
40 C.F.R. § 158.2280

Environmental fate.

(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 environmental fate data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Environmental fate data are required to support the registrations of all end-use and manufacturing-use antimicrobial products.

(2) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/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.

(3) 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.

(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; ROC = residue of concern.

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

Table—Antimicrobial Environmental Fate 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	
Degradation Studies—Laboratory									
835.2120	Hydrolysis	R	R	R	R	R	TGAI or PAIRA	TGAI or PAIRA	1
835.2240	Photodegradation in water	R	R	R	R	R	TGAI or PAIRA	TGAI or PAIRA	2
835.2410	Photodegradation in soil	NR	NR	R	NR	NR	TGAI or PAIRA	TGAI or PAIRA	10
Toxicity and Fate in Wastewater Systems									
850.6800	Activated Sludge, Respiration Inhibition Test	R	R	R	NR	R	TGAI	TGAI	21
	OECD 209								
835.1110	Activated Sludge Sorption Isotherm	CR	CR	CR	NR	CR	TGAI	TGAI	19, 20
835.3110	Ready Biodegradability	CR	CR	CR	NR	CR	TGAI	TGAI	3, 4, 18
835.3220	Porous Pot Study	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals Discharged in Wastewater	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18
835.3240	Simulation Test—Aerobic Sewage Treatment: A. Activated Sludge Units	CR	CR	CR	NR	CR	TGAI	TGAI	3, 18
Mobility Studies									

835.1230	Leaching and adsorption/de-sorption	R	R	R	R	CR	TGAI or PAIRA	TGAI or PAIRA	5, 6
835.1240									
Metabolism Studies—Laboratory									
835.4100	Aerobic soil metabolism	CR	NR	R	CR	CR	TGAI or PAIRA	TGAI or PAIRA	7, 8, 9
835.4200	Anaerobic soil metabolism	NR	NR	R	NR	CR	TGAI or PAIRA	TGAI or PAIRA	5, 8
835.4300	Aerobic aquatic metabolism	R	R	R	R	CR	TGAI or PAIRA	TGAI or PAIRA	5, 8
835.4400	Anaerobic aquatic metabolism	R	R	R	R	CR	TGAI or PAIRA	TGAI or PAIRA	5, 8
Dissipation Studies—Field									
835.6200	Aquatic (sediment)	CR	R	CR	R	CR	TEP	TEP	11, 12, 13
Ground and Surface Water Monitoring									
None	Monitoring of representative U.S. waters	CR	CR	CR	CR	CR	ROC	ROC	11, 14, 17
Special Studies									
None	Special leaching	NR	R	R	NR	NR	TGAI	TEP	15, 16

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