Registration Review Proposed Process

Antimicrobial Pesticide Case Study

PPDC Workgroup Meeting

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Antimicrobial Pesticide Case Background

Regulatory History

• First Registered: Mid-1980s
• RED: Mid 1990s, Pre-FQPA
• Pesticide Type:
  • Disinfectant
  • Algaecide
  • Bacteriostat regulator
  • Microbiocide/Microbiostat
  • Fungicide/Fungistat
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Use Profile

- **Indirect food uses**: Pulp/paper, dishwashing liquids (products touch food-contact surfaces); has FDA 409 clearance

- **Non-food indoor uses**: Cleaners, laundry detergents, textiles/fabrics, consumer/institutional products, paints, oil field systems, air washer systems, air conditioning/humidifying systems, cooling water systems, papermills, absorbent clays, metal working fluids, printing inks, adhesives

- **Outdoor uses**: Open industrial waste water systems, sewage settling ponds, sewage systems, ground wood/saw dust (as an absorbent)
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Last Major Assessments

• Registration Eligibility Decision (RED): Mid 1990s, Pre-FQPA
  • Toxicology Assessment (complete database)
  • Occupational Assessment (complete assessment at time, not all application methods evaluated, exposure database has significant limitations)
• Residential Assessment (very limited, children not assessed, not all uses evaluated; lacked residential Standard Operating Procedures)
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Last Major Assessments Cont.

- Ecological Toxicity Assessment (hazard only, no plant data or chronic fish or invertebrate data)
- Environmental Fate Assessment
- Ecological risks not estimated (no Risk Quotients or levels of concern estimated; not standard practice at that time)
- No dietary, drinking water or aggregate assessments (no SOP’s at that time)

- Recent Heating Ventilation and Air-Conditioning (HVAC) Assessment
  - Occupational Assessment
  - Residential Assessment
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Hazard Profile For Human Health

• High to moderate toxicity for acute oral, dermal, eye and skin irritation

• Severe gastrointestinal irritant following repeated oral exposure

• Developmental and reproductive effects only in the presence of maternal toxicity

• Negative for genotoxicity

• No evidence of carcinogenicity in two chronic rodent studies

• No reported human incidence data
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Occupational/Residential Exposure & Risks

• No risks of concern for all worker scenarios in RED after mitigation measures

• No risks of concern for residential handlers of paints or adhesives using a paintbrush

• No risks of concern from HVAC use
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Environmental Fate

• Stable to hydrolysis under normal conditions; may rapidly hydrolyze at warmer temperature and/or high pH

• Parent compound expected to have a relatively short half-life in the environment (photoreactive in water)

• The major degradate has a much longer half-life than the parent raising chronic concerns

• Unlikely to bioaccumulate
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Hazard Profile for Ecological Effects, Exposure, & Risk

• Only have acute studies
• Practically non-toxic to slightly toxic to birds
• Slightly to moderately toxic to freshwater fish and terrestrial invertebrates
• Moderately to highly toxic to estuarine/marine invertebrates
• Slightly toxic to estuarine/marine fish
Antimicrobial Pesticide Case

Background

Hazard Profile for Ecological Effects, Exposure, & Risk (cont.)

- Exposure to non-target aquatic organisms is expected from industrial discharges to surface water
- Discharges may adversely affect aquatic life. Chronic effects to invertebrates are also possible due to slow degradation of degradates
- In the RED, deferred to Office of Water, since aquatic environments are regulated under National Pollution Discharge Elimination System (NPDES) permitting program (current practice in mid-1990s).
PPDC Workgroup Response

Discussion

Opinion:
- Easy Off?
- Need New Risk Assessment(s)?
- Need New Risk Assessment(s), New Data?