ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 170

[OPP–250103; FRL–4948–5]

RIN No. 2070–AC69 and 2070–AC82

Amendments to the Worker Protection Standard Requirements for Crop Advisors and Training Requirements for Agricultural Workers and Pesticide Handlers; Notification to Secretary of Agriculture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification to Secretary of Agriculture.

SUMMARY: Notice is given that the Administrator of EPA has forwarded to the Secretary of Agriculture a final rule amending the crop advisor provisions of the Worker Protection Standard and a final rule amending the training requirements for workers and pesticide handlers. These final rules are being issued under the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA).

FOR FURTHER INFORMATION CONTACT: Donald Eckerman, Certification and Training, Occupational Safety Branch (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 1101, CM #2, 1921 Jefferson Davis Highway, Arlington, VA., (703) 305–7371.

SUPPLEMENTARY INFORMATION: Pursuant to Section 25(a)(2)(B) of FIFRA, the Administrator shall provide the Secretary of Agriculture with a copy of any final rule before publication in the Federal Register. If the Secretary comments in writing to the Administrator regarding the final rule, the Administrator shall issue for publication in the Federal Register, with the final rule, the comments of the Secretary of Agriculture, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. The Administrator has forwarded to the Secretary of Agriculture a copy of the final rule amending the requirements for training employees and a final rule amending the requirements for crop advisors.

The Administrator has also provided a copy of these final rules to the Committee on Agriculture of the House of Representatives, and the Committee on Agriculture and Forestry of the Senate.

List of Subjects in 40 CFR Part 170

Administrative Practice and Procedures, Occupational Safety and Health, Pesticides and Pests.

Dated: April 5, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

[FR Doc. 95–9167 Filed 4–11–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 2E4051/P608; FRL–4943–1]

RIN 2070–AC18

Difenoconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to establish import tolerances for residues of the fungicide difenoconazole in or on the raw agricultural commodities barley grain, rye grain, and wheat grain at 0.1 part per million; fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep and eggs at 0.05 ppm; and milk at 0.01 ppm. Ciba-Geigy Corp. requested the proposed regulation to establish a maximum permissible level of the fungicide in or on the commodities.

DATES: Comments, identified by the document control number, [PP 2E4051/P608], must be received on or before May 12, 1995.

ADDRESSES: By mail, submit written comments 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Information submitted as a comment concerning this notice 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 comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5540; e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA is proposing to establish import tolerances for residues of the fungicide difenoconazole, [(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-(2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1H-1,2,4-triazole, in or on the raw agricultural commodities (RACs) barley grain, rye grain, and wheat grain at 0.1 ppm; fat, meat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, poultry, and sheep and eggs at 0.05 ppm; and milk at 0.01 ppm. The proposed regulation to establish a maximum permissible level of the fungicide in or on this commodity was requested in a pesticide petition (PP 2E4051) submitted by Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300, that requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.475 by establishing import tolerances for residues of the fungicide.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerance include:

1. A rat acute oral study with an LD_{50} of 1,453 milligrams (mg)/kilogram (kg).

2. A 13-week rat feeding study with a no-observed-effect-level (NOEL) of 20 ppm (1 mg/kg/day).

3. A 13-week mouse feeding study with a NOEL of 20 ppm (3.6 mg/kg/day).

4. A 26-week dog feeding study with a NOEL of 1,000 ppm (3.3 mg/kg/day).

5. A 21-day rabbit dermal study with a NOEL of 10 mg/kg and reduction in body weight gain and food consumption from exposure to doses equal to or greater than 100 mg/kg.

6. A carcinogenicity study in mice with a NOEL of 30 ppm (5 mg/kg/day) and a lowest-effect-level (LEL) of 300 ppm (50 mg/kg/day) owing to reductions in cumulative body weights. There was limited evidence of carcinogenicity based on the occurrence of increased benign and/or malignant liver tumors in males and females. The carcinogenic effects observed are discussed below.

7. A rat chronic feeding/carcinogenicity study with a NOEL of 20 ppm (1 mg/kg/day) for systemic effects and a LEL of 500 ppm (25 mg/kg/day) owing to reductions in cumulative body weight gains and hepatotoxicity in males. There was no evidence of carcinogenicity under conditions of the study.

8. A 1-year dog chronic feeding study with a NOEL of 100 ppm (3.5 mg/kg/day); the LEL was 500 ppm (18 mg/kg/day) owing to reduction in food consumption and increase in alkaline phosphatase in males at high dose.

9. A two generation reproduction study in rats with a parental and reproductive NOEL of 25 ppm (1.25 mg/kg/day) and an LEL of 250 ppm (12.5 mg/kg/day) owing to reduction of female body weight gain and significant reductions in male pup weight at day 21.

10. A developmental toxicity study in rabbits with a maternal NOEL of 25 mg/kg and an LEL of 75 mg/kg/day owing to decreased body weight, death of one doe and abortion, and a developmental NOEL of 25 mg/kg, and an LEL of 75 mg/kg owing to increased postimplantation loss and resorptions and significantly decreased fetal weight.

11. A developmental toxicity study in rats with a maternal NOEL of 16 mg/kg and an LEL of 85 mg/kg owing to excess salivation, and decreased body weight gain and food consumption, and a developmental NOEL of 85 mg/kg/day, and an LEL of 171 mg/kg owing to increase bifid or unilateral ossification of thoracic vertebrate, increased average number of ossified hyoid, and decrease in average number of sternal centers of ossification.

12. A microbial gene mutation study and an unscheduled DNA synthesis in rat hepatocyte study were both negative. An *in vivo* micronucleus assay/chromosomal analysis study showed no increase in micronucleated polychromatic erythrocytes at any dose tested.

13. A rat metabolism study showed that difenoconazole was adequately absorbed and mainly eliminated via the bile. No evidence of bioaccumulation in any tissue was noted.

The Health Effects Division, Carcinogenicity Peer Review Committee, has concluded that the available data provide limited evidence of the carcinogenicity of difenoconazole in mice and has classified difenoconazole as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the Federal Register in 1986 (51 FR 33992; Sept. 24, 1986) and recommended that quantitative risk assessment is not appropriate for the following reasons:

1. The carcinogenic response observed with this chemical, statistically significant increases in hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of CD-1 mice, occurred only at doses considered to be excessively high for carcinogenicity testing.

2. There were no apparent tumor increases in either sex in Sprague-Dawley rats at dietary levels up to 2,500 ppm.

3. Difenoconazole was not mutagenic in three well conducted genotoxic assays.

Based on this evidence, EPA concludes that difenoconazole poses at most a negligible cancer risk to humans and that for purposes of risk characterization the Reference Dose (RfD) and Margin of Exposure (MOE) approaches should be use for quantification of human risk. In a spring wheat processing study, no residues were detected in grain or any processed fraction. Therefore, food/feed additive tolerances are not needed in conjunction with this use on barley, rye, and wheat.

Using a 100-fold safety factor and the NOEL of 1 mg/kg/day determined from the rat chronic feeding study (the most sensitive species), the Reference Dose RfD is 0.01 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.00042 mg/kg/day and utilizes 4 percent of the RfD for the overall U.S. population. For exposure of the most highly exposed subgroups in the population, children (ages 1 to 6 years old) and nonnursing infants (less than 1 year old), the TMRC is 0.000947 mg/kg/day and 0.000960 mg/kg/day and utilizes 9 and 10 percent of the RfD, respectively.

The dietary acute exposure MOE for developmental toxicity effects was calculated to be 62,500 for high exposure in the females 13+ subgroup. For substances whose acute NOEL is based on animal studies, the Agency is not generally concerned unless the MOE is below 100.

The metabolism of difenoconazole in plants is adequately understood. The tolerances established for milk, eggs, meat, fat, and meat byproducts will cover any dietary exposure from secondary residues in these RACs. There are currently no actions pending against the continued registration of this chemical.

An adequate analytical method, gas chromatography with nitrogen phosphorous detection, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 242, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-4432).

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 2E4051/P608]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

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. 96-354, 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: March 28, 1995.

James J. Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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.

2. In § 180.475, by adding new paragraph (c), to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

* * * * *

(c) Tolerances are established for difenoconazole, [(2S,4R)/(2R,4S)]/[(2R,4R/2S,4S)] 1-(2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl)-1H-1,2,4-triazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain[1]	0.1
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, mbyp	0.05
Eggs	0.05
Goats, fat	0.05
Goats, meat	0.05
Goats, mbyp	0.05
Hogs, fat	0.05
Hogs, mbyp	0.05
Horses, fat	0.05
Horses, meat	0.05
Horses, mbyp	0.05
Milk	0.01
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, mbyp	0.05
Rye, grain[1]	0.1
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, mbyp	0.05
Wheat, grain	0.1

[1] There are no U.S. registrations as of April 12, 1995 for use on barley and rye.

[FR Doc. 95–8728 Filed 4–11–95; 8:45 am]

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40 CFR Part 180

[OPP–300384; FRL–4945–7]

RIN 2070–AC18

Oleyl Alcohol; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that oleyl alcohol (CAS Reg. No. 143-28-2) be exempted from the requirement of a tolerance when used as a cosolvent in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Henckel Corp., Emery Group, requested this proposed regulation.

DATES: Comments, identified by the document control number [OPP-300384], must be received on or before May 12, 1995.

ADDRESSES: By mail, submit written comments 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, deliver comments to: Rm. 1132, Crystal Mall, Building #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part of 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by the EPA without prior notice. The public docket is available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Amelia M. Acierto, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703)-308-8375; e-mail: Acierto.Amelia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Henkel Corp., Emery Group, 4900 Este Ave., Cincinnati, OH 45232-1491, submitted pesticide petition (PP) 4E4335 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(c) by establishing an exemption from the requirement of a tolerance for oleyl alcohol when used as a cosolvent in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency established data requirements which will be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. Exemptions from some or all of the requirements may be granted if it can be determined that the inert ingredient will present minimal or no risk. The Agency has decided that the data normally required to support the proposed tolerance exemption for oleyl alcohol will not need to be submitted. The rationale for this decision is described below: