

§ 158.310

40 CFR Ch. I (7–1–14 Edition)

(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 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 sam-

ple 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					

Environmental Protection Agency

§ 158.310

PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
830.1550	Product identity and composition	R	MP	EP	1
830.1600	Description of materials used to produce the product	R	MP	EP	2
830.1620	Description of production process	R	MP	EP	3
830.1650	Description of formulation process	R	MP	EP	4
830.1670	Discussion of formulation of impurities	R	MP, and possibly TGAI	EP, and possibly TGAI	5
830.1700	Preliminary analysis	CR	MP, and possibly TGAI	EP, and possibly TGAI	6, 9, 10
830.1750	Certified limits	R	MP	EP	7
830.1800	Enforcement analytical method	R	MP	EP	8
830.1900	Submittal of samples	CR	MP, PAI and TGAI	EP, PAI, TGAI	9, 11
Physical and Chemical Properties					
830.6302	Color	R	MP and TGAI	EP	9
830.6303	Physical state	R	MP and TGAI	EP and TGAI	9
830.6304	Odor	R	MP and TGAI	EP	9
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	R	MP and TGAI	EP	9, 12, 26
830.6314	Oxidation/reduction: chemical incompatibility	CR	MP	EP	13
830.6315	Flammability	CR	MP	EP	14
830.6316	Explosibility	CR	MP	EP	15
830.6317	Storage stability	R	MP	EP	
830.6319	Miscibility	CR	MP	EP	16
830.6320	Corrosion characteristics	R	MP	EP	
830.6321	Dielectric breakdown voltage	CR	NR	EP	17
830.7000	pH	CR	MP and TGAI	EP and TGAI	9, 18
830.7050	UV/visible light absorption	R	TGAI or PAI	NR	--
830.7100	Viscosity	CR	MP	EP	19
830.7200	Melting point/melting range	R	TGAI or PAI	TGAI or PAI	9, 20
830.7220	Boiling point/boiling range	R	TGAI or PAI	TGAI or PA	9, 21
830.7300	Density/relative density/bulk density	R	MP and TGAI	EP and TGAI	9
830.7370	Dissociation constants in water	R	TGAI or PAI	TGAI or PAI	9, 22
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI or PAI	EP	23
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	R	TGAI or PAI	TGAI or PAI	24
830.7840 830.7860	Water solubility	R	TGAI or PAI	TGAI or PAI	9

PRODUCT CHEMISTRY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern	Test substance to support		Test Note No.
		All	MP	EP	
830.7950	Vapor pressure	R	TGAI or PAI	TGAI or PAI	9, 25

(f) *Test notes.* The following test notes are applicable to the product chemistry data requirements in the table to paragraph (e) of this section:

1. Data must be provided in accordance with § 158.320.
2. Data must be provided in accordance with § 158.325.
3. Data must be provided in accordance with § 158.330.
4. Data must be provided in accordance with § 158.335.
5. Data must be provided in accordance with § 158.340.
6. Data must be provided in accordance with § 158.345.
7. Data must be provided in accordance with § 158.350.
8. Data must be provided in accordance with § 158.355.
9. If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI.
10. Data are required if the product is produced by an integrated system.
11. Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produced by an integrated system must be submitted on a case-by-case basis.
12. Data on the stability to metals and metal ions are required only if the TGAI is expected to come into contact with either material.
13. Required when the product contains an oxidizing or reducing agent.
14. Required when the product contains combustible liquids.
15. Required when the product is potentially explosive.
16. Required when the product is an emulsifiable liquid and is to be diluted with petroleum solvent.
17. Required when the EP is a liquid and is to be used around electrical equipment.
18. Required when the test substance is soluble or dispersible in water.
19. Required when the product is a liquid.
20. Required when the TGAI is solid at room temperature.

21. Required when the TGAI is liquid at room temperature.

22. Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

23. Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter of ≥ 0.1 μm .

24. Required if technical chemical is organic and non-polar.

25. Not required for salts.

26. Data on stability of the MP and TGAI to storage at normal temperatures are required. Data on the stability of the TGAI to high temperatures are required if the TGAI is expected to be subjected to temperatures >50 °C (122 °F) during production or storage.

§ 158.320 Product identity and composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b), and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) of this section must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.350.

(2) If the source of any active ingredient in the product is not an EPA-registered product: