

40 C.F.R. § 158.2050

Biochemical pesticides human health assessment data requirements table.

- (a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the biochemical human health assessment data requirements for a particular biochemical pesticide product.
- (2) The data in this section are not required for straight chain lepidopteran pheromones when applied up to a maximum use rate of 150 grams active ingredient/acre/year.
- (b) *Use patterns.* (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.
- (2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use; aquatic nonfood residential use; aquatic nonfood outdoor use; aquatic nonfood industrial use; greenhouse nonfood crop use; forestry use; residential outdoor use; residential indoor use; indoor food use; indoor nonfood use; indoor medical use.
- (c) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; Residue of concern = the active ingredient and its metabolites, degradates, and impurities of toxicological concern; All = All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:
- (d) *Table.* The following table shows the data requirements for biochemical pesticides human health assessment. The test notes are shown in paragraph (e) of this section.

Table—Biochemical Pesticides Human Health Assessment Data Requirements

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	<i>In vitro</i> mammalian cell assay	R	CR	TGAI	TGAI	10, 11
Tier II						
Mutagenicity Testing (<i>In vivo</i> cytogenetics)						
870.5385 870.5895	<i>In vivo</i> Mammalian Cytogenetics	CR	CR	TGAI	TGAI	13
Developmental Toxicity						
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	9
Special Tests						
880.3550	Immunotoxicity	CR	CR	TGAI	TGAI	12, 13
Applicator/User Exposure						
875.1100	Dermal outdoor exposure	CR	CR	TGAI	TGAI	15
875.1200	Dermal indoor exposure	CR	CR	TGAI	TGAI	15
875.1300	Inhalation outdoor exposure	CR	CR	TGAI	TGAI	15
875.1400	Inhalation indoor exposure	CR	CR	TGAI	TGAI	15
875.1500	Biological monitoring	CR	CR	TGAI	TGAI	15
Tier III						
Chronic Testing/Special Testing						

880.3800	Immune response	CR	CR	TGAI	TGAI	14
870.3800	Reproduction and fertility effects	CR	CR	TGAI	TGAI	16
870.4100	Chronic oral - rodent and nonrodent	CR	CR	TGAI	TGAI	17
870.4200	Carcinogenicity - two species - rat and mouse preferred	CR	CR	TGAI	TGAI	18
870.5380	Mammalian spermatogonial chromosome aberration test	CR	CR	TGAI	TGAI	19
Special Testing						
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	20

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