

There are presently 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 will protect the public health. Therefore, the tolerance is 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 shows 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

EPA has established a record for this rulemaking under docket number [PP 0E3853/RR2223] (including any comments and data submitted electronically). 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.

Electronic comments may be sent directly to EPA at: opp-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 any copies of 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 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, 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 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 26, 1996.

Daniel M. Barolo,

Director, 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.

2. By adding new § 180.488 to read as follows:

§ 180.488 Hexaconazole; tolerance for residues.

A tolerance is established for residues of the fungicide hexaconazole, [alpha-butyl-alpha-(2,4-dichloro-phenyl)-1H-1,2,4-triazole-1-ethanol], in or on the imported raw agricultural commodity bananas at 0.1 part per million. This tolerance will expire on [insert date 3 years after the signature date]. There are no U.S. registrations as of March 26, 1996 for use on bananas.

[FR Doc. 96-8946 Filed 4-9-96; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Parts 180 and 185

[PP 0F3860, 3F4238; FAP 6H5740 and 6H5742/R2227; FRL-5361-1]

RIN 2070-AB78

Sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1) (formerly glyphosate-trimesium/sulfosate); Pesticide Tolerances and Food/Feed Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes permanent tolerances for the residues of the herbicide sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1) (formerly glyphosate-trimesium/sulfosate) in or on the raw agricultural commodity stone fruit group and a food additive regulation for the processed commodity prunes. In addition, this regulation establishes a 2-year time limited tolerance for the residue of this herbicide in or on the raw agricultural commodities soybean forage, soybean

aspirated grain fractions, soybean hay, and soybean seed and establishes a feed additive regulation for this herbicide in or on soybean hulls. The regulations to establish maximum permissible levels for residues of the pesticide in or on the commodities were requested in petitions submitted by Zeneca Ag Products.

EFFECTIVE DATE: This regulation becomes effective April 10, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 0F3860 and 3F4238; FAP 6H5740 and 6H5742/R2227], 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 requests to Rm. 1132 CM #2, 1921 Jefferson Davis Highway, 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.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 0F3860 and 3F4238; FAP 6H5740 and 6H5742/]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic 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.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information".

CBI should not be submitted through e-mail. Information marked as CBI 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 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager (PM) 25, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 241, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703) 305-6027; e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued the following notices in the Federal Register which announced that Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850-5458, had submitted pesticide petitions (PP 0F3860 and 3F4238) and food additive petitions (FAP) 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), amend 40 CFR part 180 by establishing tolerances for residues of the herbicide sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1), in or on certain raw agricultural commodities (RACs).

1. *FAPs 6H5740 and 6H5742.* FAPs 6H5740 and 6H5742 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348), amend 40 CFR part 185 by establishing food additive regulations for the residues of the herbicide sulfonium, trimethyl-salt with *N*-(phosphonomethyl) glycine (1:1) in or on the processed food commodities: prunes, (of which no more than 0.05 ppm is trimethylsulfonium) at 0.2 ppm and soybean, hulls (of which no more than 2 ppm is trimethylsulfonium) at 7.0 ppm.

2. *PP 0F3860.* Published in the Federal Register (PF-638; FRL-4986-8) of November 15, 1995 (60 FR 57423), the notice proposed establishing a regulation to permit the residues of the herbicide sulfonium, trimethyl-salt with *N*-(phosphonomethyl) glycine (1:1) in or on the raw agricultural commodities soybean forage at 2.00 ppm (of which no

more than 1 ppm is trimethylsulfonium (TMS)), soybean aspirated grain fractions at 210.0 ppm (of which no more than 60 ppm is TMS), soybean hay at 5.00 ppm (of which no more than 2 ppm is TMS) and soybean seed at 3.00 ppm (of which no more than 1 ppm is TMS).

3. *PP 3F4238.* Published in the Federal Register (PF-581; FRL-4645-7) of October 21, 1993 (58 FR 54355), the notice proposed establishing a regulation to permit residues of the herbicide sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1) in or on the raw agricultural commodities stone fruit group at 0.05 ppm.

4. *PP 6H5740.* Published in the Federal Register (PF-642; FRL-4992-9) of January 31, 1996 (61 FR 3401), the notice proposed establishing a regulation to permit residues of the herbicide, sulfonium, trimethyl-salt with *N*-(phosphonomethyl) glycine (1:1) in or on feed commodity soybean hulls at 7.0 ppm (of which no more than 2 ppm is TMS).

5. *PP 6H5742.* Published in the Federal Register (PF-642; FRL-4992-9) of January 31, 1996 (61 FR 3401), the notice proposed establishing a regulation to permit the residues of the herbicide, sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1) in or on the processed commodity prunes at 0.2 ppm (of which no more than 0.05 ppm is TMS).

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

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

1. Several acute toxicology studies placing technical grade sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1) in Toxicity Category III and Toxicity Category IV.

2. A subchronic feeding study with dogs fed dosage levels of 0, 2, 10 and 50 milligrams/kilogram/day (mg/kg/day) with a no observable effect level (NOEL) of 10/mg/kg/day.

3. A chronic feeding/carcinogenicity study in male and female rats fed dosage levels of 0, 100, 500, and 1,000 parts per million (ppm) (0, 4.2, 21.2 or 41.8 mg/kg/day in males and 0, 5.4, 27.0 or 55.7 mg/kg/day in females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including the 1,000 ppm highest dose tested (HDT) and a systemic NOEL of 1,000 ppm. There were no biologically significant effects observed

in the study. The study was considered to be acceptable because the highest dose level tested was approaching one half of what would be considered an adequate dose level for carcinogenicity testing and because there was no indication of any carcinogenic response to warrant repeat of the study. This assessment was based on toxic effects observed in the subchronic and reproductive toxicity studies in rats at higher dose levels.

4. A chronic feeding/carcinogenicity study in male and female mice fed dosage levels of 0, 100, 1,000, and 8,000 ppm (0, 11.7, 118 or 991 mg/kg/day in males and 0, 16, 159 or 1,341 mg/kg/day in females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including the 8,000 ppm HDT (highest dose may have been excessive) and systemic NOEL of 1,000 ppm based on decreases in body weight and feed consumption (both sexes), increases in the incidences of white matter degeneration in the lumbar spinal cord (males only), and increased incidences of duodenal epithelial hyperplasia (females only).

5. A developmental toxicity study in rats given doses of 0, 30, 100, and 333 mg/kg/day with a developmental NOEL of 100 mg/kg/day based on significant decreases in fetal body weight, and a maternal NOEL of 100 mg/kg/day based on undetermined deaths of two dams at HDT; decreases in bodyweight, bodyweight gain and feed intake; and increased salivation, chromorrhinorrhea and lethargy (HDT).

6. A developmental toxicity study in rabbits given doses of 0, 10, 40, and 100 mg/kg/day with a developmental NOEL of 40 mg/kg/day based on four abortions and a reduction in the number of live fetuses/doe. In addition, there were only seven litters available for examination. This was not a sufficiently high number of animals to absolutely conclude that no developmental toxicity was occurring at the highest dose level. The maternal NOEL was 40 mg/kg/day based on 6 deaths/17 pregnant does, 4 abortions in 11 survivors and decreased body weight, body weight gain, food consumption.

7. A two generation reproduction study with rats fed dosage rates of 0, 150, 800, and 2,000 ppm (0, 6.1, 35 or 88.5 mg/kg/day in males and 0, 8, 41 or 98 mg/kg/day in females) with a reproductive/ developmental NOEL of 150 ppm based on decreased litter size in the F0a and F1b litters at 2,000 ppm and on decreased mean pup weights during lactation in the second litters at 800 ppm and in all litters at 2,000 ppm; and a systemic NOEL of 150 ppm based on reduced feed intake, body weights

and body weight gains and reduced absolute and sometimes relative thymus, heart, liver and kidney weights.

8. Mutagenicity data included two Ames tests with *Salmonella typhimurium*; a sex linked recessive lethal test with *Drosophila melanoga*; a forward mutation (mouse lymphoma) test; an *in vivo* bone marrow cytogenetics test in rats; a micronucleus assay in mice; an *in vitro* chromosomal aberration test in Chinese hamster ovary cells (CHO) (no aberrations were observed either with or without S9 activation and there were no increases in sister chromatid exchanges); and a morphological transformation test in mice (all negative).

The reference dose (RfD) based on a chronic dog feeding study (NOEL of 10 mg/kg body weight(bwt)/day) and using a hundred-fold safety factor is calculated to be 0.1 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) for all proposed tolerances (almond hulls; bananas; citrus fruit group; corn; eggs; grapes; fat, meat by-products, meat of cattle, goats, hogs, horses and sheep; pome fruit group; poultry fat, poultry liver, poultry meat by-products and poultry meat; soybeans; stone fruit group; tree nut group; and wheat; and food regulations (prunes, raisins, and soybean hulls) is 0.019760 mg/kg/day or 19.760 percent of the RfD for the overall U.S. population. For U.S. subgroup populations, nonnursing infants and children 1 to 6 years of age, the current action, previously proposed tolerances and the food additive regulations utilize a total of 0.044461 mg/kg/day and 44.461 percent of the RfD, assuming that residue levels are at the established tolerance levels and that 100 percent of the crop is treated.

The RfD/Peer Review Committee, in a consensus review dated July 26, 1994, classified sulfonium, trimethyl-salt with *N*-(phosphonomethyl)glycine (1:1) as a Group E carcinogen: no evidence of carcinogenicity in rat and mouse studies.

An adequate analytical method, gas chromatography for the cation and liquid chromatography for the anion and its metabolite AMPA, is available for enforcement purposes and the methodology will be published in the "Pesticide Analytical Manual" (PAM), Vol. II.

There are presently no actions pending against the continued registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health, and the

establishment of food additive regulations by amending 40 CFR part 185 would 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 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 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 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 [PP 0F3860 and 3F4238; FAP 6H5740 and 6H5742/R2227] (including comments and data submitted electronically). 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 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.

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, or establishing or raising food additive regulations 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

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additive, Pesticides and pests

Dated: March 27, 1996.

SStephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, title 40 of the Code of Federal Regulations is 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. Section 180.489 is amended by adding an entry for stone fruit group to the table in paragraph (a), and by revising paragraph (b) to read as follows:

§ 180.489 Sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1); tolerances for residues.

(a) * * *

Commodities	Parts per million
* * *	*
Stone fruit group	0.05

(b) Time-limited tolerances are established for the residues of the herbicide sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1) in or on the following raw agricultural commodities:

Commodities	Parts per million	Expiration date
Cattle, fat	0.10	March 9, 1998
Cattle, mbyp	1.00	Do.
Cattle, meat	0.20	Do.
Corn, fodder (of which no more than 0.20 ppm is trimethylsulfonium)	0.30	Do.
Corn, forage	0.10	Do.
Corn, grain (of which no more than 0.10 is trimethylsulfonium)	0.20	Do.
Eggs	0.02	Do.
Goats, fat	0.10	Do.
Goats, mbyp	1.00	Do.
Goats, meat	0.20	Do.
Hogs, fat	0.10	Do.
Hogs, mbyp	1.00	Do.
Hogs, meat	0.20	Do.
Horses, fat	0.10	Do.
Horses, mbyp	1.00	Do.
Horses, meat	0.20	Do.
Milk	0.20	Do.
Poultry, fat	0.05	Do.
Poultry, liver	0.05	Do.
Poultry, mbyp	0.10	Do.
Poultry, meat	0.05	Do.
Sheep, fat	0.10	Do.
Sheep, mbyp	1.00	Do.
Sheep, meat	0.20	Do.
Soybean, forage (of which no more than 1 ppm is trimethylsulfonium)	2.00	April 10, 1998
Soybean, aspirated grain fractions (of which no more than 60 ppm is trimethylsulfonium)	210.00	Do.
Soybean, hay (of which no more than 2 ppm is trimethylsulfonium)	5.00	Do.
Soybean, seed (of which no more than 1 ppm is trimethylsulfonium)	3.00	Do.

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

b. In § 185.5375, the table in paragraph (a) is amended by adding entries for prunes, and soybean, hulls to read as follows:

§ 185.5375 Sulfonium, trimethyl-salt with N-(phosphonomethyl)glycine (1:1).

(a) * * *

Commodities	Parts per million
Prunes, (of which no more than 0.05 ppm is trimethylsulfonium)	0.2
Soybean, hulls (of which no more than 2 ppm is trimethylsulfonium)	7.0
* * * * *	*

[FR Doc. 96-8945 Filed 4-9-96; 8:45 am]
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40 CFR Parts 180 and 186

[PP 1F3973, PP 4F4345, FAP 1H5611 and 4H5693/R2227; FRL-5361-9]

RIN 2070-AB78

Avermectin B₁ and Its Delta-8,9-Isomer; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This rule establishes tolerances for combined residues of the insecticide Avermectin B₁ and its delta-8,9-isomer in or on the raw agricultural commodities (RACs) almonds, apples, and walnuts; and in or on processed feed items apples, wet pomace and almonds, hulls. The regulation to establish a maximum permissible level for residues of the insecticide was requested in a petition submitted by the Merck Research Laboratories, Division of Merck Co., Inc.

EFFECTIVE DATE: This regulation becomes effective April 10, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [PP 1F3973, PP 4F4345, FAP 1H5611 and 4H5693/R], 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 docket 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. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as a ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disk in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 1F3973, PP 4F4345, FAP 1H5611 and 4H5693/R]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic 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 Highway, Arlington, VA 22202. (703) 305-6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued notices published in the Federal Register of May 29, 1991 (56 FR 24189) and July 13, 1994 (59 FR 35720), which announced that Merck Research Laboratories had submitted pesticide petitions (PPs) 1F3973 and 4F4345 to EPA requesting the that Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR 180.449 by establishing tolerances for the combined residues of the insecticide avermectin B₁ and its delta-8,9-isomer,

in or on the RACs almonds at 0.005 parts per million (ppm); apples at 0.02 ppm; and walnuts at 0.005 ppm. In the same notices, Merck Research Laboratories submitted feed additive petitions (FAPs) 1H5611 and 4H5693 requesting that the Administrator, pursuant to section 409(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348(b), amend 40 CFR 186.300 by establishing a feed additive regulations for the combined residues of the insecticide avermectin B₁ and its delta-8,9-isomer, in or on processed feed commodities apples, wet pomace at 0.10 ppm and almonds, hulls at 0.10 ppm.

There were no comments received in response to the notice of filing.

The data submitted in support of this tolerance and other relevant material have been reviewed. The toxicological and metabolism data and analytical methods for enforcement purposes 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) on cottonseed, and August 2, 1989 (54 FR 31836) on 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 B₁ 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 actions are estimated at 0.000017 mg/kg bwt/day and utilizes 4.3% of the RfD for the U.S. population. For non-nursing infants less than 1 year old (the subgroup population with the highest exposure level) the ARC for established tolerances and the current actions are estimated at 0.000040 mg/kg bwt/day and utilizes 10.0% of the RfD. Generally