#### KENTUCKY-OZONE—Continued

Designated area	Designation		Classification	
	Date 1	Туре	Date <sup>1</sup>	Type*
Defferson County		Non-attainment Non-attainment		

(1) This date is November 15, 1990, unless otherwise noted.

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[FR Doc. 95–23320 Filed 9–19–95; 8:45 am] BILLING CODE 6560–50–P

## 40 CFR Part 180

[PP 0E3858/R2171; FRL-4977-7]

RIN 2070-AB78

# Cinnamaldehyde; 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 pesticide tolerance for residues of the fungicidal pest control agent Cinnamaldehyde in or on all raw agricultural commodities. The Interregional Research Project No. 4 (IR-4) requested this tolerance exemption

on behalf of Monterey Laboratories and pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA). This regulation eliminates the need to establish a maximum permissible level for residues of cinnamaldehyde.

**DATES:** This regulation becomes effective September 20, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 0E3858/ R2171], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections 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 should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations 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 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [0E3858/R2171]. 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. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number: CS1, 5th floor, 2800 Crystal Drive, Crystal City, VA 22202, (703)-308-8733; e-mail:

bacchus.shanus@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the
Federal Register of July 26, 1995 (60 FR
38331), EPA issued a notice of PP
OE3858 from IR-4, New Jersey, 08903,
proposing to amend 40 CFR part 180 by
establishing a regulation pursuant to
section 408 of the FFDCA, 21 U.S.C.
346a(d), to exempt from the requirement
of a tolerance the residues of
cinnamaldehyde, a pest control agent, in
or on all raw agricultural commodities
when used to control certain fungal pest
species.

There were no comments received in response to the notice of filing. The data submitted in the petition and all other relevant material have been evaluated and are summarized below.

Cinnamaldehyde (cinnamic aldehyde) is the main component in cassia oil as well as cinnamon bark oil and is used in flavoring compounds to impart a cinnamon flavor. Considerable safety data exist from the food and flavoring industry, which use food-grade cinnamaldehyde in nonalcoholic beverages, ice cream, candy, baked goods, chewing gum, condiments, and meats at levels ranging from 9 parts per million (ppm) to 4,900 ppm. Cinnamaldehyde is Generally Recognized As Safe (GRAS) by the Flavoring Extract Manufacturers' Association and is approved for food use (21 CFR 182.60) by the Food and Drug Administration. Cinnamon oil, which contains 70% to 90% cinnamaldehyde, is also classified as GRAS and, like cinnamaldehyde, is used in the food and flavoring industry.

### Toxicology Assessment

The toxicological data provided in support of the exemption from the requirement of a tolerance include the following: two acute dermal toxicity studies and published data/information for acute oral toxicity, eye irritation, dermal irritation, and dermal sensitization. The registrant has requested waivers for the remaining acute mammalian toxicology requirements (Series 152B) as outlined in 40 CFR 158.690.

Acute Oral Toxicity in Rats, Guideline 152B-10. The published information submitted was used to establish an acute oral LD $_{50}$  of 1.15 g/kg (guinea pig), 2.25 g/kg or 3.35 g/kg (rat). Classification: Acceptable. Toxicity Category III.

Acute Dermal Toxicity in Rats, Guideline No. 152B-11. Two acute dermal toxicity studies were submitted. From these studies, the  $LD_{50}$ , was determined to be greater than 1.2 g/kg. This  $LD_{50}$  value corresponds to the dermal  $LD_{50}$  value of 1.31 g/kg (rabbit) provided in the material safety data (MSDS) sheet submitted by the registrant.

Classification: Acceptable. Toxicity Category II.

Primary Eye Irritation, Guideline No. 152B-13. Exposure of human test subjects for 48 hours to a solution of 8% active ingredient demonstrated that it is an eye irritant. Although no corneal involvement was observed in this study, no information was provided as to the time for the eye irritation to clear. *Classification:* Acceptable. Toxicity Category II.

Primary Dermal Irritation, Guideline 152B-14. No primary dermal irritation was observed in human subjects exposed for 48 hours to a solution containing 3% active ingredient, while severe primary dermal irritation was observed in human subjects after exposure to 8% active ingredient. Classification: Acceptable. Dermal irritant.

Dermal Sensitization, Guideline 152B-15. Cinnamaldehyde was considered a sensitizer based on published results of the dermal effects of a 2% active ingredient on guinea pigs. Classification: Acceptable. Strong sensitizer.

Other Toxicology Data: Reference Dose (RfD) and maximum permissible intake (MPI) considerations are not relevant to this petition because of the low toxicity of the pesticide as reported in the data submitted.

## Residue Chemistry Data

Residue chemistry data are necessary only if the submitted toxicology studies indicate that additional Tier II or III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity via the oral route. Therefore, neither Tier II or III toxicology data nor residue chemistry data were required for this registration action.

The toxicological data provided are sufficient to demonstrate that there are no foreseeable human health hazards likely to arise from cinnamaldehyde when applied as a pesticide to mushrooms because of its low toxicity profile and the long history of use of both the active and inert ingredients in the food and flavoring industry.

Based on the information cited above, the Agency concludes that the establishment of a tolerance for the active ingredient, antifungal agent cinnamaldehyde, is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing 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 issue(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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [0E3858/R2171] (including objections and hearing requests submitted electronically as described below). 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2,

1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 0E3858/R2171], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at: opp-Docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 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 objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-365, 94 Stat. 1164, 5 U.S.C. 601-612),

the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: September 11, 1995.

Janet L. Andersen,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

#### PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1156, to read as follows:

## § 180.1156 Cinnamaledhyde; exemption from the requirement of a tolerance.

Cinnamaldehyde is exempted from the requirement of a tolerance when used as a plant pesticide on soil casing for mushrooms.

[FR Doc. 95–23317 Filed 9–19–95; 8:45 am] BILLING CODE 6560–50–F

#### 40 CFR Part 180

[PP 4F4368/R2166; FRL-4974-1]

RIN 2070-AB78

## Fliocladium Virens Isolate GL-21; Exemption From the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This document establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide *Gliocladium virens* GL-21 in or on terrestrial food crops grown

outdoors. W.R. Grace & Co. requested this tolerance exemption pursuant to the Federal Food, Drug and Cosmetic Act

(FFDCA).

**EFFECTIVE DATE:** This regulation becomes effective September 20,1995. **ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 4F4368/

R2166], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations 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 request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections 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 objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 4F4368/R2166]. No Confidential Business Information (CBI) should be submitted through email. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: CS51L6, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8263; e-mail:

greenway.denise@epamail.epa.gov. SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of September 28, 1994 (59 FR 49397), which announced that W.R. Grace & Co., 7379 Route 32, Columbia, MD 21044, had submitted pesticide petition (PP) 4F4368 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C 346a(d), establish an exemption from the requirement of a tolerance for residues of Gliocladium