

## 40 C.F.R. § 158.2240

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### Nontarget organisms.

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(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the terrestrial and aquatic nontarget organisms data requirements for a particular antimicrobial pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Terrestrial and aquatic nontarget organism data are required to support the registration of most end-use and manufacturing-use antimicrobial products.

(2) Data are generally not required to support end-use products of a gas, highly volatile liquid, highly reactive solid, or a highly corrosive material.

(3) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation/degradation products or leachate residues meet one of the following criteria:

(i) More toxic, persistent, or bioaccumulative than the parent;

(ii) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(iii) The moiety of concern (*i.e.*, functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(4) If an antimicrobial may be applied to a field crop, horticultural crop, or turf, then the data requirements in § 158.630 apply.

(5) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(i) Agricultural premises and equipment.

(ii) Food-handling/storage establishments, premises, and equipment.

(iii) Commercial, institutional and industrial premises and equipment.

(iv) Residential and public access premises.

(v) Medical premises and equipment.

(vi) Human drinking water systems.

(vii) Materials preservatives.

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(viii) Swimming pools.

(b) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAIRA = Pure active ingredient radiolabeled; a.i. = active ingredient.

(c) *Antimicrobial nontarget organism data requirements table.* The following table shows the data requirements for nontarget organisms. The test notes appear in paragraph (d) of this section.

Table—Antimicrobial Nontarget Organism Data Requirements

Guideline No.	Data requirement	Use pattern					Test substance		Test note No.
		Industrial processes and water systems	Antifoulant coatings and paints	Wood preservatives	Aquatic areas	All other use patterns category	MP	EP	
<b>Tier One Testing</b>									
850.2100	Acute avian oral toxicity	R	R	R	R	R	TGAI	TGAI	1
850.1010	Acute freshwater invertebrates toxicity	R	R	R	R	R	TGAI	TGAI	2
850.1075	Acute freshwater fish toxicity	R	R	R	R	R	TGAI	TGAI	3
<b>Higher Tier Testing</b>									
Avian Testing									
850.2200	Avian dietary toxicity	CR	CR	CR	CR	CR	TGAI	TGAI	4
850.2300	Avian reproduction	CR	CR	CR	CR	CR	TGAI	TGAI	1, 6
<b>Aquatic Organisms Testing</b>									
850.1010	Acute freshwater invertebrates toxicity	CR	CR	CR	CR	CR		TEP	2, 5, 7
850.1075	Acute freshwater fish toxicity	CR	CR	CR	CR	CR		TEP	3, 5, 7
850.1025	Acute estuarine and marine organisms toxicity	CR	R	CR	CR	CR	TGAI	TGAI	8, 9
850.1035									
850.1045									
850.1055	Acute estuarine and marine organisms toxicity	CR	CR	CR	CR	CR		TEP	5, 7, 8

850.1075									
850.1400	Fish early-life stage	R	R	R	R	R	TGAI	TGAI	10
850.1300	Aquatic invertebrate life-cycle	R	R	R	R	R	TGAI	TGAI	10
850.1350									
850.1500	Fish life-cycle	CR	CR	CR	CR	CR	TGAI	TGAI	11, 12
850.1710	Aquatic organisms, bioavailability, biomagnification, toxicity tests	CR	CR	CR	CR	CR	TGAI, PAI, degradable	TGAI, PAI, degradable	13
850.1730									
850.1850									
850.1950	Simulated or actual field testing for aquatic organisms	CR	CR	CR	CR	CR	TEP	TEP	14, 15, 16
<b>Sediment Testing</b>									
850.1735	Whole sediment; acute freshwater invertebrates	CR	CR	CR	CR	CR	TGAI	TGAI	15, 17
850.1740	Whole sediment; acute marine invertebrates	CR	CR	CR	CR	CR	TGAI	TGAI	15, 17, 19
None	Whole sediment; chronic invertebrates fresh-water and marine	CR	CR	CR	CR	CR	TGAI	TGAI	15, 18, 19
<b>Insect Pollinator Testing</b>									
850.3020	Honeybee acute contact	NR	NR	R	NR	CR	TGAI	TGAI	20
850.3030	Toxicity of residues to honeybees	NR	NR	R	NR	CR	TGAI	TEP or treated wood	20, 21

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