

**40 CFR Part 180**

[OPP-300383; FRL-4945-6]

RIN 2070-AB78

**Poly(phenylhexylurea), Cross-Linked; 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 poly(phenylhexylurea), cross-linked, when used as an inert ingredient (encapsulating agent) in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d) to replace the existing exemption from the requirement of a tolerance for residues of cross-linked polyurea-type encapsulating polymer under 40 CFR 180.1082. The Monsanto Co. requested this proposed regulation.

**DATES:** Written comments, identified by the document control number, [OPP-300383], must be received on or before June 2, 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, 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 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 [OPP-300383]. 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: Mary Waller, 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)-308-8811; e-mail:

Waller.Mary@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** The Monsanto Co., Suite 1100, 700 14th St., NW., Washington, DC 20005, submitted pesticide petition (PP) 4E04408 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(e)), propose to amend 40 CFR part 180 by replacing the existing exemption from the requirement of a tolerance for residues of cross-linked polyurea-type encapsulating polymer listed under 40 CFR 180.1082 with an exemption from the requirement of a tolerance for residues of poly(phenylhexylurea), cross-linked, when used as an inert ingredient (encapsulating agent) in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d).

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 poly(phenylhexylurea), cross-linked, 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. Poly(phenylhexylurea), cross-linked, conforms to the definition of a polymer given in 40 CFR 723.250(b)(11) and meets the following criteria that are used to identify low-risk polymers.

1. The minimum number-average molecular weight of poly(phenylhexylurea), cross-linked, is 36,000. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal tract. Chemicals not absorbed through skin or GI tract generally are incapable of eliciting a toxic response.

2. Poly(phenylhexylurea), cross-linked, is not a cationic polymer, nor is it reasonably expected to become a cationic polymer in a natural aquatic environment.

3. Poly(phenylhexylurea), cross-linked, does not contain less than 32.0 percent by weight of the atomic element carbon.

4. Poly(phenylhexylurea), cross-linked, contains as an integral part of its composition the atomic elements carbon, hydrogen, nitrogen, and oxygen.

5. Poly(phenylhexylurea), cross-linked, 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)(3)(ii).