

(i) Incorporation by reference.

(A) Laws of Minnesota for 1992, Chapter 575, section 29(b), enacted by the legislature and signed into law on April 29, 1992.

[FR Doc. 96-3789 Filed 2-20-96; 8:45 am]

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40 CFR Part 180

[OPP-300411; FRL-4995-9]

RIN 2070-AC78

Acrylate Polymers/copolymers; Exemptions From The Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This document establishes a generic exemption from the requirement of a tolerance for acrylate polymers and copolymers when used as inert ingredient in pesticide formulations applied on raw agricultural commodities. This tolerance exemption covers the acrylate polymers/copolymers which are intrinsically safe and already listed in the TSCA inventory or will meet the polymer tolerance exemption from requirements of premanufacturing notification. Polymers that are exempted can be used as dispensers, resins, fibers, and beads, as long as the fibers, beads and resins particle sizes are greater than 10 microns and insoluble in water. Polymers with high molecular weights (3,000 to 100,000 daltons) are generally not readily absorbed through the intact skin or intact gastrointestinal (GI) tract. Polymers with particle size greater than 10 microns are generally not readily absorbed by respiration. Chemicals not absorbed through the skin, GI tract, and respiratory system are generally incapable of eliciting a toxic response. This exemption pertains to the acrylate polymers/copolymers used as inert ingredient for sprayable and dispenser pesticide formulations that are used on food crops. Any acrylate polymers/copolymers used for encapsulating material must be cleared as an inert ingredient when used in pesticide formulations that are applied on food crops.

EFFECTIVE DATE: This regulation becomes effective February 21, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP OPP-300411], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW.,

Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300411]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this 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: Freshteh Toghrol, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor, Crystal Station 1, 2800 Crystal Drive, Arlington, VA 22202; (703) 308-7014, e-mail: toghrol.freshteh@epamail.epa.gov

SUPPLEMENTARY INFORMATION: In the November 15, 1995 Federal Register (PF-631; FRL-4971-5) EPA issued a notice of filing PP 5E4524 at the request of Russel Cook Associates, REDA Bldg., Suit 217, 401 S.E. Dewey, Bartlesville, OK 74005, on behalf of Biosys, by establishing an generic exemption from the requirement of a food tolerance for acrylate polymers and copolymers which fit the Toxic Substances Control Act (TSCA) definition of polymers which are intrinsically safe. This tolerance exemption covers the acrylate

polymers/copolymers that are already listed in the TSCA inventory or will meet the polymer tolerance exemption under 40 CFR 723.250 as amended on March 29, 1995.

I. Background

Inert ingredients are substances, other than the active ingredient, which are intentionally included in a pesticide product as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients: solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers, copolymers, 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" does not imply lack of toxicity; the ingredient may or may not be chemically active.

For the purposes of this exemption, acrylate polymers/copolymers used as inert ingredients in an end-use formulations must meet the definition for a polymer as given in 40 CFR 723.250 (b), are not automatically excluded by 40 CFR 723.250 (d), and meet the tolerance exemption criteria 40 CFR 723.250 (e)(1), 40 CFR 723.250 (e)(2) or 40 CFR 723.250(e)(3). Therefore, acrylate polymers and copolymers that are already listed in the TSCA inventory or will meet the polymer tolerance exemption under 40 CFR 723.250 as amended on March 29, 1995 are covered by this exemption.

The Agency believes that the acrylate polymers/copolymers meeting the criteria noted above and outlined as follows will present minimal, if any risk to human health when used as inert ingredients in pesticide formulations applied to growing raw agricultural commodities.

1. The acrylate polymer/copolymers minimum molecular weight may range from 3,000 to greater than 100,000 daltons as are established under 40 CFR 180.1112 and 40 CFR 180.1001(c). Substances with high molecular weights (greater than 3,000 daltons to 100,000 daltons) are generally not readily absorbed through intact skin or intact gastrointestinal (GI) tract, respectively. Chemicals not absorbed through the skin or GI tract are generally incapable of eliciting a toxic response.

2. These acrylate polymers/copolymers can be used as dispensers, fiber, resin, and beads, as long as the fiber, bead and resin sizes are well over 10 microns and are insoluble in water. Acrylate polymers/copolymers of high molecular weight with well over 10

micron particle size are generally not absorbed by inhalation.

3. The acrylate polymers and copolymers that are exempted are not cationic or are not anticipated to be converted (by degradation or decomposition) to a cationic state.

4. Acrylate and methacrylate are listed as high-concern reactive functional groups. Therefore, to meet the exemption criteria § 723.250 (e)(1)(ii)(C) the minimum permissible combined functional group equivalent weight is 5,000 daltons, when a number-average molecular weight (NAVG MW) of a polymer is greater than 1,000 and lower than 10,000 daltons. Additionally, in this range of molecular weight (greater than 1,000 and less than 10,000 daltons) the polymer must contain less than 10 percent oligomer content of molecular weight below 500 daltons and less than 25 percent oligomer content of molecular weight below 1,000 daltons.

5. The polymers with NAVG MW equal to or greater than 10,000 daltons (§ 723.250 (e)(2)), the polymer must contain less than 2 percent oligomer content of molecular weight below 500 daltons and must not exceed 5 percent oligomer content of molecular weight below 1,000 daltons. Water soluble polymers in this molecular weight range are excluded from exemption under § 723.250(d), with no restriction regarding the functional group.

6. For a polymer or polyester to meet the exemption criteria § 723.250 (e)(3), each feedstock, monomer or reactant in the chemical identity of the polymers at greater than 2 percent composition must be on the list. Excluded from this exemption would be biodegradable polyesters and highly water-absorbing polyester with NAVG MW greater than 10,000 daltons.

7. The acrylate polymers and copolymers must contain as an integral part of their composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, sulfur, or silicon (40 CFR § 723.250(d)(3)). A previous requirement in the 1984 rule stated that an eligible polymer contain at least 32 percent carbon. This requirement was deleted since cases reviewed to date contain less than 32 percent carbon, have either received low concern rating, or have been excluded for other reasons.

8. Certain other elements are permitted in the acrylate polymers and copolymers as an integral part of the polymers, except if present as impurities. The allowed elements (40 CFR § 723.250(d)(3)), in addition to the atomic elements carbon, hydrogen, nitrogen, oxygen, sulfur, silicon (C, H, N, O, S, Si) are: fluorine, chlorine, bromine, and iodine (F, Cl, Br, and I)

when covalently bonded to carbon, and monoatomic counterions such as chlorine, bromide, and iodide (Cl⁻, Br⁻, I⁻), sodium, magnesium, aluminum, potassium, and calcium (Na⁺, Mg²⁺, Al³⁺, K⁺, and Ca²⁺). Less than 0.2 percent weight total (in any combination) of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium (Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn, and Zr) are permitted. No other elements are permitted except as impurities.

9. The acrylate polymers and copolymers are not biopolymers, they are synthetic equivalents of a biopolymer, or derivatives or modifications of a biopolymer that is substantially intact. These polymers do not contain reactive functional groups that are anticipated to be converted to a cationic state.

10. The acrylate polymers and copolymers are not designated or reasonably anticipated to be substantially degraded, decomposed, or depolymerized. Based upon the above information and review of its use, EPA has found that when used in accordance with good agricultural practice, these inert ingredients are useful and a tolerance is not necessary to protect public health. Therefore, EPA proposes that the exemptions from the requirement of tolerance be established for acrylate polymers/copolymers used as inert ingredient for pesticide formulations.

II. Filing of Objections

Any person adversely affected by this regulation may, within 30 days after publication of this document, file written objections and/or request a hearing with the Hearing Clerk and a copy submitted to the OPP docket for this rulemaking at the addresses given above.

III. Regulatory Assessment Requirement

A. Executive Order 12866

The Office of Management and Budget has exempted this notice from the requirement of section 3 of Executive Order 12866.

B. Regulatory Flexibility Act

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).

Dated: February 7, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is 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. By adding new § 180.1162 to subpart D to read as follows:

§ 180.1162 Acrylate Polymers and Copolymers; exemption from the requirement of a tolerance.

(a) Acrylate polymers and copolymers are exempt from the requirement of a tolerance when used as inert ingredients in pesticidal formulations applied to growing, raw agricultural commodities. This tolerance exemption covers the acrylate polymers/copolymers that are intrinsically safe and already listed in TSCA inventory or will meet the polymer tolerance exemption from requirements of premanufacturing notification under 40 CFR 723.250. Polymers exempted can be used as dispensers, resins, fibers, and beads, as long as the fibers, beads and resins particle sizes are greater than 10 microns and insoluble in water. This exemption pertains to the acrylate polymers/copolymers used as inert ingredients for sprayable and dispenser pesticide formulations that are applied on food crops. Any acrylate polymers/copolymers used for encapsulating material must be cleared as an inert ingredient when used in pesticide formulation applied on food crops.

(b) For the purposes of this exemption, acrylate polymers/copolymers used as inert ingredients in an end-use formulation must meet the definition for a polymer as given in 40 CFR 723.250(b), are not automatically excluded by 40 CFR 723.250(d), and meet the tolerance exemption criteria in 40 CFR 723.250(e)(1), 40 CFR 723.250 (e)(2) or 40 CFR 723.250(e)(3). Therefore, acrylate polymers and copolymers that are already listed in the TSCA inventory or will meet the polymer tolerance exemption under 40 CFR 723.250 as amended on March 29, 1995 are covered by this exemption.

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