

This ANPRM is issued under section 301 *et seq.* of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under the authority of the Commissioner of Food and Drugs.

Dated: May 28, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96-13980 Filed 6-3-96; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[INTL-0054-95]

RIN 1545-AT96

#### Proposed Amendments to the Regulations on the Determination of Interest Expense Deduction of Foreign Corporations and Branch Profits Tax; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to notice of proposed rulemaking.

**SUMMARY:** This document contains a correction to the notice of proposed rulemaking [INTL-0054-95] which was published in the Federal Register for Friday, March 8, 1996 (61 FR 9377). The notice of proposed rulemaking relate to the determination of the interest expense deduction of foreign corporations, and the branch profits tax.

**FOR FURTHER INFORMATION CONTACT:** Ahmad Pirasteh or Richard Hoge (202) 622-3870 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking that is subject to these corrections are under sections 882 and 884 of the Internal Revenue Code.

##### Need for Correction

As published, the proposed rulemaking contains errors that are in need of clarification.

##### Correction of Publication

Accordingly, the publication of the proposed rulemaking which is the subject of FR Doc. 96-5264 is corrected as follows:

1. On page 9378, in the preamble under column 2, following the paragraph heading "*B. Hedging transactions*", line 6, the language "case may be, the amount of their U.S." is corrected to read "case may be, the amount of its U.S.".

#### § 1.882-5 [Corrected]

2. On page 9379, column 3, § 1.882-5(d)(6), *Example 4.* (i), line 18, the language "liabilities of 90x U.S. dollars and 1000 x" is corrected to read "liabilities of 90x U.S. dollars and 1000x".

#### § 1.884-1 [Corrected]

3. On page 9380, column 3, § 1.884-1(d)(2)(xi), *Example 8.*, last line, the language "from securities) of the value of the securities." is corrected to read "from securities) of the amount of the securities.".

Cynthia E. Grigsby,

*Chief, Regulations Unit, Assistant Chief Counsel (Corporate).*

[FR Doc. 96-13722 Filed 6-3-96; 8:45 am]

BILLING CODE 4830-01-U

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[PP 5E04443/P659; FRL-5371-5]

RIN 2070-AB18

#### 1,1-Difluoroethane; Proposed Exemption from Tolerance

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes that residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) be exempted from the requirement of a tolerance when used as an inert ingredient (aerosol propellant) in aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals. This proposed regulation was requested by The Dupont Company, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** Comments, identified by the docket control number [PP 5E04443/P659], must be received on or before July 5, 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. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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). 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 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 5E04443/P659]. No 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. Acierito, 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: acierito.amelia@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** The Dupont Company, 1007 Market Street, Wilmington, DE 19898 has submitted pesticide petition (PP) 5E04443 to EPA requesting that the Administrator, pursuant to section 408(e) of the FFDCA, 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(c) and (e) by establishing an exemption from the requirement of a tolerance for the residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) when used as an inert ingredient (aerosol propellant) in aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.

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 that 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 1,1-difluoroethane will need to be submitted. The rationale for this decision is described below:

1. 1,1-Difluoroethane has been designated by the EPA as a substance about which it has little concern regarding its ozone-depleting potential and is listed as an acceptable substitute for certain uses of currently used ozone-depleting propellants. 1,1-Difluoroethane is now used in consumer products (e.g., hair sprays, baby oil mousse, spray bandage, rug shampoos and oven cleaners).

2. An acute rat toxicity study which showed no mortality when animals were exposed to 1,1-difluoroethane at concentrations up to 200,000 ppm, indicating that the substance is essentially non-toxic following acute inhalation exposure.

3. A chronic rat inhalation toxicity study with exposures for 6 hours, 5 days/week for 2 years, with a no-observed-effect-level (NOEL) of 27,000 mg/M<sup>3</sup> and LOEL of 67,500 mg/M<sup>3</sup> based on mild reversible renal effects.

4. A rat inhalation developmental toxicity study with pregnant CD rats exposed to concentrations of 0, 5,000 or 50,000 ppm for 6 hours/day on gestation days 6 through 15 showing no treatment-related maternal or fetal effects at any dose level, indicating that 1,1-difluoroethane is not a developmental toxicant at dose levels of equal or less than 50,000 ppm.

5. A human (volunteers) study reported no adverse effects except for

reversible analgesia and feelings of impending loss of consciousness after acute inhalation exposure to 500,000 ppm of 1,1-difluoroethane.

6. 1,1-Difluoroethane is approved under 21 CFR 178.3010 by the United States Food and Drug Administration (FDA) as an indirect food additive (e.g., blowing agent in the production of polystyrene articles which come in contact with food).

7. 1,1-Difluoroethane is a gas at ambient temperatures. Therefore, rapid volatilization of the substance and dilution by ambient air is expected, suggesting that human exposure would be insignificant. It would not be expected that the Reference Dose (RfD) of 74 ppm (200 mg/M<sup>3</sup>) established by the Agency for this chemical would be reached or exceeded in exposures resulting from its intended use as an aerosol propellant.

The toxicological profile indicates a lack of chronic, subchronic or developmental toxicity. Based upon the physico-chemical characteristics, and review of its use, and the determination that there is no reasonable expectation of finite residues in food or feed items as a result of its use as a propellant in pesticide formulations, the Agency has concluded that the use of 1,1-difluoroethane would result in negligible risks to human health and the environment. Accordingly, the Agency has found that, 1,1-difluoroethane, when used in accordance with good agricultural practice, is useful and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a 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 proposal be referred to an Advisory Committee in accordance with section 408(e) of FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the docket control number, [PP 5E04443/P659]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4:30 p.m. Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP

5E04443/P659] (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<sup>2</sup>, 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.

The Office of Management and Budget has exempted this proposed rule from the requirements of section 3 of Executive Order 12866.

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), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

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: May 15, 1991.

Stephen L. Johnson,

*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 180.1001 is amended in paragraphs (c) and (e) in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

**§ 180.1001 Exemptions from the requirements of a tolerance.**

\* \* \* \* \*

(c) \* \* \* \*

Inert Ingredients	Limits	Uses
* * *	* * *	* *
1,1-difluoroethane (CAS Reg. No. 75-37-6) .....	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.	Aerosol propellant
* * *	* * *	* *

\* \* \* \* \* (e) \* \* \*

Inert Ingredients	Limits	Uses
* * *	* * *	* *
1,1-difluoroethane (CAS Reg. No. 75-37-6) .....	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals	Aerosol propellant
* * *	* * *	* *

[FR Doc. 96-13440 Filed 6-3-96; 8:45 am]  
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**40 CFR Part 180**

[PP 6E04704/P657; FRL-5369-5]

RIN 2070-AC18

**$\alpha$ -Alkyl (C<sub>10</sub>-C<sub>15</sub>)- $\omega$ -Hydroxy Poly(oxyethylene) Sulfate and its Ammonium, Calcium, Magnesium, Potassium, Sodium and Zinc Salts; Tolerance Exemption**

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes that the current exemption from the requirement of a tolerance for  $\alpha$ -alkyl (C<sub>12</sub>-C<sub>15</sub>)- $\omega$ -hydroxy poly(oxyethylene) sulfate and its ammonium, calcium, magnesium, potassium, sodium and zinc salts; the polyoxyethylene content averages 3 moles be amended to include alkyl groups ranging from C<sub>10</sub>-C<sub>14</sub>. This proposed regulation was requested by Henkel Corporation pursuant to Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** Comments, identified by the docket control number [PP 6E04704/P657], must be received on or before July 5, 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. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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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 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number, [PP 6E04704/P657]. No 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: Bipin Gandhi, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs,