Registration Review Proposed Process

Biochemical Pesticide Case Study

PPDC Workgroup Meeting
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September 28, 2004
Biochemical Pesticide Case Background

Regulatory Background

• First Registered: 1970s
• RED: 1990s
• In the mid-1980s, EPA compiled the scientific information and EPA policies on the regulation of pheromones and other semiochemicals
• This compilation provided the basis for regulatory relief based on the low toxicity of the class of compounds and low exposure when used in a trap and/or at low application rates
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Use Profile

- While use sites include what would be considered food or feed sites, the use pattern is classified as Terrestrial Non-Food Crop. The chemical is used in a trap and not applied directly to food or feed.

- **Terrestrial Non-Food Crop**: agricultural crops, soils and vegetables, orchards and deciduous fruit trees, grapes and other food commodities

- **Terrestrial Non-Food & Outdoor Residential**: ornamental shade trees, ornamental herbaceous plants, ornamental non-flowering plants, ornamental woody shrubs and vines
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Nature of Biochemical Pesticides

• Natural substances, or synthetically derived compounds that are structurally and functionally equivalent

• Non-toxic to the target pest and generally non-toxic to other organisms

• Typically used at low application rates

• Compounds do not have toxic endpoints for Tier I studies, and therefore do not trigger higher tiered studies such as sub-chronic or chronic studies.
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Hazard Profile For Human Health

• Mammalian toxicology database is complete and sufficient to characterize the toxicity and assess the risk of the chemical
• Very low acute toxicity for all routes of exposure
• Exposure is limited because of use pattern (used in traps)
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Hazard Profile For Ecological Effects, Exposure and Risks

• Effects to non-target organisms are not expected because mode of action is specific to target pest

• Exposures to birds, fish, or aquatic organisms are not expected because the chemical is enclosed in a dispenser within a trap
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**Occupational/Residential Exposure & Risks**

- No occupational studies triggered due to lack of significant toxicological concerns
- Limited exposure if label instructions are followed
  - The chemical is used in small quantities and enclosed in a retrievable trap resulting in very low exposure
  - Release rate from the trap is comparable to the release from insect pest during peak infestation periods
  - Individuals setting up trap are exposed to higher concentrations than emitted from the trap
  - There is no toxicological concern to the user if a trap is only set up once a year
PPDC Workgroup Response

Discussion

Opinion:

• Easy Off?
• Need New Risk Assessment(s)?
• Need New Risk Assessment(s), New Data?