

## Environmental Protection Agency

## § 157.36

expected lifetime of the package, taking into account the number of times the package is customarily opened and closed. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors of packaging, the force required for activation, and other relevant factors.

### § 157.34 Certification.

(a) *General.* (1) The registrant of a pesticide product required to be in child-resistant packaging shall certify to the Agency that the package meets the standards of § 157.32.

(2) Certification must be submitted with each application for new registration, if applicable. If the Agency determines, in accordance with § 157.24(a)(1)(ii), (2)(ii), or (b)(4), that a currently registered product is required to be packaged in child-resistant packaging, a certification must be submitted within 6 months after the Agency finally notifies the registrant of the requirement.

(b) *Contents of certification.* The certification must contain the following information:

(1) The name and EPA registration number of the product to which the certification applies, the registrant's name and address, the date, and the name, title and signature of the company official making the certification.

(2) A statement that the packaging that is being used for the product will meet the standards of § 157.32. The statement, "I certify that the packaging that will be used for this product meets the standards of 40 CFR 157.32," will suffice for this purpose.

### § 157.36 Recordkeeping.

For as long as the registration of a pesticide product required to be in child-resistant packaging is in effect, the registrant must retain the records listed in this section. The registrant must, upon request by the Agency, make them available to Agency representatives for inspection and copying, or must submit them to the Agency.

(a) A description of the package, including a description of:

(1) The container and its dimensions and composition.

(2) The closure or child-resistant mechanism, including the name of its manufacturer and the manufacturer's designation for the closure or the physical working of the child-resistant packaging mechanism.

(b) A copy of the certification statement required by § 157.34.

(c) One of the following types of records verifying that each package for the product is child-resistant:

(1) Test data on the package based on the Consumer Product Safety Commission protocol in 16 CFR 1700.20.

(2) Test data, not conforming to the protocol in 16 CFR 1700.20, or a set of measurements on the package, together with an explanation as to why such data or measurements demonstrate that the package is child-resistant.

(3) Test data, whether or not conforming to the protocol in 16 CFR 1700.20, on a different package, together with an explanation of why such data demonstrate that the package being used is child-resistant.

(4) Written evidence that verifies that testing on the package has been conducted according to the protocol in 16 CFR 1700.20. Written evidence may be one of the following:

(i) A letter or literature from the packaging supplier;

(ii) A letter from the facility that conducted the testing; or

(iii) A specification in the contract between the registrant or applicant and the packaging supplier;

(5) When the container and closure are purchased separately by the registrant:

(i) Information of the kinds described in paragraphs (c) (1) through (4) of this section showing that the closure is child-resistant; and

(ii) A written explanation of why the container is child-resistant; and

(iii) Information showing that the closure and container are compatible with each other, and a written explanation of why the resulting package is child-resistant.

(6) A combination of the records listed in paragraphs (c) (1) through (5).

(d) Records verifying that the package meets the compatibility and durability standards of §157.32(b) and (c).

[51 FR 21286, June 11, 1986 and 51 FR 36692, Oct. 15, 1986, as amended at 65 FR 39304, June 26, 2000]

## PART 158—DATA REQUIREMENTS FOR REGISTRATION

### Subpart A—General Provisions

- Sec.
- 158.20 Overview.
  - 158.25 Applicability of data requirements.
  - 158.30 Timing of the imposition of data requirements.
  - 158.32 Format of data submission.
  - 158.33 Procedures for claims of confidentiality of data.
  - 158.34 Flagging of studies for potential adverse effects.
  - 158.35 Flexibility of the data requirements.
  - 158.40 Consultation with the Agency.
  - 158.45 Waivers.
  - 158.50 Formulators' exemption.
  - 158.55 Agricultural vs. non-agricultural pesticides.
  - 158.60 Minor uses.
  - 158.65 Biochemical and microbial pesticides.
  - 158.70 Acceptable protocols.
  - 158.75 Requirements for additional data.
  - 158.80 Acceptability of data.
  - 158.85 Revision of data requirements and guidelines.

### Subpart B—How To Use Data Tables

- 158.100 How to determine registration data requirements.
- 158.101 Required vs. conditionally required data.
- 158.102 Distinguishing between what data are required and what substance is to be tested.
- 158.108 Relationship of Pesticide Assessment Guidelines to data requirements.

### Subpart C—Product Chemistry Data Requirements

- 158.150 General.
- 158.153 Definitions.
- 158.155 Product composition.
- 158.160 Description of materials used to produce the product.
- 158.162 Description of production process.
- 158.165 Description of formulation process.
- 158.167 Discussion of formation of impurities.
- 158.170 Preliminary analysis.
- 158.175 Certified limits.
- 158.180 Enforcement analytical method.
- 158.190 Physical and chemical characteristics.

### Subpart D—Data Requirement Tables

- 158.202 Purposes of the registration data requirements.
- 158.240 Residue chemistry data requirements.
- 158.290 Environmental fate data requirements.
- 158.340 Toxicology data requirements.
- 158.390 Reentry protection data requirements.
- 158.440 Spray drift data requirements.
- 158.490 Wildlife and aquatic organisms data requirements.
- 158.540 Plant protection data requirements.
- 158.590 Nontarget insect data requirements.
- 158.640 Product performance data requirements.
- 158.690 Biochemical pesticides data requirements.
- 158.740 Microbial pesticides—Product analysis data requirements.

### APPENDIX A TO PART 158—DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX.

AUTHORITY: 7 U.S.C. 136-136y.

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted.

### Subpart A—General Provisions

#### § 158.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136-136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or