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