

TABLE—EXPERIMENTAL USE PERMIT ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	Greenhouse	In-doors	For-estry	Resi-dential Out-doors		
Degradation Study - Laboratory									
835.2120	Hydrolysis	R	R	R	NR	R	R	TGAI or PAIRA	1
Metabolism Studies - Laboratory									
835.4100	Aerobic soil	R	CR	NR	NR	R	NR	TGAI or PAIRA	2
835.4300	Aerobic aquatic	NR	R	NR	NR	NR	NR	TGAI or PAIRA	--
Mobility Study									
835.1230 835.1240	Leaching and adsorption/desorption	R	NR	NR	NR	R	NR	TGAI or PAIRA	3

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Study is required for indoor uses in cases where environmental exposure is likely to occur. Such sites include, but are not limited to, agricultural premises, in or around farm buildings, barnyards, and beehives.
2. Required for aquatic uses for aquatic sites that are intermittently dry. Such sites include, but are not limited to cranberry bogs and rice paddies.
3. Adsorption and desorption using a batch equilibrium method is preferred. However, in some cases, for example, where the pesticide degrades rapidly, soil column leaching with unaged or aged columns may be more appropriate to fully characterize the potential mobility of the parent compound and major transformation products.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.270 Experimental use permit data requirements for residue chemistry.

All residue chemistry data, as described in §158.1410, are required for an experimental use permit for which a temporary tolerance under FFDCA section 408(r) is sought. Residue chemistry data are not required for an experimental use permit issued on a crop-destruct basis.

§§ 158.280–158.290 [Reserved]

Subpart D—Product Chemistry

§ 158.300 Definitions.

The following terms are defined for the purposes of this subpart:

Active ingredient means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, defoliant, or nitrogen stabilizer, within the meaning of FIFRA sec. 2(b).

End-use product means a pesticide product whose labeling:

- (1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, or as a nitrogen stabilizer, and
- (2) does not state that the product may be used to manufacture or formulate other pesticide products.

Formulation means:

- (1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended

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chemical reaction, to obtain a manufacturing-use product or an end-use product, or

(2) The repackaging of any registered product.

Impurity means any substance (or group of structurally similar substances if specified by the Agency), in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

Impurity associated with an active ingredient means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

Inert ingredient means any substance (or group of structurally similar substances if designated by the Agency), other than the active ingredient, which is intentionally included in a pesticide product.

Integrated system means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

Manufacturing-use product means any pesticide product other than an end-use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

Nominal concentration means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

Starting material means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

Technical grade of active ingredient means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot plant production scale (whether or not it is ever held for sale).

§ 158.310 Product chemistry data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product chemistry 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 (f) of the section.

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

(c) *Test substance.* Data requirements that list only the manufacturing-use product 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.

(d) *Key.* R=Required; CR=Conditionally required; MP=Manufacturing-use product; NR=Not required; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient.

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

PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
Product Identity and Composition					
830.1550	Product identity and composition	R	MP	EP	1