

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 An exemption may be withdrawn in accordance with paragraph (b)(4) of this section.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, 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.

§ 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

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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.

(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 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: