 70 percent of the population in each of its license areas within seven years, and to appropriate penalties if these