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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**EPA-HQ-OPP-2012-0945; FRL-9400-6]**

# FD&C Yellow No. 5; 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 FD&C Yellow No. 5 (CAS Reg. No. 1934-21-0) when used as an inert ingredient (dye) in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. Exponent, Inc. 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. These regulations eliminate the need to establish a maximum permissible level for residues of FD&C Yellow No. 5**.**

**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-2012-0945, 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:** 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. 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*. 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-2012-0945 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-2012-0945, 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 IN-10528) by Exponent, Inc. on behalf of Ecolab, Inc., 370 N. Wabasha Street, St. Paul, MN 55102. The petition requested an exemption from the requirement of a tolerance be established for residues of FD&C Yellow No. 5 (CAS Reg. No. 1934-21-0) when used as an inert ingredient under 40 CFR 180.940(a) for use in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at an end-use concentration not to exceed 1,000 parts per million (ppm). That document referenced a summary of the petition submitted by Ecolab, Inc., 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 FD&C Yellow No. 5 including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with FD&C Yellow No. 5 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 FD&C Yellow No. 5 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.

FD&C Yellow No. 5 is a FDA permanently listed color additive used in food, drugs and cosmetics, including drugs and cosmetics for the eye area. FDA's color additive evaluation included the consideration of an extensive set of toxicological data on FD&C Yellow No. 5. FDA concluded that this colorant was safe and established a maximum acceptable daily intake for FD&C Yellow No. 5. Similarly, the Joint Expert Committee on Food Additives of the Food and Agriculture Organization/World Health Organization (JECFA) as well as the European Union Scientific Committee for Food (SCF) has evaluated FD&C Yellow No. 5 for the purpose of establishing estimates of acceptable daily intake (ADI) as a food additive. In 2004, EPA conducted a tolerance reassessment of the tolerance exemptions for FD&C Yellow No. 5 (also referred to as tartrazine) under 40 CFR 180.910, 180.930, 180.940(b), and 180.940(c) which included a summary of the FDA and JECFA evaluations of FD&C Yellow No. 5.

The FDA and JECFA evaluations of FD&C Yellow No. 5 included reviews of an extensive set of toxicological data including genotoxicity, chronic toxicity /carcinogenicity and reproductive and developmental toxicity. Both evaluations concluded that the available data demonstrated that no adverse effects were seen in studies at limit dose levels. The FDA evaluation resulted in the establishment of an ADI

of 5.0 milligrams/kilogram/day (mg/kg/day) based on a chronic oral toxicity study in dogs in which the no-observed adverse effect level (NOAEL) was 500 mg/kg/day (highest dose tested) with a safety factor of 100. The JECFA and SCF evaluations of FD&C Yellow No. 5 established ADIs of 7.5 mg/kg/day based upon a chronic dietary toxicity study in rats in which the no-observed adverse effect level (NOAEL) was 750 mg/kg/day (highest dose tested) with a safety factor of 100. More recently, the European Food Safety Authority has reevaluated FD&C Yellow No. 5 and concluded that the present database does not give reason to revise the ADI of 7.5 mg/kg bw/day.

As a result of these extensive evaluations of FD&C Yellow No. 5, in which either no adverse effects were noted, or the effects of single or repeated dosing were observed only at levels beyond the respective limit doses, EPA has utilized a qualitative approach to assessing human health risks from exposure to FD&C Yellow No. 5. No hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), or for the short-, intermediate-, and long-term residential assessments (via all exposure routes), therefore, acute and chronic dietary and short-, intermediate-, and long-term residential exposure assessments were not performed.

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

There were no adverse effects in repeat dose toxicity, reproductive, and developmental studies with FD&C Yellow No. 5 at or above limit dose levels to either parental animals or their offspring. Based on the available mutagenicity studies, EPA concluded that FD&C Yellow No. 5 is not likely to be genotoxic. There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24 and 18 months, respectively. 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 FD&C Yellow No. 5.

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to FD&C Yellow No. 5, EPA considered exposure under the proposed exemptions from the requirement of a tolerance. Dietary exposure to FD&C Yellow No. 5 can occur when eating food treated with pesticide formulation containing this inert ingredient. In addition, dietary exposure to FD&C Yellow No. 5 could occur via residues from treated food contact surfaces; and from food that contains FD&C Yellow No. 5, as a color additive. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment for FD&C Yellow No. 5 was not conducted.

2. *Dietary exposure from drinking water***.** Dietary exposure from drinking water to FD&C Yellow No. 5 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 FD&C Yellow No. 5 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, tables).

Residential (oral, dermal and inhalation) exposure to FD&C Yellow No. 5 from its use as an inert ingredient in food-contact surface sanitizing solutions for public eating

places, dairy-processing equipment, food-processing equipment and utensils is possible. Residential exposure to, FD&C Yellow No. 5 as a result of its use as a color additive in foods, drugs and cosmetics is also possible. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for FD&C Yellow No. 5 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 FD&C Yellow No. 5 to share a common mechanism of toxicity with any other substances, and FD&C Yellow No. 5 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that FD&C Yellow No. 5 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 website at *http://www.epa.gov/pesticides/cumulative*.

*D. Safety Factor for Infants and Children*

The toxicity database for FD&C Yellow No. 5 contains several acute, subchronic, long-term, developmental, reproductive and carcinogenic studies, as well as mutagenicity studies. No adverse effects were identified in those studies. There were no clinical signs of neurotoxicity or systemic toxicity observed with FD&C Yellow No. 5 in the available

database up to the limit dose. No developmental or reproductive effects were seen in the available developmental and reproductive toxicity studies at doses of FD&C Yellow No. 5 up to the limit dose, 1,064 mg/kg/day. Thus, there is no residual uncertainty regarding prenatal and/or postnatal toxicity of FD&C Yellow No. 5. Due to the lack of toxicity of FD&C Yellow No. 5, the Agency determined that a quantitative risk assessment using safety factors was not necessary for assessing risk. For the same reason, no additional safety factor is needed for assessing risk to infants and children.

*E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on FD&C Yellow No. 5, 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 FD&C Yellow No. 5 under reasonable foreseeable circumstances. Therefore, the establishment of exemptions from tolerance under 180.940(a) for residues of FD&C Yellow No. 5 when used as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, food-processing equipment and utensils, is safe under FFDCA section 408.

## 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 FD&C Yellow No. 5.

## VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of FD&C Yellow No. 5 (CAS Reg. No. 1934-21-0) under 180.940(a) when used as an inert ingredient (dye) in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, 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: September 17, 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, alphabetically add the following inert ingredient 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 |
|---|---|---|
| * * | * * | * * * |
| FD&C Yellow No. 5 | 1934-21-0 | When ready for use, the end-use concentration is not to exceed 1000 ppm |
| * * | * * | * * * |

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[FR Doc. 2013-23391 Filed 09/25/2013 at 8:45 am; Publication Date: 09/26/2013]