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Stanley F. Mires,*Chief Counsel, Legislative.*

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300777; FRL-6052-5]

RIN 2070-AB78

Copper-ethylenediamine Complex; Exemption From the Requirement of a Tolerance**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of copper-ethylenediamine complex in or on potatoes when applied/used in accordance with good agricultural practice as an active ingredient in pesticide formulations as a desiccant/harvest aid. The Interregional Research Project Number 4 (IR-4) submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Copper-ethylenediamine complex in or on potatoes.

DATES: This regulation is effective February 3, 1999. Objections and requests for hearings must be received by EPA on or before March 5, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300777], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300777], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk

may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300777]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson (PM5), Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-7610, e-mail: jackson.sidney@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 29, 1997 (62 FR 56179) (FRL-5749-7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 announcing the filing of a pesticide tolerance petition by IR-4. This notice included a summary of the petition prepared by the Griffin Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Copper-ethylenediamine complex.

I. Background and Statutory Authority

New section 408(b)(2)(A)(i) of the 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.

II. Toxicological Profile

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-ethylenediamine complex are discussed below:

Copper-ethylenediamine complex and copper sulfate pentahydrate are the active ingredient components of INFERNO™ Plant Desiccant, a formulation containing 8% elemental copper. An identical product, KOMEEN® Aquatic Herbicide (EPA Reg. No. 1812-312), is approved for use in slow moving or quiescent bodies of water including potable water reservoirs. Copper sulfate pentahydrate is already exempt from the requirement of a tolerance according to 40 CFR 180.1001(b)(1).

Copper is ubiquitous in nature and is a nutritionally required element for plants and animals. The National Academy of Science has established a recommended daily dietary intake for copper. In addition, humans possess a natural efficient homeostatic mechanism for regulating copper body levels over a wide range of dietary intake. The toxicity of the copper ion is well-characterized in the published literature. There is no evidence of any chronic effects induced by dietary ingestion of copper unless the intake is of such enormous magnitude that there is a disruption of the natural homeostatic mechanism for controlling body levels. Consequently, there is no reason to expect that long-term exposure to the copper ion in the diet is likely to lead to adverse health effects.

The EPA toxicology database on copper-ethylenediamine complex shows this compound has similar toxicological properties to other copper compounds already exempt from the requirement of a tolerance such as copper hydroxide and cuprous oxide.

The Agency does not require subchronic, chronic, reproductive or developmental toxicity studies for the copper salts.

Results of a battery of acute toxicity studies show copper-ethylenediamine complex (Komeen) is slightly to moderately toxic upon acute oral, dermal and inhalation exposure, slightly irritating to the skin and moderately irritating to the eye.

In rats, the acute oral lethal dose (LD)₅₀ (95% confidence limits) for Komeen was 498 milligram (mg)/kilogram (kg) (349–710 mg/kg) for a Toxicity Category II classification.

The acute dermal LD₅₀ in rabbits for Komeen was determined to be > 2,000 mg/kg (Toxicity Category III).

In acute inhalation studies with Sprague-Dawley rats, the lethal concentration (LC)₅₀ (95% confidence limits) for Komeen was 0.81 mg/liter(l) (0.26–1.37 mg/l).

In rabbit studies, Komeen was shown to be moderately irritating to the eye with all signs of ocular irritation cleared within 10 days of treatment (Toxicity Category III).

III. 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 groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* Based on the proposed used pattern of potato vine desiccation, minimal copper residues are expected to occur in potatoes and the dietary exposure would be negligible by comparison to the normal daily intake of copper. A single day's diet may contain 10 mg or more of copper. The daily recommended allowance of copper for adults nutritional needs is 2 mg.

Copper levels toxic to plants induce a chlorosis condition which causes decreased growth and yield before hazardous copper levels are reached. Since the INFERNO™ formulation will be applied to the potato vine above ground, the potato tubers below ground

will not be directly treated. Moreover, copper is naturally found in several types of food, such as fruits and vegetables, at levels ranging from 0.3 to 3.9 ppm. The Agency believes that residues of copper, if any, in potatoes from pesticidal application of copper-ethylenediamine complex are not likely to exceed these naturally occurring levels. Additionally, the Agency has waived all residue chemistry study requirements for copper-ethylenediamine complex since copper is naturally occurring in plants and it is impossible to distinguish copper residues resulting from naturally occurring copper or copper-ethylenediamine complex.

2. *Drinking water exposure.* Copper is ubiquitous in the environment and found in natural water. Komeen is registered for use in water including potable water, livestock watering, fish hatcheries, etc. The average copper concentration in drinking water is 0.13 ppm. In 1991, the US EPA established a maximum contamination level (MCL) for copper in drinking water of 1.3 mg/l. The Agency believes that no impact on copper levels found naturally in water would occur as a result of potato vine desiccant use of copper-ethylenediamine complex.

B. Other Non-Occupational Exposure

Copper is registered for use as an aquatic herbicide for outdoor residential sites. Any contributions to aggregate exposure from this use would not be expected to be significant.

1. *Dermal exposure.* No significant dermal exposure would be expected to result from intended use of copper-ethylenediamine complex.

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 indicate that air levels of copper are much lower. The Agency does not expect the air concentration of copper to be significantly affected by the use of copper-ethylenediamine complex on potatoes.

IV. Cumulative Effects

The Agency believes that copper has no significant toxicity to humans and that no cumulative adverse effects are expected from long-term exposure to copper salts. No other elements are expected to produce cumulative toxicity with copper-ethylenediamine complex.

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

Copper compounds such as copper sulfate pentahydrate are considered as Generally Recognized as Safe (GRAS) by the Food and Drug Administration. EPA has exempted various copper compounds from the requirement of a tolerance when used as aquatic herbicides (40 CFR 180.1021). Copper compounds are also exempt from the requirement of a tolerance when applied to growing crops when used as a plant fungicide in accordance with good agricultural practices (40 CFR 180.1001(b)(1)).

1. *U.S. population.* Copper is a component of the human diet and an essential element. Use of copper-ethylenediamine complex is not expected to increase the amount of copper in the diet as a result of potato vine desiccation.

2. *Infants and children.* Infants and children also require copper in their diets and EPA believes that no special sensitivity for this population subgroup would be expected as a result of the proposed use. Because of copper's low toxicity, EPA has not used a safety factor approach to analyzing the safety of copper-ethylenediamine complex used as a potato vine desiccant. For similar reasons, an additional tenfold margin of safety is not necessary for the protection of infants and children.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to Copper-ethylenediamine complex residues. Accordingly, EPA finds that exempting Copper-ethylenediamine complex from the requirement of a tolerance will be safe.

VI. Other Considerations

A. Endocrine Disruptors

Since copper is required for homeostasis, low copper dietary exposures would not be expected to result in any adverse endocrine effects. Moreover, the Agency has no information to suggest that copper will adversely affect the immune or endocrine systems. The Agency is not requiring information on the endocrine effects of copper at this time; Congress has allowed three (3) years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

B. Analytical Method(s)

A practical analytical method for copper-ethylenediamine complex is not required for crop use since it is expected

that no residues will occur in potatoes. Additionally, the Agency is establishing an exemption from the requirement of a tolerance without any numeric limitation; therefore, the Agency is not requiring an analytical method for enforcement purposes for copper-ethylenediamine complex.

C. Existing Tolerances

There are no existing tolerance(s) for copper-ethylenediamine complex.

D. International Tolerances

No maximum residue level has been established for copper-ethylenediamine complex by the Codex Alimentarius Commission.

VII. Objections and Hearing Requests

The new FFDCA 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) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by March 5, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA,

(703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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). 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). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300777] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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). 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) (Pub.L. 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629), February 16, 1994, or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In additions, since tolerance 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for

the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an

effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

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 the rule in the **Federal Register**. This 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 21, 1998.

James Jones,

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. 346a and 371.

§ 180.1001 [Amended]

2. Section 180.1001 in subpart D is amended in paragraph (b)(1), by adding alphabetically "copper-ethylenediamine complex,".

[FR Doc. 98-34702 Filed 12-31-98; 8:45 am]

BILLING CODE 6560-50-F