

for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(h) *New respirator requirement established for pesticide handlers in this part—*

(1) *General requirement.* If the table in paragraph (e) of this section indicates a respiratory protection device is required, and existing product labeling has no respiratory protection requirement, the registrant shall add a respiratory protection statement that specifies a: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C)."

(2) *Exception.* The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device required in paragraph (h)(1) of this section would not be adequately protective or might increase risks to the user unnecessarily.

(i) *Additional personal protective equipment requirements for pesticide handlers.* In addition to the minimum personal protective equipment and work clothing requirements given in the table in paragraph (e) of this section, the labeling statement for any product in toxicity category I or II on the basis of dermal toxicity or skin irritation potential (or their surrogate as specified in paragraph (d)(2) of this section), shall include the following personal protective equipment instructions, additions, or substitutions as applicable:

(1) If the product is not ready-to-use and there is no existing requirement for a chemical-resistant suit, the following statement shall be included: "Mixers/Loaders: add a chemical-resistant apron."

(2) If the application of the product may result in overhead exposure to any handler (for example, applicator exposure during airblast spraying of orchards or flagger exposure during aerial application), the following statement shall be included: "Overhead Exposure: wear chemical-resistant headgear."

(3) If any type of equipment other than the product container may be used to mix, load, or apply the product, and there is no requirement for a chemical-resistant protective suit, the following statement shall be included: "For Cleaning Equipment: add a chemical-resistant apron."

(j) *Personal protective equipment for early-entry workers.* This paragraph specifies minimum requirements for personal protective equipment (as defined in §170.240 of this chapter) and work clothing for early-entry workers.

(1) For all pesticide products, add the statement: "For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (list the body protection, glove, footwear, protective eyewear, and protective headgear, if applicable, statements specified for applicators and other handlers, but omit any respiratory protection statement)."

(2) If the body protection statement in the personal protective equipment requirement for handlers specifies a long-sleeved shirt and long pants, "coveralls" must be specified in the statement of personal protective equipment for early-entry workers.

(3) If there is no statement requiring gloves and no prohibition against gloves for applicators and other handlers under the heading HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) in the labeling, add a requirement for "waterproof gloves" in the statement of personal protective equipment for early-entry workers.

[57 FR 38146, Aug. 21, 1992, as amended at 58 FR 34203, June 23, 1993]

PART 157—PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

Sec.	
157.20	General.
157.21	Definitions.
157.22	When required.
157.24	Exemptions.
157.27	Unit packaging.

§ 157.20

- 157.30 Voluntary use of child-resistant packaging.
- 157.32 Standards.
- 157.34 Certification.
- 157.36 Recordkeeping.

AUTHORITY: 7 U.S.C. 136w.

SOURCE: 51 FR 21286, June 11, 1986 and 51 FR 36692, Oct. 15, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Child-Resistant Packaging

§ 157.20 General.

This subpart prescribes requirements for child-resistant packaging of pesticide products and devices. The requirements are established under the authority of FIFRA section 25(a)(1), which authorizes the Administrator to issue regulations to carry out the purposes of the Act, and FIFRA section 25(c)(3), which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated under the Act.

§ 157.21 Definitions.

Terms used in this subpart shall have the following meanings:

(a) *Appropriate*, when used with respect to child-resistant packaging, means that the packaging is chemically compatible with the pesticide contained therein.

(b) *Child-resistant packaging* means packaging that is designed and constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

(c) *Package* or *packaging* means the immediate container or wrapping, including any attached closure(s), in which the pesticide is contained for distribution, sale, consumption, use or storage. The term does not include any shipping or bulk container used for

40 CFR Ch. I (7–1–03 Edition)

transporting or delivering the pesticide unless it is the only such package.

(d) *Practicable*, when used with respect to child-resistant packaging, means that the packaging can be mass produced and can be used in assembly line production.

(e) *Residential use* means use of a pesticide or device:

(1) Directly on humans or pets;

(2) In, on, or around any structure, vehicle, article, surface or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles; or

(3) In or around any preschool or day care facility.

(f) *Technically feasible*, when applied to child-resistant packaging, means that the technology exists to produce the child-resistant packaging for a particular pesticide.

(g) *Unit packaging* means a package that is labeled with directions to use the entire contents of the package in a single application.

§ 157.22 When required.

Unless exempted under § 157.24, a pesticide product must be distributed and sold in child-resistant packaging complying with § 157.32 if it meets both of the following criteria:

(a) *Toxicity criterion*. Based upon testing with an appropriate test species, the product meets any of the following toxicity criteria:

(1) The pesticide has an acute oral LD₅₀ of 1.5 g/kg or less;

(2) The pesticide has an acute dermal LD₅₀ of 2000 mg/kg or less;

(3) The pesticide has an acute inhalation LC₅₀ of 2 mg/liter or less;

(4) The pesticide is corrosive to the eye (causes irreversible destruction of ocular tissue) or causes corneal involvement or irritation persisting for 21 days or more;

(5) The pesticide is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe skin irritation (severe erythema or edema) at 72 hours; or

(6) The pesticide or device has such characteristics that, based upon human toxicological data, use history, accident data or such other evidence as is

Environmental Protection Agency

§ 157.24

available, the Agency determines there is serious hazard of accidental injury or illness which child-resistant packaging could reduce; and

(b) *Use criterion.* The product's labeling either directly recommends residential use or reasonably can be interpreted to permit residential use.

§ 157.24 Exemptions.

(a) *General exemptions.* The Agency hereby exempts from the requirement for child-resistant packaging the following classes of products:

(1) *Products classified for restricted use.*

(i) A product restricted to use by or under the supervision of a certified applicator is not required to be distributed and sold in child-resistant packaging.

(ii) Notwithstanding the exemption in paragraph (a)(1)(i) of this section, the Agency may require the use of child-resistant packaging for a product classified for restricted use by or under the direct supervision of a certified applicator if the Agency determines that the product poses a risk of serious accidental injury or illness which child-resistant packaging could reduce. If the Agency makes such a determination, it will notify the registrant in writing and provide a short statement of the basis of its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to require the product to be distributed only in child-resistant packaging and will notify the registrant of its decision.

(2) *Products packaged in large sizes.* (i) Except as provided by paragraph (a)(2)(ii) of this section, a product is not required to be in child-resistant packaging if distributed and sold in the following sizes:

(A) If the product is a solid product, regardless of pesticide type, a size of 50 pounds or greater;

(B) If the product is a liquid product intended for use in swimming pools, a size greater than 7.5 gallons by volume;

(C) If the product is a liquid product intended for any other pesticide use, a size of 5 gallons or greater by volume;

(D) If the product is packaged as an aerosol (measured by weight), regard-

less of pesticide type, a weight of 2 pounds or greater.

(ii) The Agency may require that a product packaged in a size exceeding that listed in paragraphs (a)(2)(i) (A) through (D) of this section be distributed and sold only in child-resistant packaging if the Agency determines that the product is, or is intended to be, distributed or sold to homeowners or other members of the general public. If the Agency makes such a determination, it will notify the registrant in writing and provide a short statement of the basis of its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to require the product to be distributed only in child-resistant packaging and will notify the registrant of its decision.

(b) *Exemptions requiring Agency approval.* The Agency may, in accordance with paragraphs (b) (1) through (3) of this section, grant an exemption from the requirements of this subpart. An exemption may be withdrawn in accordance with paragraph (b)(4) of this section.

(1) *Requesting an exemption.* A request for an exemption must be submitted to the Agency, and must be accompanied by two copies of the following information:

(i) The name, address, and telephone number of the requester;

(ii) The name and registration number (or file symbol) of the product(s) for which the exemption is requested;

(iii) A description of the package and the size(s) for which the exemption is requested; and

(iv) Documentation supporting the request for exemption, including the length of time for which the exemption is requested.

(2) *Exemption based upon lack of toxicity.* The Agency may grant an exemption from the requirements of this subpart if the registrant or applicant demonstrates to the Agency's satisfaction that the hazards indicated by the toxicity criteria in § 157.22(a) are not indicative of the hazards to man. If granted,

§ 157.27

an exemption shall apply to other products of substantially similar composition. A notice will be issued in the FEDERAL REGISTER stating the nature of and reasons for the exemption.

(3) *Exemption based upon technical factors.* The Agency may grant an exemption from the requirements of this subpart based upon technical considerations. If granted, the exemption will be for a specified length of time, and will apply to other products of substantially similar composition and intended uses. A notice of the granting of an exemption will be issued in the FEDERAL REGISTER. In considering whether to grant an exemption, the Agency will consider, among other things, the following:

(i) Whether the toxicity of the product is such that it should not be allowed to be distributed or sold except in child-resistant packaging.

(ii) Whether child-resistant packaging is technically feasible, practicable, or appropriate. An exemption may be granted if the Agency determines that any one of these criteria has not been met.

(iii) Whether the composition or use pattern of the product necessitates a particular form of packaging for proper use.

(iv) Whether child-resistant packaging that is technically feasible, practicable, and appropriate is available for the product or can reasonably be made available to the registrant in sufficient quantities to meet his packaging needs. This determination does not include a consideration of whether the packaging would be adaptable to a registrant's existing package type or packaging equipment.

(v) Whether the registrant has made a timely and good faith effort to obtain child-resistant packaging for the product.

(vi) If child-resistant packaging which is technically feasible, practicable, and appropriate is not yet available, when such packaging is likely to be available.

(4) An exemption may be withdrawn by the Agency at any time if the lack of child-resistant packaging results in serious illnesses or injuries to children. If the Agency determines that an exemption should be withdrawn, it will

40 CFR Ch. I (7-1-03 Edition)

notify the registrant, stating the basis for its determination. The registrant will then have 30 days to request a hearing on the Agency's determination. Thereafter the Agency will decide whether to withdraw the exemption, and will notify the registrant of its decision.

§ 157.27 Unit packaging.

Pesticide products distributed or sold as an aggregate of one or more unit packages and meeting the criteria of § 157.22 must be distributed or sold in child-resistant packaging either for each unit package or for the outer retail container which contains the unit packages. Child-resistant packaging is not required for both the outer package and the unit packages unless the Agency determines, on a case-by-case basis, that it is necessary for risk reduction.

§ 157.30 Voluntary use of child-resistant packaging.

A registrant whose product is not required to be in child-resistant packaging may distribute or sell his pesticide product in child-resistant packaging. If he does so, that packaging must meet the standards for child-resistant packaging stated in § 157.32. The registrant must certify to this effect in accordance with § 157.34, and must retain the records required by § 157.36.

§ 157.32 Standards.

(a) *Effectiveness standard.* The child-resistant packaging, when tested by the protocol specified in 16 CFR 1700.20, shall meet the effectiveness specifications in 16 CFR 1700.15(b).

(b) *Compatibility standard.* The child-resistant packaging must continue to meet the effectiveness specifications of paragraph (a) of this section when in actual use as a pesticide container. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the child-resistant packaging to determine that the chemical and physical characteristics of the pesticide will not compromise or interfere with the proper functioning of the child-resistant packaging and that the packaging will not be detrimental to the integrity of the product during storage and use.

Environmental Protection Agency

§ 157.36

(c) *Durability standard.* The child-resistant packaging must continue to meet the effectiveness and compatibility standards of paragraphs (a) and (b) of this section for the reasonably 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 copy-

ing, 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