

# Firelce

## Classified as Inert per EPA and USDA

Firelce products are manufactured using Acrylic Acid and Acrylate Copolymers. Secondary research produced results that substantiate the claim that the ingredients that comprise Firelce products are classified as inert ingredients. In addition, Alganesh Debesai Ph. D, Inert Assessment Branch of the EPA in Washington DC, expressed that "Acrylic acid/Acrylamide copolymers have an exemption from a tolerance in 40 CFR180.960 (polymer exemption) with a minimum number average molecular weight (in amu), 1,200".

The following information can be found on the U.S. Environmental Protection Agency (EPA) and the United States Department of Agriculture (USDA) websites.

### Acrylic Acid

#### C. Exposures and Risks

1. From food and feed uses, drinking water, and non-dietary exposures. For the purposes of assessing the potential dietary exposure, EPA considered that these tolerance exemptions could be present in all raw and processed agricultural commodities and drinking water and that non-occupational, non-dietary exposure was possible. EPA concluded that, based on these chemical's categorization as a polymer conforming to the definition of a polymer under 40 CFR 723.250(b) that also meet the criteria used to identify low-risk polymers, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable.

2. Cumulative exposure to substances with common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

In the case of acrylic acid, styrene, <greek-a>-methyl styrene copolymer, ammonium salt; and styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer, the lack of expected toxicity of these substances based on its conformance to the definition of polymers as given in 40 CFR 723.250(b) as well as the criteria that identify low-risk polymers results in no expected cumulative effects; a cumulative risk assessment is therefore not necessary.

#### D. Aggregate Risks and Determination of Safety for U.S. Population

Based on these chemical's conformance to the definition of a polymer given in 40 CFR 723.250(b) as well as the criteria that are used to identify low-risk polymers, EPA concludes that there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to acrylic acid, styrene, <greek-a>-methyl styrene copolymer, ammonium salt; and styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer. EPA believes these compounds present no

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dietary risk under reasonably foreseeable circumstances.

#### E. Aggregate Risks and Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a Margin of Exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Because EPA has concluded these substances pose minimal or no risk it did not use a margin of safety analysis for assessing risk to the general population of this compound. For the same reason, application of an additional margin of safety is unnecessary.

#### V. Other Considerations

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that analytical methods are not required for enforcement purposes for acrylic acid, styrene, <greek-a>-methyl styrene copolymer, ammonium salt; and styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer.

There are no Codex Alimentarius Commission (Codex), Canadian or Mexican, residue limits for acrylic acid, styrene, <greek-a>-methyl styrene copolymer, ammonium salt; and styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer.

#### VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of acrylic acid, styrene, <greek-a>-methyl styrene copolymer, ammonium salt; and styrene, 2-ethylhexyl acrylate, butyl acrylate copolymer. (Environmental Protection Agency, 1998)

#### **Acrylamide Copolymers**

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 acrylamide-acrylate-acrylic acid copolymer, crosslinked, will need to be submitted. The rationale for this decision is described below.

In the case of certain chemical substances that are defined as

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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. Acrylamide acrylate-acrylic acid copolymer, cross-linked, conforms to the definition of a polymer 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 acrylamide acrylate-acrylic acid copolymer, crosslinked, is estimated to be approximately 1,000,000. 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. Acrylamide acrylate-acrylic acid copolymer, crosslinked, is not a cationic polymer, nor is it reasonably expected to become a cationic polymer in a natural aquatic environment.

3. Acrylamide acrylate-acrylic acid copolymer, crosslinked, does not contain less than 32.0 percent by weight of the atomic element carbon.

4. Acrylamide acrylate-acrylic acid copolymer, crosslinked, contains as an integral part of its composition the atomic elements carbon, hydrogen, nitrogen, and oxygen.

5. Acrylamide acrylate-acrylic acid copolymer, crosslinked, 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).

6. Acrylamide acrylate-acrylic acid copolymer, crosslinked, is not a biopolymer, a synthetic equivalent of a biopolymer, or a derivative or modification of a biopolymer that is substantially intact.

7. Acrylamide acrylate-acrylic acid copolymer, crosslinked, is not manufactured from reactants containing, other than impurities, halogen atoms or cyano groups.

8. Acrylamidem acrylate-acrylic acid copolymer, crosslinked, does not contain a reactive functional group that is intended

or reasonably expected to undergo further reaction.

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9. Acrylamide acrylate-acrylic acid copolymer, crosslinked, is neither designed nor reasonably expected to substantially degrade, decompose, or depolymerize.

Based on the information above and review of its use, EPA has found

that, when used in accordance with good agricultural practice, this ingredient is useful, and a tolerance is not necessary to protect the public health. (Environmental Protection Agency, 1994)

#### **Conclusion:**

Based on collected secondary data from the U.S. Environmental Protection Agency and the United States Department of Agriculture the components; Acrylic Acid and Acrylate Copolymers that are used to manufacture Firelce products are inert.