

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: September 20, 1995.

Peter Caulkins,

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

Therefore, it is proposed that 40 CFR part 180 be 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 § 180.184, paragraph (a) is amended in the table therein by revising the entry for asparagus, to read as follows:

#### **§ 180.184 Linuron; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Asparagus .....	7.0
* * * * *	* * * * *

[FR Doc. 95-24210 Filed 9-28-95; 8:45 am]

BILLING CODE 6560-50-F

#### **40 CFR Part 180**

[PP 1E3979/P632; FRL-4977-6]

RIN 2070-AC18

#### **Clopyralid; Pesticide Tolerance**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish a tolerance for residues of the herbicide clopyralid in or on the raw agricultural commodity asparagus. The proposed regulation to establish a maximum permissible level for residues of the herbicide was requested in a petition submitted under the Federal Food, Drug and Cosmetic Act (FFDCA) by the Interregional Research Project No. 4 (IR-4).

**DATES:** Comments, identified by the document control number [PP 1E3979/P632], must be received on or before October 30, 1995.

**ADDRESSES:** By mail, submit written comments 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 comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Comments and data may also be submitted to OPP by sending electronic mail (e-mail) to:

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. Comments 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 [PP 1E3979/P632]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the

"SUPPLEMENTARY INFORMATION" section of 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: Hoyt L. Jamerson, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8783; e-mail: jamerson.hoyt@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition (PP) 1E3979 to EPA on behalf of the Agricultural Experiment Stations of Arkansas, California, Maryland, Michigan, Minnesota, and Washington. The petition requests that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR 180.431 by establishing a tolerance for residues of the herbicide clopyralid (3,6-dichloro-2-pyridinecarboxylic acid) in or on the raw agricultural commodity asparagus at 1.0 part per million (ppm).

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

1. A 1-year feeding study in dogs, which were fed diets containing 0, 100, 320, and 1,000 milligrams (mg)/kilogram (kg)/day, with a no-observed-effect-level (NOEL) of 100 mg/kg/day. The lowest-observed-effect level (LOEL) was established at 320 mg/kg/day based on increased liver weights and decreased erythrocyte counts and hemoglobin and hematocrit values.

2. A developmental toxicity study in rats, which was given the chemical by gavage at doses of 0, 15, 75, and 250 mg/kg, with no developmental toxicity observed under the conditions of the study. The NOEL for maternal toxicity was established at 75 mg/kg based on decreased body weight and reduced food consumption at the LOEL (250 mg/kg/day).

3. A developmental toxicity study in rabbits, which was given the chemical by gavage at doses of 110 and 250 mg/kg, with no developmental or maternal toxicity observed under the conditions of the study.

4. A 2-year chronic feeding/carcinogenicity study in mice, which were fed diets containing 0, 100, 500, and 2,000 mg/kg/day, with a NOEL for systemic effects of 500 mg/kg. Decreased body weight was observed in male mice fed 2,000 mg/kg/day (LOEL). No carcinogenic effects were observed under the conditions of the study.

5. A 2-year chronic feeding/carcinogenicity study in rats fed diets containing 0, 5, 15, 50, and 150 mg/kg/day with a NOEL for systemic effects of 50 mg/kg/day. The LOEL was established at 150 mg/kg/day based on decreased mean body weight in females in the high-dose group. No carcinogenic effects were observed under the conditions of the study.

6. A two-generation reproduction study in rats fed diets containing 0, 150, 500, and 1,500 mg/kg/day with no observed effect on reproductive performance. A systemic NOEL of 500 mg/kg/day was established for the study based on reduced terminal body weight in the F0 generation at the 1,500 mg/kg/day level.

7. Mutagenicity studies including dominant-lethal assay in rats, *in vivo* rat cytogenetic, *in vitro* Salmonella and Saccharomyces assays, *in vivo* mouse host-mediated assay, and an unscheduled DNA synthesis assay, which were all negative.

8. In a metabolism study in rats, radio-labeled clopyralid was readily absorbed after being ingested and the majority of the radioactive dose was excreted within 24 hours of ingestion.

The reference dose (RfD) for clopyralid is established at 0.5 mg/kg body weight (bwt)/day. The RfD is based on a NOEL of 50 mg/kg/bwt/day from the 2-year feeding study in rats and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from established tolerances utilizes less than 2 percent of the RfD for the overall U.S. population. The TMRC for the subgroup most highly exposed, children aged 1 to 6 years, utilizes less than 4 percent of the RfD.

The dietary risk assessment indicates that there is no appreciable risk from establishment of the proposed tolerance for asparagus.

The nature of the residue in plants is adequately understood. The residue of concern is parent clopyralid. 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 method in the Pesticide Analytical Manual, the analytical method is being made available, in the interim, to anyone with an interest 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)-305-5937.

No secondary residues are expected to occur in milk, eggs, or meat as a result of this use; asparagus is not considered a livestock feed commodity.

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 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDC.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 1E3979/P632].

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.

A record has been established for this rulemaking under docket number [PP 1E3979/P632] (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, excluding 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 Hwy., 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 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: September 20, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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 180.431 is amended in paragraph (a) in the table therein by adding and alphabetically inserting an entry for the commodity asparagus, to read as follows:

**§ 180.431 Clopyralid; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Asparagus .....	1.0
* * * * *	*

[FR Doc. 95-24209 Filed 9-28-95; 8:45 am]

BILLING CODE 6560-50-F

**40 CFR Part 180**

[PP 5E4540/P633; FRL-4977-8]

RIN 2070-AC18

**α-Alkyl (C<sub>21</sub>-C<sub>71</sub>)-ω-Hydroxypoly(Oxyethylene); Tolerance Exemption**

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes that residues of α-alkyl (C<sub>21</sub>-C<sub>71</sub>)-ω-hydroxypoly(oxyethylene) be exempted 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).

**DATES:** Comments, identified by the document control number [PP 5E4540/P633], must be received on or before October 30, 1995.

**ADDRESSES:** By mail, submit written comments 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, deliver comments to: Rm. 1132, Crystal Mall, Building #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part of 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 comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by the EPA without prior notice. The public docket is 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.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 5E4540/P633]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed 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: Amelia M. Acierro, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, Arlington, VA 22202, (703)-308-8375; e-mail: acierro.amelia@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Petrolite Corp., Polymers Division, 6910 East 14th St., Tulsa, OK 74112, submitted pesticide petition (PP) 5E4540 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal

Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for α-alkyl (C<sub>21</sub>-C<sub>71</sub>)-ω-hydroxypoly(oxyethylene) when used at levels not to exceed 10% as a wetting agent or granule coating in pesticide formulations applied to growing crops only.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the Federal Register of April 22, 1987 (52 FR 13305), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without these data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient. The Agency has decided that no data, in addition to that described below, for α-alkyl (C<sub>21</sub>-C<sub>71</sub>)-ω-hydroxypoly(oxyethylene) will need to be submitted. The rationale for this decision is described below:

1. The rat acute oral toxicity studies with acute oral LD<sub>50</sub> values varying from 410 mg/kg to 25,000 mg/kg.
2. The acute dermal toxicity studies with acute dermal LD<sub>50</sub> values from 930 mg/kg to 11,800 mg/kg in rabbits and > 2,000 mg/kg in rats.
3. Mutagenicity studies including *Salmonella typhimurium* plate (Ames) tests with and without activation, structural chromosomal aberration test and other genotoxic effects tests were negative.
4. The 90-day feeding toxicity study in rats with a NOEL 15 mg/kg/day.