Biopesticides Registration Improvement Course

Biochemical Pesticides Human Health Assessments

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Overview for Human Health Assessments
40 CFR 158.2050

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes
		Food	Nonfood	MP	EP	
Tier I						
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI and EP	1
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	2, 4
none	Hypersensitivity incidents	R	R	All	All	5
Subchronic Testing						
870.3100	90-day oral (one species)	R	CR	TGAI	TGAI	6
870.3250	90-day dermal - rat	CR	CR	TGAI	TGAI	7
870.3465	90-day inhalation - rat	CR	CR	TGAI	TGAI	8
Developmental Toxicity						
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	9
Mutagenicity Testing						
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	10
870.5300 870.5375	*In vitro* mammalian cell assay	R	CR	TGAI	TGAI	10, 11

Overview for Human Health Assessments

- Data required for the active ingredient (TGAI) and the manufacturing-use product (MP) and/or end-use product (EP).
- Tier 1 data requirements must be addressed (unless specified in test notes).
- Tier 2 and Tier 3 studies may be required if triggered from results of Tier 1 studies.

Resources for Human Health Assessments

- US Data Requirements in 40 CFR 158.2050
  - Online CFR: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=b321291a0d624270b7dd6acd0a083426&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl
  - Guidelines: http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm
- Biopesticide active ingredient information
  - http://www.epa.gov/pesticides/biopesticides/ingredients/index.htm
- Registration Review documents and decisions
  - http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm
- Information on satisfying data requirements through scientific literature and rationale is available from EPA upon request.

Commonly Seen Problems / Issues

Commonly Seen Problems / Issues

- Rationales for addressing data requirements
  - Difference between rationale and waivers
  - Address toxicity of inerts and mixtures
  - Generally, GRAS status, use in cosmetics, etc. is not sufficient
  - Cannot use acute toxicity data to satisfy subchronic/chronic data requirements
  - Address each data requirement individually

Commonly Seen Problems / Issues

- Exposure discussions in scientific rationale
  - Submit information on potential exposure scenarios (no blanket “lack of exposure” statements)
  - Discuss all potential user exposure, including occupational exposure
  - Pay close attention to the data table test notes
  - Discuss pesticidal exposure contributions to overall exposure
- Bridging data
  - Cannot bridge “up”

Commonly Seen Problems / Issues

- References/Citations
  - Submit all referenced studies
  - Summarize submitted literature
  - Provide scientifically credible data to validate statements
  - Use scientifically credible sources

Now that you are all experts in US human health risk assessments, are you ready to play….

Let's Make a Registration!

1. **Select the best rationale below for satisfying the 90-day dermal toxicity data requirement.**

   a. "I rub it on myself all the time, and I'm fine!"

   b. "There were no toxicity studies available in the literature."

   c. "A study conducted on rats in 2002 by John Doe et.al. resulted in a LOEL of 500 mg/kg bw and a NOEL of 100 mg/kg bw."

2. In which of the following statements is "waiver request" used properly?

a. Squashem, Inc. would like a **waiver request** for acute dermal toxicity because the active ingredient is commonly found in cosmetic products.

b. Bugs Be Gone, LLC. would like a **waiver request** for acute oral toxicity because there has been no reported toxicity for the active ingredient and it is ubiquitous in the environment.

c. No Fungus Amungus, Inc., would like a **waiver request** for primary eye irritation because the active ingredient has a pH of 1. According to the test note in 40 CFR 158.2050, this data requirement is not required for substances with a pH ≤ 2.

3. This presentation was:

a. Really good.

b. Great.

c. The best.