

Attachment B

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TITLE 40--PROTECTION OF ENVIRONMENT

CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY (CONTINUED)

PART 157--PACKAGING REQUIREMENTS FOR PESTICIDES AND DEVICES--Table of Contents

Subpart B--Child-Resistant Packaging

Sec. 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.

Sec. 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 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.

Sec. 157.22 When required.

Unless exempted under Sec. 157.24, a pesticide product must be distributed and sold in child-resistant packaging complying with Sec. 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

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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.

Sec. 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), regardless 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 Sec. 157.22(a) are not indicative of the hazards to man. If granted,

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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 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.

Sec. 157.27 Unit packaging.

Pesticide products distributed or sold as an aggregate of one or more unit packages and meeting the criteria of Sec. 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.

Sec. 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 Sec. 157.32. The registrant must certify to this effect in accordance with Sec. 157.34, and must retain the records required by Sec. 157.36.

Sec. 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.

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(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.

Sec. 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 Sec. 157.32.

(2) Certification must be submitted with each application for new registration, if applicable. If the Agency determines, in accordance with Sec. 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 Sec. 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.

Sec. 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 Sec. 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.

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(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 Sec. 157.32(b) and (c).

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