

- Three-tiered method validation process based on method use
- OST coordination of method submission and approval
  - Harmonization of 40 CFR Part 136 methods with other EPA methods to allow standardization of methods across EPA programs
  - Other streamlining issues
- Standardized data elements for reporting, to allow access to Agency databases in a standardized data format
- Withdrawal of 40 CFR Part 136 methods that contain outdated technologies
- Incorporating new methods into the Federal Register by reference and making them available through other suitable venues, to reduce publication expense

Dated: July 3, 1996.

James Hanlon,

*Deputy Director, Office of Science and Technology.*

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#### 40 CFR Part 180

[OPP-300425; FRL-5374-3]

RIN 2070-AC18

#### Maleic Anhydride-Diisobutylene Copolymer, Sodium Salt; Tolerance Exemption

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to establish an exemption from the requirement of a tolerance for residues of maleic anhydride-diisobutylene copolymer, sodium salt when used as an inert ingredient (suspending agent and dispersing agent) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and applied to animals. This proposed regulation was requested by Rhone-Poulenc North America Chemicals, Inc.

**DATES:** Written comments, identified by the docket number [OPP-300425], must be received on or before August 9, 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. 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. 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.

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 [OPP-300425]. 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: Bipin Gandhi, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, 6th Floor, Arlington, VA 22202, (703) 308-8380, e-mail: gandhi.bipin@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Rhone-Poulenc North America Chemicals, Inc., CN 5255, Princeton, NJ 08543-5255 submitted pesticide petition (PP) 6E04665 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346 a(e)), propose to amend 40 CFR 180.1001(c), (d) and (e) by establishing an exemption from the requirement of a tolerance without limitation for residues of maleic anhydride-diisobutylene copolymer, sodium salt (CAS Reg. No. 37199-81-1), when used as an inert ingredient (suspending agent and dispersing agent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, under 40 CFR 180.1001(c) and

applied to animals under 40 CFR 180.1001(e), and deleting the current exemption from the requirement of a tolerance with a use limitation of 3 percent under 40 CFR 1001(d) for application 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 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 maleic anhydride-diisobutylene copolymer, sodium salt will need to be submitted. The rationale for this decision is described below.

In the case of certain chemical substances that are defined as "polymers," the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Maleic anhydride-diisobutylene copolymer, sodium salt conforms to the definition of polymer given in 40 CFR 723.250(b) and meets the following

criteria that are used to identify low risk polymers:

1. Maleic anhydride-diisobutylene copolymer, sodium salt is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. Maleic anhydride-diisobutylene copolymer, sodium salt contains as an integral part of its composition the atomic elements carbon, hydrogen, oxygen, and sodium.

3. Maleic anhydride-diisobutylene copolymer, sodium salt does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

4. Maleic anhydride-diisobutylene copolymer, sodium salt is not designed, nor it is reasonably anticipated to substantially degrade, decompose or depolymerize.

5. Maleic anhydride-diisobutylene copolymer, sodium salt is not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. Maleic anhydride-diisobutylene copolymer, sodium salt is not water absorbing polymer.

7. The minimum number-average molecular weight of maleic anhydride-diisobutylene copolymer, sodium salt is 20,900 daltons. Substances with molecular weights (MW) greater than 400 generally are not absorbed through the intact skin, and substances with MW greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) track. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. Maleic anhydride-diisobutylene copolymer, sodium salt has a number average molecular weight of 20,900 and an oligomer content less than 2 percent below MW 500 and less than 5 percent MW 1000.

Based on the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, this ingredient is useful and tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemptions from the requirement of a tolerance be established for this polymer 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, that contains any of the ingredients listed herein, may request within 30 days after the 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 FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the docket number, [OPP-300425].

A record has been established for this rulemaking under docket number [OPP-300425] (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 address in the "ADDRESSES" at the beginning of this document.

The Office of Management and Budget has exempted this rule from the requirements of section 2 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 requirement 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 an 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 Subject in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Food additives, Pesticides and pests, Processed foods, Reporting and recordkeeping requirements.

Dated: July 1, 1996.

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 § 180.1001, paragraphs (c) and (e), the table in each paragraph is amended by adding alphabetically the inert ingredient "Maleic anhydride-dissobutylene copolymer, sodium salt (CAS Reg. No. 37199-81-8), average molecular weight (in amu) 18,000," to read as set forth below, and the table in paragraph (d) is amended by removing the entry for "Maleic anhydride dissobutylene copolymer, sodium salt."

#### § 180.1001 Exemptions from the requirement of a tolerance.

*	*	*	*	*
(c)	*	*	*	

Inert Ingredient	Limits	Uses
Maleic anhydride-dissobutylene copolymer, sodium salt (CAS Reg. No. 37199-81-8), average molecular weight (in amu) 18,000..	*	Suspending agent and dispersing agent.

Inert Ingredient	Limits	Uses
Maleic anhydride-dissobutylene copolymer, sodium salt (CAS Reg. No. 37199-81-8), average molecular weight (in amu) 18,000.	*	Suspending agent and dispersing agent.

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**40 CFR Part 180**

[PP 6E4644/P668; FRL-5380-5]

**RIN 2070-AC18**

**Polyvinylpyrrolidone Butylated Polymer; Tolerance Exemption**

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

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to establish an exemption from the requirement of a tolerance for residues of polyvinylpyrrolidone butylated polymer when used as an inert ingredient (surfactants, related adjuvant of surfactants and binder) in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and applied to animals. This proposed regulation was requested by International Specialty Products.

**DATES:** Written comments, identified by the document control number [PP 6E4644/P668], must be received on or before August 9, 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. 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. 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.

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 6E4644/P668]. 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 in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: Bipin Gandhi, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, 6th Floor, Arlington, VA 22202, 703-308-8380, e-mail: gandhi.bipin@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** International Specialty Products, 1361 Alps Road, Wayne, NJ 07470, submitted pesticide petition (PP) 6E4644 to EPA requesting that the Administrator,

pursuant to section 408(e) of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346 a(e)), propose to amend 40 CFR 180.1001(c) and (e) by exempting polyvinylpyrrolidone butylated polymer (CAS No. 26160-96-3) when used as an inert ingredient (surfactants, related adjuvant of surfactants and binder) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, under 40 CFR 180.1001(c) and applied to animals under 40 CFR 180.1001(e) and deleting the current exemption from the requirement of a tolerance under 40 CFR 180.1001(d) for application 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 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