

§ 158.2030

40 CFR Ch. I (7–1–10 Edition)

EP or both depending on the conditions set forth in the test note.

(e) The data requirements are organized into a tier-testing system with specified additional studies at higher tiers being required if warranted by adverse effects observed in lower tier studies. The lower tier studies are a subset of those required for conventional pesticides, and the studies overall are generally selected from those required for conventional pesticides.

(f) Two sets of guideline numbers are provided for some of the environmental fate data requirements. For ease of understanding, the current guidelines will be used as an interim measure until the new guidelines (in parentheses) are finalized.

§ 158.2030 Biochemical pesticides product chemistry data requirements table.

(a) *General.* (1) Sections 158.100 through 158.130 describe how to use this table to determine the product chem-

istry data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of the section.

(2) Definitions in §158.300 apply to data requirements in this section.

(b) *Use patterns.* Product chemistry data are required for all pesticide products and are not use specific.

(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.

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

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Identity and Composition					
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4
Analysis and Certified Limits					
830.1700	Preliminary analysis	CR	TGAI and MP	TGAI and EP	5, 8
830.1750	Certified limits	R	MP	EP	6
830.1800	Enforcement analytical method	R	MP	EP	7
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	8
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8
830.6304	Odor	R	TGAI	TGAI	8
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17
830.6315	Flammability	CR	MP	EP	9
830.6317	Storage stability	R	MP	EP	--

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
830.6319	Miscibility	CR	MP	EP	10
830.6320	Corrosion characteristics	R	MP	EP	--
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11
830.7050	UV/Visible light absorption	R	TGAI	TGAI	--
830.7100	Viscosity	CR	MP	EP	12
830.7200	Melting point/melting range	CR	TGAI	TGAI	8, 13
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16
830.7840	Water solubility	R	TGAI	TGAI	8
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with §158.320.

2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.

3. Data must be provided in accordance with §§158.325, 158.330, and §158.335.

4. Data must be provided in accordance with §158.340.

5. Data must be provided in accordance with §158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAI) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis.

6. Data must be provided in accordance with §158.350.

7. Data must be provided in accordance with §158.355.

8. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI. EP testing may also be appropriate.

9. Required if the product contains combustible liquids.

10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

11. Required if the test substance is soluble or dispersible in water.

12. Required if the product is a liquid.

13. Required when the technical chemical is a solid at room temperature.

14. Required when the technical chemical is a liquid at room temperature.

15. Required for water insoluble test substances (>10*g/l) and fibrous test substances with diameter ≥0.1 μm.

16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.

17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.

18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.

19. Not required for salts.

§ 158.2040 Biochemical pesticides residue data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the biochemical pesticides residue data requirements for a particular pesticide product and the substance that needs to be tested. These data requirements apply to all biochemical pesticides, *i.e.*, naturally occurring insect repellents and