

permitting requirements in Section 21 of the WAQSR to specify guidelines for best available control technology for new large mining operations. The Governor of Wyoming submitted revisions to Section 21 of the WAQSR, "Permit requirements for construction, modification, and operation," on November 12, 1993. Last, the Governor of Wyoming submitted revisions to Section 24 of the WAQSR, "Prevention of Significant Deterioration," on March 14, 1995.

(i) Incorporation by reference.

(A) Revisions to Section 25 of the WAQSR, "Sweetwater County Non-Attainment Area Particulate Matter Regulations," subsection c.(2), effective September 13, 1982.

(B) Revisions to Section 21 of the WAQSR, "Permit requirements for construction, modification, and operation," subsection c.(5), effective May 10, 1985.

(C) Revisions to Section 21 of the WAQSR, "Permit requirements for construction, modification, and operation," subsection (a)(iv), effective October 26, 1993.

(D) Revisions to Section 24 of the WAQSR, "Prevention of Significant Deterioration," subsections (a)(xix), (b)(iv), and (b)(xii)(H), effective February 13, 1995.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300848; FRL-6077-7]

RIN 2070-AB78

Methacrylic Copolymer; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the methacrylic copolymer when applied to growing crops, to raw agricultural commodities after harvest or to animals when applied/used as an inert ingredient in the pesticide formulations. Rohm and Haas Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to

establish a maximum permissible level for residues of methacrylic copolymer.

DATES: This regulation is effective May 19, 1999. Objections and requests for hearings must be received by EPA on or before July 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300848], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees) and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300848], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300848]. 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.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 713J, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703-308-8380, gandhi.bipin@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 20, 1998 (63 FR 64478) (FRL-6042-4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) announcing the filing of a pesticide tolerance petition (PP 8E4952) by Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399. This notice included a summary of the petition prepared by the petitioner Rohm and Haas Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of methacrylic copolymer.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue..."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered

available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by methacrylic copolymer are discussed in this unit:

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 compounds 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. Alkyl (C₁₂-C₂₀) Methacrylate copolymer conforms to the definition of a polymer given in 40 CFR 723.250 (b) and meet the following criteria that are used to identify low risk polymers:

1. Alkyl (C₁₂-C₂₀) Methacrylate copolymer is not a cationic polymer, nor is it capable of becoming a cationic polymer in the natural aquatic environment.

2. Alkyl (C₁₂-C₂₀) Methacrylate copolymer contains as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. Alkyl (C₁₂-C₂₀) Methacrylate copolymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250 (d)(2)(iii).

4. Alkyl (C₁₂-C₂₀) Methacrylate copolymer is not designed, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize.

5. Alkyl (C₁₂-C₂₀) Methacrylate copolymer 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. Alkyl (C₁₂-C₂₀) Methacrylate copolymer is not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.

7. The minimum number-average molecular weight of Alkyl (C₁₂-C₂₀) Methacrylate copolymer is ~ 15,000 daltons. 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 (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. Alkyl (C₁₂-C₂₀) Methacrylate copolymer has a minimum number average molecular weight of ~ 15,000 and contains less than 2% oligomeric material below molecular weight 500 and less than 5 percent oligomeric material below 1,000 molecular weight.

9. Alkyl (C₁₂-C₂₀) Methacrylate copolymer does contain aliphatic ester groups as reactive functional groups. However, these reactive groups are not intended or reasonably anticipated to undergo further reactions under usual environmental conditions.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* Alkyl (C₁₂-C₂₀) Methacrylate copolymer is not absorbed through the intact gastrointestinal tract and is considered incapable of eliciting a toxic response.

2. *Drinking water exposure.* Based upon the aqueous insolubility of Alkyl (C₁₂-C₂₀) Methacrylate copolymer, there is no reason to expect human exposure to residues in drinking water.

B. Other Non-Occupational Exposure

Typical use of Alkyl (C₁₂-C₂₀) Methacrylate copolymer is in the oil industry as a wax and viscosity modifier at very low use rates. In these uses the primary exposure rate would be dermal, however, Alkyl (C₁₂-C₂₀) Methacrylate copolymer with a molecular weight significantly greater than 400 is not absorbed through the intact skin.

IV. Cumulative Effects

There is data to support cumulative risk from Alkyl (C₁₂-C₂₀) Methacrylate copolymer, since polymers 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 (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. Therefore, there is no reasonable expectations of

increased risk due to cumulative exposure.

V. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* Alkyl (C₁₂-C₂₀) Methacrylate copolymer causes no safety concerns because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also, there are no additional pathways of exposure (non-occupational, drinking water, etc.) where there would be additional risk.

2. *Infants and children.* Alkyl (C₁₂-C₂₀) Methacrylate copolymer causes no additional concern to infants and children because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also there are no additional pathways of exposure (non-occupational, drinking water, etc.) where infants and children would be at additional risk.

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to methacrylic copolymer residues. Accordingly, EPA finds that exempting methacrylic copolymer from the requirement of a tolerance will be safe.

VI. Other Considerations

A. Endocrine Disruptors

There are no evidence that Alkyl (C₁₂-C₂₀) Methacrylate copolymer is an endocrine disrupter, where as 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 (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

B. Analytical Method(s)

Rohm and Haas has petitioned that Alkyl (C₁₂-C₂₀) Methacrylate copolymer be exempt from the requirement of a tolerance based upon the low risk polymer as per 40 CFR 723.250. Therefore, an analytical method to determine residues of Alkyl (C₁₂-C₂₀) Methacrylate copolymer in raw agricultural commodities has not been proposed.

C. Codex Maximum Residue Level

The Agency is not aware of any country requiring a tolerance for Alkyl (C₁₂-C₂₀) Methacrylate copolymer. Nor have there been any CODEX

Maximum Residue Levels (MRL's) established for any food crops at this time.

VII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 19, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the "ADDRESSES" section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40

CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300848] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the

paper record maintained at the Virginia address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not

issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes

substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 30, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, 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. 321q, 346a and 371.

2. In § 180.1001, the tables in paragraphs (c) and (e) are amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

| Inert ingredients | Limits | Uses |
|---|--------|-------|
| Methacrylic Copolymer (CAS Reg. No. 63150-03-8), minimum number average molecular weight (in amu) 15,000. | | Inert |

* * * * *

(e) * * *

| Inert ingredients | Limits | Uses |
|---|--------|-------|
| Methacrylic Copolymer (CAS Reg. No. 63150-03-8), minimum number average molecular weight (in amu) 15,000. | | Inert |