PART 180—[AMENDED]

§ 180.675 Tolfenpyrad; tolerances for residues.

(a) Section 18 emergency exemptions.

Time-limited tolerances specified in the following table are established for residues of tolfenpyrad, (4-chloro-3-ethyl-1-methyl-N-[4-(p-tolyl oxy)benzyl]pyrazole-5-carboxamide, including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only tolfenpyrad, 4-chloro-3-ethyl-1-methyl-N-[4-(p-tolyl oxy)benzyl]pyrazole-5-carboxamide. The tolerances expire on the date specified in the table.

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
<th>Expiration date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetable, fruiting, group</td>
<td>8–10</td>
<td>0.70</td>
</tr>
</tbody>
</table>

(b) Section 18 emergency exemptions.

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0330 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 5, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0330, by one of the following methods:

- Federal eRulemaking Portal: http://www.epa.gov/eregulations. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

II. Background and Statutory Findings

In the Federal Register of July 20, 2016 (81 FR 47150) (FRL–9948–45), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–10925) filed by...
Consistent with FFDCA section 408(b)(2)(D), 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. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Acrylic acid-butyl acrylate-styrene copolymer conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.
3. The polymer 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)(ii).
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.
7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF₃⁻ or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer’s number average MW of 5,200 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, acrylic acid-butyl acrylate-styrene copolymer meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to acrylic acid-butyl acrylate-styrene copolymer.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that acrylic acid-butyl acrylate-styrene copolymer 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 MW of acrylic acid-butyl acrylate-styrene copolymer is 5,200 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since acrylic acid-butyl acrylate-styrene copolymer conforms 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.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

EPA has not found acrylic acid-butyl acrylate-styrene copolymer to share a common mechanism of toxicity with any other substances, and acrylic acid-butyl acrylate-styrene copolymer does not appear to produce a toxic metabolite produced by other substances. For purposes of this tolerance action, EPA has assumed that acrylic acid-butyl acrylate-styrene copolymer does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

VI. Additional Safety Factor for the Protection of Infants and Children

EPA established an exemption from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.
addition 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 acrylic-acid-butyl acrylate-styrene copolymer, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

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, including infants and children, from aggregate exposure to residues of acrylic acid-butyl acrylate-styrene copolymer.

VIII. Other Considerations

A. 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.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acrylic acid-butyl acrylate-styrene copolymer.

IX. Conclusion

Accordingly, EPA finds that exempting residues of acrylic acid-butyl acrylate-styrene copolymer from the requirement of a tolerance will be safe.