

US EPA ARCHIVE DOCUMENT

Registration Review Proposed Process

Biochemical Pesticide Case Study

PPDC Workgroup Meeting

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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

Biochemical Pesticide Case Background

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

Biochemical Pesticide Case Background

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?