

§ 1500.40

16 CFR Ch. II (1–1–14 Edition)

(iv) A single prohibited age range written as either “Not for under 3 yrs” or “Not for under 8 yrs,” based on the most restrictive age range for all required cautionary statements for that product. Thus, if an advertised product requires the cautionary statement specified in 16 CFR 1500.19(b)(2), the prohibited age range in the abbreviated

cautionary statement shall be “Not for under 8 yrs.”

(v) For example, see Figure 8 for the abbreviated cautionary statement for an advertisement of a product that requires the cautionary statements specified in 16 CFR 1500.19(b)(1) and 16 CFR 1500.19(b)(2).

FIGURE 8

▲ CHOKING HAZARD (1,2). Not for under 8 yrs.

(f) *Alternatives to cautionary statements for individual product advertisements in catalogues and other printed materials.* Multiple identical full or abbreviated cautionary statements may be replaced with a single full cautionary statement under the following circumstances:

(1) If all products available for purchase within a catalogue require the same cautionary statement, that cautionary statement, in full, may appear on the front cover, or equally conspicuous location, of the catalogue in lieu of repeating the cautionary statement within the catalogue, provided that it is communicated to consumers that the cautionary statement applies to all products in the catalogue.

(2) If all products on one catalogue page or on two facing catalogue pages require the same cautionary statement, that cautionary statement, in full, may appear at the top of the page or pages in lieu of repeating the cautionary statement in each product advertisement, provided that it is communicated to consumers that the cautionary statement applies to all products on the catalogue page or pages.

(g) *Prominence and conspicuousness of labeling statements.* The type size of abbreviated cautionary statements shall be reasonably related to the type size of any other printed matter in the product advertisement, and must be in conspicuous and legible type by typography, layout, or color with other

printed matter in the advertisement and separated from other graphic matter.

(h) *Business to Business Catalogue Exception.* The requirements of section 24(c) of the Federal Hazardous Substances Act, as amended by section 105 of the CPSIA, do not apply to catalogues and other printed materials distributed solely between businesses unless the recipient business is one that could be expected to be purchasing the product for the use of children (instead of for resale, e.g.). Examples of businesses that can be expected to be purchasing products for the use of children include day care centers, schools, and churches.

[73 FR 67736, Nov. 17, 2008, as amended at 73 FR 71545, Nov. 25, 2008]

§ 1500.40 Method of testing toxic substances.

Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC’s animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis, including any of the following: existing human and animal data, structure activity relationships, physicochemical properties; and chemical reactivity, or validated *in vitro* or *in silico* testing are recommended to evaluate existing information before *in vivo* tests are considered. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the

number of test animals. The method of testing the toxic substances referred to in §1500.3(c)(1)(ii)(C) and (c)(2)(iii) is as follows:

(a) *Acute dermal toxicity (single exposure)*. In the acute exposures, the agent is held in contact with the skin by means of a sleeve for periods varying up to 24 hours. The sleeve, made of rubber dam or other impervious material, is so constructed that the ends are reinforced with additional strips and should fit snugly around the trunk of the animal. The ends of the sleeve are tucked, permitting the central portion to “balloon” and furnish a reservoir for the dose. The reservoir must have sufficient capacity to contain the dose without pressure. In the following table are given the dimensions of

sleeves and the approximate body surface exposed to the test substance. The sleeves may vary in size to accommodate smaller or larger subjects. In the testing of unctuous materials that adhere readily to the skin, mesh wire screen may be employed instead of the sleeve. The screen is padded and raised approximately 2 centimeters from the exposed skin. In the case of dry powder preparations, the skin and substance are moistened with physiological saline prior to exposure. The sleeve or screen is then slipped over the gauze that holds the dose applied to the skin. In the case of finely divided powders, the measured dose is evenly distributed on cotton gauze which is then secured to the area of exposure.

DIMENSIONS OF SLEEVES FOR ACUTE DERMAL TOXICITY TEST
[Test animal—Rabbits]

Measurements in centimeters		Range of weight of animals (grams)	Average area of exposure (square centimeters)	Average percentage of total body surface
Diameter at ends	Overall length			
7.0	12.5	2,500–3,500	240	10.7

(b) *Preparation of test animal*. The animals are prepared by clipping the skin of the trunk free of hair. Approximately one-half of the animals are further prepared by making epidermal abrasions every 2 or 3 centimeters longitudinally over the area of exposure. The abrasions are sufficiently deep to penetrate the stratum corneum (horny layer of the epidermis) but not to disturb the derma; that is, not to obtain bleeding.

(c) *Procedures for testing*. The sleeve is slipped onto the animal which is then placed in a comfortable but immobilized position in a multiple animal holder. Selected doses of liquids and solutions are introduced under the sleeve. If there is slight leakage from the sleeve, which may occur during the first few hours of exposure, it is collected and reapplied. Dosage levels are adjusted in subsequent exposures (if necessary) to enable a calculation of a dose that would be fatal to 50 percent of the animals. This can be determined from mortality ratios obtained at various doses employed. At the end of 24 hours the sleeves or screens are removed, the volume of unabsorbed ma-

terial (if any) is measured, and the skin reactions are noted. The subjects are cleaned by thorough wiping, observed for gross symptoms of poisoning, and then observed for 2 weeks.

[38 FR 27012, Sept. 27, 1973, as amended at 77 FR 73294, Dec. 10, 2012]

§ 1500.41 Method of testing primary irritant substances.

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC’s animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis or a validated *in vitro* test method is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing