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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0286; FRL-9904-30]

Copper Sulfate Pentahydrate; 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 copper sulfate pentahydrate when applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment at a maximum level in the end use concentration of 80 parts per million (ppm). Toxcel on behalf of OhSo Clean, 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 copper sulfate pentahydrate**.**

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-2013-0286, 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://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-2013-0286 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-2013-0286, 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 July 19, 2013 (78 FR 43115) (FRL-9392-9), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8116) by Toxcel, P.O. Box 363, 7140 Heritage Village Plaza, Gainesville, VA 20156, on behalf of OhSo Clean, Inc., 315 Pacific Ave., San Francisco, CA 94111. The petition requested that 40 CFR 180.940 be amended by establishing an exemption from the requirement of a tolerance for residues of copper sulfate pentahydrate (Chemical Abstracts Service Registry Number (CAS Reg. No.) 7758-99-8) when used as an inert ingredient (emulsion stabilizer) in antimicrobial pesticide formulations (food contact surface sanitizing solutions) not to exceed 80 ppm. That document referenced a summary of the petition prepared by Toxcel LLC., 7140 Heritage Village Plaza, Gainesville, VA 20155, 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. 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 copper sulfate pentahydrate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with copper sulfate pentahydrate 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 copper sulfate pentahydrate, 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 the final rule published in the **Federal Register** of August 11, 2006 (71 FR 46106) (FRL-8085-3).

Copper is ubiquitous in nature and is a necessary nutritional element for both animals (including humans) and plants. Copper is found naturally in the food we eat including fruits, vegetables, meats, and seafood. It is found in the water we drink, the air we breathe and in our bodies themselves. Some of the environmental copper is due to direct modification of the environment by humans such as mining and smelting of the natural ore. It is one of the elements found essential to life. The National Academy of Science establishes recommended daily allowances (RDAs) of vitamins and minerals for the diet. The RDA for copper ranges from approximately 400 micrograms per day (µg/d) in young children to 900 µg/d in adults. Additionally, over the counter dietary supplements containing copper at level ranging from 0.33 milligram (mg) to 3 mg are available for individuals with low levels of copper. The copper ion is present in the adult human body with nearly two-thirds of the body copper content located in the skeleton and muscle. The liver is the primary organ for the maintenance of plasma copper concentrations.

The 2006 Reregistration Eligibility Decision for copper compounds reviewed and summarized all toxicity studies submitted for copper and has determined that the

toxicological database is sufficient to assess the hazard from pesticides containing copper. Copper generally has moderate to low acute toxicity based on acute oral, dermal, and inhalation studies in animals. However, copper sulfate pentahydrate specifically has a been classified as moderate for acute oral toxicity, low for acute dermal toxicity and dermal irritation, and high for primary eye irritation. All effects resulting from acute exposure to copper-containing pesticides are due to acute body responses to minimize excessive absorption or exposure to copper. Current available data in animals do not show any evidence of upper limit toxicity level that warrant determining acute toxicity endpoints.

Based on available data summarized in the 2006 Reregistration Eligibility Decision for Coppers, there is no evidence of any dietary, oral, and dermal or inhalation adverse effects warranting quantitative assessment of sub-chronic or chronic risk. Available short-term feeding studies with rats and mice indicate decreased food and water intake with increasing oral concentrations of copper. Irritation of the stomach was seen at higher copper concentrations. Longer-term feeding studies indicate decreased feed intake with reductions in body weight gains, and increased copper concentration of the liver. Available reproductive and developmental studies by the oral route of exposure generally indicate that the main concern in animals for reproductive and teratogenic effects of copper has usually been associated with the deficiency rather than the excess of copper.

Oral ingestion of excessive amounts of the copper ion from pesticidal uses including the proposed use is unlikely. Copper compounds are irritating to the gastric mucosa. Ingestion of large amounts of copper results in prompt emesis. This protective

reflex reduces the amount of copper ion available for absorption into the human body. Additionally, at high levels humans are also sensitive to the taste of copper. Because of this organoleptic property, oral ingestion would also serve to limit high doses.

Only a small percentage of ingested copper is absorbed, and most of the absorbed copper is excreted. The human body appears to have efficient mechanisms in place to regulate total body copper. The copper ion occurs naturally in food and the metabolism of copper is well understood.

Finally, sulfate has little toxic effect and is routinely used in medicine as a cathartic when combined with magnesium or sodium; the only adverse manifestations from this use being dehydration if water intake is concurrently limited.

B. Toxicological Points of Departure/Levels of Concern

No endpoints of toxicological concern were identified for risk assessment purposes for copper sulfate pentahydrate. Copper sulfate pentahydrate readily hydrolyzes into the copper cation and the sulfate anion. Copper is a required essential nutritional element for both plants and animals. Indeed, current available data and literature studies indicate that there is a greater risk from the deficiency of copper intake than from excess intake. Copper also occurs naturally in a number of food items including fruits, meats, seafood, and vegetables. In humans, as part of the utilization of copper as an essential nutrient, there is an effective homeostatic mechanism that is involved in the dietary intake of copper and that protects humans from excess body copper. Given that copper is ubiquitous, is an essential nutrient, and is routinely consumed as part of the daily diet, exposure to copper as a result of the use of copper sulfate pentahydrate as a pesticide chemical would not be of toxicological concern. Further, the sulfate anion is also

ubiquitous; it is the substrate in a number of normal human biosynthetic reactions. Following ingestion, sulfate is poorly absorbed via the gastrointestinal tract and is excreted in the urine. Other than a slight laxative effect at extremely high doses, sulfate has no known adverse toxic effects.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to copper sulfate pentahydrate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from copper sulfate pentahydrate in food as follows:

The main source of copper for infants, children, and adults, regardless of age, is the diet. Copper is typically present in mineral rich foods like chocolate, fruits (peaches and raisins), grains (wheat and rye), nuts (peanuts and pecans), and vegetables (potatoes and legumes (beans and peas)) in levels that range from 0.3 to 3.9 ppm. It is not likely that the approval of this petition would significantly increase exposure over that of the existing levels of copper.

2. *Dietary exposure from drinking water*. Copper is a natural element found in the earth's crust. As a result, most of the world's surface water and ground water that is used for drinking purposes contains copper. The actual amount varies from region to region, depending on how much is present in the earth, but in almost all cases the amount of copper in water is extremely low. Naturally occurring copper in drinking water is safe for human consumption, even in rare instances where it is at levels high enough to impart a metallic taste to the water. Residues of copper in drinking water are regulated under the Safe Drinking Water Act. A Maximum Contaminant Level Goal of 1.3 ppm has been set

by the Agency for copper. According to the National Research Council's Committee on Copper in Drinking Water, this level is "set at a concentration at which no known or expected adverse health effects occur and for which there is an adequate margin of safety." The Agency believes that this level of protection would not cause any potential health problems, i.e., stomach and intestinal distress, liver and kidney damage, and anemia. It is not likely that the approval of this petition would significantly increase exposure over that of the existing levels of copper.

3. *From non-dietary exposure***.** The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., carpets; hard surface disinfection on walls, floors, and tables; swimming pools; and textiles (clothing and diapers)).

Residential (oral, dermal, and inhalation) exposure to copper sulfate pentahydrate from its use as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy processing equipment, and food-processing equipment and utensils is possible. However, since there are no toxicological effects of concern identified in the available database, it is not necessary to conduct a quantitative assessment of residential (non-occupational) exposures.

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 copper sulfate pentahydrate to share a common mechanism of toxicity with any other substances, and copper sulfate

pentahydrate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that copper sulfate pentahydrate 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

FFDCA, as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional 10X safety factor (SF), to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10X FQPA SF only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children. Since copper is an essential trace element, with copper deficiency more common in humans than toxicity from the excess, a quantitative assessment using safety factors was not conducted for potential human health exposure to copper sulfate pentahydrate. For the same reason the 10X FQPA SF was not retained.

E. Aggregate Risks and Determination of Safety

Taking into consideration the information discussed on copper sulfate pentahydrate, 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 copper sulfate pentahydrate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180**.**940(a) for residues of copper sulfate pentahydrate 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 at a limit of 80 ppm 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 not establishing a numerical tolerance for residues of copper sulfate pentahydrate in or on any food commodities. EPA is establishing a limitation on the amount of copper sulfate pentahydrate that may be used in pesticide formulations.

The limitation is 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 pesticide for sale or distribution that contains greater than 80 ppm of copper sulfate pentahydrate in the pesticide formulation.

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 copper sulfate pentahydrate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for copper sulfate pentahydrate (CAS Reg. No. 7758-99-8) when used in antimicrobial pesticide formulations applied to all food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum level in the end use concentration of 80 ppm.

VII. Statutory and Executive Order Reviews

This final rule establishes 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This 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: December 20, 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
* * *	*	* * *
Copper sulfate pentahydrate	7758-99-8	When ready for use, the end-use concentration is not to exceed 80 ppm
* * *	*	* * *

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[FR Doc. 2013-31101 Filed 12/26/2013 at 8:45 am; Publication Date: 12/27/2013]