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]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 2F4105/R2191; FRL–4989–2]

RIN 2070–AB78

Metalaxyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on clover, forage at 1.0 part per million (ppm) and clover, hay at 2.5 ppm. Ciba-Geigy Corp. submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish a maximum permissible level for residues of the fungicide.

EFFECTIVE DATE: This rule is effective on December 4, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4105/R2191], 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 any 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 document number [PP 2F4105/R2191]. 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: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6226; e-mail: welch.connie@.epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice of filing, published in the Federal Register of June 15, 1995 (60 FR 31465), which announced that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419, had submitted a pesticide petition, PP 2F4105, to EPA requesting that the Administrator, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), establish tolerances for combined residues of the fungicide metalaxyl [*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl) alanine methyl ester] and its metabolites containing the 2,6-dimethylaniline moiety and *N*-(2-hydroxymethyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl, in or on the raw agricultural commmodities cover, forage at 1.0 ppm and clover, hay at 2.5 ppm.

There were no comments received in response to the notice of filing. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include:

1. A 3-month dietary study in rats with a no-observed-effect level (NOEL) at 17.5 milligrams per kilogram (mg/kg) body weight (bwt)/day (250 parts per million (ppm)).

2. A developmental toxicity study in rats with a NOEL of 50 mg/kg bwt for developmental toxicity and maternal toxicity.

3. A developmental toxicity study in rabbits with a NOEL of 300 mg/kg bwt highest dose tested (HDT). Metalaxyl did not cause developmental toxicity, even in the presence of maternal toxicity.

4. Metalaxyl was negative in bacterial and mammalian gene mutation. The fungicide also did not increase the frequency of reverse mutations in yeast. Metalaxyl was negative in an *in vivo* cytogenetics assay (hamsters) and a dominant-lethal assay (mice).

Metalaxyl did not increase unscheduled DNA synthesis in rat primary hepatocytes or in human fibroblasts. These results suggest that metalaxyl is not genotoxic.

5. A three-generation rat reproduction study with a NOEL of 63 mg/kg bwt/day (1,250 ppm).

6. A 6-month dog feeding study with a NOEL of 6.3 mg/kg bwt/day (250 ppm). Effects found at 25 mg/kg were increased serum alkaline phosphatase activity and increased liver weight and liver-to-brain weight ratios without histological changes.

7. A 2-year rat chronic feeding/carcinogenicity study with no compound-related carcinogenic effects under the conditions of the study at dietary levels up to 1,250 ppm. The NOEL is 13 mg/kg bwt/day (250 ppm). The lowest-observed-effect level (LOEL) is 63 mg/kg/day based upon slight increases in liver weight to body weight ratios and periacinar vacuolation of hepatocytes.

8. A 2-year mouse oncogenic study with no compound-related carcinogenic effects under the conditions of the study at dietary levels up to 190 mg/kg/day.

Because of concerns raised over some equivocal increases in tumor incidences in the male mouse liver and the male rat adrenal medulla, and the female rat thyroid, the two chronic feeding studies were submitted to the Environmental Pathology Laboratories (EPL) for an independent reading of the microscopic slides. The new pathological evaluation by EPL and the original reports of the rat and mouse oncogenicity studies were then both submitted for review to EPA's Carcinogen Assessment Group (CAG). A final review of the carcinogenicity studies and related material was performed by the Peer Review Committee of the Toxicology Branch (TB) of the Office of Pesticide Programs (OPP).

The four major issues evaluated by CAG and the peer review group included: (1) Perifollicular cell adenomas in the thyroid of female rats; (2) adrenal medullary tumors (pheochromocytomas) in male rats; (3) liver tumors in male mice; and (4) whether the HDT (1,250 ppm) in the rat and mouse oncogenicity studies represented a maximum-tolerated dose (MTD).

Regarding the thyroid tumors in female rats, the peer review group concluded that the increased incidences of thyroid tumors in females of treated groups were not compound related. This

conclusion was based on the following: (1) There was no progression of benign tumors (adenomas) to malignancy (carcinomas); (2) there was no increase in hyperplastic changes; (3) there was no dose-response relationship; and (4) the two reevaluations of the microscopic slides by the pathologists at EPL and TB in OPP further did not confirm any apparent effects observed in the original report.

The issue of a possible treatment-related increase of adrenal medullary gland tumors, namely, pheochromocytomas, in the male rat was also reassessed by both CAG and the Peer Review Committee. Both concluded that the data, especially in view of the reevaluation of the microscopic slides performed by EPL, did not support a compound-related increase of adrenal medullary tumors; the incidence of pheochromocytomas more accurately represented spontaneous variations of a commonly occurring tumor in the aged rat.

The analysis of the significance of the equivocal increase in the incidence of liver tumors in male mice was very similar to that performed for the rat thyroid and adrenal gland tumors. The original pathological reading of the tissue slides reported an elevated increase of tumors in some treatment groups; however, these increases were not evident after a reevaluation of themicroscopic slides was performed by an independent pathologist at EPL and by the reading of a CAG pathologist. The Peer Review Committee concurred that the reevaluation of the slides is reliable and does not show any compound-related increase in the incidence of liver tumors in the mouse.

The Agency believes that the data from the rat and mouse long-term studies are sufficient to support the conclusion that metalaxyl does not show a carcinogenic potential in laboratory animals. This conclusion is supported by the following: (1) The doses tested in both the rat and mouse long-term studies approached an MTD based upon compound-related changes in liver weight and/or liver histology; (2) extensive available mutagenic evidence indicates no potential genotoxic activity which correlates with the negative carcinogenic potential demonstrated in long-term testing; (3) metalaxyl is not structurally related to known carcinogens; and (4) under the conditions of the rat and mouse tests, no indication of compound-related carcinogenic effects was noted at any of the treatment doses, sexes, or species.

The reference dose (RfD), anticipated residue contribution (ARC), and food additive regulations are covered by existing tolerances.

The nature of the residue is adequately understood. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume 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 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 Highway, Arlington, VA 22202, (703)-305-5232.

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 will protect the public health. 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 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 2F4105/R2191] (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 a.m. to 4:30 p.m., Monday through Friday, except legal holidays. The public record is located in Rm. 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 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.

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, EPA must judge whether a rule is ''major'' and therefore requires a Regulatory Impact Analysis. This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12866.

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA 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 4, 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.

2. In § 180.408(a) by revising the introductory text and by amending the table therein by adding and alphabetically inserting new entries for clover, forage and clover, hay, to read as follows:

§ 180.408 Metalaxyl; tolerances for residues.

(a) Tolerances are established for the combined residues of the fungicide metalaxyl [*N*-(2,6-dmethylphyenyl)-*N*-(methoxyacetyl) alanine methylester] and its metabolites containing the 2,6-dimethylaniline moiety, and *N*-(2-hydroxy methyl-6-methylphenyl)-*N*-(methoxyacetyl)-alanine methyl ester, each expressed as metalaxyl equivalents, in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * * *	
Clover, forage	1.0
Clover, hay	2.5
* * * * *	

* * * * *

[FR Doc. 95–30976 Filed 12–19–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 721

[OPPTS–50582L; FRL–4982–9]

RIN 2070–AB27

1,3-Propanediamine, N, N'-1,2-ethanediylbis-, Polymer with 2,4,6-Trichloro-1,3,5-triazine, Reaction Products with N-Butyl-2,2,6,6-tetramethyl-4-piperidinamine; Modification of Significant New Use Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is modifying the significant new use rule (SNUR) promulgated under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 1,3-propanediamine, *N, N'*-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with *N*-butyl-2,2,6,6-tetramethyl-4-piperidinamine based on a modification to the TSCA 5(e) consent order regulating the substance. EPA is modifying this rule based on receipt of toxicity data.

EFFECTIVE DATE: The effective date of this rule is January 19, 1996.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, TSCA Assistance Office (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 15, 1990 (55 FR 33296), EPA issued a SNUR (FRL–3741–8) establishing significant new uses for 1,3-propanediamine, *N, N'*-1,2-ethanediylbis-, polymer with 2,4,6-trichloro-1,3,5-triazine, reaction products with *N*-butyl-2,2,6,6-tetramethyl-4-piperidinamine based on the section 5(e) consent order for the substance. Because of additional data EPA has received for this substance, EPA is modifying the SNUR.

I. Background

The Agency proposed the modification of the SNUR (FRL–4919–6) for this substance in the Federal Register of May 30, 1995 (60 FR 28075). The background and reasons for the modification of the SNUR are set forth in the preamble to the proposed modification. The Agency received no public comment concerning the proposed modification. As a result EPA is modifying this SNUR.

II. Objectives and Rationale of Modification of the Rule

During review of the premanufacture notice (PMN) submitted for the chemical substance that is the subject of this modification, EPA concluded that regulation was warranted under section 5(e) of TSCA pending the development of information sufficient to make a reasoned evaluation of the health and environmental effects of the substances. EPA identified the tests considered necessary to evaluate the risks of the substances and identified the protective equipment necessary to protect any workers who may be exposed to the substances. The basis for such findings is in the rulemaking record referenced in Unit III of this preamble. Based on these findings, a section 5(e) consent order modification was negotiated with the PMN submitter.

In light of the petition to modify the consent order and SNUR, the 90-day subchronic test, the data on structurally similar polycationic polymers, and the recalculation of the risk assessment of the PMN substances based on information provided by the petitioner, the Agency determined that it could no longer support a finding that the PMN substance may present an unreasonable risk to human health or the environment for the hazard communication and respiratory protection requirements in this modification. The modification of SNUR provisions for the substances designated herein is consistent with the provisions of the section 5(e) order.

III. Rulemaking Record

The record for the rule which EPA is modifying was established at OPPTS–50582. This record includes information considered by the Agency in developing this rule and includes the modification to consent orders to which the Agency has responded with this modification.

A public version of the record, without any Confidential Business Information, is available in the OPPT Non-Confidential Information Center (NCIC) from 12 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA NCIC is located in the Northeast Mall Basement Rm. B–607, 401 M St., SW., Washington, DC.

IV. Regulatory Assessment Requirements

EPA is modifying the requirements of this rule by eliminating several requirements. Any costs or burdens associated with this rule will be reduced when the rule is modified. Therefore, EPA finds that no additional assessments of costs or burdens are necessary under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 605(b)), or the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: December 11, 1995.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR part 721 is amended to read as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows: