

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 issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request 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 information 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.

**VIII. Public Docket**

A record has been established for this rulemaking under docket control number [OPP-300490]. A public version of this record, 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 Information and Records Integrity Branch, Information Resources and Services 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, is kept in

paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

**IX. Regulatory Assessment Requirements**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: May 8, 1997.

**James Jones,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR Chapter I 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. Section 180.505 is added to read as follows:

**§ 180.505 Emamectin benzoate; tolerances for residues.**

- (a) *General.* [Reserved]
- (b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide emamectin benzoate: 4''-epi-methylamino-4''-deoxyavermectin B1 benzoate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Cabbage (head and Napa) .....	0.025	December 31, 1998.

(c) *Tolerances with regional restrictions.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]  
 [FR Doc. 97-12787 Filed 5-15-97; 8:45 am]  
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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300487; FRL-5716-8]

**Carbon Disulfide; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the nematocidal, insecticide, and fungicide, carbon disulfide (Chemical Code Number 16401 and CAS Number 75-15-0), in or on the food commodities almond nutmeat, almond hulls, peaches, and plums (fresh prunes) from the application of sodium tetrathiocarbonate (Chemical Code Number 128904 and CAS Number 7345-69-9). Entek Corporation submitted a petition to EPA under the

Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting the tolerances. **DATES:** This regulation becomes effective May 16, 1997. Objections and hearing requests must be received on or before July 15, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [OPP-300487], 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: 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.

A 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 [OPP-300487]. 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: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 229, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703-305-7740), e-mail: giles-parker.cynthia@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 12, 1997 (62 FR 6526)(FRL-5586-5), EPA issued a notice pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition (PP 5F4482) by Entek Corporation, P.O. Box 458, Brea, CA 92622-0458 to EPA requesting that the Administrator amend 40 CFR part 180 by establishing a tolerance for residues of the nematocide, insecticide, and fungicide, carbon disulfide, in or on the food commodities almond nutmeat, almond hulls, peaches, and plums (fresh prunes) at 0.1 parts per million (ppm) from the application of sodium tetrathiocarbonate. There were no comments received in response to the notice of filing.

Sodium tetrathiocarbonate stoichiometrically converts to carbon disulfide, sodium hydroxide, hydrogen sulfide and sulfur in the soil after application to the crops. Carbon disulfide is the pesticide's active compound.

The data submitted in the petition and all other relevant material have been evaluated. The data listed below were considered in support of these tolerances.

#### I. Toxicological Profile

1. The toxicology data for sodium tetrathiocarbonate include:

a. A rat acute oral study with an LD<sub>50</sub> of 587 milligrams (mg)/kilogram (kg) for females and 631 mg/kg for combined sexes for sodium tetrathiocarbonate. The LD<sub>50</sub> for carbon disulfide is 456 mg/kg.

b. A developmental toxicity study in rats for sodium tetrathiocarbonate with a maternal no-observed effect level (NOEL) of 150 mg/kg and a lowest effect level (LEL) of 400 mg/kg (death) and a developmental NOEL of 450 mg/kg.

c. A developmental toxicity study in rabbits for sodium tetrathiocarbonate with a maternal NOEL of 75 mg/kg and a LEL of 150 mg/kg (convulsions, prostration) and a developmental NOEL of 150 mg/kg and a LEL of 185 mg/kg (increased resorption, post implantation loss, increase incidence 13th rib).

d. Sodium tetrathiocarbonate was negative in a bacterial gene mutation study with and without S9 activation, unscheduled mammalian DNA synthesis, and *in vitro* chromosomal aberration without S9 activation, but weakly positive with S9 activation.

2. The toxicology data for carbon disulfide include:

a. In a 90-day rat inhalation study with carbon disulfide the NOEL for neuropathology was 50 ppm, the LOEL was 300 ppm based on axonal swelling

in the spinal cord and peripheral nerves. No NOEL was determined for brain-weight effects.

b. In a 90-day rat inhalation study with carbon disulfide the NOEL was 50 ppm and the LEL was 300 ppm (axonal swelling in the spinal cord and peripheral nerves).

c. In a 90-day mouse inhalation study with carbon disulfide the NOEL was 300 ppm and the LEL was 800 ppm (lesions of peripheral nerves, spinal cord, kidney and spleen).

d. A developmental toxicity study in rats with carbon disulfide with a maternal no-observed effect level (NOEL) of 100 mg/kg/day and a LEL of 200 mg/kg/day based on clinical signs and decreased body-weight gains and a developmental NOEL of 100 mg/kg/day and developmental LEL of 200 mg/kg/day, based on decreased fetal body weight in both sexes.

e. A developmental toxicity study in rabbits with carbon disulfide with no NOEL for maternal effects (the number and percentage of does with 100% intrauterine deaths and the percentage of resorptions/litter [mean litter percentage] were increased in a dose-related manner with statistical significance at all dose levels for mean litter percentage). The NOEL for developmental toxicity was 75 mg/kg/day with a LEL of 150 mg/kg/day based on increased malformations.

#### II. Aggregate Exposures

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *From food and feed uses.* The nature of residues is understood. Entek Corporation has documented that the level of free or bound carbon disulfide is extremely low in the treated crops (less than 50 parts per billion (ppb)). Carbon disulfide is a naturally occurring compound found in grapes and citrus at 5 to 20 ppb and up to 1 to 73 ppm in Shiitake mushrooms. The Analytical Method has been validated. A tolerance for carbon disulfide is established at the analytical level of quantification of 0.1 ppm. Dietary exposure to carbon disulfide from treatment of the almonds, peaches and plums with sodium tetrathiocarbonate will not be appreciably different from the natural background levels of carbon disulfide in

these crops. Therefore, further toxicity testing for carbon disulfide was not required and the standard risk assessment approach of using the Reference Dose (RfD) based on systemic toxicity are not relevant to this petition.

2. *From potable water.* Two prospective ground water monitoring studies were conducted for sodium tetrathiocarbonate. In both studies, sodium tetrathiocarbonate was applied above very shallow aquifers (3 to 7 ft. below the surface) and the ground water was analyzed for carbon disulfide. Transient groundwater contamination with carbon disulfide was detected. Carbon disulfide, however, which is very volatile rapidly moves upward through the soil profile and diffuses to the atmosphere. With the proposed and registered uses of sodium tetrathiocarbonate only in the Western United States with its deeper aquifers and a label restriction prohibiting application within 100 feet of a potable water well, carbon disulfide is not likely to be a residual ground water contaminant.

3. *From non-dietary uses.* There are no non-food uses of sodium tetrathiocarbonate registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

4. Cumulative exposure to substances with common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that

EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

EPA does not have, at this time, available data to determine whether carbon disulfide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. There is the possibility that other pesticides such as metam sodium or the EDBC's (such as zineb or maneb) may degrade to carbon disulfide. However, we do not have information to indicate that use of the other pesticides would raise the level of carbon disulfide in treated crops above the background level. For the purposes of this tolerance action, therefore, EPA has not assumed that carbon disulfide has a common mechanism of toxicity with other substances. The general populations dietary exposure to carbon disulfide from treatment of the crops with sodium tetrathiocarbonate will not be appreciably different from the natural background levels of carbon disulfide the untreated crops.

### III. Determination Of Safety For Infants And Children

FFDCA section 408 provides that EPA shall apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base, unless EPA determines that such an additional factor is not necessary to protect the safety of infants and children. The level of free or bound carbon disulfide or parent sodium tetrathiocarbonate is extremely low in the treated crops (less than 50 ppb). Carbon disulfide is a naturally occurring compound found in grapes and citrus at 5 to 20 ppb and up to 1 to 73 ppm in Shiitake mushrooms. A tolerance for carbon disulfide is established at the analytical level of quantification of 0.1 ppm. Children's dietary exposure to carbon disulfide resulting from treatment of the almonds, peaches and plums with sodium tetrathiocarbonate will not be appreciably different from the natural background levels of carbon disulfide in the untreated crops.

### IV. Other Considerations

1. *Endocrine effects.* An evaluation of the potential effects on the endocrine

systems of mammals has not been determined; however, no evidence of such effects were reported in the toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that carbon disulfide causes endocrine effects.

2. *Metabolism in plants and animals.* The metabolism of carbon disulfide and sodium tetrathiocarbonate in plants is adequately understood. There is no reasonable expectation of secondary residues occurring in milk, eggs, and meat of livestock or poultry.

3. *Analytical method.* An adequate analytical method, gas chromatography, 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: Room 1130A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA (703-305-5937).

4. *International tolerances.* There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for carbon disulfide.

### V. Summary of Findings

The analysis for carbon disulfide shows the proposed uses on almonds, peaches and plums will not cause exposure at which the Agency believes there is an appreciable risk.

Based on the information cited above, the Agency has determined that the establishment of the tolerances by amending 40 CFR part 180 will be safe; therefore, the tolerances are established as set forth below.

### VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a tolerance regulation issued by EPA under new section 408(e) and (1)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use

those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 15, 1997, file written objections to any aspect of this 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 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 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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information 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.

**VII. Public Docket**

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket number [OPP-300487] (including comments and data 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the

Virginia address in "ADDRESSES" at the beginning of this document.

Electronic comments can 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. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-300487]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

**VIII. Regulatory Assessment Requirements**

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), this action is not a "significant regulatory action" and since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable.

Pursuant to 5 U.S.C. 801(a)(1)(A), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements

Dated: May 6, 1997

**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 amending § 180.467 to alphabetically add the food commodities: almond hulls; almond nutmeat; peaches; and plums (fresh prunes) to the table as follows:

**§ 180.467 Carbon disulfide; tolerances for residues.**

Commodity	Parts per million
Almond hulls .....	0.1
Almond nutmeat .....	0.1
* * * * *	*
Peaches .....	0.1
Plums (fresh prunes) .....	0.1

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300491; FRL-5718-2]

RIN 2070-AB78

**Clopyralid; Pesticide Tolerance for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of the herbicide clopyralid in or on the food commodity canola in connection with EPA's granting emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on canola in Idaho, Montana, Minnesota, North Dakota and Washington. The tolerance will expire and is revoked on July 31, 1998.

**DATES:** This regulation becomes effective May 16, 1997. Objections and requests for hearings must be received by EPA on or before July 15, 1997.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP-300491],