Dated: December 5, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 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.

§ 180.407 [Amended]

2. Section 180.407 *Thiodicarb; tolerances for residues* is amended in paragraph (b) introductory text by changing ''August 15, 1996'' to read ''August 15, 1997'', and in paragraph (c) introductory text by changing ''August 15, 1996'' to read ''August 15, 1997''.

[FR Doc. 95–30974 Filed 12–19–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 9F3787/R2194; FRL–4991–1]

RIN 2070–AB78

Avermectin B_1 and Its Delta-8,9-Isomer; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity pears. Merck Research Laboratories requested this regulation to establish a maximum permissible level for residues of the insecticide pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

EFFECTIVE DATE: This regulation becomes effective December 20, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number [PP 9F3787/R2194], 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 copy of objections and hearing requests 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: 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 9F3787/R2194]. 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: George LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george.@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of November 1, 1989 (54 FR 46118), which announced that Merck Research Laboratories, Inc., Hillsborough Rd., Three Bridges, NJ 98887, had submitted a pesticide petition (PP 9F3787) 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 a tolerance for combined residues of the insecticide avermectin B_1 and its delta-8,9-isomer in or on the raw agricultural commodity (RAC) pears at 0.035 part per million (ppm). In a letter dated September 22, 1993, Merck requested that the pesticide petition be amended by proposing a lower tolerance on pears at 0.02 ppm. No comments were received in response to the notice of filing (See 58 FR 64583; Dec. 8, 1993).

The data submitted in support of this tolerance and other relevant material have been reviewed. The toxicological and metabolism data considered in support of this tolerance are discussed in detail in related documents published in the Federal Register of May 31, 1989 (54 FR 23209, cottonseed) and August 2, 1989 (54 FR 31836, citrus). The Agency used a two-generation rat reproduction study with an uncertainty factor of 300 to establish a Reference Dose (RfD). The 300-fold uncertainty factor was utilized for (1) inter- and intra-species differences, (2) the extremely serious nature (pup death) observed in the reproduction study, (3) maternal toxicity (lethality) no-observable-effect level (NOEL) (0.05 mg/kg/day), and (4) cleft palate in the mouse developmental toxicity study with isomer (NOEL = 0.06 mg/kg/day). Thus, based on a NOEL of 0.12 mg/kg/day from the two-generation rat reproduction and an uncertainty factor of 300, the RfD is 0.0004 mg/kg/body weight(bwt)/day.

A chronic dietary exposure/risk assessment has been performed for avermectin B_1 using the above RfD. Available information on anticipated residues and 100% crop treated was incorporated into the analysis to estimate the Anticipated Residue Contribution (ARC). The ARC is generally considered a more realistic estimate than an estimate based on the tolerance level residues. The ARC for established tolerances and the current action is estimated at 0.000013 mg/kg/bwt/day and utilizes 3.4 percent of the RfD for the U.S. population. For nonnursing infants less than 1-year old (the sub-group population with the highest exposure level) the ARC for established tolerances and the current action is estimated at 0.000030 mg/kg bwt/day and utilizes 7.5% of the RfD. Generally speaking, the Agency has no cause for concern if anticipated residues contribution for all published and proposed tolerances is less than the RfD.

Because of the developmental effects seen in animal studies, the Agency used the mouse teratology study (with a NOEL of 0.06 mg/kg/day for developmental toxicity for the delta-8,9 isomer) to assess acute dietary exposure and determine a margin of exposure (MOE) for the overall U.S. population and certain subgroups. Since the toxicological end point pertains to developmental toxicity, the population group of interest for this analysis is women aged 13 and above, the subgroup which most closely approximates women of child-bearing ages. The MOE is calculated as the ratio of the NOEL to the exposure. For this analysis, the Agency calculated the MOE for the high-end exposures for women ages 13 and above. The MOE is 1,000. Generally speaking, MOEs greater than 100 for

developmental toxicity do not raise concerns.

The metabolism of the chemical in plants and animals for the use is adequately understood. Secondary residues occurring in livestock and their by-products are not expected since there are no known animal feed stock uses for pears. Adequate analytical methodology (HPLC-Fluorescence Methods) is available for enforcement purposes. 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 from Calvin Furlow, Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. 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 tolerances established by amending 40 CFR part 180 will be adequate to cover residues in or on pears. There are currently no actions pending against the continued registration of this chemical. 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 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 a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor or 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 9F3787/R2194] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper version 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, Crystall Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

oop-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 all comments 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 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. 96-354, 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: December 7, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 continues to read as follows:

PART 180—[AMENDED]

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

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

2. By amending § 180.449(b) in the table therein by adding and alphabetically inserting an entry for pears, to read as follows:

§ 180.449 Avermectin B_1 and its delta-8,9-isomer; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million
* * * * *	
Pears	0.02
* * * * *	

[FR Doc. 95–30975 Filed 12–19–95; 8:45 am]

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