

TABLE—EUP BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor		
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood		
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	NR	R	NR	TGAI, EP	2, 4

(e) *Test notes.* The following test notes are applicable to the data requirements for experimental use permit biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Not required for any use groups if the pesticide is highly volatile (estimated volatility >5 X 10⁻³atm m³/mol).

3. Preferred test species are: upland game, waterfowl, or passerine for avian acute oral toxicity studies; upland game or waterfowl for avian dietary studies; and coldwater fish for acute freshwater fish studies.

4. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

Subpart V—Microbial Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.

§ 158.2100 Microbial pesticides definition and applicability.

(a) This subpart applies to all living or dead microbial pesticides as described in paragraphs (b) and (c) of this section.

(b) *Definition.* *Microbial pesticide* is a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

(1) Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;

(2) Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaeobacteria; or

(3) Is a parasitically replicating microscopic element, including, but not limited to, viruses.

(c) *Applicability.* (1) This part applies to microbial pesticides as specified in paragraphs (c)(2), (3) and (4) of this section.

(2) Each new isolate of a microbial pesticide is treated as a new strain and must be registered independently of any similar registered microbial pesticide strain and supported by data required in this subpart.

(3) Genetically modified microbial pesticides may be subject to additional data or information requirements on a case-by-case basis depending on the particular microbial agent and/or its parental strains, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified.

(4) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in § 152.20 (a) of this chapter.

§ 158.2110 Microbial pesticides data requirements.

(a) *For all microbial pesticides.* (1) The following § 158.2120 through § 158.2150 identify the data requirements that are required to support registration of microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) Each data table includes “use patterns” under which the individual data are required, with variations including all use patterns, food and nonfood uses

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for terrestrial and aquatic applications, greenhouse, indoor, forestry, and residential outdoor applications under certain circumstances.

(3) The categories for each data requirement are “R,” which stands for required, and “CR” which stands for conditionally required. If a bracket appears around the “R” or “CR,” the data are required for both the registration and experimental use permit requests. Generally, “R” indicates that the data are more likely required than for those data requirements with “CR.” However, in each case, the regulatory text preceding the data table and the test notes following the data table must be used to determine whether the data requirement must be satisfied.

(4) Each table identifies the test substance that is required to be tested to satisfy the data requirement. Test substances may include: technical grade active ingredient (TGAI), manufacturing-use product (MP), end-use product (EP), typical end-use product (TEP), residue of concern, and pure active ingredient (PAI) or all of the above (All). Commas between the test substances (*i.e.*, TGAI, EP) indicate that data may be required on the TGAI or EP or both depending on the conditions set forth in the test note. Data requirements which list two test substances (*i.e.*, TGAI and EP) indicate that both are required to be tested. Data requirements that list only MP as the test substance apply to products containing solely the technical grade of the active ingredient and manufacturing-use products to which other ingredients have been intentionally added. Data requirements listing the EP as the test substance apply to any EP with an ingredient in the end-use formulation other than the active ingredient that is

expected to enhance the toxicity of the product.

(b) *Additional data requirements for genetically modified microbial pesticides.* Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the “new” traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2120 **Microbial pesticides product analysis data requirements table.**

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *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; 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:

(c) *Table.* The following table shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	--