

Dated: June 26, 1996.  
 Carol M. Browner,  
*Administrator.*  
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#### 40 CFR Part 136

[FRL-5535-4]

### A Public Meeting on Method Flexibility and Streamlining Approval of Analytical Methods at 40 CFR Part 136

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

**ACTION:** Notice of meeting.

**SUMMARY:** The Office of Science and Technology within EPA's Office of Water is conducting a public meeting on approaches to method flexibility and streamlining the proposal and promulgation of analytical methods at 40 CFR Part 136 under Section 304(h) of the Clean Water Act and at 40 CFR Part 141 under Sections 1401 and 1445 of the Safe Drinking Water Act. This public meeting on streamlining EPA's water methods approval programs will be held in conjunction with the Trace Metals Workshop announced concurrently in the Federal Register.

This public meeting follows a series of three public meetings on streamlining held in Seattle, Washington on September 28, 1995, in Boston, Massachusetts on January 25, 1996, and in Chicago, Illinois on February 14, 1996. The Seattle meeting was announced in an FR notice titled, "A Public Meeting and Availability of Documents on Streamlining Approval of Analytical Methods at 40 CFR Part 136 and flexibility in Existing Test Methods" [FRL-5294-6] published in the Federal Register on September 12, 1995 at 60 FR 47325. This FR notice provided extensive supplementary information regarding the 304(h) streamlining effort and made available several supporting documents. The supporting documents and summaries of the Seattle, Boston, and Chicago public meetings can be obtained through the contact identified in this notice.

**DATES:** EPA will conduct the public meeting on 304(h) streamlining on Wednesday, July 24, 1996, in Denver, Colorado. Registration for the meeting will begin at 8 a.m. The meeting will be held from 9 a.m. to 5 p.m.

**ADDRESSES:** The meeting will be held in the USGS Lecture Hall, Building 25, Denver Federal Center, 6th & Kipling, Denver, Colorado.

#### FOR FURTHER INFORMATION CONTACT:

Questions concerning this notice can be directed to Marion Thompson by phone at (202) 260-7117 or by facsimile at (202) 260-7185.

**SUPPLEMENTARY INFORMATION:** Meeting arrangements are being coordinated by DynCorp, Inc. For information on registration, contact Cindy Simbanin, 300 N. Lee Street, Suite 500, Alexandria, VA 22314. Phone: (703) 519-1386. Facsimile number: (703) 684-0610. Space is limited and reservations are being taken on a first come, first served basis. No fees will be charged to attend.

Hotel reservations may be made by contacting the Comfort Suites in Lakewood, Colorado at (303) 231-9929. The hotel address is 11909 W. 6th Avenue, Lakewood, Colorado 80033. Single occupancy guest rates are \$83.55, including tax. When making reservations, you must specify that you are affiliated with the EPA Meeting to qualify for the quoted rate.

Accommodations are limited, so please make your reservations early. The Comfort Suites does not provide transportation to/from the airport or to the Federal Center. Guests should take the Airport shuttle to/from the airport and use taxi service to the Federal Center. The Federal Center is within walking distance of the Comfort Suites, but it is not an easy walk due to the location of the main gate into the Federal Center.

**Title:** A Public Meeting on Method Flexibility and Streamlining Approval of Analytical Methods at 40 CFR Part 136

#### Abstract

Under Section 304(h) of the Clean Water Act, EPA is responsible for promulgating analytical methods at 40 CFR Part 136 for use in monitoring pollutant discharges. EPA uses these methods to support development of effluent guidelines promulgated at 40 CFR Parts 400-499, and both EPA and the regulated community use the methods for establishing compliance with National Pollutant Discharge Elimination System (NPDES) permits and other monitoring purposes. The methods approved for use at 40 CFR Part 136 have been developed by EPA, by industrial associations such as the American Society for Testing Materials, and by other governmental agencies such as the U.S. Geological Survey. In the past, the methods proposal and promulgation process has been cumbersome, and has not provided the flexibility to take advantage of new analytical technologies in a timely manner. In response to the Administration's Environmental

Technology Initiative, EPA is proposing a comprehensive Section 304(h) streamlining initiative to increase method flexibility to allow use of emerging technologies and to expedite the method approval process, to encourage development of new methods and technologies by organizations outside of EPA.

The Office of Ground Water and Drinking Water within EPA's Office of Water is also developing approaches to increasing method flexibility and streamlining the approval of analytical methods at 40 CFR Part 141 under Sections 1401 and 1445 of the Safe Drinking Water Act. EPA is coordinating these efforts with the CWA Section 304(h) streamlining effort in an overall initiative to streamline its water methods approval programs.

EPA has held three public meetings to outline plans for method flexibility and for streamlining proposal and promulgation of new methods, and to elicit stakeholder views regarding these plans. EPA had compiled and evaluated stakeholder input received at the public meetings and has revised its approach to streamlining accordingly.

#### Agenda Topics

The purpose of the public meetings on 304(h) streamlining is to outline plans for method flexibility and for streamlining proposal and promulgation of new methods at 40 CFR Part 136 under Section 304(h) of the Clean Water Act, and to elicit stakeholder views regarding these plans. The following topics will be addressed at the public meetings:

- Increasing method flexibility to allow use of new technologies and to identify modifications that are acceptable within the scope of existing methods and do not require proposal of an alternate method
- Interpretation of flexibility in existing 40 CFR Part 136 methods
- Advantages and disadvantages of method flexibility (no flexibility, limited flexibility, and unlimited flexibility)
- Proposal to allow nearly unlimited "front-end" method modifications as long as the determinative technique is not changed and method performance is demonstrated to be equivalent
- Establishing standardized quality control (QC) and QC acceptance criteria to support determination of method equivalency
- Streamlining the method proposal process to take advantage of emerging analytical technologies in a timely manner
- Standardized format for preparing new methods

- 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