

§ 1500.210

to lead to a lifetime excess risk of one in a million. Exposure refers to the anticipated exposure from normal lifetime use of the product, including use as a child as well as use as an adult.

(ii) *ADI for Neurotoxicological and Developmental/Reproductive Agents*. Due to the difficulties in using a numerical risk assessment method to determine risk for neurotoxicological or developmental/reproductive toxicants, the Commission is using a safety factor approach, as explained below.

(A) *Human Data*. If the hazard is ascertained from human data, a safety factor of ten will be applied to the lowest No Observed Effect Level (“NOEL”) seen among the relevant studies. If no NOEL can be determined, a safety factor of 100 will be applied to the Lowest Observed Effect Level (“LOEL”). Both the NOEL and LOEL are defined in terms of daily dose level.

(B) *Animal Data*. If the hazard is ascertained from animal data, a safety factor of one hundred will be applied to the lowest NOEL. If no NOEL can be determined, a safety factor of one thousand will be applied to the lowest LOEL. Both the NOEL and LOEL are defined in terms of daily dose level.

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§ 1500.210 Responsibility.

The provisions of these regulations (16 CFR subchapter C of chapter II) with respect to the doing of any act shall be applicable also to the causing of such act to be done.

§ 1500.211 Guaranty.

In the case of the giving of a guaranty or undertaking referred to in section 5(b)(2) of the act, each person signing such guaranty or undertaking, or causing it to be signed, shall be considered to have given it. Each person causing a guaranty or undertaking to be false is chargeable with violations of section 4(d) of the act.

§ 1500.212 Definition of guaranty; suggested forms.

(a) A guaranty or undertaking referred to in section 5(b)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to

16 CFR Ch. II (1–1–02 Edition)

the invoice or bill of sale covering such shipment of delivery; or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered, or caused to be shipped or delivered, by the person who gives the guaranty of undertaking.

(b) The following are suggested forms of guaranty or undertaking referred to in section 5(b)(2) of the act.

(1) *Limited form for use on invoice or bill of sale.*

(Name of person giving the guaranty or undertaking)

hereby guarantees that no article listed herein is misbranded within the meaning of the Federal Hazardous Substances Act.

(Signature and post-office address of person giving the guaranty or undertaking)

(2) *General and continuing forms.*

The article comprising each shipment or other delivery hereafter made by _____

(Name of person giving the guaranty or undertaking)

to, or on the order of _____

(Name and post-office address of person to whom the guaranty or undertaking is given)

is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not misbranded within the meaning of the Federal Hazardous Substances Act.

(Signature and post-office address of person giving the guaranty or undertaking)

(c) The application of a guaranty or undertaking referred to in section 5(b)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes misbranded within the meaning of the act.

§ 1500.213 Presentation of views under section 7 of the act.

(a) Presentation of views under section 7 of the act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 5(b)(2) of the act applicable to the article on which such notice was based, such

guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, reasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 7 of the act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Consumer Product Safety Commission that issued the notice.

§ 1500.214 Examinations and investigations; samples.

When any officer or employee of the Commission collects a sample of a hazardous substance for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Commission indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory not organized with a legislative body. Only samples so designated by an officer or employee of the Commission shall be considered to be official samples:

(a) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(b) The owner of a hazardous substance of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

§ 1500.230 Guidance for lead (Pb) in consumer products.

(a) *Summary.* (1) The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in consumer products.¹ The Com-

mission identifies the major factors that it considers when evaluating products that contain lead, and informs the public of its experience with products that have exposed children to potentially hazardous amounts of lead.

(2) To reduce the risk of hazardous exposure to lead, the Commission requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children.

(b) *Hazard.* Young children are most commonly exposed to lead in consumer products from the direct mouthing of objects, or from handling such objects and subsequent hand-to-mouth activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of the product. The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided. The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood as a threshold level of concern with respect to lead poisoning. To avoid exceeding that level, young children should not chronically ingest more than 15 micrograms of lead per day from consumer products.

(c) *Guidance.* (1) Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), household products

¹This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Compa-

nies should read that Act and the accompanying regulations in this part for more detailed information.