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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0572; FRL-9917-14]

FD&C Red No. 40; 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 Red No. 40 when used as an inert ingredient as colorant in antimicrobial pesticide formulation in food-contact surface sanitizer products at a maximum level in the end-use concentration of 20 parts per million (ppm). Diversey 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 FD&C Red No. 40**.**

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-2012-0572, 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: Susan T. Lewis, 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 Printing 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-2012-0572 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-2012-0572, 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 August 22, 2012 (77 FR 50664) (FRL-9358-9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7843) by Diversey Inc., 8310 16th Street, Sturtevant, Wisconsin 53177. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of FD&C Red No. 40 (CAS No. 25956-17-6) when used as an inert ingredient (colorant) in food-contact surface sanitizing solutions at a maximum level in the end-use concentration of 20 parts per million (ppm). That document referenced a summary of the petition prepared by Diversey Inc., the petitioner, which is available in the docket, EPA-HQ-OPP-2012-0572, at *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 Red No. 40 including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with FD&C Red No. 40 is detailed in a May 9, 2014 Memorandum entitled “Decision Document for Petition Number 1E7843: FD&C Red No. 40 (CAS Reg. No. 25956-17-6); Human Health Risk Assessment and Ecological Effects Assessment for Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations” which is

available in the docket for this rule, EPA-HQ-OPP-2012-0572. A summary of that assessment 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 is discussed in this unit.

The European Food Safety Authority (EFSA) has conducted the most recent (2009) full review of the toxicology of FD&C Red No. 40. This document relied heavily on the earlier reviews (1980), conducted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Union Scientific Committee for Food (SCF) in 1984 and 1989. These evaluations of FD&C Red No. 40 included reviews of an extensive set of toxicological data including genotoxicity, chronic toxicity, carcinogenicity, reproductive and developmental toxicity and metabolism. The available data demonstrated that no adverse effects were seen in studies at limit dose levels.

Briefly, no compound related clinical signs of toxicity were observed when FD&C Red No. 40 (Allura Red AC) was given to rats by gavage at doses varying from 215 to 10,000 milligrams/kilogram (mg/kg). It was not irritating to the skin of rabbits. Repeated dose toxicity studies were conducted in rats, dogs and pigs. No evidence of systemic toxicity was observed in rats fed FD&C Red No. 40 in the diet for six weeks at doses up to 2,595 mg/kg/day. The dog studies (two) were determined to be too limited to derive a NOAEL. No compound related effects were reported in pigs given gavage dose

of 1,000 mg/kg/day for 21 days and then increased to 1,500 mg/kg/day for an additional 54 days.

In chronic studies, no dye-related anomalies were noted in terms of survival, or gross and histopathology of major organs and the skin in mice treated dermally with FD&C Red No. 40 with a 5% test solution twice weekly for 20 months. A moderate growth depression was observed in both sexes of rat fed at the highest dose level of 2,595 mg/kg/day for 92 weeks. No compound-related effects were observed regarding appearance, behavior, survival, organ weights, clinical laboratory studies, or gross and histopathology in rats.

FD&C Red No. 40 was evaluated for its mutagenic activity in adequate range of *in vivo* and *in vitro* mutagenicity assays. Overall, it gave a negative response for mutagenicity in *in vivo* and *in vitro* assays except Comet assay. EFSA Panel considered this finding in the light of negative carcinogenicity studies, and determined that the biological significance of the Comet assay results is uncertain.

As summarized by EFSA, no evidence of carcinogenicity was observed in male rats at doses up to 2,595 mg/kg/day and 2,829 mg/kg/day in female rats; and in mice at dose levels up to 7,422 mg/kg/day in males and 8,304 mg/kg/day in females.

Relevant reproductive and developmental toxicity studies are summarized in the EFSA document. In a multi-generation reproduction study in rats at a dietary levels of 0, 0.37, 0.72, 1.39 or 5.19% (equivalent to 0, 185, 360, 695 and 2,595 mg/kg bw/day), no treatment related adverse effects were observed in the parental animals. Only slight growth retardation was observed at the high dose levels in F_1 and F_2 pups. The NOAEL for offspring toxicity was 695 mg/kg/day and the LOAEL was 2,595 mg/kg/day. No

reproductive or developmental toxicity was seen at high doses in three chronic studies in rats and mice in which these parameters were evaluated concurrently. Rats (group number not reported) were exposed up to 10% of FD&C Red No. 40 in the diet (calculated doses of 0, 1,250, 2,500 and 5,000 mg/kg/day). Litter mortality was increased between 22-24 days of age at a concentration of 10% in the diet. Significantly decreased running wheel activity was observed in all exposed groups. Increased open-field rearing was observed in the two highest dose groups. The LOAEL was determined to be 1,250 mg/kg/day; a NOAEL could not be determined from this study. No neurobehavioral effects were observed in mice administered 1.68% FD&C Red No. 40 via diet (equivalent to 2,400 mg/kg/day) for 2-generations. Teratology studies in rats and rabbits showed no evidence of adverse effects at doses up to 200 mg/kg/day administered via gavage during gestation days (GD) 0-19 in rats, and at doses up to 700 mg/kg/day administered via gavage during GD 6-18 in rabbits. In rats (group number not reported) dosed with FD&C Red No. 40 up to 0.7% in drinking water (equivalent to 939 mg/kg bw/day) during GDs, on GD 0-20 a significant increase in the incidence of fetuses with reduced ossification of the hyoid was observed at the highest dose level. No other fetal malformations were observed. The NOAEL from this study was determined to be 546 mg/kg/day.

In rats fed 5.19% FD&C Red No. 40 in the diet, only 0.1% and 29% of the unmetabolized dye was found to be excreted in the urine and feces, respectively. Several metabolites, possibly resulting from azo-reduction in the gastrointestinal tract (two identified as aromatic amines, p-cresidine sulfnic acid being the major one), were also found in the feces and urine. Finally, significant retention in the washed intestines of rat was observed, probably due to adhesion to the intestinal wall.

B. Toxicological Points of Departure/Levels of Concern

Based on the low potential hazard, toxicological endpoints of concern have not been identified for FD&C Red No. 40. 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. JEFCA and EFSA established the acceptable daily intake (ADI) of 0-7 mg/kg/day based on the NOAEL of 695 mg/kg/day derived from a reproductive toxicity study in rats, which revealed slight growth suppression observed mainly at the high test levels of 2,595 mg/kg/day in F_1 and F_2 pups and from a teratogenicity study in rats which revealed lower body weights and growth rates at the highest dose level of 2,595 mg/kg/day but not at 695 mg/kg bw/day. Since adverse effects in these two studies were observed at 2.5 times the limit dose of 1,000 mg/kg/day; EPA concluded that it is not warranted to conduct a quantitative risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses and drinking water*. Dietary exposure (food and drinking water) to FD&C Red No. 40 can occur following ingestion of foods with residues from food-contact surface sanitizing solutions for public eating places, treated dairy- and food-processing equipment and utensils; pre- and post-harvest crop uses and as a direct food additives. In addition, dietary exposures to FD&C Red No. 40 can occur as a result of its use as a color additive in foods. However, EPA did not conduct a quantitative dietary exposure assessment since no endpoint of concern for risk assessment has been identified.

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).

FD&C Red No. 40 is used as an inert ingredient in agricultural pesticide products that could result in short- and intermediate-term residential exposure. Residential exposure can occur via dermal and inhalation routes of exposure to residential applicator. Dermal and inhalation exposure can occur from the use of consumer products and foods/food additives containing FD&C Red No. 40. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for FD&C Red No. 40 was not conducted.

3. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found FD&C Red No. 40 to share a common mechanism of toxicity with any other substances, and FD&C Red No. 40 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 Red No. 40 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

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

At this time, there is no concern for potential sensitivity to infants and children resulting from exposures to FD&C Red No. 40. There is no reported quantitative or qualitative evidence of increased susceptibility of rat fetuses to in utero exposure to FD&C Red No. 40 in developmental toxicity studies in rats. No quantitative or qualitative evidence of increased susceptibility has been reported following the pre/postnatal exposure to rats in 2-generation reproduction toxicity studies in rats. Given the lack of adverse toxicological effects at limit dose levels, a safety factor analysis has not been used to assess the risk. For these reasons the additional tenfold safety factor is unnecessary.

E. Aggregate Risks and Determination of Safety

In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. Dietary (food and drinking water) and non-dietary (residential) exposures of concern are not anticipated for FD&C Red No. 40

because of its low toxicity based on animal studies showing toxicity at or above the limit dose of 1,000 mg/kg/day. Taking into consideration all available information on FD&C Red No. 40, 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 Red No. 40 under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.940(a) for residues of FD&C Red No. 40 when used as an inert ingredient (colorant) in pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment and food processing equipment and utensils up to 20 ppm in antimicrobial pesticide formulations 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 an exemption from the requirement of a tolerance without any numerical limitation. EPA is establishing a limitation on the amount of FD&C Red No. 40 that may be used in pesticide formulations.

The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. EPA will not register any food-contact surface antimicrobial pesticide for sale or distribution with concentrations of FD&C Red No. 40 exceeding 20 ppm in the end use formulation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for FD&C Red No. 40 (CAS No. 25956-17-6) when used as an inert ingredient (colorant) in pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment and food-processing equipment and utensils up to 20 ppm in end use formulation.

VII. Statutory and Executive Order Reviews

This final rule establishes an exemption 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) (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: October 30, 2014.

Susan Lewis,
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 alphabetically adding an entry for “FD&C Red No. 40” before the entry for “FD&C Yellow No. 5” 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 Red No. 40	25956-17-6	When ready for use, the end-use concentration is not to exceed 20 ppm
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[FR Doc. 2014-26526 Filed 11/06/2014 at 8:45 am; Publication Date: 11/07/2014]