

§ 158.175 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

- (1) An upper and lower limit for each active ingredient.
- (2) An upper and lower limit for each inert ingredient.
- (3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.
- (4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

| If the nominal concentration (N) for the ingredient is: | The certified limits for that ingredient will be as follows: | |
|---|--|-------------|
| | Upper limit | Lower limit |
| N ≤ 1.0% | N + 10%N | N - 10%N |
| 1.0% < N ≤ 20.0% | N + 5%N | N - 5%N |
| 20.0% < N ≤ 100.0%. | N + 3%N | N - 3%N |

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicant must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

- (i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.
- (ii) Allow for all sources of variability likely to be encountered in the production process.
- (iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale of distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard or applicant-proposed), the Agency will inform the applicant of its determination and will provide supporting reasons. EPA may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

- (1) More precise limits.
- (2) More thorough explanation of how the certified limits were determined.
- (3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [product name], EPA Reg. No.

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[insert registration number], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 158.190 Physical and chemical characteristics.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the physical and chemical characteristics data requirements and the substance to be tested.

| Kind of data required | (b) Notes | All general use patterns (requirements are the same for every use pattern) | Test substance | | Guidelines reference No. |
|--|-----------|--|---------------------|----------------------|--------------------------|
| | | | Data to support MP | Data to support EP | |
| Color | | [R] | MP and TGAI | EP* and TGAI | 63-2 |
| Physical state | | [R] | MP and TGAI | EP* and TGAI | 63-3 |
| Odor | | [R] | MP and TGAI | EP* and TGAI | 63-4 |
| Melting point | (1) | [R] | TGAI | TGAI | 63-5 |
| Boiling point | (2) | [R] | TGAI | TGAI | 63-6 |
| Density, bulk density, or specific gravity | | [R] | MP and TGAI | EP* and TGAI | 63-7 |
| Solubility | | [R] | TGAI or PAI | TGAI or PAI | 63-8 |
| Vapor pressure | | [R] | TGAI or PAI | TGAI or PAI | 63-9 |
| Dissociation constant | | [R] | TGAI or PAI | TGAI or PAI | 63-10 |
| Octanol/water partition coefficient | (3) | [CR] | PAI | PAI | 63-11 |
| pH | (4) | [CR] | MP and TGAI | EP* and TGAI | 63-12 |
| Stability | | [R] | TGAI | TGAI | 63-13 |
| Oxidizing or reducing action | (5) | [CR] | | | |
| Flammability | (6) | [CR] | MP | EP* | 63-15 |
| Explosibility | (7) | [R] | MP | EP* | 63-16 |
| Storage stability | | [R] | MP | EP* | 63-17 |
| Viscosity | (8) | [CR] | MP | EP* | 63-18 |
| Miscibility | (9) | [CR] | MP | EP* | 63-19 |
| Corrosion characteristics | | [R] | MP | EP* | 63-20 |
| Dielectric breakdown voltage | (10) | [CR] | | EP* | 63-21 |
| Other requirements: Submittal of samples .. | (11) | [CR] | MP, TGAI, PAI | EP*, TGAI, PAI | 64-1 |

Key: R = Required; CR = Conditionally Required; [] = Brackets (i.e. [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (i.e. formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

- (b) *Notes.* The following notes are referenced in column two of the table contained in paragraph (a) of this section.
- (1) Required if technical chemical is a solid at room temperature.
- (2) Required if technical chemical is a liquid at room temperature.
- (3) Required if technical chemical is organic and non-polar.
- (4) Required if test substance is dispersible with water.
- (5) Required if product contains an oxidizing or reducing agent.
- (6) Required if product contains combustible liquids.
- (7) Required if product is potentially explosive.
- (8) Required if product is a liquid.
- (9) Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- (10) Required if end-use product is a liquid and is to be used around electrical equipment.
- (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.

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