

with none and/or one or more of the following monomers: Acrylamide, N-methyl acrylamide, N-octylacrylamide, maleic anhydride, maleic acid, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate, and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine, and/or triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1,200 (also referred to as modified acrylic polymers) were previously determined to meet the set of criteria identifying categories of polymers that should present minimal or no risk (66 FR 53720; October 24, 2001).

These criteria of 40 CFR 723.250 would continue to be met with the addition of N,N-dimethyl acrylamide as one of the acrylic polymer monomers. Therefore, based on its conformance to the criteria for a polymer to be considered low risk under 40 CFR 723.250, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to modified acrylic polymers.

V. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that modified acrylic polymers could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average molecular weight of modified acrylic polymers is greater than 1,200 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since modified acrylic polymers conform to the criteria that identify a low risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

VI. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of a particular chemical's residues and "other substances that have a common mechanism of toxicity." The Agency has not made any conclusions as to whether or not modified acrylic polymers share a common mechanism of toxicity with any other chemicals. However, modified

acrylic polymers conform to the criteria that identify a low risk polymer. Due to the expected lack of toxicity based on the above conformance, the Agency has determined that a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population

Based on the conformance to the criteria used to identify a low risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of modified acrylic polymers.

VIII. Determination of Safety for Infants and Children

FFDCA section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of modified acrylic polymers, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Other Considerations

A. Endocrine Disruptors

There is no available evidence that modified acrylic polymers is an endocrine disruptor.

B. Existing Exemptions from a Tolerance

An exemption from the requirement of a tolerance exists (see 40 CFR 180.960) for acrylic polymers composed of one or more of the following monomers: Acrylic acid, methyl acrylate, ethyl acrylate, butyl acrylate, hydroxyethyl acrylate, hydroxypropyl acrylate, hydroxybutyl acrylate, carboxyethyl acrylate, methacrylic acid, methyl methacrylate, ethyl methacrylate, butyl methacrylate, isobutyl methacrylate, hydroxyethyl methacrylate, hydroxypropyl methacrylate, hydroxybutyl methacrylate, lauryl methacrylate, and stearyl methacrylate with none and/or one or more of the following monomers: Acrylamide, N-methyl acrylamide, N-octylacrylamide, maleic anhydride, maleic acid, monoethyl maleate, diethyl maleate, monooctyl maleate, dioctyl maleate, and their corresponding sodium, potassium, ammonium, isopropylamine, triethylamine, monoethanolamine, and/or triethanolamine salts; the resulting

polymer having a minimum number average molecular weight (in amu), 1,200.

C. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for modified acrylic polymers nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

X. Conclusion

Accordingly, EPA finds that exempting residues of modified acrylic polymers from the requirement of a tolerance will be safe.

XI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0079 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 2, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR