urea in or on the following raw agricultural commodities:

Commodity	Parts per million
Cereal grains group (except rice and wild rice), grain	0.01
Cereal grains group (except rice and wild rice), forage	0.10
Cereal grains group (except rice and wild rice), fodder	0.01
Cereal grains group (except rice and wild rice), straw	0.02
Cereal grains group (except rice and wild rice), hay	0.20

[FR Doc. 96–9472 Filed 4–16–96; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 0E3835/P648; FRL–5356–5]

RIN 2070–AB18

Pesticide Tolerance for Diflubenzuron

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA proposes to establish a tolerance for residues of the insecticide diflubenzuron (*N*[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) in or on the raw agricultural commodity artichokes at 6.0 parts per million (ppm). The proposed regulation to establish a maximum permissible level for residues of the insecticide was requested in a petition submitted by the Interregional Research Project No. 4 (IR–4).

DATES: Comments, identified by the document control number [PP 0E3835/P648], must be received on or before May 17, 1996.

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 Highway, 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 0E3835/P648]. 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). 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 Virginia 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 Highway, Arlington, VA 22202, 703–308–8783, e-mail address: 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 0E3835) to EPA on behalf of the Agricultural Experiment Station of California. This 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 180.377 by establishing a tolerance for residues of the insecticide diflubenzuron (*N*[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide) in or on the raw agricultural commodity artichoke at 6.0 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 chronic feeding study with dogs administered 0, 2, 10, 50 or 250 mg/kg/day with a no-observed-effect level (NOEL) established at 2 mg/kg/day. Statistically significant increases in methemoglobin and sulfhemoglobin in male and female dogs were observed at dose levels of 10 mg/kg/day and higher. Signs of hemolytic anemia, destruction of erythrocytes and of compensatory regeneration of erythrocytes were observed at dose levels of 50 mg/kg/day and higher.

(2) A 2–year feeding/carcinogencity study with rats fed diets containing 0, 156, 625, 2,500, or 10,000 ppm (equivalent to 0, 7.8, 31, 125, or 500 mg/kg/day) with statistically significant increases in methemoglobin and sulfhemoglobin observed at all treatment levels tested. Signs of hemolytic anemia and increased spleen and liver weights were observed in males and females at treatment levels of 2,500 ppm and 10,000 ppm. Histological signs of erythrocyte destruction and compensatory regeneration were observed in males and females at dose levels of 156 ppm and higher. A no-observed-effect level was not established for this study, since effects were observed at the lowest dose tested. There were no carcinogenic effects observed under the conditions of this study.

(3) A 91–week carcinogenicity study with mice fed diets containing 0, 16, 80, 400, 2,000, or 10,000 ppm (equivalent to 0, 2.4, 12, 60, 300, or 1,500 mg/kg/day). Increases in methemoglobin and sulfhemoglobin were consistently observed in male and female mice at dose levels of 80 ppm and higher. Signs of hemolytic anemia, erythrocyte destruction and compensatory regeneration, and histopathological effects in the liver were observed at dose levels of 80 ppm and higher. No evidence of carcinogenicity was observed under the conditions of this study.

(4) A 2–generation reproduction study with rats fed diets containing 0, 500, 5,000, or 50,000 ppm (equivalent to 0, 25, 250, or 2,500 mg/kg/day). No effects on reproductive performance were observed in the parental adults. The NOEL for reproductive effects in the progeny is 250 mg/kg/day based on decreased body weight in the pups from birth to 21 days postpartum.

(5) Developmental toxicity studies with rats and rabbits given technical grade diflubenzuron by gavage at dose levels of 0 or 1,000 mg/kg/day with no maternal toxicity or toxicity to the developing fetus observed under the conditions of the study.

(6) Mutagenicity studies using diflubenzuron as the test material were negative. These studies included a Salmonella/mammalian microsome

plate incorporation assay with and without metabolic activation, an *in vitro* chromosome damage assay using cultures of Chinese hamsters ovary cells with and without metabolic activation, and an unsheduled DNA synthesis assay using cultures of primary rat hepatocytes.

The qualitative nature of the residue is adequately understood in plants based on data from citrus, mushroom, and soybean metabolism studies. Para-chloroaniline (PCA) and 4-chlorophenylurea (CPU) are metabolites of diflubenzuron that have been observed in mushrooms but not in citrus and soybeans. Diflubenzuron is also known to be metabolized to PCA and CPU in lactating goats, lactating cows, poultry, and rats.

OPP's Health Effects Division Peer Review Committee has concluded that there is no evidence of carcinogenicity for diflubenzuron per se and has placed the chemical in Group E of EPA's classification system for carcinogens. The Committee also classified PCA as a Group B2 carcinogen (a probable human carcinogen). The classification for PCA was based on the results of National Toxicology Program studies in which PCA was administered for 2 years by gavage to rats at doses of 0, 2, 6, or 18 mg/kg/day and to mice at doses of 0, 3, 10, or 30 mg/kg/day. Treatment-related increased incidences of uncommon sarcomas (fibrosarcomas, hemangiosarcomas and/or osteosarcomas) of the spleen were observed in male rats, and increased incidences of liver adenomas and carcinomas, and hemangiosarcomas in the spleen and/or liver were observed in male mice.

The reference dose (RfD) for diflubenzuron is 0.02 mg/kg/day. The RfD is based on the NOEL of 2.0 mg/kg/day from the 1–year chronic feeding study in dogs and an uncertainty factor of 100. Available information relating to anticipated residues and percent of crop treated for established tolerances were used to calculate the Anticipated Residue Contribution (ARC) from residues of diflubenzuron in the human diet. The ARC from published tolerances is calculated at 0.00008 mg/kg/day, which utilizes less than 1 percent of the RfD for the overall population. The ARC for children 1 to 6 years old, the population subgroup most highly exposed, utilizes 1 percent of the RfD. The Theoretical Maximum Residue Contribution from the proposed tolerance for artichokes would utilize an additional 0.1 percent of the RfD for the U.S. population and for children 1 to 6 years old. This dietary risk assessment indicates that there is no appreciable risk from the establishment of the proposed tolerance for artichokes.

A quantitative cancer risk assessment was performed for PCA and CPU. Possible human exposure to PCA and CPU may occur as a result of the ingestion of PCA and CPU formed in animals which have consumed feeds containing diflubenzuron residues and from the metabolic conversion of diflubenzuron to PCA and CPU in the human body. For the purposes of this risk assessment, it was assumed that CPU has the same carcinogenic potential and potency as PCA. Although there is strong evidence supporting the carcinogenicty of PCA in rats and mice, the assumption that CPU also may be carcinogenic is not based on direct testing in animals, but rather on a comparison of the chemical structures of CPU and PCA. An assumption of a 2 percent conversion of diflubenzuron to PCA was used for the cancer risk assessment.

The upper-bound cancer risk from dietary exposure to residues of PCA and CPU from existing uses of diflubenzuron is estimated at 1.3×10^{-6}. The additional cancer risk from the proposed tolerance for artichokes is estimated at 2×10^{-8}. EPA concludes that the potential cancer risk from residues of PCA and CPU resulting from established tolerances and the proposed use on artichokes is negligible.

An adequate analytical method, gas chromatography using an electron capture detector, is available for enforcement purposes. The analytical method for enforcing this tolerance has been published in the *Pesticide Analytical Manual*, Vol. II (PAM-II). There is no reasonable expectation that secondary residues will occur in milk, eggs, or meat and meat byproducts of livestock and poultry: there are no livestock feed items associated with artichokes.

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 notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

A record has been established for this rulemaking under docket number [PP 0E3835/P648] (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 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 Virginia 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: April 3, 1996.

Susan Lewis,

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 § 180.377, the table in paragraph (a) is amended by adding alphabetically the entry for artichoke to read as follows:

§ 180.377 Diflubenzuron; tolerances for residues.

(a) * * *

Commodities	Parts per million
Artichoke	6.0
* * * *	*

* * * * *

[FR Doc. 96–9474 Filed 4–16–96; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[OPP–300419; FRL–5355–7]

RIN 2070–AB18

Pentaerythritol Stearates; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that residues of a mixture of chemicals known as pentaerythritol stearates (CAS Reg. No. 85116-93-4), which include pentaerythritol monostearate (CAS Reg. No. 78-23-9), pentaerythritol distearate (CAS Reg. No. 13081-97-5), pentaerythritol tristearate (CAS Reg. No. 28188-24-1), and pentaerythritol tetrastearate (CAS Reg. No. 115-83-3) be exempted from the requirement of a tolerance when used as an inert ingredient (emulsifier) at a concentration of no more than 25 ppm in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest. This proposed regulation was requested by Wacker Silicones Corporation.

DATES: Comments, identified by the docket control number [OPP–300419], must be received on or before May 17, 1996.

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. 1128, Crystal Mall, Building #2, 1921 Jefferson Davis Highway, Arlington, VA.

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 [OPP–300419]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the **SUPPLEMENTARY INFORMATION** unit 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 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 may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Amelia M. Acierto, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 2800 Crystal Drive, North Tower, Arlington, VA, (703) 308-8375; e-mail: acierto.amelia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Wacker Silicones Corporation, 3301 Sutton Road, Adrian Michigan 49221-9397 submitted pesticide petition (PP) number 4E04378 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(c) by establishing an exemption from the requirement of a tolerance for a mixture of chemicals known as pentaerythritol stearates (pentaerythritol monostearate (CAS Reg. No. 78-23-9), pentaerythritol distearate (CAS Reg. No. 13081-97-5), pentaerythritol tristearate (CAS Reg. No. 28188-24-1), and pentaerythritol tetrastearate (CAS Reg. No. 115-83-3) when used as an emulsifier in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. 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.