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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0356; FRL-7341-1]

Copper (II) Hydroxide; 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 (II) hydroxide on raw agricultural commodities when used as an inert ingredient (for pH control) in pesticide products. Syngenta Crop Protection submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of copper (II) hydroxide.

DATES: This regulation is effective January 28, 2004. Objections and requests for hearings, identified by docket ID number OPP-2003-0356, must be received on or before March 29, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; e-mail address: campbell.princess@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal Production (NAICS code 112)
- Food manufacturing (NAICS code 311)

- Pesticide manufacturing (NAICS code 32532)

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

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0356. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in

the system, select “search,” then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of July 2, 2003 (68 FR 39554) (FRL-7315-2), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 2E6471) by Syngenta Crop Protection, P.O. Box 18300, Greensboro, North Carolina 27419-8300. The notice included a summary of the petition prepared by the petitioner Syngenta Crop Protection. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1021 be amended by establishing an exemption from the requirement of a tolerance for residues of copper (II) hydroxide (CAS Reg. No. 20427-59-2).

Section 408(b)(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) 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) 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. Human Health Assessment

Consistent with section 408(b)(2)(D) of FFDCA, 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 copper (II) hydroxide are discussed in this unit. However, for copper (II) hydroxide, toxicity has not been assessed based on the results of animal toxicity data. As discussed below the toxicity is characterized by a discussion of the use of an hydroxide as a neutralizing agent, the natural occurrence of copper, and the highly reactive nature of any hydroxide.

In formulating a pesticide product, a basic chemical such as copper (II) hydroxide serves a specific purpose, that of a neutralizing agent or a pH adjuster. During the manufacture of a pesticide product (or, in fact, many industrial chemicals), it may be necessary to adjust the pH of the product. A base functions as a neutralizing agent when the hydroxyl ion combines with the H^+ in an acidic solution to form a molecule of water. Small amounts of the hydroxide would be added to the solution until a neutral pH is reached. After the pH adjustment is performed and the neutralization reaction occurs, copper (II) hydroxide is no longer present. The reaction products that are then present are the copper (II) positively charged ion and water.

Alternatively, it might be necessary to have a pesticide product maintain a

basic pH; thus, the copper hydroxide would be added during the manufacturing process to deliberately raise the pH, which would mean an excess of the hydroxyl ion. Such products are not likely to be sold to the residential market.

On November 15, 2000, the Agency published in the **Federal Register** (65 FR 68908) (FRL-6747-3) a final rule establishing a tolerance exemption for copper sulfate pentahydrate. That final rule discussed the Agency's evaluation of the toxicity of copper which is also applicable to copper (II) hydroxide. As stated in that final rule, copper is a naturally-occurring material, i.e. ubiquitous in nature, is a necessary nutritional element, and is found naturally in the food we consume for nutrition. Oral ingestion of excessive amounts of the copper ion from pesticidal use is very unlikely. In fact, if large amounts of copper are ingested prompt emesis will occur. This is the body's protective reflex.

As a chemical class, hydroxides are significantly different from many of the chemicals regulated as inert ingredients in pesticide products. First, hydroxides are highly corrosive. Due to this property, toxicity testing can only be performed on very diluted solutions. Therefore, toxicity studies performed with undiluted copper (II) hydroxide are not available. Second, hydroxides are

highly reactive, and therefore are not expected to be persistent in the food supply, the environment, or in water resources. Copper (II) hydroxide would be expected to dissociate and immediately react with both plant and animal materials.

Chemically, an hydroxide is known as a base, a substance that when dissolved in water yields hydroxyl (OH^-) ions. The increase of the concentration of the OH^- ion raises the pH. It is the hydroxyl ion that is highly reactive, thus displaying the corrosive characteristic. The consequences of acute exposure to hydroxides are well understood: They are corrosive to the eyes, the skin, and the respiratory tract. The hazard of any hydroxide chemical derives directly from and is due to these irritation and caustic effects.

Copper (II) hydroxide is not considered to be a strong base. The strongest bases (the most reactive) are those of the alkali metal and alkali earth groups, such as sodium, potassium, calcium, and magnesium. Even the strongest base hydroxides, however, have been approved by the Food and Drug Administration (FDA) for many uses including direct use in the food supply. In fact FDA has evaluated the following hydroxides and determined that the following substances are GRAS (generally recognized as safe) when used as direct food additives.

Chemical	FDA GRAS Citation	GRAS Use Pattern
Ammonium hydroxide	21 CFR 184.1139	Leavening agent, pH control agent, surface-finishing agent, boiler water additive
Calcium hydroxide	21 CFR 184.1205	(No limitations specified)
Magnesium hydroxide	21 CFR 184.1428	Nutrient supplement, pH control agent, processing aid
Potassium hydroxide	21 CFR 184.1631	Formulation aid, pH control agent, processing aid, stabilizer and thickener
Sodium hydroxide	21 CFR 184.1763	pH control agent, processing aid

There is no available information on any hydroxide chemical indicative of a human health hazard from the ingestion of food directly treated with these hydroxides resulting from the FDA GRAS uses. According to FDA, no data were found "... suggesting that the use of sodium or potassium hydroxides, as currently practiced in food processing, is hazardous to consumers. The corrosive effect of ingestion of large amounts of strong alkalis such as sodium and potassium hydroxides has been amply demonstrated. However, these alkalis are not present as such in foods as consumed. The small amounts added for pH adjustment during food

processing react rapidly with food acids to form neutral salts. Moreover, any free alkali that might be present in food ... is converted to neutral salts in the stomach."

Given the structural similarities of copper (II) hydroxide and the stronger bases evaluated in the FDA GRAS evaluation, there is no expectation that copper (II) hydroxide would react in a different manner. Thus, the likelihood of any unreacted copper (II) hydroxide being available in the food supply is extremely unlikely.

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

1. *Food.* Copper is ubiquitous in nature and is a necessary nutritional element for both animals (including

humans) and plants. It is 1 of 26 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 diet. Copper is needed for certain critical enzymes to function in the body. Too little copper in the body can actually lead to disease.

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 (peach and raisins), and chocolate in levels ranging from 0.3 to 3.9 parts per million (ppm). A single day's diet may contain 10 milligrams (mg) or more of copper. The daily recommended allowance of copper for adults' nutritional needs ranges from 2 to 3 mg/day.

Given the widespread occurrence of copper and hydroxides in the existing food supply, the amount of copper (II) hydroxide that can be applied to food as a result of a use in a pesticide product would not be expected to significantly increase the existing amounts of either copper or hydroxide in the food supply. The EPA-regulated uses as an inert ingredient in a pesticide product would be considerably less than all of the FDA GRAS uses of hydroxides. More importantly, generally all of hydroxide used as an inert ingredient would either be neutralized in the pesticide solution or in the environment prior to any human exposure.

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. 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. The Agency has set a maximum contaminant level (MCL) for copper in drinking water at 1.3 ppm.

As previously stated, hydroxides, including copper (II) hydroxide, are not expected to be persistent in the environment, or in water resources. Copper (II) hydroxide would be expected to dissociate, react with organic or inorganic materials, and complex with ionic substrates.

B. Other Non-Occupational Exposure

Copper is a naturally occurring element present in the earth's crust, and it is therefore naturally occurring in soil, water, and air. Soils would be considered copper deficient if they

contain less than 1 to 2 ppm available copper in the context of plant health. 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.

As a group, hydroxides constitute a group of chemicals with many industrial uses. However, considering the reactivity and corrosivity of any hydroxide, there are few uses of even diluted solutions of hydroxides in and around the home.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of the 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 does not have, at this time, available data to determine whether copper (II) hydroxide has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to copper (II) hydroxide and any other substances, and copper (II) hydroxide does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that copper (II) hydroxide has 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 the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

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

Copper is a naturally occurring element present in the earth's crust, and it is therefore naturally occurring in soil, water, and air. Copper is a component of the diet of all humans (including infants and children). Copper is an essential trace element for which the National Academy of Sciences has issued a recommended daily allowance

(RDA) ranging from 2 to 3 mg/day for adults. The RDA reflects a level needed to avoid nutritional deficiencies, not an upper limit. The Agency believes that copper has no significant toxicity to humans. Given the ubiquitous nature of copper, there is reasonable certainty that no harm will result from the aggregate exposure of the U.S. population to copper.

Given the ubiquitous nature of copper, there is reasonable certainty that no harm will result from the aggregate exposure of infants and children to copper. A safety factor analysis has not been used to assess the risk. The additional tenfold safety factor for the protection of infants and children is unnecessary.

Hydroxide chemicals have been used in the food supply for a number of years. Use of various hydroxides as direct food additives has been reviewed by FDA and granted GRAS status. Given the structural similarities of copper (II) hydroxide and the stronger bases evaluated in the FDA GRAS evaluations, it is expected that copper (II) hydroxide would react in a similar manner. No significant exposure to copper (II) hydroxide is expected from use of copper hydroxide as an inert ingredient in pesticide products. It is extremely unlikely that use of copper (II) hydroxide in pesticide products will lead to any unreacted copper (II) hydroxide in the food supply.

VII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . ." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing copper (II) hydroxide (for endocrine effects) may be required.

B. Analytical Method(s)

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.

C. Existing Tolerances

Copper (II) hydroxide has been exempted from the requirement of a tolerance under 40 CFR 180.1021(b)

when applied (primarily) as a fungicide to growing crops.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for copper (II) hydroxide, and no CODEX maximum residue levels have been established for any food crops at this time.

VIII. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to copper (II) hydroxide. Accordingly, EPA finds that exempting copper (II) hydroxide (CAS Reg. No. 20427-59-2) from the requirement of a tolerance will be safe.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0356 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 29, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing

is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy

of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0356, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement 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 rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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.*, or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). 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); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive

Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 12, 2004.

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), 346(a) and 371.

■ 2. Section 180.1021 is amended by adding paragraph (d) to read as follows:

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

* * * * *

(d) Copper (II) hydroxide (CAS Reg. No. 20427-59-2) is exempt from the requirement of a tolerance when applied to growing crops or to raw agricultural commodities as an inert ingredient (for pH control) in pesticide products.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0392; FRL-7340-9]

Formaldehyde, polymer with α -[bis(1-phenylethyl)phenyl]- ω -hydroxypoly(oxy-1,2-ethanediyl); Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of formaldehyde, polymer with α -[bis(1-phenylethyl)phenyl]- ω -hydroxypoly(oxy-1,2-ethanediyl) when used as an inert ingredient in a pesticide product. Nichino America submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of formaldehyde, polymer with α -[bis(1-phenylethyl)phenyl]- ω -hydroxypoly(oxy-1,2-ethanediyl).

DATES: This regulation is effective January 28, 2004. Objections and requests for hearings, identified by docket ID number OPP-2003-0392, must be received on or before March 29, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0371; e-mail address: parker.james@epa.gov.

SUPPLEMENTARY INFORMATION: