

40 CFR Parts 180 and 186

[PP 4F4340 and FAP 5H5722/R2146; FRL-4961-7]

RIN 2070-AB78

Clethodim; Pesticide Tolerances**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: These regulations establish tolerances for the residues of the herbicide clethodim [(E)- \pm]-2-[1-[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)-cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on the raw agricultural commodities sugar beet roots at 0.20 ppm; sugar beet tops at 0.50 ppm; and onions (dry bulb) at 0.20 ppm; and in or on the food additive commodity sugar beet molasses at 2.0 ppm. Valent U.S.A. Corp. submitted petitions for these regulations that establish maximum permissible levels for residues of the herbicide in or on the commodities.

EFFECTIVE DATE: These regulations become effective June 28, 1995.

ADDRESSES: Written objections, identified by the document control number, [PP 4F4340 and FAP 5H5722/R2146], 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 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: 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 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 4F4370 and FAP 5H5722/R2146]. 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: Joanne I. Miller, Product Manager (PM-23), Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-7830; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 2, 1994 (59 FR 54906), EPA issued a notice announcing that Valent U.S.A. Corp., 1333 North California Blvd., Walnut Creek, CA, had submitted a pesticide petition (PP 4F4340) to EPA under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), proposing to amend 40 CFR part 180 by establishing tolerances for residues of the herbicide clethodim and its metabolites containing the 2-cyclohexen-1-one moiety in or on sugar beet, roots, at 0.2 ppm, sugar beet, tops, 0.2 ppm, and onion (dry bulb) at 0.5 ppm. On March 13, 1995, Valent subsequently submitted a revision to PP 4F4340 to amend the proposed tolerances on sugar beet, tops from 0.20 to 0.50 ppm and onions (dry bulb) from 0.50 to 0.20 ppm. In addition, EPA issued a notice, published in the **Federal Register** of May 3, 1995 (60 FR 21816), which announced that Valent had submitted a food additive petition (FAP 5H5722) to EPA under section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348), proposing to amend 40 CFR part 186 by establishing a regulation to permit the residues of the herbicide clethodim [(E)- \pm]-2-[1-[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones,

expressed as clethodim, in or on sugar beet molasses at 2.0 ppm.

There were no comments or requests for referral to an advisory committee received in response to the notices of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data described below were considered in support of these tolerances and food additive regulations.

1. Several acute toxicology studies placing the technical-grade herbicide in Toxicity Category III.

2. A 2-year rat chronic toxicity/carcinogenicity study found the compound to be noncarcinogenic to rats under the conditions of the study. The systemic no-observed-effect level (NOEL) was 500 ppm (approximately 19 mg/kg/day), and the systemic lowest-observed-effect level (LOEL) was 2,500 ppm (approximately 100 mg/kg/day) based on the observed body weight gain, the increases in liver weights, and the presence of centrilobular hepatic hypertrophy.

3. An 18-month mouse carcinogenicity study which showed the compound to be noncarcinogenic to mice under the conditions of the study. The systemic NOEL was 200 ppm (8 mg/kg/day), and the systemic LOEL was 1,000 ppm (50 mg/kg/day) based on treatment-related effects on survival, red cell mass, absolute and relative liver weights, and microscopic findings in liver and lung.

4. A 1-year feeding study in dogs with a systemic NOEL of 1 mg/kg/day in both sexes and an LOEL of 75 mg/kg/day based on increased absolute and relative liver weights, and alteration and clinical chemistry.

5. A developmental toxicity study in rats with a developmental and maternal NOEL and LOEL of 100 and 350 mg/kg/day, respectively. The NOEL and LOEL for developmental toxicity were based on reductions in fetal body weight and increases in skeletal anomalies.

6. A developmental toxicity study in rabbits with a maternal toxicity NOEL and LOEL of 25 and 100 mg/kg/day, respectively. Maternal toxicity was manifested as clinical signs of toxicity and reduced weight gain and food consumption during treatment. Developmental toxicity was not observed, and therefore the developmental toxicity NOEL was 300 mg/kg/day (HDT).

7. A two-generation reproduction study in the rat with parental toxicity NOEL and LOEL of 500 and 2,500 ppm (51 and 263 mg/kg/day), respectively, based on reductions in body weight in males, and decreased food consumption

in both generations. The NOEL for reproductive toxicity was 2,500 ppm (263 mg/kg/day, HDT).

8. A mutagenicity test with *Salmonella* Ames assay showed nonmutagenicity in three strains. Clethodim imine sulfone was negative for reverse gene mutation in *Salmonella* and *E. coli* exposed up to 10,000 ug/plate with or without activation. Clethodim was negative for chromosomal damage in bone marrow cells of rats treated orally up to toxic dose (1,500 mg/kg).

The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified clethodim in Group E carcinogen (no evidence of carcinogenicity) under the Agency's "Guidelines for Carcinogen Risk Assessment," published in the **Federal Register** of September 24, 1986 (51 FR 33992). In its evaluation, CPRC gave consideration to the weight change in the 2-year feeding study in rats and the 18-month feeding study in mice.

The Reference dose (RfD) is established at 0.01 mg/kg body weight/day based on a NOEL of 1.0 mg/kg/body weight/day from the 1-year feeding study in dogs and an uncertainty factor of 100. Using anticipated residues and 100 percent crop treated, the Anticipated Residue Contribution (ARC) from the current action is estimated at 0.00087 mg/kg/body weight/day for the general population, or 8.7 percent of the RfD for the general U.S. population. The ARC for the most exposed subgroups is 0.002527 mg/kg body weight/day for nonnursing infants (less than 1 year old) and 0.001776 mg/kg body weight/day for children (1 to 6 years old), or 25.27 and 17.76 percent of the RfD, respectively. Therefore, no appreciable risk is expected from chronic dietary intake since the RfD is not exceeded for either the general population or any subgroup.

The nature of the residue is adequately understood for the purposes of the tolerance.

An adequate analytical method is available for enforcement purposes. A common moiety analytical method for tolerance enforcement (gas chromatography with a flame photometric detector in the sulfur mode) was satisfactorily tested and is available. This method, however, cannot distinguish between clethodim and sethoxydim, a closely related herbicide with tolerances established under 40 CFR 180.412. A compound-specific confirmatory method (HPLC with a UV detector) that can distinguish between derivatives of clethodim and sethoxydim was confirmed.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested for: Calvin Furlow, Public Response and Program Resources 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. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-5232.

The pesticide is considered useful for the purpose for which the tolerances are sought, and the tolerances are capable of achieving the intended physical or technical effect. There are currently no actions pending against the registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR parts 180 and 186 will protect the public health and that use of the pesticide in accordance with the terms of the proposed food additive tolerance will be safe. Therefore, the tolerances are established 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 to the 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 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 show 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(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 [PP 4F4340 and FAP 5H5722/R2146] (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 4F4340 and FAP 5H5722/R2146], 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, October 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

of 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 of legal mandates, the President's priorities, or the principles set forth in the 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 the 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 Parts 180 and 186

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

Dated: June 9, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR parts 180 and 186 are amended as follows:

PART 180—[AMENDED]

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

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

b. In § 180.458, by designating the existing text as paragraph (a) and adding new paragraph (b), to read as follows:

§ 180.458 Clethodim ((E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one); tolerances for residues.

(a) * * *

(b) Tolerances are established for the herbicide clethodim [(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-

[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim tolerance residues for the following raw agricultural commodities:

Commodity	Parts per million
Onions (dry bulb)	0.20
Sugar beet, roots	0.20
Sugar beet, tops	0.50

PART 186—[AMENDED]

2. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348.

b. In § 186.1075, by revising the section heading, designating the existing text as paragraph (a), and adding new paragraph (b), to read as follows:

§ 186.1075 Clethodim ((E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one).

(a) * * *

(b) Tolerances are established for the herbicide clethodim [(E)-(±)-2-[1-[[3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexen-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexen-3-one moieties and their sulphoxides and sulphones, expressed as clethodim tolerance residues for the following feeds:

Commodity	Parts per million
Sugar beet, molasses	2.0

[FR Doc. 95-15579 Filed 6-27-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Parts 185 and 186

[PP 5H5712/R2140; FRL-4957-1]

RIN 2070-AB78

Cyfluthrin; Food/Feed Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends a regulation for residues of the synthetic pyrethroid cyfluthrin in food/feed areas of food/feed-handling establishments. Miles Corp., Agricultural Division, petitioned EPA to amend the food/feed additive regulations to allow the use of a dust formulation in crack and crevice treatment. This rule was requested pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

EFFECTIVE DATE: This regulation becomes effective June 28, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [FAP 5H5712/R2140], may 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 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

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FOR FURTHER INFORMATION CONTACT: By mail: George T. Larocca, Product Manager (PM 13), Registration Division (7505C), Office of Pesticide Programs,