PART 81—[AMENDED]

4. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7407, 7501–7515, 7601.

Subpart C—Section 107 Attainment Status Designations

5. Section 81.346 is amended by revising the table ''Vermont-TSP'' to read as follows:

§ 81.346 Vermont.

VERMONT—TSP

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standard
Champlain Valley Air Management Area: Essex Town (includes Essex Junction), Burlington City, South Burlington City, Winoski City			X	
Central Vermont Air Management area: Barre City			X	
Remainder of State				X

* * * * *

[FR Doc. 97–19644 Filed 7–31–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300524; FRL–5734–7]

RIN 2070–AB78

Copper Octanoate; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for the fungicide copper octanoate (CAS Reg. No. 20543–04–8, PC Code 23306) when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops. The petitioner, W. Neudorff GmbH KG requested this tolerance exemption under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170) in pesticide petition 6F4734.

DATES: This regulation is effective August 1, 1997. Objections and requests for hearings must be received by EPA on or before September 30, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300524], 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–300524], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e–mail) to: opp–docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300524]. No Confidential Business Information (CBI) should be submitted through e–mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles–Parker, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–305–7740, e–mail: giles–parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 1997 (62 FR 2154)(FRL–5580–4), EPA, issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346(a)(d) announcing the filing of a pesticide petition (PP) 6F4734 proposing to amend the 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for copper octanoate in or on all raw agricultural commodities when applied to growing crops. This notice included a summary of the petition prepared by W. Neudorff GmbHKG (''Neudorff''), the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(b)(1) be amended by adding copper octanoate to the list of copper compounds which are exempt from the requirement of a tolerance.

I. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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 Copper Octanoate and to make a determination, consistent with section 408(b)(2), for an exemption from tolerance requirements for Copper Octanoate. EPA's assessment of the data associated with establishing the tolerance exemption follows.

A. Product and Residue Chemistry

1. *Product chemistry.* Copper octanoate, is a copper salt of a fatty acid. Copper octanoate is biodegraded first by water hydrolysis into the copper ion and fatty acid components, and then the fatty acids are further degraded by two carbon units at a time until they eventually degrade to water and CO_2.

2. *Magnitude of the residue anticipated at the time of harvest and method used to determine the residue.* No residues are expected at the time of harvest on crops treated with copper

octanoate, because rainwater readily washes copper octanoate off plants, and this chemical is biodegraded by water hydrolysis into its copper ion and fatty acid components, and then the fatty acids are further degraded by two carbon units at a time until they eventually degrade to water and CO_2. In addition, the physio–chemical properties of soils naturally modify copper ion availability, and when soils are adjusted/limed to the pH required for normal crop production, the effect is to reduce copper availability to the crop. Furthermore, toxic copper levels in plants induce an imbalance with iron which causes plant dwarfing, stunted roots and decreased growth and yields, which effects appear before significant copper buildup occurs, and consequently acts as a warning which prevents excess application of copper compounds to food/feed crops. Last, even if residues were to remain on plants, the copper ion is a trace element, or micronutrient, essential for the growth and well being of higher plants and animals, including man. Therefore, the amount of this chemical proposed for application to plants is highly unlikely to cause harm to plants or animals or to leave excess residues on the plants.

3. *Analytical method for detecting and measuring the levels of the pesticide residue are not needed.* The Agency proposes to establish exemptions from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that analytical methods are not required for enforcement purposes for copper octanoate.

B. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. The nature of the toxic effects caused by Copper Octanoate are discussed below.

1. *Acute toxicity.* Results of studies conducted on a concentrate product containing copper octanoate and for which Neudorff has applied for registration indicate that this chemical has low acute toxicities. The following outlines the results of the acute toxicity studies:

a. *An oral LD_{50} rat study.* Male and female rats were orally administered single doses of undiluted test material at a dose level of 2,000 milligrams (mg)/kilogram(kg) mg/kg. The estimated acute oral LD_{50} for copper octanoate 10% copper fatty acids was > 2,000 mg/kg for the sexes combined.

b. *A dermal LD_{50} rat study.* Male and female rats received a dermal application of undiluted test material at a mg/kg (limit dose) for 24 hours. The acute dermal LD_{50} for Copper octanoate (10% copper fatty acid) in male and female rats was > 2,000 mg/kg.

c. *Inhalation LC_{50} rat study.* Groups of rats were exposed to an aerosol concentration of 0.38 mg/L NEU 1140 F for 4 hours. There were no mortalities and clinical signs observed. The acute inhalation LC_{50} was > 0.38 mg/L (the highest achievable concentration) in both sexes of rats. Since no mortality and clinical signs occured at the highest achievable concentration of 0.38 mg/L, NEU 1140 F was classified as Toxicity Category III for inhalation.

d. *Primary rabbit eye irritation study.* Approximately 0.1 ml of test material was instilled into the conjunctival sac of one eye of three male rabbits. The other eye served as an untreated control. Application of NEU 1140 F caused irritation of conjunctivae in all rabbits which was reversible within 48 hours. The study demonstrated that NEU 1140 F produces transient ocular irritation in rabbits.

e. *Primary rabbit skin irritation study.* Test material, 0.5 g, moistened with 0.5 ml of 0.5% distilled water was applied to a clipped skin area of three rabbits for 4 hours. The study demonstrated that copper ocatnoate is non–irritating to the rabbit skin.

f. *Dermal sensitization guinea pig study.* In a Maximization Test, 20 guinea pigs received 3 intradermal injections of 0.5% NEU 1140 F in distilled water and an epidermal application of undiluted test material during the induction phase. During the challenge phase, a topical appication of 50% test substance concentraton in distilled water was administered to animals. The study showed that NEU1140 is a non–sensitizer of skin in female guinea pigs.

2. *Genotoxicity, reproductive and developmental toxicity, subchronic toxicity, and chronic toxicity.* There is adequate information available to characterize the toxicity of the copper ion. Copper is ubiquitous in nature and is a necessary nutritional element for both animals and plants. It is 1 of 26 elements found essential to life. The copper ion is present in the adult human body at levels of 80–150 mg. Oral ingestion of excessive amounts of the copper ion from pesticidal uses is unlikely; copper compounds are irritating to the gastric mucosa and emesis usually occurs promptly, thereby reducing the amount of copper ion available for absorption into the human body. Only a small percentage of ingested copper is absorbed, and most of the absorbed copper is excreted. In view of the facts that the copper ion occurs naturally in most foods and the metabolism of copper is well understood, there is no reason to expect that long–term exposure to the copper ion in the diet is likely to pose the risks of chronic or sub–chronic adverse effects. It is unlikely that the toxicity profile for copper octanoate would differ significantly from the numerous other copper compounds which are already exempted from the requirement of a tolerance.

C. Aggregate Exposure

As part of the hazard assessment process, the Agency reviews the available toxicological database to determine the endpoints of concern for acute and chronic dietary exposure; and short, intermediate and chronic term occupational and residential exposure. In the case of copper octanoate the Agency only reviewed acute toxicity data on the end–use product formulations, since information currently available to the Agency indicates that there is no significant toxicity from exposure to copper octanoate that lasts from 1 day to several months. The Agency has exempted from the requirement of a tolerance other compounds similar to copper octanoate, such as the, copper salts of fatty acids that include: copper oleate, copper lineolate and copper acetate which are listed in 40 CFR 1011(b)(1). Therefore, no risk assessments are required for any exposure scenarios.

After taking into account the factors set forth in section 408(b)(2)(D), EPA concludes that copper does not present a dietary risk under reasonably forseeable circumstances. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to consumers, including infants and children, from aggregate exposure to copper. Because copper has no significant toxicity EPA has not assessed its risk using a margin of safety approach and, therefore, the requirement pertaining to an additional safety factor for infants and children is not applicable to EPA's safety determination for this exemption.

D. Existing Tolerances

1. *Existing tolerances or tolerance exemptions.* EPA has not established a tolerance or an exemption from the requirement for a tolerance for this chemical. However, EPA has promulgated a tolerance exemption for a group of similar copper–based chemicals, i.e., Bordeaux mixture, copper acetate, basic copper carbonate (malachite), copper hydroxide, copper–

lime mixtures, copper linoleate, copper oleate, copper oxychloride, copper sulfate basic, copper sulfate monohydrate, copper sulfate pentahydrate, copper–zinc chromate, cupric oxide, and cuprous oxide (two of these chemicals are copper salts of fatty acids), when they are applied to growing crops in accordance with good agricultural practice. See 40 CFR 180.1001(b)(1). In addition, EPA has promulgated a tolerance exemption for copper residues in meat, milk, poultry, eggs, fish, and irrigated crops when they result from the use of certain copper compounds, i.e., copper sulfate, basic copper carbonate, copper triethanolamine, copper monoethanolamine, and cuprous oxide, at certain sites. See 40 FR 180.1021. The common basis for EPA's tolerance exemptions for the compounds in these two classes of copper compounds appears to be the fact that the copper ion is the entity responsible for their fungicidal action, and there is adequate data on the copper ion upon which EPA can make judgments about its potential for causing unreasonable adverse effects to humans or the environment.

2. *International tolerances.* No maximum residue level has been established for this substance by the Codex Alimentarius Commission.

II. Conclusion

Therefore, an exemption from requirement of a tolerance is established for copper octanoate in pesticide formulations applied to growing crops.

III. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) 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 September 30, 1997, 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 above (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). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (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 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 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 Confidential Business Information (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. regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than

IV. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300524] (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 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp–docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above 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 rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

V. Regulatory Assessment Requirements

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). 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 prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 addition, since these 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. Nevertheless, the Agency has 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.

VI. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **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: July 24, 1997.

Stephen L. Johnson,

Acting Director, 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. In § 180.1001, Exemptions from the requirement of a tolerance, by adding and alphabetically inserting copper octanoate in paragraph (b)(1).

[FR Doc. 97–20361 Filed 7-31-97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300520; FRL–5732–5]

RIN 2070–AB78

Fludioxonil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fludioxonil in or on potatoes . This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on potatoes. This regulation establishes a maximum permissible level for residues of fludioxonil in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on August 1, 1998.

DATES: This regulation is effective August 1, 1997. Objections and requests for hearings must be received by EPA on or before September 30, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300520], 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–300520], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300520]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the fungicide fludioxonil, in or on potatoes at 0.02 part per million (ppm). This tolerance will expire and is revoked on August 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL-5572-9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish 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