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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0865; FRL-9929-51]

Cuprous oxide; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the tolerance exemption for copper in/on meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use of cuprous oxide embedded in polymer emitter heads used in irrigation systems for root incursion prevention. This regulation eliminates the need to establish a maximum permissible level for residues of copper resulting from this use of cuprous oxide.

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-2014-0865, 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: Jennifer McLain, Antimicrobials Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 308-0293; email address: *mclain.jennifer@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 Federal Food, Drug and Cosmetic Act (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-2014-0865 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-2014-0865, 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. Background and Statutory Findings

In the **Federal Register** of April 22, 2015 (80 FR 22466) (FRL-9925-79), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F8324) by Cupron, Inc., 800 East Leigh St., Richmond, VA 23219. The petition requested that 40 CFR 180.1021 be amended by establishing an exemption from the requirement of a tolerance for residues of copper in/on meat, milk, poultry, eggs, fish, shellfish, and irrigated crops by including the use of cuprous oxide (also referred to as copper oxide) embedded in polymer emitter heads used in irrigation systems for agricultural crops or residential food commodities for algicidal or root incursion prevention. That document referenced a summary of the petition prepared by Cupron, Inc., which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

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 exemption is "safe." Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. The nature of the toxic effects caused by cuprous oxide are discussed in this unit.

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 cuprous oxide, 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 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. 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 end points.

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.

B. Toxicological Points of Departure/Levels of Concern

No endpoints of toxicological concern were identified for risk assessment purposes for copper oxide. Cuprous oxide readily hydrolyzes into the copper cation and oxygen 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 oxide as a pesticide chemical would not be of toxicological concern.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Copper is ubiquitous in nature and is necessary nutritional element for both animals (including humans) and plants. It is one of several elements found essential to life. The human body must have copper to stay healthy. In fact, for a variety of biochemical processes in the body to operate normally, copper must be part of our daily diet. Copper is needed for certain

critical enzymes to function in the body. Actually, too little copper in the body can actually lead to disease.

1. *Food*. 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 vegetables (potato, legumes (beans and peas), nuts (peanuts and pecans), grains (wheat and rye), fruits (peaches and raisins), and chocolate in levels that range from 0.3 to 3.9 parts per million (ppm). A single day's diet may contain 10 milligram (mg) or more of copper. It is not likely that the approval of this petition would significantly increase exposure over that of existing levels of copper. In any event, given the lack of toxicity of copper, EPA does not expect any increased exposure resulting from approval of this petition to be unsafe.

2. *Drinking water exposure*. 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. In any event, given the lack of toxicity of copper, EPA does not expect any increased exposure resulting from approval of this petition to be unsafe.

B. Other Non-Occupational Exposure

Copper compounds have many uses on crops (food as well as non-food) and ornamentals as a fungicide.

1. *Dermal exposure*. Given the prevalence of copper in the environment, no significant dermal exposure increase above current levels would be expected from this non-occupational use of cuprous oxide. In any event, given the lack of toxicity of copper, EPA does not expect any increased exposure resulting from approval of this petition to be unsafe.

2. *Inhalation exposure*. Air concentrations of copper are relatively low. A study based on several thousand samples assembled by EPA's Environmental Monitoring Systems Laboratory showed copper levels ranging from 0.003 to 7.32 micrograms per cubic meter. Other studies indicated that air levels of copper are much lower. The Agency does not expect the air concentrations of copper to be significantly affected by this use of cuprous oxide. In any event,

given the lack of toxicity of copper, EPA does not expect any increased exposure resulting from approval of this petition to be unsafe.

V. 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 cuprous oxide to share a common mechanism of toxicity with any other substances, and cuprous oxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cuprous oxide 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*.

VI. Determination of Safety for U.S. Population, Infants and Children

Cuprous oxide is considered Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA). EPA has also exempted various copper compounds from the requirement of a tolerance when used as herbicide and algicide (40 CFR 180.1021), including cuprous oxide when contained in antifouling coatings on submerged concrete or other (irrigation) structures (40 CFR 180.1021(a)(4)). Copper compounds including cuprous oxide are also exempt from the requirements of a tolerance when applied to growing crops when used as a plant fungicide in accordance with good agricultural practices (40 CFR 180.1021(b)).

1*. U. S. population*. Copper is a component of the human diet and an essential element. In addition, no acute or chronic dietary endpoints were selected because no endpoints of toxicological concern have been identified for risk assessment purposes. Use of cuprous oxide is not expected to increase the amount of copper in the diet as a result of its use on growing crops and post-harvest use.

2. *Infants and children*. Copper is also component of the diet of infants and children as is also an essential element of their diet. Since no endpoints have been identified, EPA has not conducted a quantitative risk assessment for cuprous oxide. The Agency has also determined that the special Food Quality Protection Act safety factor (FQPA SF) to protect infants and children was not needed since there are no toxicity endpoints or uncertainty surrounding exposure.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues. Accordingly, EPA finds that exempting residues of cuprous oxide from the requirement of a tolerance will be safe.

VII. 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. Revisions to Petitioned-For Tolerances

The Agency is establishing an exemption for cuprous oxide that differs slightly from the exemption that was requested. First, the Agency has removed the phrase "for agricultural crops or residential food commodities" because the current structure of section 180.1021(a) makes that language duplicative and potentially confusing. With today's exemption, residues of copper on any irrigated crop that result from uses of cuprous oxide in polymer emitter heads for irrigation are exempt from the requirement of a tolerance; it is not necessary to further clarify where the irrigation heads are intended to be used. Also, the term algaecidal was deleted from the proposed tolerance exemption expression because the product is not intended to act as an algaecide.

VIII. Conclusion

Based on the information contained in the document, EPA concludes that there is no reasonable certainty of harm from aggregate exposure to residues of cuprous oxide. Accordingly, EPA finds that the exemption for residues of copper in or on meat, milk, poultry, egg, fish, shellfish, and irrigated crops from use of cuprous oxide embedded in polymer emitter heads used in irrigation systems for root incursion prevention will be safe. Therefore, an exemption is established for residues of copper oxide embedded in polymer emitter heads used in irrigation systems for root incursion prevention.

IX. Statutory and Executive Order Reviews

This action 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 action 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 action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (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 (NTTAA) (15 U.S.C. 272 note).

X. 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, cuprous oxide.

Dated: June 18, 2015.

Jennifer L. McClain,

Acting Director, Antimicrobials 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. Add paragraph (a)(5) to §180.1021 to read as follows:

§ 180.1021 Copper; exemption from the requirement of a tolerance.

(a) * * *

(5) Copper oxide embedded in polymer emitter heads used in irrigation systems for root incursion prevention.

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[FR Doc. 2015-16224 Filed: 6/30/2015 08:45 am; Publication Date: 7/1/2015]