tribal governments in the aggregate, or to the private sector, will not be or exceed $100 million. Thus, today's rule is not subject to the requirements of Section 202 and 205 of the Act. Because the rule contains no regulatory requirements that might significantly or uniquely affect small governments, it also is not subject to the requirements of Section 203 of the Act. Small governments are subject to the same requirements as other entities whose duties result from this rule and they have the same ability as other entities to retain and pump out treated sewage or discharge outside of the designated zones.

List of Subjects in 40 CFR Part 140

Environmental protection, Sewage disposal, Vessels.

Dated: December 5, 1995.

Jeanne M. Fox,

Regional Administrator.

For the reasons set out in the preamble, 40 CFR Part 140 is amended as follows:

PART 140—[AMENDED]

1. The authority citation for Part 140 continues to read as follows:

Authority: Sec. 312, as added Oct. 18, 1972, Pub. L. 92–500, Sec. 2, 86 Stat. 871. Interpret or apply Sec. 312(b)(1), 33 U.S.C. 1322(b)(1).

2. In § 140.4 paragraph (b)(1) is amended by designating the undesignated text after the colon as paragraph (b)(1)(i) and by adding paragraph (b)(1)(ii) to read as follows:

§ 140.4 Complete prohibition.

* * * * *

(b) * * *

(1) * * *

(ii) Two portions of the Hudson River in New York State, the first is bounded by an east-west line through the most northern confluence of the Mohawk River which will be designated by the Troy-Waterford Bridge (126th Street Bridge) on the south and Lock 2 on the north, and the second of which is bounded on the north by the southern end of Houghtaling Island and on the south by a line between the Village of Roseton on the western shore and Low Point on the eastern shore in the vicinity of Chelsea, as described in Items 2 and 3 of 6 NYCRR Part 858.4.

[FR Doc. 95–30406 Filed 12–12–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180

[PP 3F4222/R2192; FRL–4989–4]

RIN 2070–AB78

Tebuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for residues of the fungicide tebuconazole (*alpha*-[2-(4-chlorophenyl)ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in or on the raw agricultural commodities cherries at 4.0 parts per million (ppm) and peaches (includes nectarines) at 1.0 ppm. Miles, Inc. (now Bayer Corp.) submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) for the regulation to establish these maximum permissible levels for residues of the fungicide.

EFFECTIVE DATE: The effective date of this rule is November 22, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 3F4222/R2192], 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 3F4222/R2192]. 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, published in the Federal Register of August 17, 1995 (60 FR 42885), which announced that Miles, Inc., Agricultural Division (formerly Mobay Corp., Agricultural Chemicals Division, now Bayer Corp.), P.O. Box 4913, Kansas City, MO 64120-0013, had submitted pesticide petition (PP) 3F4222 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 residues of the fungicide tebuconazole (*alpha*-(4-chlorophenyl)ethyl]-*alpha*-(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol) in or on the raw agricultural commodities cherries at 4.0 parts per million (ppm) and peaches (includes nectarines per 40 CFR 180.1(h)) at 1.0 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 90-day rat feeding study with a no-observed-effect level (NOEL) of 34.8 milligrams per kilogram of body weight per day (mg/kg bw/day) (400 ppm) and a lowest-effect-level (LEL) of 171.7 mg/kg bw/day (1,600 ppm) in males, based on decreased body weight gains and histological changes in the adrenals. For females, the NOEL was 10.8 mg/kg bw/day (100 ppm) and the LEL was 46.5 mg/kg bw/day (400 ppm) based on decreased body weights, decreased body weight gains, and histological changes in the adrenals.

2. A 90-day dog-feeding study with a NOEL of 200 ppm (73.7 mg/kg bw/day in males and 73.4 mg/kg bw/day in females) and an LEL of 1,000 ppm (368.3 mg/kg bw/day in males and 351.8 mg/kg bw/day in females). The LEL was

based on decreases in mean body weights, body weight gains, and food consumption, and an increase in liver *N*-demethylase activity.

3. A 1-year dog feeding study with a NOEL of 1 mg/kg bw/day (40 ppm) and an LEL of 5 mg/kg bw/day (200 ppm), based on lenticular and corneal opacity and hepatic toxicity in either sex (the current Reference Dose was determined based on this study). A subsequent 1-year dog feeding study, using lower doses to further define the NOEL for tebuconazole, defines a systemic LOEL of 150 ppm (based on adrenal effects in both sexes) and a systemic NOEL of 100 ppm.

4. A 2-year rat chronic feeding study defined, a NOEL of 7.4 mg/kg bw/day (100 ppm), and an LEL of 22.8 mg/kg bw/day (300 ppm) based on body weight depression, decreased hemoglobin, hematocrit, MCV and MCHC, and increased liver microsomal enzymes in females. Tebuconazole was not oncogenic at the dose levels tested (0, 100, 300, and 1,000 ppm).

5. A rat oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day based on elevation of absolute and relative liver weights. For developmental toxicity, a NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day was determined, based on delayed ossification of thoracic, cervical and sacral vertebrae, sternum, fore and hind limbs and increase in supernumerary ribs.

6. A rabbit oral developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day based on depression of body weight gains and food consumption. A developmental NOEL of 30 mg/kg bw/day and an LEL of 100 mg/kg bw/day were based on increased post-implantation losses, from both early and late resorptions and frank malformations in eight fetuses of five litters.

7. A mouse oral developmental toxicity study with a maternal NOEL of 10 mg/kg bw/day and an LEL of 20 mg/kg bw/day based on a supplementary study indicating reduction in hematocrit and histological changes in liver. A developmental NOEL of 10 mg/kg bw/day and an LEL of 30 mg/kg bw/day based on dose-dependent increases in runts/dam at 30 and 100 mg/kg bw/day.

8. A mouse dermal developmental toxicity study with a maternal NOEL of 30 mg/kg bw/day and an LEL of 60 mg/kg bw/day based on a supplementary study indicating increased liver microsomal enzymes and histological changes in liver. The NOEL for developmental toxicity in the dermal study in the mouse is 1,000 mg/kg bw/day, the highest dose tested (HDT).

9. A two-generation rat reproduction study with a dietary maternal NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) based on depressed body weights, increased spleen hemosiderosis, and decreased liver and kidney weights. A reproductive NOEL of 15 mg/kg bw/day (300 ppm) and an LEL of 50 mg/kg bw/day (1,000 ppm) were based on neonatal birth weight depression.

10. An Ames mutagenesis study in *Salmonella* that showed no mutagenicity with or without metabolic activation.

11. A micronucleus mutagenesis assay study in mice that showed no genotoxicity.

12. A sister chromatid exchange mutagenesis study using CHO cells that was negative at dose levels 4 to 30 *u*g/mL without activation or 15 to 120 *u*g/mL with activation.

13. An unscheduled DNA synthesis (UDS) study that was negative for UDS in rat hepatocytes.

Additionally, a mouse oncogenicity study at dietary levels of 0, 20, 60, and 80 ppm for 21 months did not reveal any oncogenic effect for tebuconazole at any dose tested. Because the maximum-tolerated-dose (MTD) was not reached in this study, the study was classified as supplementary. A followup mouse study at higher doses (0, 500, and 1,500 ppm in the diet), with an MTD at 500 ppm, revealed statistically significant incidences of hepatocellular adenomas and carcinomas in males and carcinomas in females. The initial and followup studies, together with supplementary data submitted by Miles, Inc., were classified as core minimum.

The Office of Pesticide Programs' Health Effects Division's Carcinogenicity Peer Review Committee (CPRC) has classified tebuconazole as a Group C carcinogen (possible human carcinogen). This classification is based on the Agency's ''Guidelines for Carcinogen Risk Assessment'' published in the Federal Register of September 24, 1986 (51 FR 33992). The Agency has chosen to use the reference dose calculations to estimate human dietary risk from tebuconazole residues. The decision supporting classification of tebuconazole as a possible carcinogen (Group C) rather than a probable carcinogen (Group B) was primarily based on the statistically significant increase in the incidence of hepatocellular adenomas, carcinomas, and combined adenomas/carcinomas in both sexes of NMRI mice both by positive trend and pairwise comparison at the HDT, and the structural correlation with at least six other related triazole pesticides that produce liver tumors.

The Reference Dose (RfD) is established at 0.01 mg/kg of body weight (bwt)/day, based on a no-observed-effect level (NOEL) of 1.00 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is based on a 1-year dog-feeding study that demonstrated lenticular and corneal opacity and hepatic toxicity as an endpoint effect. A chronic exposure analysis was performed using tolerance level residues and 100 percent crop-treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups.

The Theoretical Maximum Residue Contribution (TMRC) from the published uses is estimated at 0.000008 mg/kg bwt/day and utilizes 0.075% of the RfD for the general population of the lower 48 States. The proposed use on peaches, cherries, and necatrines contributes 0.000377 mg/kg bwt/day (3.8% of the RfD) which raises the TMRC to 0.000385 mg/kg bwt/day or 3.9% of the RfD.

The TMRC for the most highly exposed subgroup, nonnursing infants (less than 1-year old) is 0.000003 mg/kg bwt/day which represents 0.03% of the RfD. The proposed use on peaches, cherries, and nectarines for nonnursing infants (less than 1-year old) raises the TMRC to 0.002525 or 25.3% of the RfD.

The nature of the residue in cherries, peaches, and nectarines is adequately understood. An adequate analytical method using gas chromatography is available for enforcement purposes.

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 Hwy., Arlington, VA 22202, (703)-305-5232.

There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat of livestock and poultry since there are no livestock feed items associated with this action.

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 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 3F4222/R2192] (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 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 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).

OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 180

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

Dated: November 22, 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 § 180.474, by amending the table therein by adding and alphabetically inserting new entries for cherries and peaches (includes nectarines), to read as follows:

§ 180.474 Tebuconazle (alpha-[2-(4-chlorophenyl)-ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole); tolerances for residues.

* * * * *

Commodity	Parts per million
* * * * *	
Cherries	4.0
* * * * *	
Peaches (includes necatrines)	1.0
* * * * *	

[FR Doc. 95–29986 Filed 12–12–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 5E4540/R2186; FRL–4985–7]

RIN 2070–AB78

α-Alkyl(C_{21}-C_{71})-ω-Hydroxypoly (Oxyethylene); Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document exempts α-alkyl(C_{21}-C_{71})-ω-hydroxypoly (oxyethylene) from the requirement of a tolerance when used at levels not to exceed 10% as a wetting agent or granule coating in pesticide formulations. Petrolite Corp. requested this regulation under the Federal Food, Drug and Cosmetic Act (FFDCA).

EFFECTIVE DATE: This regulation becomes effective December 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 5E4540/R2186], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests 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,