
40 C.F.R. § 158.2230

Toxicology.

- (a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (g) of this section to determine the toxicology data requirements for an antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (h) of this section.
- (b) *Uses.* The applicant for registration must first determine whether the use is likely to result in pesticide residues in food or water and therefore consult the “Food Use” columns of the table in paragraph (g) of this section. Generally, if the residues of the antimicrobial result from an application to a surface or if incorporated into a material that may come into contact with food or feed, and residues may be expected to transfer to such food or feed, then the “Indirect Food Uses” columns is to be consulted.
- (c) *Tiering of data requirements.* Applicants for registration of antimicrobials may perform tests in a tiered fashion. After the initially required tests are conducted, additional testing may be required if results of the initial tests trigger the need for additional data. Conditions that trigger the need for additional data are given in the test notes in paragraph (h) of this section.
- (d) *200 parts per billion (ppb).* The 200 ppb level was originally used by the Food and Drug Administration with respect to the concentration of residues in or on food for tiering of data requirements for indirect food use biocides. The Agency has also adopted this same residue level for determining toxicology data requirements for indirect food uses of antimicrobial pesticides. The 200 ppb level is the concentration of antimicrobial residues in the total estimated daily dietary intake.
- (e) *Use of OSHA standards.* If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration (OSHA standards), provide adequate protection for a particular pesticide or a particular use pattern, additional toxicity data may not be required for that pesticide or the use pattern.
- (f) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled; Choice = choice of several test substances depending on studies required.
- (g) *Antimicrobial toxicology data requirements table.* The following table shows the data requirements for toxicology. The test notes applicable to the data requirements in this table appear in paragraph (h) of this section.

Table—Antimicrobial Toxicology Data Requirements

Guideline No.	Data requirement	Food uses			Nonfood uses		Test substance		Test note No.
		Direct food uses	Indirect food uses (>200 ppb)	Indirect food uses (≤200 ppb)	Swimming pools, aquatic areas, wood preservatives, metal working fluids	All other nonfood uses	MP	EP	
Acute Testing									
870.1100	Acute oral toxicity—rat	R	R	R	R	R	MP and TGAI	EP and TGAI	1, 2
870.1200	Acute dermal toxicity	R	R	R	R	R	MP and TGAI	EP and TGAI	1, 2, 3
870.1300	Acute inhalation toxicity—rat	R	R	R	R	R	MP and TGAI	EP and TGAI	2, 4
870.2400	Primary eye irritation—rabbit	R	R	R	R	R	MP and TGAI	EP and TGAI	1, 2, 3
870.2500	Primary dermal irritation	R	R	R	R	R	MP and TGAI	EP and TGAI	1, 2, 3
870.2600	Dermal sensitization	R	R	R	R	R	MP and TGAI	EP and TGAI	1, 2, 3, 5
870.2600	Acute neurotoxicity—rat	R	R	CR	R	CR	TGAI	TGAI	6, 11
Subchronic Testing									
870.3100	90-Day oral toxicity—rodent	R	R	R	R	CR	TGAI	TGAI	8, 9, 15, 38
870.3150	90-Day oral toxicity—nonrodent	R	R	CR	R	CR	TGAI	TGAI	10, 15
870.3200	21/28-Day dermal toxicity	CR	CR	CR	CR	CR	TGAI	EP and TGAI	12, 13

870.3250	90-Day dermal toxicity	CR	CR	CR	CR	CR	TGAI	EP and TGAI	7, 13, 14, 15
870.3465	90-Day inhalation toxicity—rat	CR	CR	CR	CR	CR	TGAI	TGAI	7, 15, 16, 17
870.6200	90-Day neurotoxicity—rat	R	R	CR	R	CR	TGAI	TGAI	6, 8
Chronic Testing									
870.4100	Chronic oral toxicity—rodent	R	R	CR	R	CR	TGAI	TGAI	18, 19, 20
870.4200	Carcinogenicity—two rodent species—rat and mouse preferred	R	R	CR	R	CR	TGAI	TGAI	19, 21, 22
Developmental Toxicity and Reproduction									
870.3700	Prenatal developmental toxicity—rat and rabbit preferred	R	R	R	R	R	TGAI	TGAI	23, 24, 25, 26
870.3800	Reproduction and fertility effects	R	R	R	R	R	TGAI	TGAI	26, 27, 28, 29
870.6300	Developmental neurotoxicity	CR	CR	CR	CR	CR	TGAI	TGAI	28, 29, 30
Mutagenicity									
870.5100	Reverse mutation assay	R	R	R	R	R	TGAI	TGAI	31, 32
870.5300 870.5375	<i>In vitro</i> mammalian gene mutation	R	R	R	R	R	TGAI	TGAI	31, 33
870.5385 870.5395	<i>In vivo</i> cytogenetics	R	R	R	R	R	TGAI	TGAI	31, 34
Special Testing									

870.7485	Metabolism and pharmacokinetics	R	R	CR	R	CR	PAI or PAIRA	PAI or PAIRA	35, 39
870.7200	Companion animal safety	CR	CR	CR	CR	CR	NR	Choice	36
870.7600	Dermal penetration	CR	CR	CR	CR	CR	Choice	Choice	3, 37
870.7800	Immunotoxicity	R	R	R	R	R	TGAI	TGAI	8

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