

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

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§ 1500.1 Scope of subchapter.

Set forth in this subchapter C are the regulations of the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act as amended (see § 1500.3(a)(1)).

§ 1500.2 Authority.

Authority under the Federal Hazardous Substances Act is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)).

§ 1500.3 Definitions.

(a) *Certain terms used in this part.* As used in this part:

(1) *Act* means the Federal Hazardous Substances Act (Pub. L. 86-613, 74 Stat. 372-81 (15 U.S.C. 1261-74)) as amended by:

(i) The Child Protection Act of 1966 (Pub. L. 89-756, 80 Stat. 1303-05).

(ii) The Child Protection and Toy Safety Act of 1969 (Pub. L. 91-113, 83 Stat. 187-90).

(iii) The Poison Prevention Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74).

(2) *Commission* means the Consumer Product Safety Commission established May 14, 1973, pursuant to provisions of the Consumer Product Safety

Act (Pub. L. 92-573, 86 Stat. 1207-33 (15 U.S.C. 2051-81)).

(b) *Statutory definitions.* Except for the definitions given in section 2 (c) and (d) of the act, which are obsolete, the definitions set forth in section 2 of the act are applicable to this part and are repeated for convenience as follows (some of these statutory definitions are interpreted, supplemented, or provided with alternatives in paragraph (c) of this section):

(1) *Territory* means any territory or possession of the United States, including the District of Columbia and the Commonwealth of Puerto Rico but excluding the Canal Zone.

(2) *Interstate commerce* means (i) commerce between any State or territory and any place outside thereof and (ii) commerce within the District of Columbia or within any territory not organized with a legislative body.

(3) *Person* includes an individual, partnership, corporation, and association.

(4)(i) *Hazardous substance* means:

(A) Any substance or mixture of substances which is toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(B) Any substance which the Commission by regulation finds, pursuant to the provisions of section 3(a) of the act, meet the requirements of section 2(f)(1)(A) of the act (restated in (A) above).

(C) Any radioactive substance if, with respect to such substance as used in a particular class of article or as packaged, the Commission determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with the act in order to protect the public health.

(D) Any toy or other article intended for use by children which the Commission by regulation determines, in accordance with section 3(e) of the act, presents an electrical, mechanical, or thermal hazard.

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(ii) *Hazardous substance* shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house. "Hazardous substance" shall apply, however, to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of section 2(f)(1) of the Federal Hazardous Substances Act (re-stated in paragraph (b)(4)(i) of this section) by reason of bearing or containing such a pesticide.

(iii) *Hazardous substance* shall not include any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

(5) *Toxic* shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

(6)(i) *Highly toxic* means any substance which falls within any of the following categories:

(A) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered; or

(B) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or 2 milligrams per liter by volume or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or

(C) Produces death within 14 days in half or more than half of a group of 10 or more rabbits tested in a dosage of

200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.

(ii) If the Commission finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages and concentrations specified in paragraph (b)(6)(i) of this section, the human data shall take precedence.

(7) *Corrosive* means any substance which in contact with living tissue will cause destruction of tissue by chemical action, but shall not refer to action on inanimate surfaces.

(8) *Irritant* means any substance not corrosive within the meaning of section 2(i) of the act (restated in paragraph (b)(7) of this section) which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(9) *Strong sensitizer* means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(10) The terms *extremely flammable*, *flammable*, and *combustible* as they apply to any substances, liquid, solid, or the contents of any self-pressurized container, are defined by regulations issued by the Commission and published at §1500.3(c)(6).

(11) *Radioactive substance* means a substance which emits ionizing radiation.

(12) *Label* means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the cases of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto. A requirement made by

or under authority of the act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (i) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (ii) on all accompanying literature where there are directions for use, written or otherwise.

(13) *Immediate container* does not include package liners.

(14) *Misbranded hazardous substance* means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance, except as otherwise provided by or pursuant to section 3 of the act (Federal Hazardous Substances Act), fails to bear a label:

(i) Which states conspicuously:

(A) The name and place of business of the manufacturer, packer, distributor, or seller;

(B) The common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name;

(C) The signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic;

(D) The signal word "WARNING" or "CAUTION" on all other hazardous substances;

(E) An affirmative statement of the principal hazard or hazards, such as "Flammable," "Combustible," "Vapor Harmful," "Causes Burns," "Absorbed Through Skin," or similar wording descriptive of the hazard;

(F) Precautionary measures describing the action to be followed or avoided,

except when modified by regulation of the Commission pursuant to section 3 of the act;

(G) Instruction, when necessary or appropriate, for first-aid treatment;

(H) The word *Poison* for any hazardous substance which is defined as "highly toxic" by section 2(h) of the act (restated in paragraph (b)(6) of this section);

(I) Instructions for handling and storage of packages which require special care in handling or storage; and

(J) The statement (1) "Keep out of the reach of children" or its practical equivalent, or, (2) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard; and

(ii) On which any statements required under section 2(p)(1) of the act (restated in paragraph (b)(14)(i) of this section) are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

Misbranded hazardous substance also means a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in section 2(f)(1) of the Federal Hazardous Substances Act (restated in paragraph (b)(4)(i)(A) of this section) and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(15)(i) *Banned hazardous substance* means:

(A) Any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or

(B) Any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as a "banned hazardous substance" on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under the act for that substance, the degree or nature of the hazard involved in the presence or

use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce; *Provided*, That the Commission by regulation (1) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section) articles, such as chemistry sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved, or necessarily present an electrical, mechanical, or thermal hazard, and which bear labeling giving adequate directions and warnings for safe use and are intended for use by children who have attained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings, and (2) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section), and provide for the labeling of, common fireworks (including toy paper caps, cone fountains, cylinder fountains, whistles without report, and sparklers) to the extent that the Commission determines that such articles can be adequately labeled to protect the purchasers and users thereof.

(ii) Proceedings for the issuance, amendment, or repeal of regulations pursuant to section 2(q)(1)(B) of the act (restated in paragraph (b)(15)(i)(B) of this section) shall be governed by the provisions of section 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act: *Provided*, That if the Commission finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, the Commission may by order published in the FEDERAL REGISTER give notice of such finding, and thereupon such substance when intended or offered for household use, or when so packaged as to be suitable for such use, shall be deemed to be a “banned hazardous substance” pending the completion of proceedings relating to the issuance of such regulations.

(16) “Electrical hazard”—an article may be determined to present an electrical hazard if, in normal use or when

subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock.

(17) “Mechanical hazard”—an article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness:

(i) From fracture, fragmentation, or disassembly of the article;

(ii) From propulsion of the article (or any part or accessory thereof);

(iii) From points or other protrusions, surfaces, edges, openings, or closures;

(iv) From moving parts;

(v) From lack or insufficiency of controls to reduce or stop motion;

(vi) As a result of self-adhering characteristics of the article;

(vii) Because the article (or any part or accessory thereof) may be aspirated or ingested;

(viii) Because of instability; or

(ix) Because of any other aspect of the article’s design or manufacture.

(18) “Thermal hazard”—an article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces.

(c) *Certain statutory definitions interpreted, supplemented, or provided with alternatives.* The following items interpret, supplement, or provide alternatives to definitions set forth in section 2 of the act (and restated in paragraph (b) of this section):

(1) To provide flexibility as to the number of animals tested, and to emphasize *in vitro* testing methods, the following is an alternative to the definition of “highly toxic” in section 2(h) of the act (and paragraph (b)(6) of this section); *Highly toxic* means:

(i) A substance determined by the Commission to be highly toxic on the basis of human experience; and/or

(ii) A substance that produces death within 14 days in half or more than half of a group of:

(A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams or less per kilogram of body weight is administered orally;

(B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or

(C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours or less by the method described in §1500.40.

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

(iii) A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(2) To give specificity to the definition of "toxic" in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition. "Toxic" applies to any substance that is "toxic" (but not "highly toxic") on the basis of human experience. The following categories are not intended to be inclusive.

(i) *Acute toxicity.* Toxic means any substance that produces death within 14 days in half or more than half of a group of:

(A) White rats (each weighing between 200 and 300 grams) when a single dose of from 50 milligrams to 5 grams per kilogram of body weight is administered orally. Substances falling in the toxicity range between 500 milligrams

and 5 grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of the act, under §1500.82, upon a showing that such labeling is not needed because of the physical form of the substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors;

(B) White rats (each weighing between 200 and 300 grams) when an atmospheric concentration of more than 200 parts per million but not more than 20,000 parts per million by volume of gas or vapor, or more than 2 but not more than 200 milligrams per liter by volume of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or

(C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of more than 200 milligrams but not more than 2 grams per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours by the method described in §1500.40.

(D) The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices. *Toxic* also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in §1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: Existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(ii) *Chronic toxicity.* A substance is toxic because it presents a chronic hazard if it falls into one of the following categories. (For additional information see the chronic toxicity guidelines at 16 CFR 1500.135.)

(A) *For Carcinogens.* A substance is toxic if it is or contains a known or probable human carcinogen.

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(B) *For Neurotoxicological Toxicants.* A substance is toxic if it is or contains a known or probable human neurotoxin.

(C) *For Developmental or Reproductive Toxicants.* A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant.

(3) The definition of corrosive in section 2(i) of the act (restated in paragraph (b)(7) of this section) is interpreted to also mean the following: Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if a weight-of-evidence analysis suggests that it is corrosive, or validated *in vitro* test method suggests that it is corrosive, or if, when tested by the *in vivo* technique described in §1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: Existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; and/or a substance that can be considered a primary irritant based on

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the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; and/or means a substance that can be considered an eye irritant based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

(5) The definition of *strong sensitizer* in section 2(k) of the Federal Hazardous Substances Act (restated in paragraph (b)(9) of this section) is supplemented by the following definitions:

(i) *Sensitizer.* A sensitizer is a substance that is capable of inducing a state of immunologically mediated hypersensitivity (including allergic photosensitivity) following a variable period of exposure to that substance. Hypersensitivity to a substance will become evident by an allergic reaction elicited upon reexposure to the same substance.

(ii) *Significant potential for causing hypersensitivity.* (A) Before designating any substance a "strong sensitizer," the Commission shall find that the substance has significant potential for causing hypersensitivity. *Significant potential for causing hypersensitivity* is a relative determination that must be made separately for each substance. The determination may be based on documented medical evidence of hypersensitivity reactions upon subsequent

exposure to the same substance obtained from epidemiological surveys or case histories; controlled *in vivo* or *in vitro* experimental studies; susceptibility profiles (*e.g.*, genetics, age, gender, atopic status) in non-sensitized or allergic subjects; and chemical or functional properties of the substance.

(B) In determining whether a substance is a "strong" sensitizer, the Commission shall consider the available data for a number of factors, following a weight-of-evidence approach. The following factors (if available), ranked in descending order of importance, should be considered: well-conducted clinical and diagnostic studies, epidemiological studies, with a preference for general population studies over occupational studies, well-conducted animal studies, well-conducted *in vitro* test studies, cross-reactivity data, and case histories.

(C) Additional consideration may be given to Quantitative Structure-Activity Relationships (QSARs), *in silico* data, specific human sensitization threshold values, other data on potency and sensitizer bioavailability, if data are available and the methods validated. Bioavailability is the dose of the allergen available to interact with a tissue. Bioavailability is a reflection of how well the skin or another organ can absorb the allergen and the actual penetrating ability of the allergen, including factors such as size and composition of the chemical.

(D) Criteria for a "well-conducted" study would include: validated outcomes, relevant dosing, route of administration, and use of appropriate controls. Studies should be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP).

(E) Before the Commission designates any substance as a "strong" sensitizer, frequency of occurrence and range of severity of reactions in exposed subpopulations having average or high susceptibility will be considered. The minimal severity of a reaction for the purpose of designating a material as a "strong sensitizer" is a clinically important reaction. A clinically impor-

tant reaction would be considered one with a significant impact on quality of life. Consideration should be given to the location of the hypersensitivity response, such as the face, hands, and feet as well as persistence of clinical manifestations. For example, strong sensitizers may produce substantial illness, including any or all of the following: substantial physiological effects, such as discomfort and distress, substantial hardship, functional or structural impairment, persistent morbidity, or in rare cases, mortality.

(iii) *Normal living tissue.* The allergic hypersensitivity reaction occurs in normal living tissues, including the skin, mucous membranes (*e.g.*, ocular, oral), and other organ systems, such as the respiratory tract and gastrointestinal tract, either singularly or in combination, following sensitization by contact, ingestion, or inhalation.

(6) The Consumer Product Safety Commission, by the regulations published in this section, defines the terms *extremely flammable*, *flammable*, and *combustible*, appearing in section 2(1) of the Federal Hazardous Substances Act, as follows:

(i) The term *extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F (−6.7 °C) as determined by the test method described at §1500.43a, except that, any mixture having one component or more with a flashpoint higher than 20 °F (−6.7 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be an extremely flammable substance.

(ii) The term *flammable* shall apply to any substance having a flashpoint above 20 °F (−6.7 °C) and below 100 °F (37.8 °C), as determined by the method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint at or above 100 °F (37.8 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a flammable substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be flammable if the mixture does not present a significant flammability hazard when used by consumers.

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(iii) The term *combustible* shall apply to any substance having a flashpoint at or above 100 °F (37.8 °C) to and including 150 °F (65.6 °C) as determined by the test method described at §1500.43a, except that:

(A) Any mixture having one component or more with a flashpoint higher than 150 °F (65.6 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a combustible hazardous substance; and

(B) Any mixture containing 24 percent or less of water miscible alcohols, by volume, in aqueous solution is not considered to be combustible if the mixture does not present a significant flammability hazard when used by consumers.

(iv) To determine flashpoint temperatures for purposes of enforcing and administering requirements of the Federal Hazardous Substances Act applicable to “extremely flammable,” “flammable,” and “combustible” hazardous substances, the Commission will follow the procedures set forth in §1500.43a. However, the Commission will allow manufacturers and labelers of substances and products subject to those requirements to rely on properly conducted tests using the Tagliabue open-cup method which was in effect prior to the issuance of §1500.43a (as published at 38 FR 27012, September 27, 1973, and set forth below), and the definitions of the terms “extremely flammable,” “flammable,” and “combustible” in this section before its amendment (as published at 38 FR 27012, September 27, 1983, and amended 38 FR 30105, November 1, 1973, set forth in the note following this section) if all of the following conditions are met:

(A) The substance or product was subject to and complied with the requirements of the Federal Hazardous Substances Act for “extremely flammable,” “flammable,” or “combustible” hazardous substances before the effective date of §1500.43a; and

(B) No change has been made to the formulation or labeling of such substance or product after the effective date of §1500.43a, prescribing a closed-cup test apparatus and procedure.

(v) *Extremely flammable solid* means a solid substance that ignites and burns at an ambient temperature of 80 °F or

less when subjected to friction, percussion, or electrical spark.

(vi) *Flammable solid* means a solid substance that, when tested by the method described in §1500.44, ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

(vii) *Extremely flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening and the flashpoint, when tested by the method described in §1500.43a is less than 20 °F (−6.7 °C).

(viii) *Flammable contents of self-pressurized container* means contents of a self-pressurized container that, when tested by the method described in §1500.45, a flame projection exceeding 18 inches is obtained at full valve opening, or flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening.

(7) The definition of *hazardous substance* in section 2(f)(1)(A) of the act (restated in paragraph (b)(4)(i)(A) of this section) is supplemented by the following definitions or interpretations or terms used therein:

(i) A substance or mixture of substances that “generates pressure through decomposition, heat, or other means” is a hazardous substance:

(A) If it explodes when subjected to an electrical spark, percussion, or the flame of a burning paraffin candle for 5 seconds or less.

(B) If it expels the closure of its container, or bursts its container, when held at or below 130 °F. for 2 days or less.

(C) If it erupts from its opened container at a temperature of 130 °F. or less after having been held in the closed container at 130 °F. for 2 days.

(D) If it comprises the contents of a self-pressurized container.

(ii) *Substantial personal injury or illness* means any injury or illness of a significant nature. It need not be severe or serious. What is excluded by the word “substantial” is a wholly insignificant or negligible injury or illness.

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(iii) *Proximate result* means a result that follows in the course of events without an unforeseeable, intervening, independent cause.

(iv) *Reasonably foreseeable handling or use* includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

(8) The definition of "radioactive substance" in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following: *Radioactive substance* means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter. Source materials, special nuclear material, and byproduct materials described in section 2(f)(3) of the act are exempt.

(9) In the definition of "label" in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(10) The definition of "misbranded hazardous substance" in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein:

(i) *Hazardous substances intended, or packaged in a form suitable, for use in the household* means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed in-

cluding, but not limited to, a garage, carport, barn, or storage shed. The term includes articles, such as polishes or cleaners, designed primarily for professional use but which are available in retail stores, such as hobby shops, for nonprofessional use. Also included are items, such as antifreeze and radiator cleaners, that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled as, and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household; the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning's prominence and conspicuousness are: Location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label.

NOTE: The definitions of *extremely flammable*, *flammable*, and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10, 1987. The definitions remaining in effect until August 10, 1987, as published at 38 FR 27012, Sept. 27, 1973, and amended at 38 FR 30105, Nov. 1, 1973, are set forth below. Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in § 1500.3(c)(6)(iv), as amended.

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F. as determined by the Tagliabue Open Cup Tester; *flammable* shall apply to any substance which has a flashpoint of above 20 °F., to and including 80 °F., as determined by the Tagliabue Open Cup Tester; and *combustible* shall apply to any substance

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which has a flashpoint above 80 °F. to and including 150 °F., as determined by the Tagliabue Open Cup Tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found by the Commission to be generally applicable to such materials or containers, respectively, and established by regulations issued by the Commission, which regulations shall also define the terms *flammable*, *combustible*, and *extremely flammable* in accord with such methods.

* * * * *

(c)(6)(i) *Extremely flammable* means any substance that has a flashpoint at or below 20 °F. as determined by the method described in § 1500.43.

(ii) *Flammable* means any substance that has a flashpoint of above 20 °F., to and including 80 °F., as determined by the method described in § 1500.43.

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 30105, Nov. 1, 1973; 49 FR 22465, May 30, 1984; 51 FR 28536, Aug. 8, 1986; 51 FR 29096, Aug. 14, 1986; 51 FR 30209, Aug. 25, 1986; 57 FR 46669, Oct. 9, 1992; 77 FR 73293, Dec. 10, 2012; 79 FR 8831, Feb. 14, 2014; 83 FR 8341, Feb. 27, 2018]

§ 1500.4 Human experience with hazardous substances.

(a) Reliable data on human experience with any substance should be taken into account in determining whether an article is a “hazardous substance” within the meaning of the act. When such data give reliable results different from results with animal data, the human experience takes precedence.

(b) Experience may show that an article is more or less toxic, irritant, or corrosive to man than to test animals. It may show other factors that are important in determining the degree of hazard to humans represented by the substance. For example, experience shows that radiator antifreeze is likely to be stored in the household or garage and likely to be ingested in significant quantities by some persons. It also shows that a particular substance in liquid form is more likely to be ingested than the same substance in a paste or a solid and that an aerosol is more likely to get into the eyes and the nasal passages than a liquid.

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§ 1500.5 Hazardous mixtures.

For a mixture of substances, the determination of whether the mixture is a “hazardous substance” as defined by section 2(f) of the act (repeated in § 1500.3(b)(4)) should be based on the physical, chemical, and pharmacological characteristics of the mixture. A mixture of substances may therefore be less hazardous or more hazardous than its components because of synergistic or antagonistic reactions. It may not be possible to reach a fully satisfactory decision concerning the toxic, irritant, corrosive, flammable, sensitizing, or pressure-generating properties of a substance from what is known about its components or ingredients. The mixture itself should be tested.

§ 1500.12 Products declared to be hazardous substances under section 3(a) of the act.

(a) The Commission finds that the following articles are hazardous substances within the meaning of the act because they are capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use:

(1) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating.

(2) Metal-cored candlewicks that have a lead content of more than 0.06 percent of the total weight of the metal core, and candles made with such wicks.

(b) [Reserved]

[38 FR 27012, Sept. 27, 1973, as amended at 68 FR 19147, Apr. 18, 2003]

§ 1500.13 Listing of “strong sensitizer” substances.

On the basis of frequency of occurrence and severity of reaction information, the Commission finds that the following substances have a significant potential for causing hypersensitivity and therefore meet the definition for “strong sensitizer” in section 2(k) of the act (repeated in § 1500.3(b)(9)):

(a) Paraphenylenediamine and products containing it.

(b) Powdered orris root and products containing it.

(c) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200.

(d) Formaldehyde and products containing 1 percent or more of formaldehyde.

(e) Oil of bergamot and products containing 2 percent or more of oil of bergamot.

§ 1500.14 Products requiring special labeling under section 3(b) of the act.

(a) Human experience, as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, and opinions of informed medical experts establish that the following substances are hazardous:

(1) Diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol.

(2) Ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol.

(3) Products containing 5 percent or more by weight of benzene (also known as benzol) and products containing 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates such as kerosine, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates.

(4) Methyl alcohol (methanol) and mixtures containing 4 percent or more by weight of methyl alcohol (methanol).

(5) Turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and mixtures containing 10 percent or more by weight of such turpentine.

(b) The Commission finds that the following substances present special hazards and that, for these substances, the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act, the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

(1) *Diethylene glycol*. Because diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful if swallowed."

(2) *Ethylene glycol*. Because ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful or fatal if swallowed."

(3) *Benzene, toluene, xylene, petroleum distillates*. (i) Because inhalation of the vapors of products containing 5 percent or more by weight of benzene may cause blood dyscrasias, such products shall be labeled with the signal word "danger," the statement of hazard "Vapor harmful," the word "poison," and the skull and crossbones symbol. If the product contains 10 percent or more by weight of benzene, it shall bear the additional statement of hazard "Harmful or fatal if swallowed" and the additional statement "Call physician immediately."

(ii) Because products containing 10 percent or more by weight of toluene, xylene, or any of the other substances listed in paragraph (a)(3) of this section may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger," the statement of hazard "Harmful or fatal if swallowed," and the statement "Call physician immediately."

(iii) Because inhalation of the vapor of products containing 10 percent or more by weight of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "Vapor harmful" in addition to the statements prescribed in paragraph (b)(3)(ii) of this section.

(4) *Methyl alcohol (methanol)*. Because death and blindness can result from the ingestion of methyl alcohol, the label for this substance and for mixtures containing 4 percent or more by weight

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of this substance shall include the signal word “danger,” the additional word “poison,” and the skull and crossbones symbol. The statement of hazard shall include “Vapor harmful” and “May be fatal or cause blindness if swallowed.” The label shall also bear the statement “Cannot be made nonpoisonous.”

(5) *Turpentine.* Because turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and products containing 10 percent or more by weight of such turpentine, in addition to oral toxicity resulting in systemic poisoning, may be aspirated into the lungs with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word “danger” and the statement of hazard “Harmful or fatal if swallowed.”

(6) *Charcoal.* Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating.

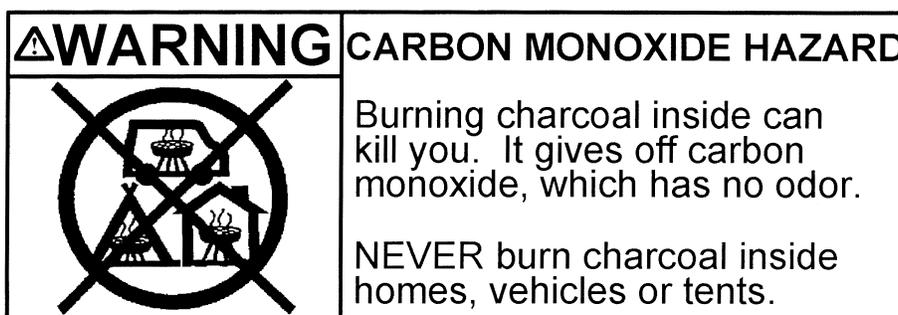
(i)(A) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas may cause serious injury or death, con-

tainers of such products packaged before November 3, 1997, shall bear the following borderlined statement:

WARNING: Do Not Use for Indoor Heating or Cooking Unless Ventilation Is Provided for Exhausting Fumes to Outside. Toxic Fumes May Accumulate and Cause Death

(B) For bags of charcoal packaged before November 3, 1997, the statement specified in paragraph (b)(6)(i) of this section shall appear within a heavy borderline in a color sharply contrasting to that of the background, on both front and back panels in the upper 25 percent of the panels of the bag at least 2 inches below the seam, and at least 1 inch above any reading material or design elements in type size as follows: The signal word “WARNING” shall appear in capital letters at least three-eighths inch in height; the remaining text of the warning statement shall be printed in letters at least three-sixteenths inch in height.

(ii)(A) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas can cause serious injury or death, containers of such products packaged on or after November 3, 1997, shall bear the following borderlined label.



(B) Except as provided in paragraph (b)(6)(ii)(C) of this section, the following requirements apply to bags of charcoal subject to paragraph (b)(6)(ii)(A) of this section. The label specified in paragraph (b)(6)(ii)(A) of this section shall appear within a heavy borderline, in a color sharply contrasting to that of the background,

on both the front and back panels in the upper 25 percent of the panels of the bag, and with the outer edge of the borderline at least 2.54 cm (1 inch) below the seam and at least 2.54 cm (1 inch) above any other reading material or design elements. The signal word “WARNING” shall be in bold capital letters in at least 7.14 mm (9/32 inch)

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type. The remaining text of the warning statement shall be in at least 4.763 mm (3/16 inch) type. The phrase "CARBON MONOXIDE HAZARD" shall be in bold. This phrase and the word "NEVER" shall be in all capital letters. The lettering shall have a strokewidth-to-height ratio of 1:6 to 1:8. The label shall be at least 50.8 mm (2 inches) high and 147.5 mm (5 13/16 inches) wide. The label's lettering, spacing between the bottom of the letters of one line and the top of the letter of the next line, and pictogram shall have the size relation to each other and to the remainder of the label shown in paragraph (b)(6)(ii)(A) of this section.

(C) For bags of charcoal subject to paragraph (b)(6)(ii)(A) of this section that are 6 inches or less wide, the minimum label height may be reduced to 38 mm (1.5 inches) and the minimum width may be reduced to 139.7 mm (5.5 inches). The signal word "WARNING" shall be in capital letters in at least 6.32 mm (0.249 inch) type. The remaining text of the warning shall be in at least 4.23 mm (0.166 inch) type. All other requirements of paragraphs 6(b)(ii) (A) and (B) of this section shall apply to these bags.

(7) *Fireworks devices.* Because of the special hazards presented by fireworks devices if not used in a certain manner, the following listed fireworks devices shall be labeled as indicated:

(i) *Fountains.*

WARNING (OR CAUTION)

FLAMMABLE (or EMITS SHOWERS OF SPARKS, if more descriptive). Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Place on level surface. Light fuse and get away.

(ii) *California candles.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Hold in hand at bottom of tube. Point away from body so that neither end points toward body.

(iii) *Spike and handle cylindrical fountains.*

(A) *Spike fountains.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Stick firmly in ground in an upright position. Do not hold in hand. Light fuse and get away.

(B) *Handle fountains.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Hold in hand—point away from body. Light fuse.

(iv) *Roman Candles.*

WARNING (OR CAUTION) SHOOTS FLAMING BALLS

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Stick butt end in ground. Do not hold in hand. Light fuse and get away.

(v) *Rockets with sticks.*

WARNING (OR CAUTION) FLAMMABLE

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Place in wooden trough or iron pipe at 75° angle, pointing away from people or flammable material. Do not hold in hand. Light fuse and get away.

(vi) *Wheels.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Attach securely by means of a nail through the hole (or place on hard flat surface, for ground spinners). Light fuse and get away.

(vii) *Illuminating torches.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.) For outdoor use only. Hold in hand—point away from body, clothing, or other flammable material (or place upright on level ground. Do not hold in hand, if more descriptive).

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Light fuse (or light fuse and get away, if more descriptive).

(viii) *Sparklers.*

On the front and back panels:

WARNING (OR CAUTION) FLAMMABLE

On the side, front, back, top, or bottom panel.

CAUTION

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Do not touch glowing wire (or do not touch hot plastic, wood, etc., if more descriptive).

Hold in hand with arm extended away from body.

Keep burning end or sparks away from wearing apparel or other flammable material.

(ix) *Mines and shells.*

WARNING (OR CAUTION) EMITS SHOWERS OF SPARKS (OR SHOOTS FLAMING BALLS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place on hard smooth surface (or place upright on level ground, if more descriptive).

Do not hold in hand.

Light fuse and get away.

(x) *Whistles without report.*

WARNING (OR CAUTION) FLAMMABLE

SHOOTS WHISTLE IN AIR (if applicable)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Do not hold in hand.

Light fuse and get away.

(xi) *Toy smoke devices and flitter devices.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Do not hold in hand.

Light fuse and get away.

(xii) *Helicopter-type rockets.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place on hard, open surface.

Light fuse and get away.

(xiii) *Party poppers.*

WARNING (OR CAUTION) FLAMMABLE

Use only under [close] adult supervision. (Use of the word close is optional.)

Do not point either end toward face or other person.

Hold in hand—jerk string.

(xiv) *Missile-type rockets.*

WARNING (OR CAUTION) FLAMMABLE (OR EMITS SHOWERS OF SPARKS, IF MORE DESCRIPTIVE)

Use only under [close] adult supervision. (Use of the word close is optional.)

For outdoor use only.

Place on hard, open surface.

Light fuse and get away.

(xv) *Labeling—General.* Any fireworks device not required to have a specific label as indicated above shall carry a warning label indicating to the user where and how the item is to be used and necessary safety precautions to be observed. All labels required under this section shall comply with the requirements of §1500.121 of these regulations. (See also §1500.17(a) (3), (8) and (9); §1500.83(a)(27); §1500.85(a)(2); and part 1507).

(8) *Art materials.*

NOTE: The Labeling of Hazardous Art Materials Act (“LHAMA”), 15 U.S.C. 1277 (Pub. L. 100-695, enacted November 18, 1988) provides that, as of November 18, 1990, “the requirements for the labeling of art materials set forth in the version of the standard of the American Society for Testing and Materials [“ASTM”] designated D-4236 that is in effect on [November 18, 1988] * * * shall be deemed to be a regulation issued by the Commission under section 3(b)” of the Federal Hazardous Substances Act, 15 U.S.C. 1262(b). For the convenience of interested persons, the Commission is including the requirements of ASTM D-4236 in paragraph (b)(8)(i) of this section, along with other requirements (stated in paragraph (b)(8)(ii) of this section) made applicable to art materials by the LHAMA. The substance of the requirements specified in LHAMA became effective on November 18, 1990, as mandated by Congress.

(i) *ASTM D-4236—(A) Scope—(1)* This section describes a procedure for developing precautionary labels for art materials and provides hazard and precautionary statements based upon knowledge that exists in the scientific and medical communities. This section concerns those chronic health hazards known to be associated with a product or product component(s), when the component(s) is present in a physical form, volume, or concentration that in

the opinion of a toxicologist (see paragraph (b)(8)(i)(B)(11) of this section) has the potential to produce a chronic adverse health effect(s).

(2) This section applies exclusively to art materials packaged in sizes intended for individual users of any age or those participating in a small group.

(3) Labeling determinations shall consider reasonably foreseeable use or misuse.

(4) Manufacturers or repackagers may wish to have compliance certified by a certifying organization. Guidelines for a certifying organization are given in paragraph (b)(8)(i)(H) of this section.

(B) Descriptions of Terms Specific to This Standard. (1) Art material or art material product—any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and suitable for users as defined herein.

(2) Users—artists or crafts people of any age who create, or recreate in a limited number, largely by hand, works which may or may not have a practical use, but in which aesthetic considerations are paramount.

(3) Chronic adverse health effect(s)—a persistent toxic effect(s) that develops over time from a single, prolonged, or repeated exposure to a substance. This effect may result from exposure(s) to a substance that can, in humans, cause sterility, birth defects, harm to a developing fetus or to a nursing infant, cancer, allergenic sensitization, damage to the nervous system, or a persistent adverse effect to any other organ system.

(4) chronic health hazard(s) (hereafter referred to as “chronic hazard”)—a health risk to humans, resultant from exposure to a substance that may cause a chronic adverse health effect.

(5) Analytical laboratory—a laboratory having personnel and apparatus capable of performing quantitative or qualitative analyses of art materials, which may yield information that is used by a toxicologist for evaluation of potentially hazardous materials.

(6) Label—a display of written, printed, or graphic matter upon the immediate container of any art material product. When the product is unpackaged, or is not packaged in an

immediate container intended or suitable for delivery to users, the label can be a display of such matter directly upon the article involved or upon a tag or other suitable labeling device attached to the art material.

(7) Producer—the person or entity who manufactures, processes, or imports an art material.

(8) Repackager—the person or entity who obtains materials from producers and without making changes in such materials puts them in containers intended for sale as art materials to users.

(9) Sensitizer—a substance known to cause, through an allergic process, a chronic adverse health effect which becomes evident in a significant number of people on re-exposure to the same substance.

(10) Toxic—applies to any substance that is likely to produce personal injury or illness to humans through ingestion, inhalation, or skin contact.

(11) Toxicologist—an individual who through education, training, and experience has expertise in the field of toxicology, as it relates to human exposure, and is either a toxicologist or physician certified by a nationally recognized certification board.

(12) Bioavailability—the extent that a substance can be absorbed in a biologically active form.

(C) Requirements. (1) The producer or repackager of art materials shall submit art material product formulation(s) or reformulation(s) to a toxicologist for review, such review to be in accordance with paragraph (b)(8)(1)(D) of this section. The toxicologist shall be required to keep product formulation(s) confidential.

(2) Unless otherwise agreed in writing by the producer or repackager, no one other than the toxicologists shall have access to the formulation(s); except that the toxicologists shall furnish a patient’s physician, on a confidential basis, the information necessary to diagnose or treat cases of exposure or accidental ingestion.

(3) The producer or repackager, upon advice given by a toxicologist in accordance with paragraph (b)(8)(i)(D) of this section and based upon generally accepted, well-established evidence that a component substance(s) is

known to cause chronic adverse health effects adopt precautionary labeling in accordance with paragraph (b)(8)(i)(E) of this section.

(4) Labeling shall conform to any labeling practices prescribed by federal and state statutes or regulations and shall not diminish the effect of required acute toxicity warnings.

(5) The producer or repackager shall supply a poison exposure management information source the generic formulation information required for dissemination to poison control centers or shall provide a 24-hour cost-free telephone number to poison control centers.

(6) The producer or repackager shall have a toxicologist review as necessary, but at least every 5 years, art material product formulation(s) and associated label(s) based upon the then-current, generally accepted, well-established scientific knowledge.

(7) Statement of Conformance—“Conforms to ASTM Practice D-4236,” or “Conforms to ASTM D-4236,” or “Conforms to the health requirements of ASTM D-4236.” This statement may be combined with other conformance statements. The conformance statement should appear whenever practical on the product; however, it shall also be acceptable to place the statement on one or more of the following:

- (i) The individual product package,
- (ii) a display or sign at the point of purchase,
- (iii) separate explanatory literature available on requirements at the point of purchase,
- (iv) a response to a formal request for bid or proposal.

(D) Determination of Labeling. (1) An art material is considered to have the potential for producing chronic adverse health effects if any customary or reasonably foreseeable use can result in a chronic hazard.

(2) In making the determination, a toxicologist(s) shall take into account the following:

- (i) Current chemical composition of the art material, supplied by an analytical laboratory or by an industrial chemist on behalf of a manufacturer or repackager.
- (ii) Current generally accepted, well-established scientific knowledge of the

chronic toxic potential of each component and the total formulation.

(iii) Specific physical and chemical form of the art material product, bio-availability, concentration, and the amount of each potentially chronic toxic component found in the formulation.

(iv) Reasonably foreseeable uses of the art material product as determined by consultation with users and other individuals who are experienced in use of the material(s), such as teachers, or by market studies, unless such use information has previously been determined with respect to the specific art material(s) under review.

(v) Potential for known synergism and antagonism of the various components of the formulation.

(vi) Potentially chronic adverse health effects of decomposition or combustion products, if known, from any reasonably foreseeable use of the hazardous art material product.

(vii) Opinions of various regulatory agencies and scientific bodies, including the International Agency for Research on Cancer and the National Cancer Institute, on the potential for chronic adverse health effects of the various components of the formulation.

(3) Based upon the conclusion reached in conformance with review determinations set forth herein, the toxicologist(s) shall recommend precautionary labeling consistent with paragraph (b)(8)(i)(E) of this section.

(E) Labeling Practices—(1) Signal Word. (i) When a signal word for an acute hazard(s) is mandated and a chronic hazard(s) exists, the signal word shall be that for the acute hazard.

(ii) When only a chronic hazard(s) exists, the signal word WARNING shall be used.

(iii) The signal word shall be prominently visible and set in bold capitals in a size equal to or greater than the statement of potential chronic hazards.

(2) List of Potentially Chronic Hazards—Potentially chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be stated substantially in accordance with the statements listed in paragraph (b)(8)(i)(F) of this section. Potentially chronic hazards noted shall be those that are clinically significant

and that might be expected with any reasonably foreseeable use of the art material. The hazards should be grouped in the order of relative descending severity.

(3) Name of Chronically Hazardous Component(s)—All components and known decomposition products of the formulation with a potential for chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be listed prominently. Generically equivalent names may be used.

(4) Safe Handling Instructions—Appropriate precautionary statements as to work practices, personal protection, and ventilation requirements shall be used substantially conforming with those listed in paragraph (b)(8)(i)(G) of this section.

(5) List of Sensitizing Components—To protect users from known sensitizers found within art materials, each label shall contain a list of those sensitizers present in sufficient amounts to contribute significantly to a known skin or respiratory sensitization.

(6) Combined Statement—If an art material contains more than one component capable of causing a chronic adverse health effect, or if a single chemical can cause several different chronic adverse health effects, the potential effects may be combined into one statement.

(7) Information Sources—The precautionary label shall contain a statement identifying a source for additional health information substantially in conformance with one of the phrases listed below:

(i) For more health information—(24 hour cost-free U.S. telephone number),

(ii) Contact a physician for more health information, or

(iii) Call your local poison control center for more health information.

(8) Labeling Content, Product Size—Any art material product in a container larger in size than one fluid ounce (30 ml) (if the product is sold by volume) or one ounce net weight (28 g) (if the product is sold by weight) shall have full precautionary labeling, as described in paragraph (b)(8)(i)(E) of this section. Any art material product in a container equal to or smaller than one fluid ounce or one ounce net weight

shall have a label that includes a signal word in conformance with paragraph (b)(8)(i)(E)(I) of this section and a list of potentially harmful or sensitizing components in conformance with paragraphs (b)(8)(i)(E) (3) and (5) of this section.

(9) The information described in paragraph (b)(8)(i)(E) of this section must appear on:

(i) The outside container or wrapper, if any, unless it is easily legible through the outside container or wrapper and

(ii) All accompanying literature where there are directions for use, written or otherwise. Where a product that requires warning labels under paragraphs (b)(8)(i)(D) and (E) of this section is packed within a point-of-sale package that obscures the warning statement(s), the point-of-sale package shall carry the signal word conforming to paragraph (b)(8)(i)(E)(I) and the following wording: “Contains: (list hazardous product(s) that may be harmful if misused. Read cautions on individual containers carefully. Keep out of the reach of children.”

(10) Statements required under paragraphs (b)(8)(i)(D) and (E) of this section must be in the English language and located prominently in conspicuous and legible type in contrast by topography, layout, or color with other printed matter on the label.

(11) Supplemental Information—Where appropriate, more detailed information that relates to chronic hazard(s), such as physical properties, decomposition products, detailed safety instructions, or disposal recommendations, shall be included in supplemental documents, such as Material Safety Data Sheets, technical brochures, technical data sheets etc.

(F) chronic Hazard Statements
 MAY CAUSE STERILITY.
 CONTACT MAY CAUSE PERMANENT EYE DAMAGE.
 MAY BE HARMFUL BY BREATHING VAPORS/DUSTS.
 MAY BE HARMFUL IF SWALLOWED.
 MAY BE HARMFUL BY SKIN CONTACT.
 MAY PRODUCE BIRTH DEFECTS IN THE DEVELOPING FETUS.
 MAY BE EXCRETED IN HUMAN MILK.

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MAY CAUSE HARM TO THE NURSING INFANT.
CANCER AGENT! EXPOSURE MAY PRODUCE CANCER.
CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
POSSIBLE CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
MAY PRODUCE ALLERGIC REACTION BY INGESTION/INHALATION/SKIN CONTACT.
MAY PRODUCE NUMBNESS OR WEAKNESS IN THE EXTREMITIES. EXPOSURE MAY CAUSE (SPECIFY THE ORGAN(S)) DAMAGE.
HEATING/COMBUSTION MAY CAUSE HAZARDOUS DECOMPOSITION PRODUCTS.

(G) Precautionary Statements
Keep out of reach of children.
When using do not eat, drink, or smoke.
Wash hands immediately after use.
Avoid inhalation/ingestion/skin contact.
Avoid fumes from combustion.
Keep container tightly closed when not in use.
Store in well-ventilated area.
Wear protective clothing (specify type).
Wear protective goggles/face shield.
Wear NIOSH-certified mask for dusts/mists/fumes.
Wear NIOSH-certified respirator with an appropriate cartridge for (specify).
Wear NIOSH-certified supplied-air respirator.
Use window exhaust fan to remove vapors and ensure adequate cross ventilation. (Specify explosion-proof if necessary.)
Do not heat above (specify temperature) without adequate ventilation.
Use (specify type) local exhausting hood.
Do not use/mix with (specify material).

(ii) The following shall apply with respect to the standard for art materials set forth in § 1500.14(b)(8)(i).

(A) The term *art material* or *art material product* shall mean any substance marketed or represented by the producer or repackager as suitable for use in any phase of the creation of any work of visual or graphic art of any medium. The term does not include economic poisons subject to the Fed-

eral Insecticide, Fungicide, and Rodenticide Act or drugs, devices, or cosmetics subject to the Federal Food, Drug, and Cosmetics Act.

(B) The standard referred to in paragraph (b)(8)(i) of this section applies to art materials intended for users of any age.

(C) Each producer or repackager of art materials shall describe in writing the criteria used to determine whether an art material has the potential for producing chronic adverse health effects. Each producer or repackager shall submit, to the Commission's Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207, the written description of the criteria described above and a list of art materials that require hazard warning labels under this section. Upon request of the Commission, a producer or repackager shall submit to the Commission product formulations.

(D) All art materials that require chronic hazard labeling pursuant to this section must include on the label the name and United States address of the producer or repackager of the art materials, an appropriate United States telephone number that can be contacted for more information on the hazards requiring warning labels under this section, and a statement that such art materials are inappropriate for use by children.

(E) If an art material producer or repackager becomes newly aware of any significant information regarding the hazards of an art material or ways to protect against the hazard, this new information must be incorporated into the labels of such art materials that are manufactured after 12 months from the date of discovery. If a producer or repackager reformulates an art material, the new formulation must be evaluated and labeled in accordance with the standard set forth § 1500.14(b)(8)(i).

(F) In determining whether an art material has the potential for producing chronic adverse health effects, including carcinogenicity and potential carcinogenicity, the toxicologist to whom the substance is referred under the standard described above shall take into account opinions of various regulatory agencies and scientific

bodies, including the U.S. Consumer Product Safety Commission (CPSC), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).

(iii) Pursuant to the LHAMA, the Commission has issued guidelines which, where possible, specify criteria for determining when any customary or reasonably foreseeable use of an art material can result in a chronic hazard. These guidelines include criteria for determining when art materials may produce chronic adverse effects in children and adults, criteria for determining which substances contained in art materials have the potential for producing chronic adverse effects and what those effects are, criteria for determining the bioavailability of chronically hazardous substances contained in art materials when the products are used in a customary or reasonably foreseeable manner, and criteria for determining acceptable daily intake levels for chronically hazardous substances contained in art materials. Because these guidelines apply to hazardous substances in general as well as to hazardous substances in art materials, the guidelines are set forth in §1500.135 and a definition of "chronic toxicity" is provided in §1500.3(c)(2)(ii) as part of supplementation of the term "toxic" in section 2(q) of the FHSA.

(iv) *Policies and interpretations.* (A) For purposes of enforcement policy, the Commission will not consider as sufficient grounds for bringing an enforcement action under the Labeling of Hazardous Art Materials Act ("LHAMA") the failure of the following types of products to meet the requirements of §1500.14(b)(8) (i) through (iii).

(1) Products whose intended general use is not to create art (e.g., common wood pencils, and single colored pens, markers, and chalk), unless the particular product is specifically packaged, promoted, or marketed in a manner that would lead a reasonable person to conclude that it is intended for use as an art material. Factors the Commission would consider in making this determination are how an item is packaged (e.g., packages of multiple colored pencils, chalks, or markers unless promoted for non-art materials uses are likely to be art materials),

how it is marketed and promoted (e.g., pencils and pens intended specifically for sketching and drawing are likely to be art materials), and where it is sold (e.g., products sold in an art supply store are likely to be art materials). The products described in this paragraph do not meet the statutory definition of "art material."

(2) Tools, implements, and furniture used in the creation of a work of art such as brushes, chisels, easels, picture frames, drafting tables and chairs, canvas stretchers, potter's wheels, hammers, air pumps for air brushes, kilns, and molds.

(3) Surface materials upon which an art material is applied, such as coloring books and canvas, unless, as a result of processing or handling, the consumer is likely to be exposed to a chemical in or on the surface material in a manner which makes that chemical susceptible to being ingested, absorbed, or inhaled.

(4) The following materials whether used as a surface or applied to one, unless, as a result of processing or handling, the consumer is likely to be exposed to a chemical in or on the surface material in a manner which makes that chemical susceptible to being ingested, absorbed, or inhaled: paper, cloth, plastics, films, yarn, threads, rubber, sand, wood, stone, tile, masonry, and metal.

(B) For purposes of LHAMA enforcement policy, the Commission will enforce against materials including, but not limited to, paints, crayons, colored pencils, glues, adhesives, and putties, if such materials are sold as part of an art, craft, model, or hobby kit. The Commission will enforce the LHAMA requirements against paints or other materials sold separately which are intended to decorate art, craft, model, and hobby items. Adhesives, glues, and putties intended for general repair or construction uses are not subject to LHAMA. However, the Commission will enforce the LHAMA requirements against adhesives, glues, and putties sold separately (not part of a kit) if they are intended for art and craft and model construction uses. This paragraph (b)(8)(iv)(B) applies to products introduced into interstate commerce on or after August 14, 1995.

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(C) Commission regulations at § 1500.14(b)(8)(i)(C)(7) require that a statement of conformance appear with art materials that have been reviewed in accordance with the Commission standard. The Commission interprets this provision to require a conformance statement regardless of the presence of any chronic hazard warnings.

(D) Nothing in this enforcement statement should be deemed to alter any of the requirements of the Federal Hazardous Substances Act (“FHSA”), such as, but not limited to, the requirement that any hazardous substance intended or packaged in a form suitable for household use must be labeled in accordance with section 2(p) of the FHSA.

APPENDIX A TO § 1500.14(b)(8)—GUIDELINES FOR A CERTIFYING ORGANIZATION (NOT MANDATORY)

(a) The term “certifying organization,” as used in this paragraph, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

(b) The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers’ chemists, on its technical and certifying committees.

(c) Representative samples of art materials, labeled as conforming to this section and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

(d) The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

(e) In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist’s decision can be presented to the advisory board of toxicologists for arbitration.

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22934, June 8, 1976; 48 FR 16, Jan. 3, 1983; 53 FR 3018, Feb. 3, 1988; 57 FR 46669, Oct. 9, 1992; 60 FR 8193, Feb. 27, 1995; 61 FR 19829, May 3, 1996; 61 FR 33175, June 26, 1996]

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§ 1500.15 Labeling of fire extinguishers.

When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of § 1500.3(c) (1) and (2) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced that meet the definition of highly toxic in § 1500.3(c)(1), the signal word “Danger” and the statement of hazard “Poisonous gases formed when used to extinguish flame or on contact with heat” are required labeling.

(b) When substances are produced that meet the definition of toxic in § 1500.3(c)(2), the signal word “Caution” or “Warning” and the statement of hazard “Dangerous gas formed when used to extinguish flame or on contact with heat” are required labeling.

(c) Regardless of whether paragraph (a) or (b) of this section applies, any substance or mixture of substances labeled for use as a fire extinguisher that, if applied to an electrical fire, would subject the user to the likelihood of electrical shock shall be conspicuously labeled “Caution: Do not use on electrical wires.”

(d) The statements specified in paragraphs (a), (b), and (c) of this section shall be in addition to any other that may be required under the act. All such substances or mixtures of substances shall also bear the additional statements “Use in an enclosed place may be fatal” and “Do not enter area until well ventilated and all odor of chemical has disappeared.”

§ 1500.17 Banned hazardous substances.

(a) Under the authority of section 2(q)(1)(B) of the act, the Commission declares as banned hazardous substances the following articles because they possess such a degree or nature of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce:

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(1) Mixtures that are intended primarily for application to interior masonry walls, floors, etc., as a water repellent treatment and that are “extremely flammable” within the meaning of section 2(1) of the act (repeated in §1500.3(b)(10)).

(2) Carbon tetrachloride and mixtures containing it (including carbon tetrachloride and mixtures containing it used in fire extinguishers), excluding unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million.

(3) Fireworks devices intended to produce audible effects (including but not limited to cherry bombs, M-80 salutes, silver salutes, and other large firecrackers, aerial bombs, and other fireworks designed to produce audible effects, and including kits and components intended to produce such fireworks) if the audible effect is produced by a charge of more than 2 grains of pyrotechnic composition; except that this provision shall not apply to such fireworks devices if all of the following conditions are met:

(i) Such fireworks devices are distributed to farmers, ranchers, or growers through a wildlife management program administered by the U.S. Department of the Interior (or by equivalent State or local government agencies); and

(ii) Such distribution is in response to a written application describing the wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control are unavailable or inadequate. (See also §1500.14(b)(7); §1500.17(a) (8) and (9); §1500.83(a)(27); §1500.85(a)(2); and part 1507).

(4) Liquid drain cleaners containing 10 percent or more by weight of sodium and/or potassium hydroxide; except that this subparagraph shall not apply to such liquid drain cleaners if packaged in accordance with a standard for special packaging of such articles promulgated under the Poison Prevention

Packaging Act of 1970 (Pub. L. 91-601, 84 Stat. 1670-74 (15 U.S.C. 1471-76)).

(5) Products containing soluble cyanide salts, excluding unavoidable manufacturing residues of cyanide salts in other chemicals that under reasonable and foreseeable conditions of use will not result in a concentration of cyanide greater than 25 parts per million.

(6)(i) Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household that:

(A) Is shipped in interstate commerce after December 31, 1973, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(B) Is shipped in interstate commerce after December 31, 1972, and contains lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(C) [Reserved]

(D) The provisions of paragraph (a)(6)(i) of this section do not apply to artists' paints and related materials.

(ii) Any toy or other article intended for use by children that:

(A) Is shipped in interstate commerce after December 31, 1973, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.06 percent of the total weight of the contained solids or dried paint film; or

(B) Is shipped in interstate commerce after December 31, 1972, and bears any paint or other similar surface-coating material containing lead compounds of which the lead content (calculated as the metal) is in excess of 0.5 percent of the total weight of the contained solids or dried paint film.

(iii) Since the Commission has issued comprehensive regulations for lead-containing paint and certain consumer products bearing such paint at the 0.06 percent level under the Consumer Product Safety Act (see 16 CFR part 1303), paragraphs (i) and (ii) of §1500.17(a)(6) are revoked as to the subject products manufactured after February 27, 1978.

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NOTE: The effective date of paragraphs (a)(6)(i)(A) and (a)(6)(ii)(A) was stayed by an order published in the FEDERAL REGISTER of August 10, 1972 (37 FR 16078).

(7) General-use garments containing asbestos (other than garments having a bona fide application for personal protection against thermal injury and so constructed that the asbestos fibers will not become airborne under reasonably foreseeable conditions of use).

(8) Firecrackers designed to produce audible effects, if the audible effect is produced by a charge of more than 50 milligrams (.772 grains) of pyrotechnic composition (not including firecrackers included as components of a rocket), aerial bombs, and devices that may be confused with candy or other foods, such as “dragon eggs,” and “cracker balls” (also known as “ball-type caps”), and including kits and components intended to produce such fireworks except such devices which meet all of the following conditions:

(i) The fireworks devices are distributed to farmers, ranchers, or growers through a wildlife management program administered by the U.S. Department of Interior (or by equivalent State or local governmental agencies); and

(ii) Such distribution is in response to a written application describing the wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control is unavailable or inadequate. (See also §1500.17(a) (3) and (9)).

(9) All fireworks devices, other than firecrackers, including kits and components intended to produce such fireworks, not otherwise banned under the act, that do not comply with the applicable requirements of part 1507 of this chapter, except fireworks devices which meet all the following conditions:

(i) The fireworks devices are distributed to farmers, ranchers, or growers through a wildlife management program administered by the U.S. Department of the Interior (or by equivalent State or local government agencies); and

(ii) Such distribution is in response to a written application describing the

wildlife management problem that requires use of such devices, is of a quantity no greater than required to control the problem described, and is where other means of control is unavailable or inadequate. (See also §1500.17(a) (3) and (8)).

(10) Self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant manufactured or imported on or after October 7, 1974. (See also §1500.17(a) (3) and (8)).

(11)(i) Reloadable tube aerial shell fireworks devices that use shells larger than 1.75 inches in outer diameter and that are imported on or after October 8, 1991.

(ii) *Findings.* (A) *General.* In order to issue a rule under section 2(q)(1) of the Federal Hazardous Substances Act (“FHSA”), 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these findings in the regulation. These findings are discussed below.

(B) *Voluntary standard.* Although a voluntary standard relating to the risk of injury associated with reloadable tube aerial shells has been adopted, it has not been implemented. Thus, the Commission is not required to make findings covering the likelihood that the voluntary standard would result in elimination or adequate reduction of the risk of injury or that there would be substantial compliance with the voluntary standard.

(C) *Relationship of benefits to costs.* The Commission estimates that the removal of large reloadable shells from the market is likely to virtually eliminate the number of associated injuries, with only a slight offsetting increase in the number of injuries due to the use of substitute Class C fireworks products available to consumers. The estimated net benefits range from essentially zero to close to \$1 million annually. The annual costs of a ban are estimated to be very low. Included are potential costs to foreign manufacturers and U.S. importers from sales losses, production changes, and inventory retrofitting, and slightly reduced market choices

for consumers who purchase aerial display fireworks. Costs to each of these sectors are estimated to be slight, and are reduced to the extent that alternative products are perceived as adequate substitutes for large reloadable shells. Thus, the Commission finds that the benefits expected from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered several alternatives to the ban. These included: Design or performance criteria; additional or alternative labeling; inclusion of some reloadable shells 1.75 inches or smaller in the ban; and no action in reliance on the voluntary standard. The Commission determined that a ban of reloadable shells larger than 1.75 inches in outer diameter is the least burdensome alternative that would prevent or adequately reduce the risk of injury.

(1) Regarding design or performance criteria, the Commission considered requirements similar to those stated in the voluntary standard of the American Fireworks Standards Laboratory ("AFSL"). However, such criteria may increase the cost of the product and would not address all factors involved in the incidents. Further, concerns exist about the feasibility of criteria and quality control.

(2) Regarding additional or alternative labeling, the users' perception and experience concerning the amount of time available to get away may lead them to disregard an inconsistent warning. There are no data to suggest that a significant number, if any, incidents would be avoided if large reloadable shells carried more detailed labels or instructions than they currently do. It cannot be concluded that potential benefits would be greater than zero.

(3) The Commission considered including reloadable shells that are 1.75 inches or less in outer diameter and have the "equivalent explosive power" of larger shells. A kinetic energy level of 70 joules was considered to evaluate explosive power. However, any potential benefits are uncertain since the Commission concluded that a clear relation between kinetic energy and in-

jury potential could not be established. Also, costs could be slightly higher.

(4) The Commission also considered imposing no mandatory requirements on large reloadable shells and relying instead on the AFSL voluntary standard. However, it is uncertain whether any net benefits to consumers would result from this alternative, since the level of injury reduction could be near zero if, as is probable, some firms chose not to conform with some or all of the AFSL standard.

(12)(i) *Large multiple-tube devices.* Multiple-tube mine and shell fireworks devices that first enter commerce or are imported on or after March 26, 1997, that have any tube measuring 1.5 inches (3.8 cm) or more in inner diameter, and that have a minimum tip angle less than 60 degrees when tested in accordance with the procedure of §1507.12 of this part.

(ii) *Findings—(A) General.* In order to issue a rule under the section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these in the regulation. These findings are discussed in paragraphs (a)(12)(ii) (B) through (D) of this section.

(B) *Voluntary standard.* (1) One alternative to the tip-angle requirement that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. The American Fireworks Safety Laboratory (AFSL) has a standard for mines and shells intended to address the potential tip-over hazard associated with multiple-tube fireworks devices. AFSL's Voluntary Standard for Mines and Shells—Single or Multiple Shot requires that large multiple-tube devices not tip over (except as the result of the last shot) when shot on a 2-inch thick medium-density foam pad. The Commission cannot conclude that AFSL's existing voluntary standard adequately reduces the risk of injury from large devices that tip over while functioning. The Commission's tests using polyurethane foam did not find sufficient agreement between performance on foam and on grass. No other data are available to show that this dynamic test is reliable.

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(2) In addition, even if the AFSL standard is effective, the Commission does not believe that compliance with the standard will be adequate. AFSL reports that it has been testing in accordance with its standard since January 1994. However, the results of CPSC's compliance testing indicate that multiple-tube devices still tip over while functioning. In fiscal year 1994, all 24 imported devices the Commission tested, and 1 of 8 domestic devices, tipped over while functioning. In fiscal year 1995, 22 of 27 imported devices and 1 of 5 domestic devices tipped over during Commission testing. The Commission finds that there is unlikely to be substantial compliance with the voluntary standard applicable to multiple-tube devices.

(C) *Relationship of benefits to costs.* The Commission estimates that the 60-degree tip-angle standard will eliminate the unreasonable tip-over risk posed by these devices. This will provide benefits of saving one life about every 3 years, and preventing an unknown number of nonfatal injuries. The annual cost of modifying affected devices is estimated to be between \$1.5 million and \$2.7 million. The Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: a ban of all multiple-tube devices with inner tube diameters 1.5 inches or greater; a dynamic performance standard; additional labeling requirements; and relying on the voluntary standard. Although a ban of all large multiple-tube devices would address the risk of injury, it would be more burdensome than the tip-angle standard. The Commission was unable to develop a satisfactory dynamic standard that would reduce the risk of injury. Neither additional labeling requirements nor reliance on the voluntary standard would adequately reduce the risk of injury. Thus, the Commission finds that a standard requiring large multiple-tube devices to have a minimum tip angle greater than 60 degrees is the least burdensome requirement that would prevent or adequately reduce the risk of injury.

(13)(i) *Candles made with metal-cored wicks.* Candles manufactured or imported on or after October 15, 2003, made with metal-cored candlewicks, unless:

(A) The metal core of each candlewick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candles subject to paragraph (a)(13)(i)(A) of this section are shipped, including each outer container or wrapper in which such candles are distributed to a retail outlet, is labeled "Conforms to 16 CFR 1500.17(a)(13)." For purposes of this paragraph (B), the term "outer container or wrapper" does not include the immediate container in which candle(s) is/are intended to be displayed at retail or during use in the home, unless that container or wrapper is also the only container or wrapper in which the candle(s) is/are shipped to a retailer.

(ii) *Metal-cored candlewicks.* Metal-cored candlewicks manufactured or imported on or after October 15, 2003, unless:

(A) The metal core of each candlewick has a lead content (calculated as the metal) of not more than 0.06 percent of the total weight of the metal core; and

(B) Each outer container or wrapper in which candlewicks subject to paragraph (a)(13)(ii)(A) of this section is shipped, including each outer container or wrapper of a shipment distributed to a retail outlet, is labeled "Conforms to 16 CFR 1500.17(a)(13)." For purposes of this paragraph (B), the term "outer container or wrapper" does not include the immediate container in which candlewick(s) is/are intended to be displayed or sold at retail, unless that container or wrapper is also the only container or wrapper in which the candlewick(s) is/are shipped to a retailer.

(iii) *Findings—(A) General.* To issue a rule under section 2(q)(1) of the FHSA, 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include them in

the regulation. These findings are discussed in paragraphs (a)(13)(iii)(B) through (D) of this section.

(B) *Voluntary standard.* One alternative to the ban that the Commission considered is to take no mandatory action, and to depend on a voluntary standard. One organization has a standard for candlewicks intended to address the potential for substantial illness posed by such wicks and candles with such wicks. The Commission has found that the standard is technically unsound and that substantial compliance with it is unlikely. Furthermore, there is no evidence that the standard has been adopted and implemented by candlewick or candle manufacturers.

(C) *Relationship of benefits to costs.* The Commission estimates that the ban will reduce the potential for exposure to lead and resulting lead poisoning because there is no "safe" level of lead in the blood. The annual cost to the candle/wick industry of the ban is estimated by the Commission to be in the range of \$100,000 to \$300,000. On a percentage basis these costs represent only 0.005 to 0.015 percent of the overall value of candle shipments in 2000, which was approximately \$2 billion. Accordingly, the Commission finds that the benefits from the regulation bear a reasonable relationship to its costs.

(D) *Least burdensome requirement.* The Commission considered the following alternatives: no action; labeling all metal-cored candles with wicks containing more than 0.06 percent lead by weight of the metal; recordkeeping for shipments of wicks containing 0.06 percent or less lead by weight of the metal and of candles with such wicks; and relying on the voluntary standard. Neither no action, nor labeling, nor reliance on the voluntary standard would adequately reduce the risk of illness. Recordkeeping for shipments of wicks and of candles was not the least burdensome requirement that would prevent or adequately reduce the risk of illness. Therefore the Commission finds that a ban on candlewicks containing more than 0.06 percent lead by weight of the metal and candles with such wicks is the least burdensome requirement that would prevent or adequately reduce the risk of illness.

(b) [Reserved]

(Secs. 2(f)(1), (A), (B), (g), (q)(1)(B), 3(a), 74 Stat. 372, 374, as amended 80 Stat. 1304-05, 83 Stat. 187-189, 90 Stat. 503 (15 U.S.C. 1261, 1262); sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 371 (e), (f), (g)), sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[38 FR 27012, Sept. 27, 1973, as amended at 38 FR 27514, Oct. 4, 1973; 38 FR 31520, Nov. 15, 1973; 39 FR 30114, Aug. 21, 1974; 39 FR 42903, Dec. 9, 1974; 41 FR 22935, June 8, 1976; 42 FR 44202, Sept. 1, 1977; 43 FR 12310, Mar. 24, 1978; 48 FR 16, Jan. 3, 1983; 56 FR 37837, Aug. 9, 1991; 61 FR 13095, Mar. 26, 1996; 61 FR 18245, Apr. 25, 1996; 68 FR 19147, Apr. 18, 2003]

§ 1500.18 Banned toys and other banned articles intended for use by children.

(a) *Toys and other articles presenting mechanical hazards.* Under the authority of sections 2(f)(1)(D) and 24 of the act and pursuant to the provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children present a mechanical hazard within the meaning of section 2(s) of the act because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

(1) Any toy rattle containing, either internally or externally, rigid wires, sharp protrusions, or loose small objects that have the potential for causing lacerations, puncture wound injury, aspiration, ingestion, or other injury. (But see § 1500.86(a)(1)).

(2) Any toy having noisemaking components or attachments capable of being dislodged by the operating features of the toy or capable of being deliberately removed by a child, which toy has the potential for causing laceration, puncture wound injury, aspiration, ingestion, or other injury.

(3) Any doll, stuffed animal, or other similar toy having internal or external components that have the potential for causing laceration, puncture wound injury, or other similar injury. (But see § 1500.86(a)(2)); (See also §§ 1500.48 and 1500.49).

(4) Lawn darts and other similar sharp-pointed toys usually intended for

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outdoor use and having the potential for causing puncture wound injury.

(5) [Reserved]

(6) Any article known as a “baby-bouncer” or “walker-jumper” and any other similar article (referred to in this paragraph as “article(s)”), except an infant walker subject to part 1216, which is intended to support very young children while sitting, bouncing, jumping, and/or reclining, and which because of its design has any exposed parts capable of causing amputation, crushing, lacerations, fractures, hematomas, bruises, or other injuries to fingers, toes, or other parts of the anatomy of young children. Included among, but not limited to, the design features of such articles which classify the articles as banned hazardous substances are:

(i) The areas about the point on each side of the article where the frame components are joined together to form an “X” shape capable of producing a scissoring, shearing, or pinching effect.

(ii) Other areas where two or more parts are joined in such a manner as to permit a rotational movement capable of exerting a scissoring, shearing, or pinching effect.

(iii) Exposed coil springs which may expand sufficiently to allow an infant’s finger, toe, or any other part of the anatomy to be inserted, in whole or in part, and injured by being caught between the coils of the spring or between the spring and another part of the article.

(iv) Holes in plates or tubes which provide the possibility of insertion, in whole or in part, of a finger, toe, or any part of the anatomy that could then be injured by the movement of another part of the article.

(v) Design and construction that permits accidental collapse while in use. (But see §1500.86(a)(4)).

(7) Toys usually known as clacker balls and consisting of two balls of plastic or another material connected by a length of line or cord or similar connector (referred to as “cord” in §1500.86(a)(5)), intended to be operated in a rhythmic manner by an upward and downward motion of the hand so that the two balls will meet forcefully at the top and bottom of two

semicircles thus causing a “clacking” sound, which toys present a mechanical hazard because their design or manufacture presents an unreasonable risk of personal injury from fracture, fragmentations, or disassembly of the toy and from propulsion of the toy or its part(s). (But see §1500.86(a)(5).) This does not include products that are constructed so that the connecting members consist of plastic rods integrally molded to the balls and are mounted on a pivot so that movement of the balls is essentially limited to a single plane.

(8) Any pacifier that does not meet the requirements of 16 CFR part 1511 and that is introduced into interstate commerce after February 26, 1978.

(9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. For purposes of this regulation, introduction into interstate commerce is defined as follows: A toy or children’s article manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy or children’s article manufactured in the United States is introduced into interstate commerce (1) at the time of its first interstate sale, or (2) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier. Part 1501 defines the term “toy or other article intended for use by children under 3,” as used in this regulation, and exempts certain products from banning under this regulation.

(10)–(11) [Reserved]

(12) Any bicycle as defined in §1512.2(a) of this chapter (except a bicycle that is a “track bicycle” or a “one-of-a-kind bicycle” as defined in §1512.2(d) and (e) of this chapter) that is introduced into interstate commerce on or after May 11, 1976, and that does not comply with the requirements of part 1512 of this chapter, except for §§1512.5(c)(3), 1512.9(a), 1512.18(e) and 1512.18(f) which become effective November 13, 1976.

(15) Any rattle (as defined in §1510.2 of this chapter) that is introduced into interstate commerce on or after August 21, 1978, and that does not comply with the requirements of part 1510 of this chapter. For purposes of the regulation, introduction into interstate commerce is defined as follows: A rattle manufactured outside the United States is introduced into interstate commerce when it is first brought within a U.S. port of entry. A rattle manufactured in the United States is introduced into interstate commerce (a) at the time of its first interstate sale, or (b) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate.

(16) (i) Any article known as an "infant cushion" or "infant pillow," and any other similar article, which has all of the following characteristics (But see §1500.86(a)(9)):

(A) Has a flexible fabric covering. The term *fabric* includes those materials covered by the definition of "fabric" in section 2(f) of the Flammable Fabrics Act, 15 U.S.C. 1191(f).

(B) Is loosely filled with a granular material, including but not limited to, polystyrene beads or pellets.

(C) Is easily flattened.

(D) Is capable of conforming to the body or face of an infant.

(E) Is intended or promoted for use by children under one year of age.

(ii) *Findings*—(A) *General*. In order to issue a rule under section 2(q)(1) of the Federal Hazardous Substance Act (FHSA), 15 U.S.C. 1261(q)(1), classifying a substance or article as a banned hazardous substance, the FHSA requires the Commission to make certain findings and to include these findings in the regulation. These findings are discussed in paragraphs (a)(16)(ii) (B) through (D) of this section.

(B) *Voluntary standard*. No findings concerning compliance with or adequacy of a voluntary standard are necessary since no voluntary standard addressing infant cushions has been adopted or implemented.

(C) *Relationship of benefits to costs*. The Commission estimates that the removal of infant cushions from the market will result in total annual benefits of approximately five million dollars.

The potential costs to businesses are expected to be offset by production of other products, and the potential costs to consumers are likely to be offset by the availability of substitutes for a comparable price.

(D) *Least burdensome requirement*. The Commission considered labeling and a design or performance standard as alternatives to the ban. The Commission does not believe that any form of labeling would have a significant effect in preventing the hazard associated with infant cushions. The Commission also concluded that no feasible standard exists that would address the hazard. Thus, the Commission determined that a ban of infant cushions is the least burdensome alternative that would prevent or adequately reduce the risk of injury.

(17) Any ball intended for children under three years of age that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this paragraph, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

(i) For the purposes of this paragraph, the term "ball" includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term "ball" includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term "ball" also includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(ii) The term "ball" does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.52, the ball is not removed from the outer container.

(iii) In determining whether such a ball is intended for use by children under three years of age, the criteria specified in 16 CFR 1501.2(b) and the enforcement procedure established by 16 CFR 1501.5 shall apply.

(18)(i) Any bunk bed (as defined in § 1513.2(c) of this chapter) that does not comply with the requirements of part 1513 of this chapter.

(ii) *Findings.* In order to issue a rule under Section 3(e) of the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1262(e), classifying a toy or other article intended for use by children as a hazardous substance on the basis that it presents a mechanical hazard (as defined in Section 2(s) of the FHSA), the FHSA requires the Commission to make the following findings and to include these findings in the regulation: Bunk beds present a mechanical hazard; Where a voluntary standard has been adopted and implemented by the affected industry, that compliance with such voluntary standard is not likely to result in the elimination or adequate reduction of the risk of injury, or it is unlikely that there will be substantial compliance with such voluntary standard; The benefits expected from the rule bear a reasonable relationship to its costs; and The rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury for which the rule is being promulgated. These findings are made in the appendix to Part 1513.

(19)(i) Dive sticks, and other similar articles, that are used in swimming pools or other water environments for such activities as underwater retrieval games or swimming instruction, and which, when placed in the water, submerge and rest at the bottom of the pool. This includes products that are pre-weighted to sink to the bottom and products that are designed to allow the user to adjust the weight. Dive sticks and similar articles that come to rest underwater at an angle greater than 45 degrees from vertical when measured under the test at § 1500.86(a)(7) and dive sticks and similar articles that maintain a compressive force of less than 5-lbf under the test at § 1500.86(a)(8) are exempt from this banning rule. Articles that have a continuous circular

shape, such as dive rings and dive disks are also exempt.

(ii)(A) *Findings.* In order for the Commission to issue a rule under section 2(q)(1) of the FHSA classifying a substance or article as a banned hazardous substance, the Commission must make certain findings and include these findings in the regulation. 15 U.S.C. 1262(i)(2). These findings are discussed in paragraphs (a)(18)(ii)(B) through (D) of this section.

(B) *Voluntary standard.* No findings concerning compliance with and adequacy of a voluntary standard are necessary because no relevant voluntary standard addressing the risk of injury posed by dive sticks has been adopted and implemented.

(C) *Relationship of benefits to costs.* The Commission estimates the potential benefits of removing hazardous dive sticks from the market to be 2 to 4 cents per dive stick. With the availability of substitutes and the expected low cost of modifying dive sticks to conform to the rule, the Commission anticipates that necessary changes will be minimal. The Commission estimates that the costs of the rule will be no more than 2 to 4 cents per dive stick. Thus, the Commission finds that there is a reasonable relationship between the expected benefits of the rule and its costs.

(D) *Least burdensome requirement.* The Commission considered pursuing voluntary recalls, following a voluntary standard, requiring labeling or changing the scope of the rule. A banning rule would be more effective than case-by-case recalls because the impalement hazard affects all dive sticks, not a specific brand or model. Awaiting recalls would allow these hazardous items on the market until the Commission obtained recalls. No applicable voluntary standard exists, and compliance may be low if one did. Although labeling could help reduce the risk of injuries from dive sticks, it would be less effective than a banning rule. It may be difficult for a label to convey the necessary information at the time of use. Modifying the scope so that the rule would only apply to pre-weighted dive sticks would continue to permit hazardous items because the unweighted dive sticks can easily be weighted to

stand vertically at the bottom of the water. Thus, the Commission finds that a ban of dive sticks with the hazardous characteristics it has identified is the least burdensome alternative that would adequately reduce the risk of injury.

(b) *Electrically operated toys and other electrical operated children's articles presenting electrical, thermal, and/or certain mechanical hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of electrically operated toys or other electrically operated articles intended for use by children present electrical, thermal, and/or certain mechanical hazards within the meaning of section 2 (r), (s), and/or (t) of the act because in normal use or when subjected to reasonably foreseeable damage or abuse, the design or manufacture may cause personal injury or illness by electric shock and/or presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces, or because of certain mechanical hazards.

(1) Any electrically operated toy or other electrically operated article intended for use by children (as defined in §1505.1(a)(1)) that is introduced into interstate commerce and which does not comply with the requirements of part 1505 of this chapter.

NOTE: Paragraph (b)(1) was originally promulgated as 21 CFR 191.9a(b)(1) with an effective date of September 3, 1973 (38 FR 6138).

(2) [Reserved]

(c) *Toys and other articles (not electrically operated) presenting electric hazards.* Under the authority of section 2(f)(1)(D) of the act and pursuant to provisions of section 3(e) of the act, the Commission has determined that the following types of toys or other articles intended for use by children (not electrically operated) present an electrical hazard within the meaning of section 2(r) of the act.

(1) Any kite 10 inches or greater in any dimension constructed of aluminized polyester film or any kite having a tail or other component consisting of a piece of aluminized polyester film 10 inches or greater in any dimension presents an electrical hazard

and is a banned hazardous substance because its design (specifically its size and electrical conductivity) presents a risk of personal injury from electric shock due to its ability to conduct electricity and to become entangled in or otherwise contact high voltage electric power lines.

(2) [Reserved]

(15 U.S.C. 1261 (f)(1)(D), (g)(1)(A), (r); 15 U.S.C. 1262(e)(1); 15 U.S.C. 2079(a))

[38 FR 27012, Sept. 27, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1500.18, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 1500.19 Misbranded toys and other articles intended for use by children.

(a) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term "ball" includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term "ball" also includes any multi-sided object formed by connecting planes into a generally, spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term "ball" does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar outer containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm.) in a rigid template ¼ inches (6 mm.) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission's test template shall be no greater than 1.75 inches (44.4 mm.).

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(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children's toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children's games, generally as a playing piece or marker. The term "marble" does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Package* or packaging refers to the immediate package in which a product subject to labeling under section 24 of the act is sold, as well as to any outer container or wrapping for that package.

(7) *Descriptive material* means any discrete piece of written material separate from the label of the package that contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product. A catalog or other marketing material or advertisement that depicts other products in addition to the product it accompanies is not "descriptive material" unless it contains additional information, such as instructions for use of the product it accompanies or lists of accessories exclusively for use with that product, that are designed to focus the pur-

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chaser's attention on the product. Descriptive material "accompanies" a product subject to the labeling requirements when it is packaged with the product or when it is intended to be distributed with the product at the time of sale or delivery to the purchaser. "Descriptive material" does not include statements that appear on the package of a product subject to the labeling requirements. "Descriptive material" does not include material intended solely for use by children if the package it accompanies contains a separate package insert prominently identified as a warning for parents that contains the required precautionary statements.

(8) *Bin and container for retail display* mean containers in which multiple unpackaged and unlabeled items are held for direct selection by and sale to consumers.

(b) *Misbranded toys and children's articles*. Pursuant to sections 2(p) and 24 of the FHSA, the following articles are misbranded hazardous substances if their packaging, any descriptive material that accompanies them, and, if unpackaged and unlabeled, any bin in which they are held for sale, any container in which they are held for retail display, or any vending machine from which they are dispensed, fails to bear the labeling statements required in paragraphs (b) (1) through (4) and paragraph (f)(3) of this section, or if such labeling statements fail to comply with the prominence and conspicuousness requirements of paragraph (d) of this section.

(1) With the exception of books and other articles made of paper, writing materials such as crayons, chalk, pencils, and pens, modeling clay and similar products, fingerpaints, watercolors, and other paint sets, and any other article identified in 16 CFR 1501.3 (other than balloons), any article that is a toy or game intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:



WARNING:

CHOKING HAZARD--Small parts
Not for children under 3 yrs.

(2) Any latex balloon, or toy or game that contains a latex balloon, shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--Children under 8 yrs. can choke or suffocate on uninflated or broken balloons. Adult supervision required.

Keep uninflated balloons from children.
Discard broken balloons at once.

(3)(i) Any small ball intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--This toy is a small ball.
Not for children under 3 yrs.

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:



WARNING:

CHOKING HAZARD--Toy contains a small ball.
Not for children under 3 yrs.

(4)(i) Any marble intended for children three years of age or older shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--This toy is a marble.
Not for children under 3 yrs.**

(ii) Any toy or game intended for children who are at least three years old but less than eight years of age that contains a marble shall bear the following cautionary statement:



WARNING:

**CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.**

(c) *Age of intended user.* In determining the ages of the children for which any toy or article subject to this section is intended, the following factors are relevant: the manufacturer's stated intent (such as the age stated on a label) if it is reasonable; the advertising, marketing, and promotion of the article; and whether the article is commonly recognized as being intended for children in this age group. In enforcing this provision, the Commission will follow the procedures set forth in 16 CFR 1501.5.

(d) *Prominence and conspicuousness of labeling statements.* The requirements of 16 CFR 1500.121 relating to the prominence and conspicuousness of precautionary labeling statements for hazardous substances shall apply to any labeling statement required under §1500.19(b) and (f), with the following clarifications and modifications.

(1) All labeling statements required by §1500.19(b) and (f) shall be in the English language. The statements required by paragraph (b) need not appear in the format and layout depicted in paragraph (b). The statements re-

quired by 16 CFR 1500.19(b) and (f) shall be blocked together within a square or rectangular area, with or without a border. This means that the statements must appear on at least two lines. The statements shall be separated from all other graphic material by a space no smaller than the minimum allowable height of the type size for other cautionary material (e.g., the phrase "Not for children under 3 yrs.>"). If not separated by that distance, the labeling statements must be surrounded by a border line. Label design, the use of vignettes, or the proximity of other labeling or lettering shall not obscure or render inconspicuous any labeling statement required under §1500.19(b) and (f). This means that such statements shall appear on a solid background, which need not differ from the background color or any other color on the package label.

(2) The words "WARNING" or "SAFETY WARNING" required by section 24 of the FHSA shall be regarded as signal words.

(3) The statement "CHOKING HAZARD" shall be regarded as a statement

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of the principal hazard associated with the products subject to this section.

(4) All other remaining statements required by this section shall be regarded as "other cautionary material" as that term is defined in 16 CFR 1500.121(a)(2)(viii).

(5) The principal display panel for a bin, container for retail display, or vending machine shall be the side or surface designed to be most prominently displayed, shown, or presented to, or examined by, prospective purchasers. In the case of bins or containers for retail display, the cautionary material may be placed on a display card of a reasonable size in relationship to the surface area of the bin or container. The area of the display card shall constitute the area of the principal display panel. In the case of vending machines that contain a display card, the cautionary label may be placed either on the display card, on the coinage indicator decal, or on the glass or clear plastic of the machine. If there is no display card inside a vending machine, the size of the principal display panel will be calculated in accordance with 16 CFR 1500.121(c) based on the size of the front of the container

from which items are dispensed, exclusive of the area of metal attachments, coin inserts, bases, etc. Any other side or surface of such a bin, container for retail sale, or vending machine that bears information, such as price or product description, for examination by purchasers shall be deemed to be a principal display panel, excluding any side or surface with information that only identifies the company that owns or operates a vending machine.

(6) All of the labeling statements required by this section, including those classified as "other cautionary material," must appear on the principal display panel of the product, except as provided for by §1500.19(f). Any signal word shall appear on the same line and in close proximity to the triangle required by section 24 of the act. Multiple messages should be provided with sufficient space between them, when feasible, to prevent them from visually blending together.

(7) All labeling statements required by this section shall comply with the following type size requirements. 16 CFR 1500.121(c)(1) explains how to compute the area of the principal display panel and letter height.

| | | | | | | | | |
|-------------------|---|-------|-------|-------|-------|-------|-------|-------|
| Area sq. in | 0-2 + 2-5 + 5-10 + 10-15 + 15-30 + 30-100 + 100-400 + 400 | | | | | | | |
| Type Size | | | | | | | | |
| Sig. Wd | 3/64" | 1/16" | 3/32" | 7/64" | 1/8" | 5/32" | 1/4" | 1/2" |
| St. Haz | 3/64" | 3/64" | 1/16" | 3/32" | 3/32" | 7/64" | 5/32" | 1/4" |
| Oth. Mat | 1/32" | 3/64" | 1/16" | 1/16" | 5/64" | 3/32" | 7/64" | 5/32" |

(8) Labeling required by this section that appears on a bin, container for retail display, or vending machine shall be in reasonable proximity to any pricing or product information contained on the principal display panel, or, if such information is not present, in close proximity to the article that is subject to the labeling requirements.

(9) Descriptive material that accompanies a product subject to the labeling requirements, including accompanying material subject to the alternative allowed by §1500.19(f), shall comply with the requirements of 16 CFR 1500.121(c)(6) relating to literature containing instructions for use which accompanies a hazardous substance. If the descriptive material contains instructions for use, the required pre-

cautionary labeling shall be in reasonable proximity to such instructions or directions and shall be placed together within the same general area (see 16 CFR 1500.121(c)(6)).

(10) In the case of any alternative labeling statement permitted under §1500.19(e), the requirements of 16 CFR 1500.121(b)(3) and 1500.121(c)(2)(iii) shall apply to statements or indicators on the principal display panel directing attention to the complete cautionary labeling that appears on another display panel.

(11) Any triangle required by this section shall be an equilateral triangle. The height of such a triangle shall be equal to or exceed the height of the letters of the signal word "WARNING".

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The height of the exclamation point inside the triangle shall be at least half the height of the triangle, and the exclamation point shall be centered vertically in the triangle. The triangle shall be separated from the signal word by a distance at least equal to the space occupied by the first letter of the signal word. In all other respects, triangles with exclamation points shall conform generally to the provisions of 16 CFR 1500.121 relating to signal words.

(e) *Combination of labeling statements.* The labels of products that contain more than one item subject to the requirements of this section may combine information relating to each of the respective hazards, if the resulting condensed statement contains all of the information necessary to describe the hazard presented by each article. However, in the case of a product that contains a balloon and another item

subject to the labeling requirements, only the signal word and statement of hazard may be combined.

(f) *Alternative labeling statements for small packages.* Any cautionary statement required by section 1500.19(b) may be displayed on a display panel of the package of a product subject to the labeling requirement other than the principal display panel only if:

(1) The package has a principal display panel of 15 square inches or less,

(2) The full labeling statement required by paragraph (b) of this section is displayed in three or more languages on another display panel of the package of the product, and

(3)(i) In the case of a toy or game subject to §1500.19(b)(1), a small ball subject to §1500.19(b)(3), a marble subject to §1500.19(b)(4), or a toy or game containing such a ball or marble, the principal display panel of the package bears the statement:



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and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears, or

(ii) In the case of a balloon subject to §1500.19(b)(2) or a toy or game containing such a balloon, the principal display panel bears the statement:



WARNING--CHOKING HAZARD

and bears an arrow or other indicator pointing toward or directing the purchaser's attention to the display panel on the package where the full labeling statement appears.

(g) *Alternative for products manufactured outside the United States.* In the case of a product subject to the labeling requirements of §1500.19(b) which is manufactured outside the United States and is shipped directly from the manufacturer to the consumer by United States mail or other delivery

service in an immediate package that contains descriptive material, the descriptive material inside the immediate package of the product need not bear the required labeling statement only if the shipping container of the product contains other accompanying material that bears the required statements displayed in a prominent and conspicuous manner. Products shipped from abroad to a U.S. affiliate for shipment to consumers are included within the scope of this exception.

(h) *Preemption.* Section 101(e) of the Child Safety Protection Act of 1994 prohibits any state or political subdivision of a state from enacting or enforcing any requirement relating to cautionary labeling addressing small parts hazards or choking hazards associated with any toy, game, marble, small ball, or balloon intended or suitable for use by children unless the state or local requirement is identical to a requirement established by section 24 of the FHSA or by 16 CFR 1500.19. Section 101(e) allows a state or political subdivision of a state to enforce a non-identical requirement relating to cautionary labeling warning of small parts hazards or choking hazards associated with any toy subject to the provisions of section 24 of FHSA until January 1, 1995, if the non-identical requirement was in effect on October 2, 1993.

[60 FR 10752, Feb. 27, 1995, as amended at 60 FR 41802, Aug. 14, 1995]

§ 1500.20 Labeling requirement for advertising toys and games.

(a) *Scope.* This section applies to catalogue and other printed material advertisements which provide a direct means of purchase or order of products requiring cautionary labeling under sections 24(a) and (b) of the FHSA.

(b) *Effective Date.* Under the Consumer Product Safety Improvement Act of 2008, Public Law 110-314, 122 Stat. 3016 (August 14, 2008), (“CPSIA”), the effective date of the CPSIA’s amendment to Section 24 of the FHSA to require cautionary statements in catalogues and other printed materials is February 10, 2009. By this rule, the Commission is providing a grace period of 180 days, or until August 9, 2009, during which catalogues and other printed materials printed prior to February 10, 2009, may be distributed without such cautionary statements. Catalogues and other printed materials that are printed on or after February 10, 2009, must have the required cautionary statements. All catalogues and other printed materials distributed on or after August 9, 2009, must comply with this rule. This rule addresses only catalogues and other printed materials; however, the CPSIA extends the requirements for cautionary statements to Internet advertisements as well.

Internet advertisements must comply with Section 24 of the FHSA as amended by the CPSIA no later than December 12, 2008.

(c) *Definitions.* For the purposes of this section, the following definitions shall apply.

(1) *Ball* means a spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, dropped, or bounced. The term “ball” includes any spherical, ovoid, or ellipsoidal object that is attached to a toy or article by means of a string, elastic cord, or similar tether. The term “ball” also includes a multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball. The term “ball” does not include dice, or balls permanently enclosed inside pinball machines, mazes, or similar other containers. A ball is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the outer container.

(2) *Small ball* means a ball that, under the influence of its own weight, passes in any orientation, entirely through a circular hole with a diameter of 1.75 inches (44.4 mm) in a rigid template ¼ inches (6 mm) thick. In testing to evaluate compliance with this regulation, the diameter of opening in the Commission’s test template shall be no greater than 1.75 inches (44.4 mm).

(3) *Latex balloon* means a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children’s toys that are used in aquatic activities such as rafts, water wings, swim rings, or other similar items.

(4) *Marble* means a ball made of hard material, such as glass, agate, marble, or plastic, that is used in various children’s games, generally as a playing piece or marker. The term “marble” does not include a marble permanently enclosed in a toy or game. A marble is permanently enclosed if, when tested in accordance with 16 CFR 1500.53, it is not removed from the toy or game.

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(5) *Small part* means any object which, when tested in accordance with the procedures contained in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501. The use and abuse testing provisions of 16 CFR 1500.51 through 1500.53 and 1501.4(b)(2) do not apply to this definition.

(6) *Direct means of purchase or order* means any method of purchase that allows the purchaser to order the product without being in the physical presence of the product. Advertising that provides a direct means of purchase or order of a product would include catalogues or other printed advertising material that contain order blanks, telephone numbers or fax numbers for placing orders, and Internet Web sites that

enable consumers to purchase a product online or through the use of a telephone number or fax number provided on the Internet Web site.

(d) *Advertising requirements.* Any toy or game that requires a cautionary statement about the choking hazard associated with small parts, balloons, small balls, or marbles must bear that cautionary statement in the product's advertising if the advertising provides a direct means to purchase or order the product.

(1) The advertising for any article that is a toy or game intended for use by children who are at least three years old but less than six years of age shall bear or contain the following cautionary statement if the toy or game includes a small part:

FIGURE 1



WARNING:

**CHOKING HAZARD--Small parts
Not for children under 3 yrs.**

(2) The advertising for any latex balloon, or toy or game that contains a latex balloon, shall bear the following cautionary statement:

FIGURE 2



WARNING:

CHOKING HAZARD--Children under 8 yrs. can choke or suffocate on uninflated or broken balloons. Adult supervision required.

Keep uninflated balloons from children. Discard broken balloons at once.

(3)(i) The advertising for any small ball intended for children three years of age or older shall bear the following cautionary statement:

FIGURE 3



WARNING:

CHOKING HAZARD--This toy is a small ball. Not for children under 3 yrs.

(ii) The advertising for any toy or game intended for children who are at least three years old but less than eight years of age that contains a small ball shall bear the following cautionary statement:

FIGURE 4



WARNING:

CHOKING HAZARD--Toy contains a small ball. Not for children under 3 yrs.

(4)(i) The advertising for any marble intended for children three years of age or older shall bear the following cautionary statement:

FIGURE 5



WARNING:

**CHOKING HAZARD--This toy is a marble.
Not for children under 3 yrs.**

(ii) The advertising for any toy or game intended for children who are at least three years old but less than eight years of age that contains a marble shall bear the following cautionary statement:

FIGURE 6



WARNING:

**CHOKING HAZARD--Toy contains a marble.
Not for children under 3 yrs.**

(e) *Abbreviated warnings for catalogues and other printed materials.* Abbreviated versions of the required cautionary statements are permitted in each individual product advertisement, provided that the corresponding full cautionary statements appear in the catalogue and a statement referring to the precise location of the full cautionary statements—such as the page number on which the cautionary statements can be found—is located at the bottom of each catalogue page that contains one or more abbreviated cautionary statements. If abbreviated cautionary statements are used:

(1) The full cautionary statements associated with the abbreviated cautionary statements shall appear:

(i) Near the beginning of the catalogue, before any catalogue pages that contain advertisements of products available for purchase, or

(ii) Adjacent to the ordering information or order form in the catalogue.

(2) The full cautionary statements shall be in conspicuous and legible type in contrast by typography, layout or color.

(3) The full cautionary statements shall be clearly numbered according to the following scheme:

| Required cautionary statement | Number |
|---|--------|
| 16 CFR 1500.19(b)(1) ¹ | 1 |
| 16 CFR 1500.19(b)(2) ² | 2 |
| 16 CFR 1500.19(b)(3)(i) ³ | 3 |
| 16 CFR 1500.19(b)(3)(ii) ⁴ | 4 |
| 16 CFR 1500.19(b)(4)(i) ⁵ | 5 |
| 16 CFR 1500.19(b)(4)(ii) ⁶ | 6 |

¹ See figure 1.
² See Figure 2.
³ See Figure 3.
⁴ See Figure 4.
⁵ See Figure 5.
⁶ See Figure 6.

(4) The abbreviated cautionary statements shall consist of items 1500.20(e)(3)(i) through 1500.20(e)(3)(iv):

(i) A safety alert symbol substantially similar to that shown in figure 7.

FIGURE 7

(ii) The phrase, “CHOKING HAZARD,” written in capital letters.

(iii) Numbers, separated by commas and enclosed within a single set of parentheses, that identify the applicable cautionary statements for the product being advertised, followed by a period. These numbers shall match the numbers used to identify each full cautionary statement, as specified in 1500.20(e)(2).

(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.

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(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) and (2) 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 material (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; 83 FR 8342, Feb. 27, 2018]

§ 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 the dermal corrosivity and primary irritation of substances referred to in §1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. Primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in abraded and intact skin tests. Introduce under a square patch, such as surgical gauze measuring 1 inch by 1 inch and two single layers thick, 0.5 milliliter (in the case of liquids) or 0.5 gram (in the case of solids and semisolids) of the test substance. Dissolve solids in an appropriate solvent and apply the solution as for liquids. The animals are immobilized with patches secured in place by adhesive tape. The entire trunk of the animal is then wrapped with an impervious material, such as rubberized cloth, for the

24-hour period of exposure. This material aids in maintaining the test patches in position and retards the evaporation of volatile substances. After 24 hours of exposure, the patches are removed and the resulting reactions are evaluated on the basis of the designated values in the following table:

| Skin reaction | Value ¹ |
|--|--------------------|
| Erythema and eschar formation: | |
| No erythema | 0 |
| Very slight erythema (barely perceptible) | 1 |
| Well-defined erythema | 2 |
| Moderate to severe erythema | 3 |
| Severe erythema (beet redness) to slight eschar formations (injuries in depth) | 4 |
| Edema formation: | |
| No edema | 0 |
| Very slight edema (barely perceptible) | 1 |
| Slight edema (edges of area well defined by definite raising) | 2 |
| Moderate edema (raised approximately 1 millimeter) | 3 |
| Severe edema (raised more than 1 millimeter and extending beyond the area of exposure) | 4 |

¹The "value" recorded for each reading is the average value of the six or more animals subject to the test.

Readings are again made at the end of a total of 72 hours (48 hours after the first reading). An equal number of exposures are made on areas of skin that have been previously abraded. The abrasions are minor incisions through the stratum corneum, but not sufficiently deep to disturb the derma or to produce bleeding. Evaluate the reactions of the abraded skin at 24 hours and 72 hours, as described in this paragraph. Add the values for erythema and eschar formation at 24 hours and at 72 hours for intact skin to the values on abraded skin at 24 hours and at 72 hours (four values). Similarly, add the values for edema formation at 24 hours and at 72 hours for intact and abraded skin (four values). The total of the eight values is divided by four to give the primary irritation score; for example:

| Skin reaction | Exposure time (hours) | Evaluation value |
|--------------------------------|-----------------------|------------------|
| Erythema and eschar formation: | | |
| Intact skin | 24 | 2 |
| Do | 72 | 1 |
| Abraded skin | 24 | 3 |
| Do | 72 | 2 |
| Subtotal | | 8 |
| Edema formation: | | |
| Intact skin | 24 | 0 |

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| Skin reaction | Exposure time (hours) | Evaluation value |
|--------------------|-----------------------|------------------|
| Do | 72 | 1 |
| Abraded skin | 24 | 1 |
| Do | 72 | 2 |
| Subtotal | | 4 |
| Total | | 12 |

Thus, the primary irritation score is 12 ÷ 4 = 3.

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

§ 1500.42 Test for eye irritants.

Guidelines for *in vivo* and *in vitro* testing of ocular irritation 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 any of the following: Existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. If *in vivo* testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.

(a)(1) In the method of testing the ocular irritation of a substance referred to in §1500.3(c)(4), six albino rabbits are used for each test substance. Animal facilities for such procedures shall be so designed and maintained as to exclude sawdust, wood chips, or other extraneous materials that might produce eye irritation. Both eyes of each animal in the test group shall be examined before testing, and only those animals without eye defects or irritation shall be used. The animal is held firmly but gently until quiet. The test material is placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test substance is dropped. The lids are then gently held together for one second and the animal is released. The

other eye, remaining untreated, serves as a control. For testing liquids, 0.1 milliliter is used. For solids or pastes, 100 milligrams of the test substance is used, except that for substances in flake, granule, powder, or other particulate form the amount that has a volume of 0.1 milliliter (after compacting as much as possible without crushing or altering the individual particles, such as by tapping the measuring container) shall be used whenever this volume weighs less than 100 milligrams. In such a case, the weight of the 0.1 milliliter test dose should be recorded. The eyes are not washed following instillation of test material except as noted below.

(2) The eyes are examined and the grade of ocular reaction is recorded at 24, 48, and 72 hours. Reading of reactions is facilitated by use of a binocular loupe, hand slit-lamp, or other expert means. After the recording of observations at 24 hours, any or all eyes may be further examined after applying fluorescein. For this optional test, one drop of fluorescein sodium ophthalmic solution U.S.P. or equivalent is dropped directly on the cornea. After flushing out the excess fluorescein with sodium chloride solution U.S.P. or equivalent, injured areas of the cornea appear yellow; this is best visualized in a darkened room under ultraviolet illumination. Any or all eyes may be washed with sodium chloride solution U.S.P. or equivalent after the 24-hour reading.

(b)(1) An animal shall be considered as exhibiting a positive reaction if the test substance produces at any of the readings ulceration of the cornea (other than a fine stippling), or opacity of the cornea (other than a slight dulling of the normal luster), or inflammation of the iris (other than a slight deepening of the folds (or rugae) or a slight circumcorneal injection of the blood vessels), or if such substance produces in the conjunctivae (excluding the cornea and iris) an obvious swelling with partial eversion of the lids or a diffuse crimson-red with individual vessels not easily discernible.

(2) The test shall be considered positive if four or more of the animals in

the test group exhibit a positive reaction. If only one animal exhibits a positive reaction, the test shall be regarded as negative. If two or three animals a positive reaction, the test is repeated using a different group of six animals. The second test shall be considered positive if three or more of the animals exhibit a positive reaction. If only one or two animals in the second test exhibit a positive reaction, the test shall be repeated with a different group of six animals. Should a third test be needed, the substance will be regarded as an irritant if any animal exhibits a positive response.

(c) To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at <http://www.cpsc.gov/library/animaltesting.html> will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation¹ or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.²

[38 FR 27012, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973; 62 FR 46667, Sept. 4, 1997; 77 FR 73294, Dec. 10, 2012]

§ 1500.43 Method of test for flashpoint of volatile flammable materials by Tagliabue open-cup apparatus.

SCOPE

1. (a) This method describes a test procedure for the determination of open-cup flashpoints of volatile flammable materials having flashpoints below 175 °F.

(b) This method, when applied to paints and resin solutions which tend to skin over or which are very viscous, gives less reproducible results than when applied to solvents.

OUTLINE OF METHOD

2. The sample is placed in the cup of a Tag Open Tester, and heated at a slow but constant rate. A small test flame is passed at a

¹EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712-C-98-195. Washington, DC: U.S. Environmental Protection Agency. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf)

²OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: <http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf>)

uniform rate across the cup at specified intervals. The flashpoint is taken as the lowest temperature at which application of the test flame causes the vapor at the surface of the liquid to flash, that is, ignite but not continue to burn.

APPARATUS

3. The Tag open-cup tester is illustrated in Fig. 1. It consists of the following parts, which must conform to the dimensions shown, and have the additional characteristics as noted:

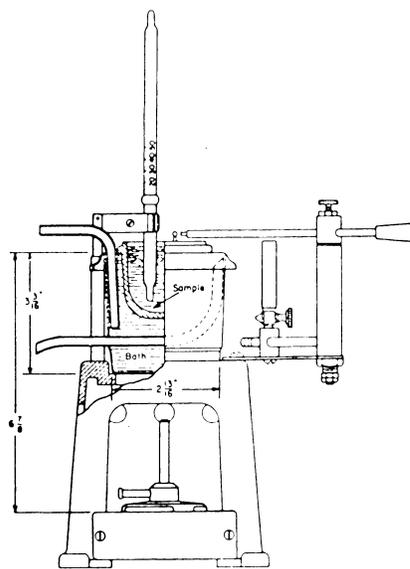


FIGURE 1—Tag open cup flash tester

(a) *Copper bath*, preferably equipped with a constant level overflow so placed as to maintain the bath liquid level $\frac{1}{8}$ -inch below the rim of the glass cup.

(b) *Thermometer holder*. Support firmly with ringstand and clamp.

(c) *Thermometer*. For flashpoints above 40 °F., use the ASTM Tag Closed Tester Thermometer, range of + 20 to + 230 °F., in 1 °F. divisions, and conforming to thermometer 9F. of ASTM Standard E 1. For flashpoints from 20 °F. to 40 °F., use ASTM Tag Closed Tester, Low Range, Thermometer 57F. For flashpoints below 20 °F., use ASTM Thermometer 33F. The original Tag Open-Cup (Paper Scale) Thermometer will be a permissible alternate until January 1, 1962. It is calibrated to -20 °F.

(d) *Glass test cup* (Fig. 2), of molded clear glass, annealed, heat-resistant, and free from surface defects.

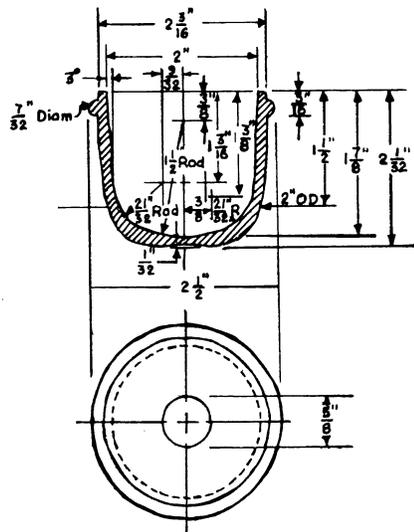


FIGURE 2—Glass test cup

(e) *Leveling device.* Leveling device or guide, for proper adjustment of the liquid level in the cup (Fig. 3). This shall be made of No. 18-gage polished aluminum, with a projection for adjusting the liquid level when the sample is added to exactly $\frac{1}{8}$ -inch below the level of the edge or rim of the cup.

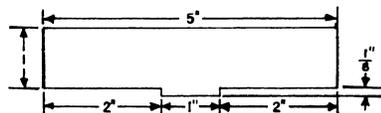


FIGURE 3—Leveling device for adjusting liquid level in test cup

(f) “Micro,” or small gas burner of suitable dimensions for heating the bath. A screw clamp may be used to help regulate the gas. A small electric heater may be used.

(g) Ignition taper, which is a small straight, blow-pipe type gas burner. The test flame torch prescribed in the method of test for flash and fire points by Cleveland Open Cup (ASTM designation: D 92) is satisfactory.

(h) Alternative methods for maintaining the ignition taper in a fixed horizontal plane above the liquid may be used, as follows:

(1) Guide wire, $\frac{3}{32}$ -inch in diameter and $3\frac{1}{2}$ inches in length, with a right-angle bend $\frac{1}{2}$ -inch from each end. This wire is placed snugly in holes drilled in the rim of the bath, so that the guide wire is $\frac{5}{8}$ -inch from the center of the cup and resting on the rim of the cup.

(2) Swivel-type taper holder, such as is used in ASTM METHOD D 92. The height and position of the taper are fixed by adjusting

the holder on a suitable ringstand support adjacent to the flash cup.

(i) Draft shield, consisting of two rectangular sheets of noncombustible material, 24 inches \times 28 inches, are fastened together along the 28-inch side, preferably by hinges. A triangular sheet, 24 inches \times 24 inches \times 34 inches is fastened by hinges to one of the lateral sheets (to form a top when shield is open). The interior of the draft shield shall be painted a flat black.

PROCEDURE

4. (a) Place the tester on a solid table free of vibration, in a location free of perceptible draft, and in a dim light.

(b) Run water, brine, or water-glycol solution into the bath to a predetermined level, which will fill the bath to $\frac{1}{8}$ -inch below the top when the cup is in place. An overflow is permissible for water-level control.

(c) Firmly support the thermometer vertically halfway between the center and edge of the cup on a diameter at right angles to the guide wire, or on a diameter passing through the center of the cup and the pivot of the taper. Place so that the bottom of the bulb is $\frac{1}{4}$ -inch from the inner bottom surface of the cup. If the old Tagliabue thermometer is used, immerse to well cover the mercury bulb, but not the wide body of the thermometer.

(d) Fill the glass cup with the sample liquid to a depth just $\frac{1}{8}$ -inch below the edge, as determined by the leveling device.

(e) Place the guide wire or swivel device in position, and set the draft shield around the tester so that the sides from right angles with each other and the tester is well toward the back of the shield.

(f) If a guide wire is used, the taper, when passed, should rest lightly on the wire, with the end of the jet burner just clear of the edge of the guide wire. If the swivel-type holder is used, the horizontal and vertical positions to the jet are so adjusted that the jet passes on the circumference of a circle, having a radius of at least 6 inches, across the center of the cup at right angles to the diameter passing through the thermometer, and in a plane $\frac{1}{8}$ -inch above the upper edge of the cup. The taper should be kept in the “off” position, at one end or the other of the swing, except when the flame is applied.

(g) Light the ignition flame and adjust it to form a flame of spherical form matching in size the $\frac{5}{32}$ -inch sphere on the apparatus.

(h) Adjust heater source under bath so that the temperature of the sample increases at a rate of 2 ± 0.5 °F. per minute. With viscous materials this rate of heating cannot always be obtained.

INITIAL TEST

5. Determine an approximate flashpoint by passing the taper flame across the sample at

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intervals of 2 °F. Each pass must be in one direction only. The time required to pass the ignition flame across the surface of the sample should be 1 second. Remove bubbles from the surface of the sample liquid before starting a determination. Meticulous attention to all details relating to the taper, size of taper flame, and rate of passing the taper is necessary for good results. When determining the flashpoint of viscous liquids and those liquids that tend to form a film of polymer, etc., on the surface, the surface film should be disturbed mechanically each time before the taper flame is passed.

RECORDED TESTS

6. Repeat the procedure by cooling a fresh portion of the sample, the glass cup, the bath solution, and the thermometer at least 20 °F. below the approximate flashpoint. Resume heating, and pass the taper flame across the sample at two intervals of 2 °F. until the flashpoint occurs.

REPORTING DATA

7. The average of not less than three recorded tests, other than the initial test, shall be used in determining the flashpoint and flammability of the substance.

STANDARDIZATION

8. (a) Make determinations in triplicate on the flashpoint of standard paraxylene and of standard isopropyl alcohol which meet the following specifications:

(i) *Specifications for p-xylene, flashpoint check grade. p-xylene shall conform to the following requirements;*

Specific gravity: 15.56 °C./15.56 °C., 0.860 minimum, 0.866 maximum

Boiling range: 2 °C. maximum from start to dry point when tested in accordance with the method of test for distillation of industrial aromatic hydrocarbons (ASTM designation: D 850), or the method of test for distillation range of lacquer solvents and diluents (ASTM designation D 1078). The range shall include the boiling point of pure *P*-xylene, which is 138.35 °C. (281.03 °F.).

Purity: 95 percent minimum, calculated in accordance with the method of test for determination of purity from freezing points of high-purity compounds (ASTM designation: D 1016), from the experimentally determined freezing point, measured by the method of test for measurement of freezing points of high-purity compounds for evaluation of purity (ASTM designation: D 1015).

(ii) *Specifications for isopropanol, flash point check grade. Isopropanol shall conform to the following requirements:*

Specific gravity: 0.8175 to 0.8185 at 20 °C./20 °C. as determined by means of a calibrated pycnometer.

Distillation range: Shall entirely distill within a 1.0 °C. range which shall include the temperature 80.4 °C. as determined by ASTM method D 1078.

Average these values for each compound. If the difference between the values for these two compounds is less than 15 °F. (8.5 °C.) or more than 27 °F. (16 °C.), repeat the determinations or obtain fresh standards.

(b) Calculate a correction factor as follows:

$$X = 92 - A$$

$$Y = 71 - B$$

$$\text{Correction} = (X + Y) / 2.$$

Where:

A = Observed flash of *p*-xylene, and

B = Observed flash of isopropyl alcohol.

Apply this correction of all determinations. Half units in correction shall be discarded.

PRECISION

9. (a) For hydrocarbon solvents having flashpoints between 60 °F. and 110 °F., repeatability is ±2 °F. and the reproducibility is ±5 °F.

(b) If results from two tests differ by more than 10 °F., they shall be considered uncertain and should be checked. This calibration procedure provided in this method will cancel out the effect of barometric pressure if calibration and tests are run at the same pressure. Data supporting the precision are given appendix III of the 1956 Report of Committee D-1 on Paint, Varnish, Lacquers and Related Products, Proceedings, Am. Soc. Testing Mats., Vol. 56 (1956).

NOTE: The test apparatus and procedure described in §1500.43 may be used by manufacturers and labelers of products subject to the Federal Hazardous Substances Act to determine flashpoint temperatures of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

[51 FR 28537, Aug. 8, 1986]

§ 1500.43a Method of test for flashpoint of volatile flammable materials.

(a) *Scope.* (1) This method describes the test procedure which the Commission will use for the determination of the flashpoint of volatile flammable materials, using a Setaflash¹ low-range closed tester, or an apparatus producing equivalent results. The method described in this section is essentially a Setaflash equilibrium procedure

¹Setaflash is a registered trademark of Stanhope-Seta Limited, Surrey, England.

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which closely parallels the test method designated ASTM D 3828-81, "Standard Test Methods for Flash Point by Setaflash Closed Tester," published by the American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, Pennsylvania 19103. Manufacturers and labelers of products subject to labeling and other requirements under the Federal Hazardous Substances Act may use other apparatus and/or test methods which produce equivalent results.

(2) At the option of the user, the procedures described in this section may be used to determine the actual flashpoint temperature of a sample or to determine whether a product will or will not flash at a specified temperature (flash/no flash).

(3) If the substance to be tested has a viscosity greater than 150 Stokes at 77 °F (25 °C), see paragraph (n) of this section for modifications to the testing procedure.

(4) If the Commission has reason to believe on the basis of reliable experience or other relevant information or data that the flammability hazard of a substance is greater or less than its flammability classification based on flashpoint temperature determined in accordance with this §1500.43a and that the substance should be reclassified, the Commission will initiate a rule-making proceeding for reclassification of the substance. Product manufacturers and labelers may use reliable experience or other relevant information or data in addition to the flashpoint temperature of a substance as a basis for compliance with any applicable requirements of the Federal Hazardous Substances Act in the absence of a rule issued by the Commission to reclassify the substance.

(b) *Summary of test methods.* (1) Method A—Flash/No Flash Test. A specified volume of sample is introduced by a syringe into the cup of the apparatus that is set and maintained at the specified temperature. After a specific time a test flame is applied and an observation made as to whether or not a flash occurred. Test procedures are set forth in detail in §1500.43a(i).

(2) Method B—Finite (or Actual) Flashpoint. (i) A specified volume of sample is introduced into the cup of

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the apparatus that is maintained at the expected flashpoint. After a specified time a test flame is applied and the observation made whether or not a flash occurred.

(ii) The specimen is removed from the cup, the cup cleaned, and the cup temperature adjusted 5 °C (9 °F), lower or higher depending on whether or not a flash occurred previously. A fresh specimen is introduced and tested. This procedure is repeated until the flashpoint is established within 5 °C (9 °F).

(iii) The procedure is then repeated at 1 °C (2 °F) intervals until the flashpoint is determined to the nearest 1 °C (2 °F).

(iv) If improved accuracy is desired the procedure is repeated at 0.5 °C (1 °F). Test procedures are set forth in detail at §1500.43a(j).

(3) The test procedures will be modified, where necessary, to ensure that the results obtained reflect the hazard of the substance under reasonably foreseeable conditions of use. Thus, for example, the material, if a mixture, will normally be tested as it comes from the container, and/or after a period of evaporation. The period of evaporation for a material which is a mixture will normally be the time required for the mixture to evaporate in an open beaker under ambient conditions to 90 percent of its original volume, or a period of four hours, whichever occurs first. However, this period of evaporation will be changed if the results obtained do not represent the hazard of the substance under reasonably foreseeable conditions of use.

(c) *Definition of flashpoint.* The lowest temperature of the sample, corrected to a barometric pressure of 101.3 kPa (760 mm Hg), at which application of a test flame causes the vapor of the sample to ignite under specified conditions of test. The sample is deemed to have flashed when a large flame appears and instantaneously propagates itself over the surface of the sample. Occasionally, particularly near actual flashpoint, the application of the test flame will cause a halo or an enlarged flame; this is not a flash and should be ignored.

(d) *Test apparatus.* The test apparatus is an equilibrium closed-cup tester

with a range up to 100 °C (212 °F). The essential dimensions and requirements are shown in figure 1 and table 3, and are described in §1500.43a(m). Closed-cup flashpoint testers and accessories meeting these requirements are available from commercial suppliers and distributors of laboratory equipment.

(e) *Safety precautions.* The operator must exercise and take appropriate safety precautions during the initial application of the test flame to the sample. Samples containing low-flash material may give an abnormally strong flash when the test flame is first applied.

(f) *Preparation of samples.* (1) Erroneously high flashpoints may be obtained if precautions are not taken to avoid the loss of volatile material. In preliminary tests of materials taken directly from the container, do not open containers unnecessarily and make a transfer unless the sample temperature is at least 10 °C (18 °F) below the expected flashpoint. Do not use samples in leaky containers for this test.

(2) Do not store samples in plastic (polyethylene, polypropylene, etc.) bottles since volatile material may diffuse through the walls of the bottle.

(3) A 2-ml specimen is required for each test. If possible, obtain at least a 50-ml sample from the bulk test site and store in a clean, tightly closed container.

(g) *Preparation of apparatus.* (1) Place the tester on a level, stable surface. Unless tests are made in a draft-free area, surround the tester on three sides with a shield for protection. Do not rely on tests made in a laboratory draft hood or near ventilators.

(2) Read the manufacturer's instructions on the care and servicing of the instrument and for correct operation of its controls.

(h) *Calibration and standardization.* (1) Before initial use determine and plot the relationship between the temperature control dial and the thermometer readings at each major (numbered) dial division as follows:

Turn the temperature control knob² fully counterclockwise ("O" reading).

²If the instrument has two temperature control knobs, set the fine control (center,

Advance the temperature control knob clockwise until the indicator light is illuminated.³ Advance the knob clockwise to the next numbered line. After the thermometer mercury column ceases to advance, record the dial reading and the temperature. Advance the knob clockwise to the next numbered line. After the thermometer mercury column ceases to advance, read the dial reading and the temperature. Repeat this procedure through the full range of the instrument. Plot the dial readings versus the respective temperatures.

(2) Standardize the instrument using a sample of material meeting the specifications in table 1. If the average of two determinations falls within the acceptable limits the instrument is assumed to be operating properly. If the average of the two determinations does not fall within this range, check the manufacturer's operating and maintenance instructions and determine that they are being followed. In particular, be sure that the cup lid assembly makes a vapor-tight seal with the cup, the shutter provides a light-tight seal, and that adequate heat transfer paste surrounds the thermometer bulb and the immersed portion of the barrel.

(i) *Test Method A—for determining Flash/No Flash.* (1) Determine the target flashpoint as follows:

(i) Target flashpoint, °C = $S_c - 0.25$ (101.3—A)

(ii) Target flashpoint, °C = $S_c - 0.03$ (760—B)

(iii) Target flashpoint, °F = $S_f - 0.06$ (760—B)

where:

S_c = specification, or uncorrected target, flashpoint, °C,

S_f = specification, or uncorrected target, flashpoint, °F,

small knob) at its mid-position and allow it to remain there throughout the calibration. The calibration is determined by adjusting the coarse control (large, outer knob) only.

³When using the tester, it will be found that the indicator light may not illuminate and the temperature may not rise until a temperature control dial setting between one and two is reached.

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B = ambient barometric pressure, mm Hg,⁴
and

A = ambient barometer pressure, kPa.⁴

(2) Inspect the inside of the sample cup, lid, and shutter mechanism for cleanliness and freedom from contamination. Use an absorbent paper tissue to wipe clean, if necessary. Put cover in place and lock securely. The filing orifice may be conveniently cleaned with a pipe cleaner.

(3) Set the instrument at the target temperature.

(i) For target temperature below ambient. The instrument power switch is to be in the off position. Fill the refrigerant-charged cooling block with a suitable material.⁵ Raise the lid and shutter assembly, and position the base of the block in the sample cup, being careful not to injure or mar the cup. When the thermometer reads approximately 6 to 10 °C (10 to 20 °F) below the target temperature, remove the cooling block and quickly dry the cup with a paper tissue to remove any moisture. Immediately close the lid and shutter assembly and secure. Prepare to introduce the sample using the syringe, both of which have been precooled to a temperature 5 to 10 °C (10 to 20 °F) below the target temperature.

(A) Caution: Do not cool the sample block below -38 °C, the freezing point of mercury.

(B) Caution: Acetone is extremely flammable. Keep away from heat, sparks, and flames and keep container closed when not actually pouring acetone. Use only in a well-ventilated area. Avoid inhalation and contact with the eyes or skin. Use cloth or leather gloves, goggles or safety shield,

⁴The barometric pressure used in this calculation must be the ambient pressure for the laboratory at the time of test. Many aneroid barometers, such as those used at weather stations and airports, are precorrected to give sea-level readings; these must not be used.

⁵If the target or specification temperature is not less than 5 °C (40 °F) crushed ice and water may be used as charging (cooling) fluid. If below 5 °C (40 °F), a suitable charging (cooling) fluid is solid carbon dioxide (dry ice) and acetone. If the refrigerant charged cooling module is unavailable, refer to the manufacturer's instruction manual for alternative methods of cooling.

and keep dry ice in a canvas bag, especially when cracking.

(ii) For target temperature above ambient. Switch the instrument on and turn the coarse temperature control knob fully clockwise (full on) causing the indicator light to illuminate.⁶ When the thermometer indicates a temperature about 3 °C (5 °F) below the target (or specification) temperature, reduce the heat input to the sample cup by turning the coarse temperature control knob counter-clockwise to the desired control point (see §1500.43a(i)(1)). When the indicator light slowly cycles on and off read the temperature on the thermometer. If necessary, adjust the fine (center) temperature control knob to obtain the desired test (target) temperature. When the test temperature is reached and the indicator lamp slowly cycles on and off, prepare to introduce the sample.

(4) Charge the syringe with a 2-ml specimen of the sample⁷ to be tested; transfer the syringe to the filling orifice, taking care not to lose any sample; discharge the test specimen into the cup by fully depressing the syringe plunger, remove the syringe.

(5)(i) Set the timer⁸ by rotating its knob clockwise to its stop. Open the gas control valve and light the pilot and test flames. Adjust the test flame with the pinch valve to conform to the size of the 4-mm (5/32-in.) gage.

(ii) After the time signal indicates the specimen is at test temperature⁸, apply the test flame by slowly and uniformly opening the shutter and closing

⁶The target temperature may be attained by originally turning the coarse temperature control knob to the proper setting (see §1500.43a(h)(1) for the temperature desired rather than the maximum setting (full on). The elapsed time to reach the temperature will be greater, except for maximum temperature. However, less attention will be required during the intervening period.

⁷For target or expected temperatures below ambient, both syringe and sample must be precooled to cup temperature (see §1500.43a(i)(3)(i)) before the specimen is taken.

⁸For target temperatures below ambient, do not set the timer. Adjust the test flame and allow the temperature to rise under ambient conditions until the target temperature is reached. Immediately apply the test flame as detailed.

it completely over a period of approximately 2½ s.⁹ Watch closely for a flash at the cup openings.

(iii) The sample is deemed to have flashed when a large flame appears and instantaneously propagates itself over the surface of the sample (see § 1500.43a(c)).

(6) Record the test results as “flash” or “no flash” and the test temperature.

(7) Turn off the pilot and test flames using the gas control valve. Remove the sample and clean the instrument. It may be necessary to allow the cup temperature to decline to a safe level before cleaning.

(j) *Test Method B—for determining Finite or Actual Flashpoint.* (1) Inspect the inside of the sample cup, lid, and shutter mechanism for cleanliness and freedom from contamination. Use an absorbent paper tissue to wipe clean, if necessary. Put cover in place and lock securely. The filling orifice may be conveniently cleaned with a pipe cleaner.

(2) For expected flashpoints below ambient. (i) The instrument power switch is to be in off position. Fill the refrigerant-charged cooling block with a suitable material.⁵ Raise the lid and shutter assembly, and position the base of the block in the sample cup, being careful not to injure or mar the cup. When the thermometer reaches a temperature 5 to 10 °C (10 to 20 °F) below the expected flashpoint, remove the cooling block and quickly dry the cup with a paper tissue to remove any moisture. Immediately close the lid and shutter assembly and secure. Prepare to introduce the sample using the syringe, both of which have been precooled to a temperature 5 to 10 °C (10 to 20 °F) below the expected temperature (See § 1500.43a(j)(5)).

(ii) Caution: Do not cool the sample block below -38 °C, the freezing point of mercury.

(3) For tests where the expected flashpoint is above ambient. Turn the coarse temperature control knob fully clockwise (full on) causing the indicator light to illuminate. When the thermometer reaches a temperature 3

⁹Never apply the test flame to the specimen more than once. Fresh portions of the sample must be used for each test.

°C (5 °F) below the estimated flashpoint, turn the coarse temperature knob counter-clockwise to the dial reading representing the estimated flashpoint temperature as shown on the calibration curve (See § 1500.43a(h)(1)). When the indicator light slowly cycles on and off, read the temperature on the thermometer. If necessary, adjust the fine temperature control knob to obtain the exact desired temperature.

(4)(i) Charge the syringe⁷ with a 2 ml specimen of the sample⁷ to be tested; transfer the syringe to the filling orifice, taking care not to lose any sample; discharge the test specimen into the cup by fully depressing the syringe plunger; remove the syringe.

(ii) Set the timer¹⁰ by rotating its knob clockwise to its stop. Open the gas control valve and ignite the pilot and test flames. Adjust the test flame with the pinch valve to conform to the size of the 4-mm (⁵/₃₂-in.) gage.

(iii) After the audible time signal indicates the specimen is at test temperature,¹⁰ apply the test flame by slowly and uniformly opening the shutter and then closing it completely over a period of approximately 2½ s. Watch closely for a flash at the cup opening.

(iv) The sample is deemed to have flashed only if a large flame appears and instantaneously propagates itself over the surface of the sample. (See § 1500.43a(c).)

(v) Turn off the pilot and test flames using the gas control valve. When the cup temperature declines to a safe level, remove the sample and clean the instrument.

(5)(i) If a flash was observed in § 1500.43a(j)(4)(iii) repeat the procedure given in § 1500.43a(j)(2) or (3), and in § 1500.43a(j)(4), testing a new specimen at a temperature 5 °C (9 °F) below that at which the flash was observed.

(ii) If necessary, repeat the procedure in § 1500.43a(j)(5)(i), lowering the temperature 5 °C (9 °F) each time, until no flash is observed.⁹

¹⁰For expected flashpoint below ambient, do not set the timing device. Adjust the test flame. Allow the temperature to rise under ambient conditions until the temperature reaches 5 °C (9 °F) below the expected flashpoint. Immediately apply the test flame.

(iii) Proceed to §1500.43a(j)(7).

(6)(i) If no flash was observed in §1500.43a(j)(4)(iii) repeat the procedure given in §1500.43a(j)(2) or (3), and in §1500.43a(j)(4), testing a fresh specimen at a temperature 5 °C (9 °F) above that at which the specimen was tested in §1500.43a(j)(4)(iii).

(ii) If necessary repeat the procedure in §1500.43a(j)(6)(i), above, raising the temperature 5 °C (9 °F) each time until a flash is observed.⁹

(7) Having established a flash within two temperatures 5 °C (9 °F) apart, repeat the procedure at 1 °C (2 °F) intervals from the lower of the two temperatures until a flash is observed.⁹ Record the temperature of the test when this flash occurs as the flashpoint, allowing for any known thermometer correction. Record the barometric pressure.⁴

(8) The flashpoint determined in §1500.43a(j)(7) will be to the nearest 1 °C (2 °F). If improved accuracy is desired (that is, to the nearest 0.5 °C (1 °F)), test a fresh specimen at a temperature 0.5 °C (1 °F) below that at which the flash was observed in §1500.43a(j)(7). If no flash is observed, the temperature recorded in §1500.43a(j)(7), is the flashpoint to the nearest 0.5 °C (1 °F). If a flash is observed at the lower temperature, record this latter temperature as the flashpoint.

(9) Turn off the pilot and test flames using the gas control valve. When the cup temperature declines to a safe level, remove the sample and clean the instrument.

(k) *Calculations.* If it is desired to correct the observed finite flashpoint for the effect of barometric pressure, proceed as follows: Observe and record the ambient barometric pressure⁴ at the time of the test. If the pressure differs from 101.3 kPa (760 mm Hg), correct the flashpoint as follows:

(1) Corrected flashpoint (°C) = C + 0.25 (101.3-A)

(2) Corrected flashpoint (°F) = F + 0.06 (760-B)

(3) Corrected flashpoint (°C) = C + 0.03 (760-B)

Where: F = Observed flashpoint, °F,

C = observed flashpoint, °C,

B = ambient barometric pressure, mm Hg;

and

A = ambient barometric pressure, kPa.

(1) *Precision.* The precision of the method as determined by statistical examination of interlaboratory results is as follows:

(1) *Repeatability.* The difference between two test results obtained by the same operator with the same apparatus under constant operating conditions on identical test material, would, in the long run, in the normal and correct operation of the test method, exceed the values shown in table 2 only in 1 case in 20.

(2) *Reproducibility.* The difference between two single and independent results obtained by different operators working in different laboratories on identical test material, would, in the long run, in the normal and correct operation of the test method, exceed the values shown in table 2 only in 1 case in 20.

(m) *Flash Test Apparatus.* (1)(i) Unit consisting of an aluminum alloy or nonrusting metal block of suitable conductivity with a cylindrical depression, or sample cup, over which is fitted a cover. A thermometer is embedded in the block.

(ii) The cover is fitted with an opening slide and a device capable of inserting an ignition flame (diameter 4±0.5 mm) into the well when the slide device shall intersect the plane of the underside of the cover. The cover is also provided with an orifice extending into the sample well for insertion of the test sample and also a suitable clamping device for securing the cover tightly to the metal block. The three openings in the cover shall be within the diameter of the sample well. When the slide is in the open position, the two openings in the slide shall coincide exactly with the two corresponding openings in the cover.

(iii) Electrical heaters are attached to the bottom of the cup in a manner that provides efficient transfer of heat. An electronic heat control is required to hold the equilibrium temperature, in a draft-free area, within 0.1 °C (0.2 °F) for the low-temperature tester. A visual indicator lamp shows when energy is or is not being applied. Energy may be supplied from 120 or 240 V, 50 or 60 Hz main service.

(2)(i) Test flame and pilot flame-regulatable test flame, for dipping into

the sample cup to try for flash, and a pilot flame, to maintain the test flame, are required. These flames may be fueled by piped gas service. A gage ring 4mm (5/32 in.) in diameter, engraved on the lid near the test flame, is required to ensure uniformity in the size of the test flame.

(ii) Caution: Never recharge the self-contained gas tank at elevated temperature, or with the pilot or test flames lighted, nor in the vicinity of other flames.

(iii) Audible Signal is required. The audible signal is given after 1 min in the case of the low-temperature tester.

(iv) Syringe. 2ml capacity, equipped with a needle suitable for use with the apparatus, adjusted to deliver 2.00±0.05 ml.

(3) Essential dimensions of the test apparatus are set forth in table 3.

(n) *Testing high-viscosity liquids.* (1) High-viscosity materials may be added to the cup by the following procedure:

(i) Back load a 5 or 10-ml syringe with the sample to be tested and extrude 2 ml into the cup. Spread the specimen as evenly as possible over the bottom of the cup.

(ii) If the sample cannot be loaded into a syringe and extruded, other means of adding the sample to the cup may be used such as a spoon. Add approximately 2 ml of material to the spoon and then push the material from the spoon into the cup.

(iii) If the test specimen does not close the sampling port in the cup, seal the cup externally by suitable means.

(2) Using the appropriate procedure, either Method A in §1500.43a(i) or Method B in §1500.43a(j), determine the flashpoint of the specimen which has been added to the tester in accordance with §1500.43a(n)(i), except that the time specified is increased from 1 to 5 minutes for samples at or above ambient temperature.

TABLE 1—CALIBRATION OF TESTER

| | |
|--|---|
| Material | <i>p</i> -xylene ^A (Caution). ^B |
| Specific gravity, 15.6/15.6 °C (60/60 °F). | 0.850 to 0.866. |

TABLE 1—CALIBRATION OF TESTER—Continued

| | |
|-----------------------------------|---|
| Boiling range | 2 °C maximum including 138.35 °C (281.03 °F). |
| Freezing point | 11.23 °C (52.2 °F) minimum. |
| Flashpoint °C (acceptable range). | 25.6 ±0.5 (78 ±1 Φ). |

^A Available as Flash Point Check Fluid (*p*-xylene) from Special Products Div., Phillips Petroleum Co., Drawer 'O,' Borger, Texas 79007.

^B Caution: Handle xylene with care. Avoid inhalation; use only in a well-ventilated area. Avoid prolonged or repeated contact with skin. Keep away from flames and heat, except as necessary for the actual flash point determination.

TABLE 2—REPEATABILITY AND REPRODUCIBILITY

| Temperature, °C (°F) | Repeatability, °C (°F) | Reproducibility, °C (°F) |
|----------------------|------------------------|--------------------------|
| 20(68) | 0.5(0.9) | 1.4(2.6) |
| 70(158) | 0.5(0.9) | 2.9(5.3) |
| 93(200) | 1.3(2.3) | 4.9(8.8) |
| 150(300) | 2.0(3.6) | 7.5(13.5) |
| 200(400) | 2.6(4.7) | 9.9(17.9) |
| 260(500) | 3.3(5.9) | 12.4(22.3) |

TABLE 3—ESSENTIAL DIMENSIONS OF FLASH TEST APPARATUS^{A B}

| Sample Block | |
|--|-------------|
| Block diameter | 61.5–62.5 |
| Sample well diameter | 49.40–49.70 |
| Sample well depth | 9.70–10.00 |
| Top of block to center of thermometer hole | 16.00–17.00 |
| Diameter of thermometer hole (approx.) | 7.0004 |
| Cover | |
| Large opening length | 12.42–12.47 |
| Large opening width | 10.13–10.18 |
| Small opening length | 5.05–5.10 |
| Small opening width | 7.60–7.65 |
| Distance between extreme edges of small openings | 48.37–48.32 |
| Filling orifice diameter | 4.00–4.50 |
| Bore or filler tube | 1.80–1.85 |
| Maximum distance of filler tube from base of well with cover closed (max.) | 0.75 |
| Slide | |
| Large opening length | 12.42–12.47 |
| Large opening width | 10.13–10.18 |
| Small opening length | 5.05–5.10 |
| Small opening width | 7.60–7.65 |
| Near edge of large opening to end of slide | 12.80–12.85 |
| Extremes of large and small openings | 30.40–30.45 |
| Jet | |
| Length of jet | 18.30–18.40 |
| External diameter at end of jet | 2.20–2.60 |
| Bore of jet | 1.60–1.65 |
| Height of jet center above top surface of cover | 11.00–11.20 |
| Jet pivot to center of block with cover closed | 12.68–12.72 |

^A The O-seal or gasket which provides a seal when the cover is shut, should be made of a heat-resistant material capable of withstanding temperatures up to 150 °C for the low-range apparatus.

^B When in position, the thermometer bulb should be surrounded with heat-conducting thermoplastic compound, such as a paste comprised of zinc oxide and mineral oil.

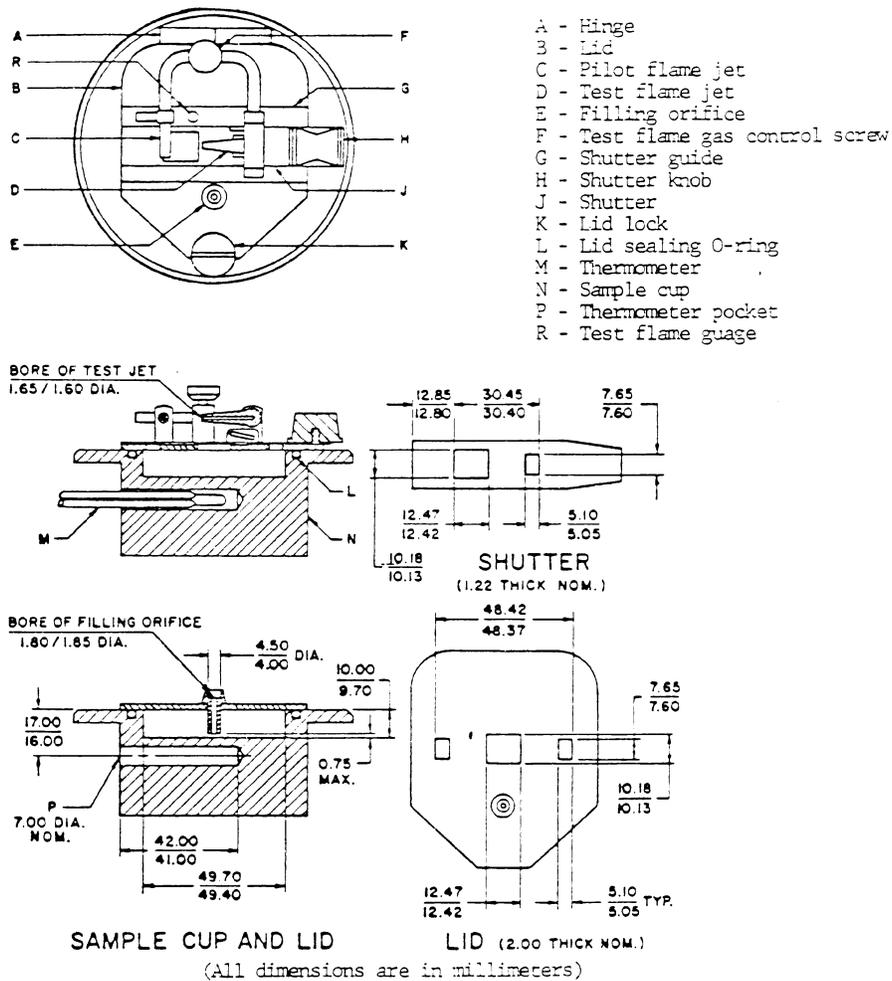


FIGURE 1 - Closed-cup tester

[51 FR 28539, Aug. 8, 1986]

§ 1500.44 Method for determining extremely flammable and flammable solids.

- (a) *Preparation of samples*—(1) *Granules, powders, and pastes.* Pack the sample into a flat, rectangular metal boat with inner dimensions 6 inches long × 1 inch wide × one-fourth inch deep.
- (2) *Rigid and pliable solids.* Measure the dimensions of the sample and sup-

port it by means of metal ringstands, clamps, rings, or other suitable devices as needed, so that the major axis is oriented horizontally and the maximum surface is freely exposed to the atmosphere.

(b) *Procedure.* Place the prepared sample in a draft-free area that can be ventilated and cleared after each test. The temperature of the sample at the

time of testing shall be between 68 °F. and 86 °F. Hold a burning paraffin candle whose diameter is at least 1 inch, so that the flame is in contact with the surface of the sample at the end of the major axis for 5 seconds or until the sample ignites, whichever is less. Remove the candle. By means of a stopwatch, determine the time of combustion with self-sustained flame. Do not exceed 60 seconds. Extinguish flame with a CO₂ or similar nondestructive type extinguisher. Measure the dimensions of the burnt area and calculate the rate of burning along the major axis of the sample.

§ 1500.45 Method for determining extremely flammable and flammable contents of self-pressurized containers.

(a) *Equipment required.* The test equipment consists of a base 8 inches wide, 2 feet long, marked in 6-inch intervals. A rule 2 feet long and marked in inches is supported horizontally on the side of the base and about 6 inches above it. A paraffin candle 1 inch or more in diameter, and of such height that the top third of the flame is at the height of the horizontal rule, is placed at the zero point in the base.

(b) *Procedure.* The test is conducted in a draft-free area that can be ventilated and cleared after each test. Place the self-pressurized container at a distance of 6 inches from the flame source. Spray for periods of 15 seconds to 20 seconds (one observer noting the extension of the flame and the other operating the container) through the top third of the flame and at a right angle to the flame. The height of the flame should be approximately 2 inches. Take three readings for each test, and average. As a precaution do not spray large quantities in a small, confined space. Free space of previously discharged material.

§ 1500.46 Method for determining flashpoint of extremely flammable contents of self-pressurized containers.

Use the apparatus described in § 1500.43a. Use some means such as dry ice in an open container to chill the pressurized container. Chill the container, the flash cup, and the bath solution of the apparatus (brine or glycol

may be used) to a temperature of about 25 °F below zero. Puncture the chilled container to exhaust the propellant. Transfer the chilled formulation to the test apparatus and test in accordance with the method described in § 1500.43a.

[51 FR 28544, Aug. 8, 1986]

§ 1500.48 Technical requirements for determining a sharp point in toys and other articles intended for use by children under 8 years of age.

(a) *Objective.* The sharp point test prescribed by paragraph (d) of this section will be used by the Commission in making a preliminary determination that points on toys and other articles intended for use by children under 8 years of age, and such points exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by puncture or laceration under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate points that are identified as presenting a potential risk of puncture or laceration injury to determine the need for individual product regulatory action.

(b) *Scope—(1) General.* The sharp point test of paragraph (d) of this section is applicable to toys or other articles that are introduced into interstate commerce on or after December 22, 1978. The sharp point test shall be applied to any accessible portion of the test sample before and after subjecting the test sample to the use and abuse tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test-paragraph (c) of each section).

(2) *Exemptions.* (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this § 1500.48: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (parts 1508, 1509, and 1512, of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48: *Provided*, Each toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp

points. An example of such toys is a toy sewing machine with a needle.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp points and that do not have any nonfunctional sharp points are exempt from this § 1500.48. An example of such articles is a ball-point pen.

(c) *Accessibility*—(1) *General*. Any point that is accessible either before or after these tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp point test of paragraph (d) of this section.

(2) *Accessible points*. (i) An accessible point for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in figure 2 of this section.

(ii) An accessible point for a toy or article intended for children over 3 years up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe B in figure 2 of this section.

(iii) An accessible point for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either probe A or B, as shown in figure 2 of this section.

(3) *Insertion depth for accessibility*. (i) For any hole, recess, or opening having a minor dimension (The minor dimension of an opening is the diameter of the largest sphere that will pass through the opening.) smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of probe A but less than 7.36 inches (186.9 millimeters), when probe A is used, or a minor dimension larger than the collar diameter of probe B but less than 9.00 inches (228.6 millimeters), when probe B is used, the total insertion depth for ac-

cessibility shall be determined by inserting the appropriate probe with the extension shown in figure 2 in any direction up to two and one-quarter times the minor dimension of the probe, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters), or larger when probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible points*. Points shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample and any gap between the point and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) either before or after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed.

(d) *Sharp point test method*—(1) *Principle of operation*. The principle of operation of the sharp point tester shown in figure 1 of this section is as follows (Detailed engineering drawings for a suggested sharp point tester are available from the Commission's Office of the Secretary.): A rectangular opening measuring 0.040 inch (1.02 millimeters) wide by 0.045 inch (1.15 millimeters) long in the end of the slotted cap establishes two reference dimensions. Depth of penetration of the point being tested determines sharpness. If the point being tested can contact a sensing head that is recessed a distance of 0.015 inch (0.38 millimeter) below the end cap and can move the sensing head a further 0.005 inch (0.12 millimeter) against a 0.5-pound (2.2-newton) force of a return spring, the point shall be identified as

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sharp. A sharp point tester of the general configuration shown in figure 1 of this section or one yielding equivalent results shall identify a sharp point. In conducting tests to determine the presence of sharp points, the Commission will use the sharp point tester shown in figure 1 of this section and the accessibility probes designated as A or B in figure 2 of this section.

(2) *Procedure.* (i) The sample to be tested shall be held in such a manner that it does not move during the test.

(ii) Part of the test sample may need to be removed to allow the sharp point testing device to test a point that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the point in question. The sharp point test shall be performed with the point supported so that its stiffness approximates but is not greater than the point stiffness in the assembled sample.

(iii) Using the general configuration shown in figure 1 of this section, the adjustment and operation of the sharp point tester is as follows: Hold the sharp point tester and loosen the lock ring by rotating it so that it moves towards the indicator lamp assembly a sufficient distance to expose the cali-

bration reference marks on the barrel. Rotate the gaging can clockwise until the indicator lamp lights. Rotate the cap counterclockwise until an equivalent of five divisions (the distance between the short lines on the cap) have passed the calibration reference mark. Lock the gaging cap in this position by rotating the lock ring until it fits firmly against the cap. Insert the point into the gaging slot in all directions in which it was accessible by the criteria of paragraph (c) of this section, and apply a force of 1.00 pound (4.45 newtons). A glowing light identifies the point as sharp.

(iv) The test instruments used by the Commission in its tests for compliance with this regulation shall have gaging slot opening dimensions no greater than 0.040 inch by 0.045 inch and shall have the sensing head recessed a depth of no less than 0.015 inch. The force applied by the Commission when inserting a point into the gaging slot shall be no more than 1.00 pound.

(e) For the purpose of conformance with the technical requirements prescribed by this §1500.48, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

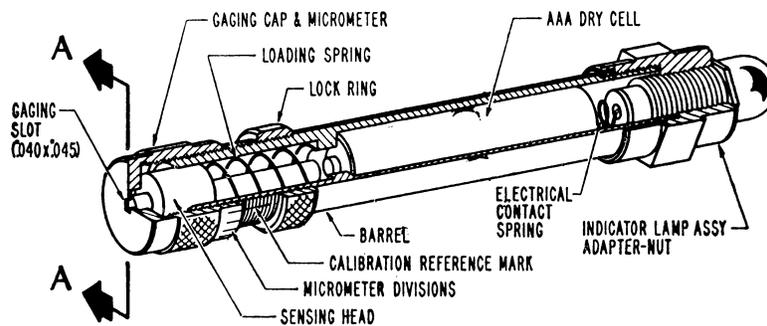
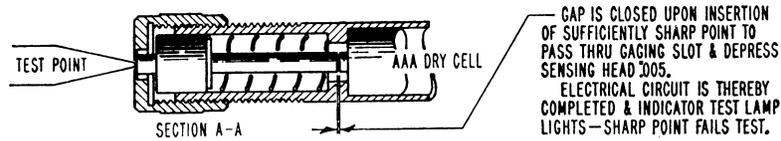
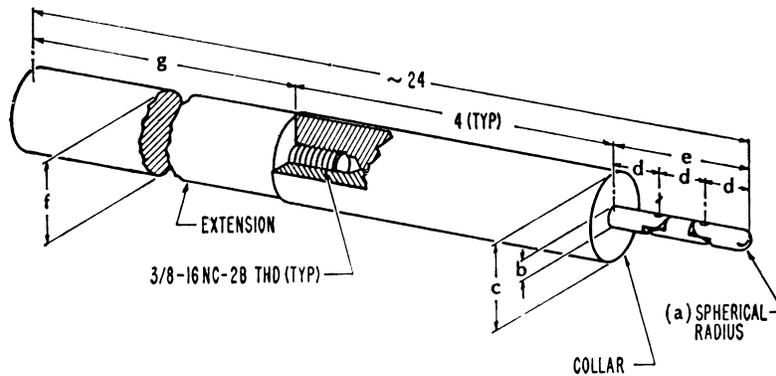


FIG 1—SHARP POINT TESTER



| | a | b | c | d | e | f | g |
|-----------------------------|---------|------|------|-------|------|-------|----------------|
| (CHILDREN 0-36 MONTHS INCL) | PROBE A | .110 | .220 | 1.020 | .577 | 1.731 | 1 18 9/32 |
| (" 37-96 " ") | PROBE B | .170 | .340 | 1.510 | .760 | 2.280 | 1 1/2 17 25/32 |

ALL DIMENSIONS IN INCHES

FIG 2—ACCESSIBILITY PROBES

§ 1500.49 **Technical requirements for determining a sharp metal or glass edge in toys and other articles intended for use by children under 8 years of age.**

(a) *Objective.* The sharp edge test method prescribed by paragraph (d) of this section will be used by the Com-

mission in making a preliminary determination that metal or glass edges on toys and other articles intended for use by children under 8 years of age, and such edges exposed in normal use or as a result of reasonably foreseeable damage or abuse of such toys and articles, present a potential risk of injury by

laceration or avulsion under section 2(s) of the Federal Hazardous Substances Act (15 U.S.C. 1261(s)). The Commission will further evaluate toys and other articles with edges that are identified as presenting a potential risk of laceration or avulsion injury to determine the need for individual product regulation.

(b) *Scope*—(1) *General*. The sharp edge test of paragraph (d) of this section is applicable to toys or other articles containing metal or glass edges that are introduced into interstate commerce after March 26, 1979. Such articles manufactured outside the United States are introduced into interstate commerce when first brought within as U.S. port of entry. Such articles manufactured in the United States are introduced into interstate commerce (a) at the time of first interstate sale, or (b) at the time of first intrastate sale if one or more components and/or raw materials were received interstate, whichever occurs earlier.

(2) *Exemptions*. (i) Toys and other children's articles that are the subject of any of the following regulations are exempt from this §1500.49: The regulations for bicycles, non-full-size baby cribs, and full-size baby cribs (parts 1508, 1509, and 1512 of this chapter).

(ii) Toys that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any nonfunctional sharp metal or glass edges are exempt from this section: Provided, the toy is identified by a conspicuous, legible, and visible label at the time of any sale, as having functional sharp metal or glass edges. Examples of these are a pair of toy scissors and toy tool kits.

(iii) Articles, besides toys, intended for use by children that by reason of their functional purpose necessarily present the hazard of sharp metal or glass edges and that do not have any non-functional sharp metal or glass edges are exempt from this section. Examples of these are children's ice skates and children's cutlery.

(3) *Definitions*—(i) *Glass*. For the purpose of this regulation the Commission defines glass as a hard, brittle, amorphous substance produced by fusion, usually consisting of mutually dis-

solved silica and silicates that also contain soda and lime.

(ii) *Metal*. For the purpose of this regulation the Commission intends the word metal to include both elemental metals and metal alloys.

(c) *Accessibility*—(1) *General*. Any metal or glass edge that is accessible either before or after the test of §§1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed shall be subject to the sharp edge test of paragraph (d) of this section. Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult.

(2) *Accessible edges*. (i) An accessible metal or glass edge for a toy or article intended for children 3 years of age or less is one that can be contacted by any portion forward of the collar of the accessibility probe designated as probe A in Figure 2 of this section.

(ii) An accessible edge for a toy or article intended for children over 3 years and up to 8 years of age is one that can be contacted by any portion forward of the collar of the accessibility probe designated as Probe B in Figure 2 of this section.

(iii) An accessible edge for a toy or article intended for children of ages spanning both age groups is one that can be contacted by any portion forward of the collar of either Probe A or Probe B, as shown in Figure 2 of this section.

(3) *Insertion depth*. (i) For any hole, recess, or opening having a minor dimension (the minor dimension of an opening is the diameter of the largest sphere that will pass through the opening), smaller than the collar diameter of the appropriate probe, the total insertion depth for accessibility shall be up to the collar on the appropriate probe. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(ii) For any hole, recess, or opening having a minor dimension larger than the collar diameter of Probe A, but less than 7.36 inches (186.9 millimeters),

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when Probe A is used, or a minor dimension larger than the collar diameter of Probe B, but less than 9.00 inches (228.6 millimeters), when Probe B is used, the total insertion depth for accessibility shall be determined by inserting the appropriate probe with the extension, shown in Figure 2, in any direction up to $2\frac{1}{4}$ times the minor dimension of the hole, recess, or opening, measured from any point in the plane of the opening. Each probe joint may be rotated up to 90 degrees to simulate knuckle movement.

(iii) For any hole, recess, or opening having a minor dimension of 7.36 inches (186.9 millimeters) or larger when Probe A is used, or a minor dimension of 9.00 inches (228.6 millimeters) or larger when Probe B is used, the total insertion depth for accessibility is unrestricted unless other holes, recesses, or openings within the original hole, recess, or opening are encountered with dimensions specified in paragraph (c)(3) (i) or (ii) of this section. In such instances, the appropriate paragraphs (c)(3) (i) or (ii) of this section shall be followed. If both probes are to be used, a minor dimension that is 7.36 inches (186.9 millimeters) or larger shall determine unrestricted access.

(4) *Inaccessible edges.* Metal or glass edges shall be considered inaccessible without testing with a probe if they lie adjacent to a surface of the test sample, and any gap between the edge and the adjacent surface does not exceed 0.020 inch (0.50 millimeter) both before and after the tests of §§ 1500.51, 1500.52, and 1500.53 (excluding the bite test—paragraph (c) of each section) are performed. For example, in a lap joint in which a metal edge is overlapped by a parallel surface, any burr or feather-edge on the side closest to the protecting parallel surface is considered inaccessible if the gap between the edge and the parallel surface is no greater than 0.020 inch (0.50 millimeter). As an additional example, when sheet metal has a hemmed edge a portion of the sheet adjacent to the edge is folded back upon itself, approximately 180 degrees, so that it is roughly parallel to the main sheet. Any burrs or feathering on the inside edge, the side closest to the protecting parallel surface of the main sheet, will be consid-

ered inaccessible if the gap between the inside edge and the parallel surface does not exceed 0.020 inch (0.50 millimeter).

(d) *Sharp edge test method*—(1) *Principle of operation.* The test shall be performed with a sharp edge tester which contains a cylindrical mandrel capable of rotation at a constant velocity. (Engineering drawings for a suitable portable sharp edge test instrument are available from the Commission's Office of the Secretary.) The full circumference of the mandrel shall be wrapped with a single layer of polytetrafluoroethylene (TFE) tape as specified in paragraph (e)(3) of this section. The mandrel shall be applied to the edge to be tested with a normal force of 1.35 pounds (6.00 Newtons) such that the edge contacts the approximate center of the width of the tape as shown in Figure 1 of this section. The mandrel shall be rotated through one complete revolution while maintaining the force against the edge constant. Linear motion of the mandrel along the line of the edge shall be prevented. The edge shall be identified as sharp if it completely cuts through the tape for a length of not less than $\frac{1}{2}$ inch (13 millimeters) at any force up to 1.35 pounds (6.00 Newtons).

(2) *Procedure.* (i) The edge of the sample to be tested shall be held in such a manner that it does not move during the test. If the full mandrel force of 1.35 pounds (6.00 Newtons) causes the edge to bend, a reduced mandrel force may be used.

(ii) Part of the test sample may need to be removed to allow the sharp edge testing device to test an edge that is accessible by the criteria of paragraph (c) of this section. Such dismantling of the test sample could affect the rigidity of the edge in question. The sharp edge test shall be performed with the edge supported so that its stiffness approximates but is not greater than the edge stiffness in the assembled sample.

(iii) Conduct of a sharp edge test is as follows: Wrap one layer of polytetrafluoroethylene (TFE) tape, described in paragraph (e)(3) of this section, around the full circumference of the mandrel in an unstretched state. The ends of

the tape shall be either butted or overlapped not more than 0.10 inch (2.5 millimeters). Apply the mandrel, at the approximate center of the tape, to the edge of the test sample with a force of 1.35 pounds (6.00 Newtons) measured in a direction at right angles to the mandrel axis. The mandrel shall be placed so that its axis is at 90 degrees \pm 5 degrees to the line of a straight test edge or 90 degrees \pm 5 degrees to a tangent at the point of contact with a curved test edge. The point of contact between the test edge and the mandrel shall be in the approximate center of the width of the tape. The axis of the mandrel may be positioned anywhere in a plane which is at right angles to either the line of a straight test edge or to a tangent at the point of contact with a curved test edge. The operator should seek the orientation most likely to cause the edge to cut the tape. Maintain the force against the edge and rotate the mandrel through one complete revolution while preventing any linear motion of the mandrel along the edge. Release the mandrel from the edge and remove the tape without enlarging any cut or causing any score to become a cut. A cut in the tape with a length of not less than $\frac{1}{2}$ inch (13 millimeters) identifies an edge as sharp. (The test instruments used by the Commission in its test for compliance with the regulation will be calibrated to insure that the force with which the mandrel is applied to a test edge does not exceed 1.35 pounds.)

(e) *Specifications for sharp edge test equipment.* The following specifications shall apply to the equipment to be used in the sharp edge test described in paragraph (d) of this section:

(1) The rotation of the mandrel shall produce a constant tangential velocity of 1.00 ± 0.08 inch per second (25.4 ± 2.0 millimeters per second) during the center 75 percent of its rotation and shall have a smooth start and stop.

(2) The mandrel shall be made of steel. The test surface of the mandrel

shall be free of scratches, nicks, or burrs and shall have a surface roughness no greater than 16 microinches (0.40 micron). The test surface shall have a hardness no less than 40 as measured on the Rockwell "C" scale, as determined pursuant to ASTM E 18-74 entitled "Standard Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials," published July 1974 and which is incorporated by reference in this regulation. (Copies are available from American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.) The diameter of the mandrel shall be 0.375 ± 0.005 inch (9.35 ± 0.12 millimeters). The mandrel shall be of suitable length to carry out the test.

(3) The tape shall be pressure-sensitive polytetrafluoroethylene (TFE) high temperature electrical insulation tape as described in Military Specification MIL-I-23594B (1971) which is incorporated by reference in this regulation. (Copies are available from Naval Publications and Forms Center, 5801 Tabor Ave., Philadelphia, Pa. 19120.) The thickness of the polytetrafluoroethylene backing shall be between 0.0026 inch (0.066 millimeter) and 0.0035 inch (0.089 millimeter).¹ The adhesive shall be pressure-sensitive silicone polymer with a nominal thickness of 0.003 inch (.08 millimeter). The width of the tape shall not be less than $\frac{1}{4}$ inch (6 millimeters). While conducting sharp edge tests the temperature of the tape shall be maintained between 70 °F (21.1 °C) and 80 °F (26.6 °C).

(f) For the purpose of conformance with the technical requirements prescribed by this §1500.49, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.

¹The tape that the Commission will use for the sharp edge test is CHR type "T" manufactured by The Connecticut Hard Rubber Co., New and East Streets, New Haven, Conn. 06509.

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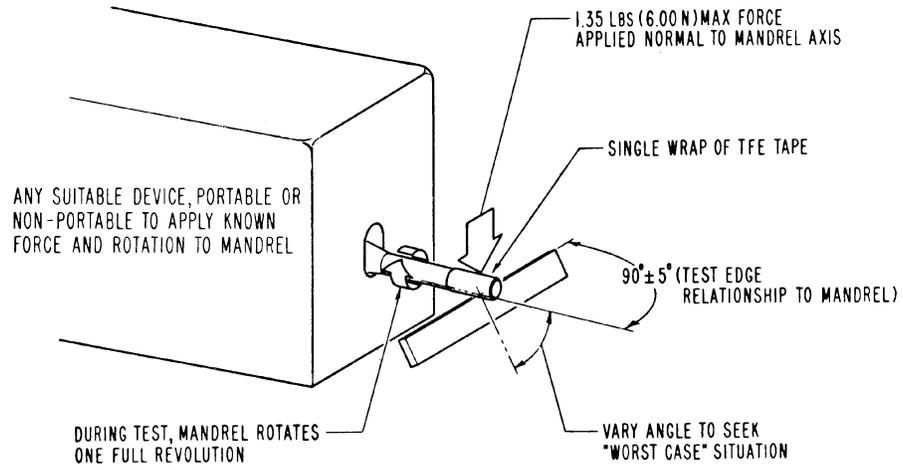


FIG I-PRINCIPLE OF SHARP EDGE TEST

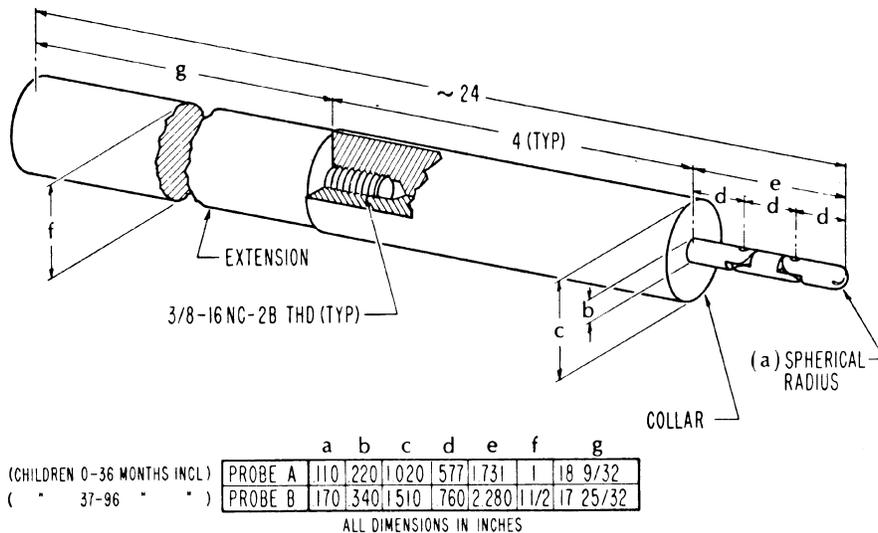


FIG 2—ACCESSIBILITY PROBES

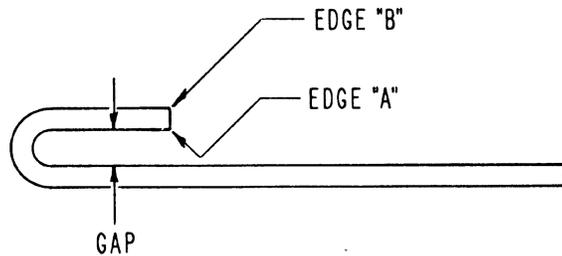


ILLUSTRATION I—HEMMED EDGE

(Secs. 2(s), 10(a), 74 Stat. 378 (15 U.S.C. 1261, 1269))

[43 FR 12645, Mar. 24, 1978, as amended at 43 FR 21324, May 17, 1978]

§ 1500.50 Test methods for simulating use and abuse of toys and other articles intended for use by children.

(a) *Objective.* The objective of §§ 1500.51, 1500.52, and 1500.53 is to describe specific test methods for simulating normal use of toys and other articles intended for use by children as well as the reasonably foreseeable damage or abuse to which the articles may be subjected. The test methods are for use in exposing potential hazards that would result from the normal use or the reasonably foreseeable damage or abuse of such articles intended for children.

(b) *Application—general.* (1)(i) The test methods described in §§ 1500.51, 1500.52 and 1500.53 are to be used in determining what is normal use and reasonably foreseeable damage or abuse when specifically referenced under § 1500.18. Other banning regulations may also reference these use and abuse toy test procedures.

(ii) The test methods described in §§ 1500.51, 1500.52, and 1500.53 have been established for articles intended for the specified age groups of children: 18 months of age or less, over 18 months but not over 36 months of age, and over 36 months but not over 96 months of

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age. If an article is marked, labeled, advertised, or otherwise intended for children of ages spanning more than one of these age groups, the article will be subjected to the tests providing the most stringent requirements. If an article is not age-labeled in a clear and conspicuous manner or, based on such factors as marketing practices and the customary patterns of usage of a product by children, is inappropriately age-labeled, and is intended or appropriate for children 96 months of age or less, it will also be subjected to the most stringent test requirements.

(2) For purposes of compliance with the test methods prescribed in §§ 1500.51, 1500.52, and 1500.53, the English system shall be used. The metric approximations are provided in parentheses for convenience and information only.

(3) Each of the test methods described in §§ 1500.51, 1500.52, and 1500.53 shall be applied to a previously untested sample except the tension test which shall be conducted with the test sample used in the torque test.

(4) Prior to testing, each sample shall be subjected to a temperature of $73^{\circ}\pm 3^{\circ}$ F. ($23^{\circ}\pm 2^{\circ}$ C.) as a relative humidity of 20–70 percent for a period of at least 4 hours. The toy testing shall commence within five minutes after the toy has been removed from the preconditioning atmosphere.

(5) Toys reasonably intended to be assembled by an adult and not intended to be taken apart by a child shall be tested only in the assembled state if the shelf package and the assembly instructions prominently indicate that the article is to be assembled only by an adult.

(6) Toys intended to be repeatedly assembled and taken apart shall have the individual pieces as well as the completed article subjected to these test procedures.

(7) In situations where a test procedure may be applied in more than one way to a toy test component, the point (or direction) of force (or torque) application which results in the most severe conditions shall be used.

(c) *Definitions.* As used in this section and in §§ 1500.51, 1500.52, and 1500.53:

(1) *Toy* means any toy, game, or other article designed, labeled, adver-

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tised, or otherwise intended for use by children.

(2) *Mouth toy* means any toy reasonably intended to be placed into or in contact with a child's mouth.

[40 FR 1483, Jan. 7, 1975; 40 FR 16191, Apr. 10, 1975]

§ 1500.51 Test methods for simulating use and abuse of toys and other articles intended for use by children 18 months of age or less.

(a) *Application.* The test methods described in this section shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use by children 18 months of age or less in conjunction with § 1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 3.0 pounds ± 0.01 pound (1.4 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* Except as provided in paragraphs (b)(4) (i) and (ii) of this section, the toy shall be dropped 10 times from a height of 4.5 feet ± 0.5 inch (1.37 meters) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop,

¹These documents may be ordered from the General Services Administration, Specifications Unit, Room 6654, 7th and D Streets, S.W., Washington, DC 20407. The price of the specification and amendment is \$1.00.

the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters), shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section. The base area for toys with permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4)(i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

(c) *Bite test*—(1) *Application.* A toy (or component or any accessible portion thereof) that has an external dimension of 1.25 inches ± 0.05 inch (3.18 centimeters) or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1.25 inches ± 0.05 inch (3.18 centimeters), for a penetration of at least 0.25 inch (0.635 centimeter), shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch ± 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch ± 0.002 inch (0.05 centimeter), for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of this section.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of

the contact mechanism, and a test load increasing to 25 pounds ± 0.5 pound (11.35 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 10 pounds ± 0.5 pound (4.55 kilograms), applied perpendicularly to the major axis of the component at a point 2 inches (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches ± 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test*—(1) *Application*—(i) *General.* A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components.* Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment*—(i) *Loading device.* The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of ± 0.2

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inch-pound (±0.23 kilogram-centimeter).

(ii) *Clamp*. The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure*. With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of 2 inch-pounds ±0.2 inch-pound (2.30 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 2 inch-pounds (2.30 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test*—(1) *Application*—(i) *General*. Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags*. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 10 pounds ±0.5 pound (4.55 kilograms) of force applied in any direction.

(2) *Test equipment*—(i) *Clamps*. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device*. The loading device is to be a self-indicating gauge or other

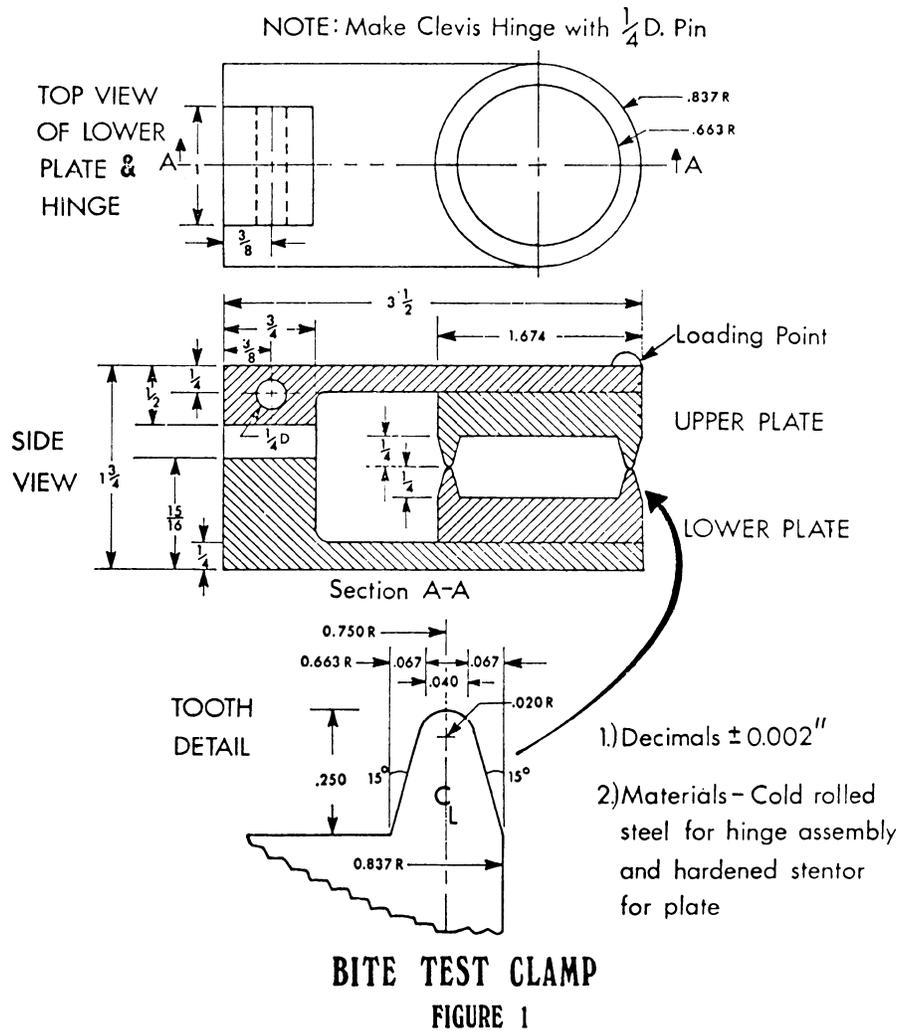
appropriate means having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure*. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 10-pound ±0.5 pound (4.55-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 10-pound ±0.5 pound (4.55-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches ±0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of 1/32 inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 20 pounds ±0.5 pound (9.1 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.



[40 FR 1484, Jan. 7, 1975; 40 FR 6210, Feb. 10, 1975; 40 FR 16192, Apr. 10, 1975; 40 FR 17746, Apr. 22, 1975, as amended at 55 FR 52040, Dec. 19, 1990; 56 FR 9, Jan. 2, 1991; 56 FR 558, Jan. 7, 1991]

§ 1500.52 Test methods for simulating use and abuse of toys and other articles intended for use by children over 18 but not over 36 months of age.

(a) *Application.* The test methods described in this section, shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use

by children over 18 but not over 36 months of age in conjunction with § 1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 4.0 pounds ± 0.01 pound (1.8 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* Except as provided in paragraph (b)(4) (i) and (ii) of this section, the toy shall be dropped four times from a height of 3 feet ± 0.5 inch (0.92 meter) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop, the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters) shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section. The base area for toys with permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4) (i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

¹ See footnote 1 to § 1500.51.

(c) *Bite test*—(1) *Application.* A toy (or component or any accessible portion thereof) that has an external dimension of 1.25 inches ± 0.05 inch (3.18 centimeters) or less and a design configuration that would permit a child to insert a portion into the mouth in any orientation up to a biting thickness of 1.25 inches ± 0.05 inches (3.18 centimeters), for a penetration of at least 0.25 inch (0.635 centimeter), shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch ± 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch ± 0.002 inch (0.05 centimeter) for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of § 1500.51.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of the contact mechanism, and a test load increasing to 50 pounds ± 0.5 pound (22.74 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 15 pounds ± 0.5 pound (6.80 kilograms) applied perpendicularly to the major axis of the component at a point 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches ± 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The

component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test*—(1) *Application*—(i) *General*. A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components*. Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment*—(i) *Loading device*. The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of ± 0.2 inch-pound (± 0.23 kilogram-centimeter).

(ii) *Clamp*. The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure*. With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the test object or component. A torque of 3 inch-pounds ± 0.2 inch-pound (3.46 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 3 inch-pounds ± 0.2 inch-pound (3.46 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test*—(1) *Application*—(i) *General*. Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall

be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags*. A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pounds ± 0.5 pound (6.80 kilograms) of force applied in any direction.

(2) *Test equipment*—(i) *Clamps*. One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device*. The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of ± 0.5 pound (± 255 grams).

(3) *Testing procedure*. With the test sample fastened in a convenient position, an appropriate clamp shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches ± 0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of $\frac{1}{32}$ inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface

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is parallel to the surface under test. A direct force of 25 pounds ± 0.5 pound (11.4 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1485, Jan. 7, 1975; 40 FR 6210, Feb. 10, 1975; 40 FR 16192, Apr. 10, 1975, as amended at 56 FR 10, Jan. 2, 1991]

§ 1500.53 Test methods for simulating use and abuse of toys and other articles intended for use by children over 36 but not over 96 months of age.

(a) *Application.* The test methods described in this section shall be used to simulate the normal and reasonably foreseeable use, damage, or abuse of toys and other articles intended for use by children over 36 but not over 96 months of age in conjunction with § 1500.18.

(b) *Impact test*—(1) *Application.* Except as provided in paragraph (b)(4) of this section, toys having a weight of less than 10.0 pounds ± 0.01 pound (4.6 kilograms) shall be subject to this test.

(2) *Impact medium.* The impact medium shall consist of a $\frac{1}{8}$ -inch (0.3-centimeter) nominal thickness of type IV vinyl-composition tile, composition 1— asbestos free, as specified by paragraphs 1.2 and 3.1.4 of Interim Amendment-1(YD), dated November 14, 1979, to the Federal Specification entitled Tile, Floor: Asphalt, Rubber, Vinyl, Vinyl-Asbestos, SS-T-312B, dated October 10, 1974,¹ over at least a 2.5-inch (6.4-centimeter) thickness of concrete. The impact area shall be at least 3 square feet (0.3 square meter). The Commission recognizes that this specified impact medium is the equivalent of, and will yield the same impact test results as, a surface covered with vinyl-asbestos tile meeting the requirements of Federal Specification SS-T-312A.

(3) *Testing procedure.* except as provided in paragraph (b)(4) (i) and (ii) of this section, the toy shall be dropped four times from a height of 3 feet ± 0.5 inch (0.92 meter) onto the impact medium described in paragraph (b)(2) of this section. The toy shall be dropped in random orientation. After each drop,

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the test sample shall be allowed to come to rest and shall be examined and evaluated before continuing.

(4) *Large and bulky toys.* (i) A toy that has a projected base area of 400 or more square inches (2,560 or more square centimeters) shall be tested for impact in accordance with paragraph (b)(4)(iii) of this subsection. The base area for toys having permanently attached legs shall be measured by calculating the area enclosed by straight lines connecting the outermost edge of each leg of the perimeter.

(ii) A toy that has a volume of more than 3 cubic feet (0.085 cubic meter), calculated by the major dimensions without regard to minor appendages, shall be tested for impact in accordance with paragraph (b)(4)(iii) of this section.

(iii) The toys described in paragraph (b)(4) (i) and (ii) of this section shall be tested for impact by tipping them over three times by pushing the samples slowly past their centers of balance onto the impact medium described in paragraph (b)(2) of this section.

(c) *Bite test*—(1) *Application.* A toy (or component) that is a mouth toy shall be subject to this test.

(2) *Test equipment*—(i) *Contact mechanism.* The contact mechanism shall be two metal strips or plates each measuring 0.25 inch ± 0.002 inch (0.635 centimeter) high and each having a contact edge radius of 0.020 inch ± 0.002 inch (0.5 centimeter) for at least a 150-degree cross-sectional arc. A suggested contact mechanism appears in figure 1 of § 1500.51.

(ii) *Loading device.* The loading device shall be a scale or force gauge having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* The test article shall be placed in the contact mechanism in any reasonable position for a penetration of 0.25 to 0.5 inch (0.64 to 1.27 centimeters), which position utilizes less than 180 degrees of the arc of the contract mechanism, and a test load increasing to 100 pounds ± 0.5 pound (45.50 kilograms) shall be evenly applied within 5 seconds. This load shall be maintained for an additional 10 seconds.

(d) *Flexure test*—(1) *Application.* This test shall be applied to each component of a toy containing metal wire(s), or

other metal material(s), for stiffening or for retention of form if the component can be bent through a 60-degree arc by a maximum force of 15 pounds ± 0.5 pound (6.80 kilograms) applied perpendicularly to the major axis of the component at a point 2 inches ± 0.05 inch (5 centimeters) from the intersection of the component with the main body of the toy or at the end of the component if the component is less than 2 inches ± 0.05 inch (5 centimeters) long.

(2) *Testing procedure.* The toy shall be secured in a vise equipped with vise shields that are fabricated from 13-gauge cold-rolled steel or other similar material and that have a 0.375-inch (0.95-centimeter) inside radius. The component shall then be bent through a 60-degree arc by a force applied at a point on the component 2 inches (5 centimeters) from the intersection of the component with the main body of the toy or applied at the end of the component if the component is less than 2 inches (5 centimeters) long. The component shall then be bent in the reverse direction through a 120-degree arc. This process shall be repeated for 30 cycles at a rate of one cycle per two seconds with a 60-second rest period occurring after each 10 cycles. Two 120-degree arc bends shall constitute one cycle.

(e) *Torque test—(1) Application—(i) General.* A toy with a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test.

(ii) *Toys with rotating components.* Projections, parts, or assemblies that are rigidly mounted on an accessible rod or shaft designed to rotate along with the projections, parts, or assemblies shall be tested with the rod or shaft clamped to prevent rotation.

(2) *Test equipment—(i) Loading device.* The loading device shall be a torque gauge, torque wrench, or other appropriate device having an accuracy of ± 0.2 inch-pound (± 0.23 kilogram-centimeter).

(ii) *Clamp.* The clamp shall be capable of holding the test component firmly and transmitting a torsional force.

(3) *Testing procedure.* With the toy rigidly fastened in any reasonable test position, the clamp is fastened to the

test object or component. A torque of 4 inch-pounds ± 0.2 inch-pound (4.60 kilogram-centimeters) shall be applied evenly within a period of 5 seconds in a clockwise direction until a rotation of 180 degrees from the original position has been attained or 4 inch-pounds ± 0.2 inch-pound (4.60 kilogram-centimeters) exceeded. The torque or maximum rotation shall be maintained for an additional 10 seconds. The torque shall then be removed and the test component permitted to return to a relaxed condition. This procedure shall then be repeated in a counterclockwise direction.

(f) *Tension test—(1) Application—(i) General.* Any projection of a toy that the child can grasp with at least the thumb and forefinger or the teeth shall be subject to this test. This test is to be conducted on the same toy that has been subjected to the torque test described in paragraph (e) of this section.

(ii) *Stuffed toys and beanbags.* A stuffed toy or beanbag constructed of pliable materials having seams (such as fabrics) shall have the seams subjected to 15 pounds ± 0.5 pound (6.80 kilograms) of force applied in any direction.

(2) *Test equipment—(i) Clamps.* One clamp capable of applying a tension load to the test component is required. A second clamp suitable for applying a tension load perpendicularly to the major axis of the test component is also required.

(ii) *Loading device.* The loading device is to be a self-indicating gauge or other appropriate means having an accuracy of ± 0.5 pound (± 225 grams).

(3) *Testing procedure.* With the test sample fastened in a convenient position, and appropriate clamp shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ± 0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the

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test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application*. Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus*. The loading device shall be a rigid metal disc 1.125 inches \pm 0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of $\frac{1}{32}$ inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of \pm 0.5 pound (\pm 225 grams).

(3) *Testing procedure*. The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 30 pounds \pm 0.5 pound (13.6 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1486, Jan. 7, 1975; 40 FR 16192, Apr. 10, 1975, as amended at 56 FR 10, Jan. 2, 1991]

§ 1500.81 Exemptions for food, drugs, cosmetics, and fuels.

(a) *Food, drugs, and cosmetics*. Substances subject to the Federal Food, Drug, and Cosmetic Act are exempted by section 2(f)(2) of the act; but where a food, drug, or cosmetic offers a substantial risk of injury or illness from any handling or use that is customary or usual it may be regarded as misbranded under the Federal Food, Drug, and Cosmetic Act because its label fails to reveal material facts with respect to consequences that may result from use of the article (21 U.S.C. 321(n)) when its label fails to bear information to alert the householder to this hazard.

(b) *Fuels*. A substance intended to be used as a fuel is exempt from the requirements of the act when in containers that are intended to be or are installed as part of the heating, cooling, or refrigeration system of a house. A portable container used for delivery or temporary or additional storage, and containing a substance that is a hazardous substance as defined in section 2(f) of the act, is not exempt from the labeling prescribed in section 2(p)

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of the act, even though it contains a fuel to be used in the heating, cooking, or refrigeration system of a house.

§ 1500.82 Exemption from full labeling and other requirements.

(a) Any person who believes a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full label compliance otherwise applicable under the act, because of the size of the package or because of the minor hazard presented by the substance, or for other good and sufficient reason, may submit to the Commission a request for exemption under section 3(c) of the act, presenting facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health. The Commission shall determine on the basis of the facts submitted and all other available information whether the requested exemption is consistent with adequate protection of the public health and safety. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order published in the FEDERAL REGISTER.

(b) The Commission may on its own initiative determine on the basis of facts available to it that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full labeling compliance otherwise applicable under the act because of the size of the package or because of the minor hazard presented by the substance or for other good and sufficient reason. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

(c) Any person who believes a particular article should be exempted from being classified as a “banned hazardous substance” as defined by section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15)(i)(A)), because its functional purpose requires inclusion of a hazardous substance, it bears labeling giving adequate directions and warnings for safe use, and it is intended for use by children who have attained sufficient maturity, and may reasonably

be expected, to read and heed such directions and warnings, may submit to the Commission a request for exemption under section 2(q)(1)(B)(i) of the act (repeated in proviso (I) under §1500.3(b)(15(i)), presenting facts in support of his contention. The commission shall determine on the basis of the facts submitted, and all other available information, whether the requested exemption is consistent with the purposes of the act. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

(d) On its own initiative, the Commission may determine on the basis of available facts that a particular banned hazardous substance should be exempted from section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15(i)(A)), because its functional purpose requires inclusion of a hazardous substance, it bears labeling giving adequate directions and warnings for safe use, and it is intended for use by children who have obtained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

§1500.83 Exemptions for small packages, minor hazards, and special circumstances.

(a) The following exemptions are granted for the labeling of hazardous substances under the provisions of §1500.82:

(1) When the sole hazard from a substance in a self-pressurized container is that it generates pressure or when the sole hazard from a substance is that it is flammable or extremely flammable, the name of the component which contributes the hazards need not be stated.

(2) Common matches, including book matches, wooden matches, and so-called "safety" matches are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the product being considered hazardous because of being an "extremely flammable solid" or "flammable solid" as defined in §1500.3(c)(6)(v) and (vi).

(3) Paper items such as newspapers, wrapping papers, toilet and cleansing tissues, and paper writing supplies are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being an "extremely flammable solid" or "flammable solid" as defined in §1500.3(c)(6)(v) and (vi).

(4) Thread, string, twine, rope, cord, and similar materials are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being an "extremely flammable solid" or "flammable solid" as defined in Sec. 1500.3(c)(6)(v) and (vi).

(5) Laboratory chemicals intended only for research or investigational and other laboratory uses (except those in home chemistry sets) are exempt from the requirements of placement provided in §1500.121 if all information required by that section and the act appears with the required prominence on the label panel adjacent to the main panel.

(6) [Reserved]

(7) Rigid or semirigid ballpoint ink cartridges are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), insofar as such requirements would be necessary because the ink contained therein is a "toxic" substance as defined in §1500.3(c)(2)(i), if:

(i) The ballpoint ink cartridge is of such construction that the ink will, under any reasonably foreseeable conditions of manipulation or use, emerge only from the ballpoint end;

(ii) When tested by the method described in §1500.3(c)(2)(i), the ink does not have an LD-50 single oral dose of less than 500 milligrams per kilogram of body weight of the test animal; and

(iii) The cartridge does not have a capacity of more than 2 grams of ink.

(8) Containers of paste shoe waxes, paste auto waxes, and paste furniture and floor waxes containing toluene (also known as toluol), xylene (also known as xylol), petroleum distillates, and/or turpentine in the concentrations described in §1500.14(a)(3) and (5) are exempt from the labeling requirements

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of §1500.14(b)(3)(ii) and (5) if the viscosity of such products is sufficiently high so that they will not flow from their opened containers when inverted for 5 minutes at a temperature of 80 °F., and are exempt from bearing a flammability warning statement if the flammability of such waxes is due solely to the presence of solvents that have flashpoints above 80 °F. when tested by the method described in §1500.43.

(9) Porous-tip ink-marking devices are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the labeling requirements of §1500.14(b)(1), (2), and (3)(ii) and (iii) insofar as such requirements would be necessary because the ink contained therein is a toxic substance as defined in §1500.3(c)(2)(i), and/or because the ink contains 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates as defined in §1500.14(a)(3), and/or because the ink contains 10 percent or more by weight of ethylene glycol; provided that:

(i) The porous-tip ink-marking devices are of such construction that:

(A) The ink is held within the device by an absorbent material so that no free liquid is within the device; and

(B) Under any reasonably foreseeable conditions of manipulation and use, including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(ii)(A) The device has a capacity of not more than 10 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(B) The device has a capacity of not more than 12 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 3.0 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than 4 percent methyl alcohol by weight are exempt from the label statement "Cannot be made nonpoisonous" required by §1500.14(b)(4) if:

(i) The total amount of methyl alcohol by weight in the product does not exceed 15 percent; and

(ii) The contents of any container does not exceed 2 fluid ounces.

(11) Packages containing polishing or cleaning products which consist of a carrier of solid particulate or fibrous composition and which contain toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates in the concentrations described in §1500.14(a) (1) and (2) are exempt from the labeling requirements of §1500.14(b)(3)(ii) if such toluene, xylene, or petroleum distillate is fully absorbed by the solid, semisolid, or fibrous carrier and cannot be expressed therefrom with any reasonably foreseeable conditions of manipulation.

(12) Containers of dry ink intended to be used as a liquid ink after the addition of water are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the labeling requirements of §1500.14(b) (1) and (2) insofar as such requirements would be necessary because the dried ink contained therein is a toxic substance as defined in §1500.3(c)(2)(i) and/or because the ink contains 10 percent or more of ethylene glycol as defined in §1500.14(a)(2); provided that:

(i) When tested by the method described in §1500.3(c)(2)(i), the dry ink concentrate does not have an LD-50 (lethal dose, median; lethal for 50 percent or more of test group) single oral dose of less than 1 gram per kilogram of body weight of the test animal.

(ii) The dry ink concentrate enclosed in a single container does not weigh more than 75 milligrams.

(iii) The dry ink concentrate does not contain over 15 percent by weight of ethylene glycol.

(13) Containers of liquid and semi-solid substances such as viscous-type paints, varnishes, lacquers, roof coatings, rubber vulcanizing preparations, floor covering adhesives, glazing compounds, and other viscous products containing toluene (also known as toluol), xylene (also known as xylo), or petroleum distillates in concentrations described in §1500.14(a)(3) are exempt from the labeling requirements of

§1500.14(b)(3)(ii) insofar as that subdivision applies to such toluene, xylene, or petroleum distillates, provided that the viscosity of the substance or of any liquid that may separate or be present in the container is not less than 100 Saybolt universal seconds at 100 °F.

(14) Customer-owned portable containers that are filled by retail vendors with gasoline, kerosene (kerosine), or other petroleum distillates are exempt from the provision of section 2(p)(1)(A) of the act (which requires that the name and place of business of the manufacturer, distributor, packer, or seller appear on the label of such containers) provided that all the other label statements required by section 2(p)(1) of the act and §1500.14(b)(3) appear on the labels of containers of the substances named in this subparagraph.

(15) Cellulose sponges are exempt from the labeling requirements of section 2(p)(1) of the act and §1500.14(b)(1) insofar as such requirements would be necessary because they contain 10 percent or more of diethylene glycol as defined in §1500.14(a)(1), provided that:

(i) The cellulose sponge does not contain over 15 percent by weight of diethylene glycol; and

(ii) The diethylene glycol content is completely held by the absorbent cellulose material so that no free liquid is within the sponge as marketed.

(16) Containers of substances which include salt (sodium chloride) as a component are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the salt contained therein is present in a quantity sufficient to render the article "toxic" as defined in §1500.3(3)(2)(i), provided that the labels of such containers bear a conspicuous statement that the product contains salt.

(17) The labeling of substances containing 10 percent or more of ferrous oxalate is exempt from the requirement of §1500.129(f) that it bear the word "poison" which would be required for such concentration of a salt of oxalic acid.

(18) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material saturated with a

mixture of drycleaning solvents, are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the "flammable solid" hazard as defined in §1500.3(c)(6)(vi), provided that:

(i) The article is packaged in a sealed foil envelope;

(ii) The total amount of solvent in each package does not exceed 4.5 milliliters; and

(iii) The article will ignite only when in contact with an open flame, and when so ignited, the article burns with a sooty flame.

(19) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material containing methyl alcohol, are exempt from the labeling requirements of §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each package does not exceed 4.5 milliliters of which not more than 25 percent is methyl alcohol; and

(ii) The liquid is completely held by the absorbent materials so that no free liquid is within the packages marketed.

(20) Cigarette lighters containing petroleum distillate fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and §1500.14(b)(3) insofar as such requirements would be necessary because the petroleum distillate contained therein is flammable and because the substance is named in §1500.14(a)(3) as requiring special labeling, provided that:

(i) Such lighters contain not more than 10 cubic centimeters of fuel at the time of sale; and

(ii) Such fuel is contained in a sealed compartment that cannot be opened without the deliberate removal of the flush-set, screw-type refill plug of the lighter.

(21) Containers of dry granular fertilizers and dry granular plant foods are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the fertilizer or plant food contained therein is a toxic substance as defined in §1500.3(c)(2)(i), provided that:

(i) When tested by the method described in §1500.3(c)(2)(i), the product

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has a single dose LD-50 of not less than 3.0 grams per kilogram of body weight of the test animal;

(ii) The label of any such exempt dry granular fertilizers discloses the identity of each of the hazardous ingredients;

(iii) The label bears the name and address of the manufacturer, packer, distributor, or seller; and

(iv) The label bears the statement “Keep out of the reach of children” or its practical equivalent.

(22) Small plastic capsules containing a paste composed of powdered metal solder mixed with a liquid flux are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The capsule holds not more than one-half milliliter of the solder mixture;

(ii) The capsule is sold only as a component of a kit; and

(iii) Adequate caution statements appear on the carton of the kit and on any accompanying labeling which bears directions for use.

(23) Chemistry sets and other science education sets intended primarily for use by juveniles, and replacement containers of chemicals for such sets, are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The immediate container of each chemical that is hazardous as defined in the act and regulations thereunder bears on its main panel the name of such chemical, the appropriate signal word for that chemical, and the additional statement “Read back panel before using” (or “Read side panel before using,” if appropriate) and bears on the back (or side) panel of the immediate container the remainder of the appropriate cautionary statement for the specific chemical in the container;

(ii) The experiment manual or other instruction book or booklet accompanying such set bears on the front page thereof, as a preface to any written matter in it (or on the cover, if any there be), the following caution statement within the borders of a rectangle and in the type size specified in §1500.121:

WARNING—This set contains chemicals that may be harmful if misused.

Read cautions on individual containers carefully. Not to be used by children except under adult supervision

; and

(iii) The outer carton of such set bears on the main display panel within the borders of a rectangle, and in the type size specified in §1500.121, the caution statement specified in paragraph (a)(23)(ii) of this section.

(24) Fire extinguishers containing fire extinguishing agents which are stored under pressure or which develop pressure under normal conditions of use are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements apply to the pressure hazard as defined in §1500.3(c)(7)(i), provided that:

(i) If the container is under pressure both during storage and under conditions of use, it shall be designed to withstand a pressure of at least 6 times the charging pressure at 70 °F., except that carbon dioxide extinguishers shall be constructed and tested in accordance with applicable Interstate Commerce Commission specifications; or

(ii) If the container is under pressure only during conditions of use, it shall be designed to withstand a pressure of not less than 5 times the maximum pressure developed under closed nozzle conditions at 70 °F. or 1½ times the maximum pressure developed under closed nozzle conditions at 120 °F., whichever is greater.

(25) Cleaning and spot removing kits intended for use in cleaning carpets, furniture, and other household objects; kits intended for use in coating, painting, antiquing, and similarly processing furniture, furnishings, equipment, sidings, and various other surfaces; and kits intended for use in photographic color processing are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the requirements of §1500.14, provided that:

(i) The immediate container of each hazardous substance in the kit is fully labeled and in conformance with the requirements of the act and regulations thereunder; and

(ii) The carton of the kit bears on the main display panel (or panels) within a

borderline, and in the type size specified in §1500.121, the caution statement “(Insert proper signal word as specified in paragraph (a)(25)(iii) of this section). This kit contains the following chemicals that may be harmful if misused: (List hazardous chemical components by name.) Read cautions on individual containers carefully. Keep out of the reach of children.”

(iii) If either the word “POISON” or “DANGER” is required on the container of any component of the kit, the same word shall be required to appear as part of the caution statement on the kit carton. If both “POISON” and “DANGER” are required in the labeling of any component or components in the kit, the word “POISON” shall be used. In all other cases the word “WARNING” or “CAUTION” shall be used.

(26) Packages containing articles intended as single-use spot removers and containing methyl alcohol are exempt from the labeling specified in §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each unit does not exceed 1 milliliter, of which not more than 40 percent is methyl alcohol;

(ii) The liquid is contained in a sealed glass ampoule enclosed in a plastic container with a firmly attached absorbent wick at one end through which the liquid from the crushed ampoule must pass, under the contemplated conditions of use; and

(iii) The labeling of each package of the cleaner bears the statement “WARNING—Keep out of the reach of children,” or its practical equivalent, and the name and place of business of the manufacturer, packer, distributor, or seller.

(27) Packaged fireworks assortments intended for retail distribution are exempt from section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The package contains only fireworks devices suitable for use by the public and designed primarily to produce visible effects by combustion, except that small devices designed to produce audible effects may also be included if the audible effect is produced by a charge of not more than 2 grains of pyrotechnic composition;

(ii) Each individual article in the assortment is fully labeled and in conformance with the requirements of the act and regulations thereunder; and

(iii) The outer package bears on the main display panel (or panels), within the borders of a rectangle and in the type size specified in §1500.121, the caution statement “WARNING—This assortment contains items that may be hazardous if misused and should be used only under adult supervision. IMPORTANT—Read cautions on individual items carefully.” (See also §1500.14(b)(7); §1500.17(a) (3), (8) and (9); §1500.85(a)(2); and part 1507).

(28) Packages containing felt pads impregnated with ethylene glycol are exempt from the labeling requirements of §1500.14(b)(1), if:

(i) The total amount of ethylene glycol in each pad does not exceed 1 gram; and

(ii) The liquid is held by the felt pad so that no free ethylene glycol is within the package.

(29) Cigarette lighters containing butane and/or isobutane fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would otherwise be necessary because the fuel therein is extremely flammable and under pressure, provided that:

(i) The lighters contain not more than 12 grams of fuel at the time of sale; and

(ii) The fuel reservoir is designed to withstand a pressure of at least 1½ times the maximum pressure which will be developed in the container at 120 °F.

(30) The outer retail containers of solder kits each consisting of a small tube of flux partially surrounded by a winding of wire-type cadmium-free silver solder are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The metal solder contains no cadmium and is not otherwise hazardous under the provisions of the act;

(ii) The tube of flux in the kit is fully labeled and in conformance with the act and regulations thereunder, and any accompanying literature that bears directions for use also bears all

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the information required by section 2(p) of the act; and

(iii) The main panel of the outer container bears in type size specified in §1500.121 the following: (A) The signal word; (B) a statement of principal hazard or hazards; (C) the statement "Keep out of the reach of children," or its practical equivalent; and (D) instructions to read other cautionary instructions on the tube of flux within.

(31) Visual novelty devices consisting of sealed units, each of which unit is a steel and glass cell containing perchloroethylene (among other things), are exempt from the requirements of §1500.121(a) that would otherwise require a portion of the warning statement to appear on the glass face of the device, provided that:

(i) The device contains not more than 105 milliliters of perchloroethylene and contains no other component that contributes substantially to the hazard; and

(ii) The following cautionary statement appears on the device (other than on the bottom) in the type size specified in §1500.121 (c) and (d):

CAUTION—IF BROKEN, RESULTANT VAPORS
MAY BE HARMFUL

Contains perchloroethylene. Do not expose to extreme heat. If broken indoors, open windows and doors until all odor of chemical is gone.

Keep out of the reach of children.

A practical equivalent may be substituted for the statement "Keep out of the reach of children."

(32) Hollow plastic toys containing mineral oil are exempt from the labeling specified in §1500.14(b)(3)(ii), if:

(i) The article contains no other ingredient that would cause it to possess the aspiration hazard specified in §1500.14(b)(3)(ii);

(ii) The article contains not more than 6 fluid ounces of mineral oil;

(iii) The mineral oil has a viscosity of at least 70 Saybolt universal seconds at 100 °F.;

(iv) The mineral oil meets the specifications in the N.F. for light liquid petrolatum; and

(v) The container bears the statement "CAUTION—Contains light liquid petrolatum N.F. Discard if broken or leak develops."

(33) Containers of mineral oil having a capacity of not more than 1 fluid ounce and intended for use in producing a smoke effect for toy trains are exempt from the labeling specified in §1500.14(b)(3), if:

(i) The mineral oil meets the specifications in the N.F. for light liquid petrolatum;

(ii) The mineral oil has a viscosity of at least 130 Saybolt universal seconds at 100 °F.;

(iii) The article contains no other ingredient that contributes to the hazard; and

(iv) The label declares the presence light liquid petrolatum and the name and place of business of the manufacturer, packer, distributor, or seller.

(34) Viscous products containing more than 4 percent by weight of methyl alcohol, such as adhesives, asphalt-base roof and tank coatings, and similar products, are exempt from bearing the special labeling required by §1500.14(b)(4), if:

(i) The product contains not more than 15 percent by weight of methyl alcohol;

(ii) The methyl alcohol does not separate from the other ingredients upon standing or through any foreseeable use or manipulation;

(iii) The viscosity of the product is not less than 7,000 centipoises at 77 °F., unless the product is packaged in a pressurized container and is dispensed as a liquid unsuitable for drinking; and

(iv) The labeling bears the statement "Contains methyl alcohol. Use only in well-ventilated area. Keep out of the reach of children."

(35) Individual detonators or blasting caps are exempt from bearing the statement, "Keep out of the reach of children," or its practical equivalent, if:

(i) Each detonator or cap bears conspicuously in the largest type size practicable the statement, "DANGEROUS—BLASTING CAPS—EXPLOSIVE" or "DANGEROUS—DETONATOR—EXPLOSIVE"; and

(ii) The outer carton and any accompanying printed matter bear appropriate, complete cautionary labeling.

(36) Individual toy rocket propellant devices and separate delay train and/or

recovery system activation devices intended for use with premanufactured model rocket engines are exempt from bearing the full labeling required by section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the articles are flammable or generate pressure, provided that:

(i) The devices are designed and constructed in accordance with the specifications in §1500.85(a)(8), (9) or (14);

(ii) Each individual device or retail package of devices bears the following:

(A) The statement “WARNING—FLAMMABLE: Read instructions before use”;

(B) The common or usual name of the article;

(C) A statement of the type of engine and use classification;

(D) Instructions for safe disposal; and

(E) Name and place of business of manufacturer or distributor; and

(iii) Each individual rocket engine or retail package of rocket engines distributed to users is accompanied by an instruction sheet bearing complete cautionary labeling and instructions for safe use and handling of the individual rocket engines.

(37) Glues with a cyanoacrylate base in packages containing 3 grams or less are exempt from the requirement of §1500.121(d) that labeling which is permitted to appear elsewhere than on the main label panel must be in type size no smaller than 6 point type, provided that:

(i) The main panel of the immediate container bears both the proper signal word and a statement of the principal hazard or hazards associated with this product, as provided by §1500.121 (a) and (c);

(ii) The main panel of the immediate container also bears an instruction to read carefully additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. The instruction to read additional warnings must comply with the size, placement, conspicuousness, and contrast requirements of §1500.121; and

(iii) The remainder of the cautionary labeling required by the act that is not on the main label panel must appear elsewhere on the label in legible type

and must appear on any outer package, accompanying leaflet, and display card. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed on a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer. That labeling which must appear on any outer package, accompanying leaflet, tag, or other suitable material must comply with the size, placement, contrast, and conspicuousness requirements of §1500.121(d).

(38) Rigid or semi-rigid writing instruments and ink cartridges having a writing point and an ink reservoir are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i) of the regulations) and of regulations issued under section 3(b) of the act (§1500.14(b)(1, 2)) insofar as such requirements would be necessary because the ink contained therein is a “toxic” substance as defined in §1500.3(c)(2)(i) and/or because the ink contains 10 percent or more by weight ethylene glycol or diethylene glycol, if all the following conditions are met:

(i) The writing instrument or cartridge is of such construction that the ink will, under any reasonably foreseeable condition of manipulation and use, emerge only from the writing tip.

(ii) When tested by the method described in §1500.3(c)(2)(i), the ink does not have an LD-50 single oral dose of less than 2.5 grams per kilogram of body weight of the test animal.

(iii) If the ink contains ethylene glycol or diethylene glycol, the amount of such substance, either singly or in combination, does not exceed 1 gram per writing instrument or cartridge.

(iv) The amount of ink in the writing instrument or cartridge does not exceed 3 grams.

[38 FR 27012, Sept. 27, 1973; 42 FR 33026, June 29, 1977, as amended at 43 FR 32745, July 28, 1978; 43 FR 47176, Oct. 13, 1978; 44 FR 42678, July 20, 1979; 46 FR 11513, Feb. 9, 1981; 48 FR 16, Jan. 3, 1983; 68 FR 4699, Jan. 30, 2003; 74 FR 27249, June 9, 2009; 75 FR 49380, Aug. 13, 2010]

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§ 1500.85 Exemptions from classification as banned hazardous substances.

(a) The term *banned hazardous substances* as used in section 2(q)(1)(A) of the act shall not apply to the following articles provided that these articles bear labeling giving adequate directions and warnings for safe use:

(1) Chemistry sets and other science education sets intended primarily for juveniles, and replacement components for such sets, when labeled in accordance with § 1500.83(a)(23).

(2) Firecrackers designed to produce audible effects, if the audible effect is produced by a charge of not more than 50 milligrams (.772 grains) of pyrotechnic composition. (See also § 1500.14(b)(7); § 1500.17(a) (3), (8) and (9); and part 1507).

(3) [Reserved]

(4) Educational materials such as art materials, preserved biological specimens, laboratory chemicals, and other articles intended and used for educational purposes.

(5) Liquid fuels containing more than 4 percent by weight of methyl alcohol that are intended and used for operation of miniature engines for model airplanes, boats, cars, etc.

(6) Novelties consisting of a mixture of polyvinyl acetate, U.S. Certified Colors, and not more than 25 percent by weight of acetone, and intended for blowing plastic balloons.

(7) Games containing, as the sole hazardous component, a self-pressurized container of soap solution or similar foam-generating mixture provided that the foam-generating component has no hazards other than being in a self-pressurized container.

(8) Model rocket propellant devices designed for use in light-weight, recoverable, and re-flyable model rockets, provided such devices:

(i) Are designed to be ignited by electrical means.

(ii) Contain no more than 62.5 grams (2.2 ounces) of propellant material and produce less than 80 newton-seconds (17.92 pound seconds) of total impulse with thrust duration not less than 0.050 second.

(iii) Are constructed such that all the chemical ingredients are preloaded into a cylindrical paper or similarly

constructed nonmetallic tube that will not fragment into sharp, hard pieces.

(iv) Are designed so that they will not burst under normal conditions of use, are incapable of spontaneous ignition, and do not contain any type of explosive or pyrotechnic warhead other than a small parachute or recovery-system activation charge.

(9) Separate delay train and/or recovery system activation devices intended for use with premanufactured model rocket engines wherein all of the chemical ingredients are preloaded so the user does not handle any chemical ingredient and are so designed that the main casing or container does not rupture during operation.

(10) Solid fuel pellets intended for use in miniature jet engines for propelling model jet airplanes, speed boats, racing cars, and similar models, provided such solid fuel pellets:

(i) Weigh not more than 11.5 grams each.

(ii) Are coated with a protective resinous film.

(iii) Contain not more than 35 percent potassium dichromate.

(iv) Produce a maximum thrust of not more than 7½ ounces when used as directed.

(v) Burn not longer than 12 seconds each when used as directed.

(11) Fuses intended for igniting fuel pellets exempt under subparagraph (10) of this paragraph.

(12) Kits intended for construction of model rockets and jet propelled model airplanes requiring the use of difluorodichloromethane as a propellant, provided the outer carton bears on the main panel in conspicuous type size the statement “WARNING—Carefully read instructions and cautions before use.”

(13) Flammable wire materials intended for electro-mechanical actuation and release devices for model kits described in paragraph (12) of this section, provided each wire does not exceed 15 milligrams in weight.

(14) Model rocket propellant devices (model rocket motors) designed to propel rocket-powered model cars, provided—

(i) Such devices:

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(A) Are designed to be ignited electrically and are intended to be operated from a minimum distance of 15 feet (4.6 m) away;

(B) Contain no more than 4 g. of propellant material and produce no more than 2.5 Newton-seconds of total impulse with a thrust duration not less than 0.050 seconds;

(C) Are constructed such that all the chemical ingredients are pre-loaded into a cylindrical paper or similarly constructed non-metallic tube that will not fragment into sharp, hard pieces;

(D) Are designed so that they will not burst under normal conditions of use, are incapable of spontaneous ignition, and do not contain any type of explosive or pyrotechnic warhead other than a small recovery system activation charge;

(E) Bear labeling, including labeling that the devices are intended for use by persons age 12 and older, and include instructions providing adequate warnings and instructions for safe use; and

(F) Comply with the requirements of 16 CFR 1500.83(a)(36)(ii and iii); and

(ii) The surface vehicles intended for use with such devices:

(A) Are lightweight, weighing no more than 3.0 oz. (85 grams), and constructed mainly of materials such as balsa wood or plastics that will not fragment into sharp, hard pieces;

(B) Are designed to utilize a braking system such as a parachute or shock absorbing stopping mechanism;

(C) Are designed so that they cannot accept propellant devices measuring larger than 0.5" (13 mm) in diameter and 1.75" (44 mm) in length;

(D) Are designed so that the engine mount is permanently attached by the manufacturer to a track or track line that controls the vehicle's direction for the duration of its movement;

(E) Are not designed to carry any type of explosive or pyrotechnic material other than the model rocket motor used for primary propulsion;

(F) Bear labeling and include instructions providing adequate warnings and instructions for safe use; and

(G) Are designed to operate on a track or line that controls the vehicles' direction for the duration of their movement and either cannot operate off the track or line or, if operated off

the track or line, are unstable and fail to operate in a guided fashion so that they will not strike the operator or bystanders.

(b) [Reserved]

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22935, June 8, 1976; 42 FR 43391, Aug. 29, 1977; 48 FR 16, Jan. 3, 1983; 68 FR 4699, Jan. 30, 2003]

§ 1500.86 Exemptions from classification as a banned toy or other banned article for use by children.

(a) The term *banned hazardous substance* as used in section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15)(i)(A)) of the act shall not apply to the following articles:

(1) Toy rattles described in §1500.18(a)(1) in which the rigid wires, sharp protrusions, or loose small objects are internal and provided that such rattles are constructed so that they will not break or deform to expose or release the contents either in normal use or when subjected to reasonably foreseeable damage or abuse.

(2) Dolls and stuffed animals and other similar toys described in §1500.18(a)(3) in which the components that have the potential for causing laceration, puncture wound injury, or other similar injury are internal, provided such dolls, stuffed animals, and other similar toys are constructed so that they will not break or deform to expose such components either in normal use or when subjected to reasonably foreseeable damage or abuse.

(3) [Reserved]

(4) Any article known as a "baby-bouncer" or "walker-jumper" and any other similar article (referred to in this paragraph as "article(s)"), except an infant walker subject to part 1216 of this chapter, described in §1500.18(a)(6) provided:

(i) The frames are designed and constructed in a manner to prevent injury from any scissoring, shearing, or pinching when the members of the frame or other components rotate about a common axis or fastening point or otherwise move relative to one another; and

(ii) Any coil springs which expand when the article is subjected to a force that will extend the spring to its maximum distance so that a space between successive coils is greater than one-

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eighth inch (0.125 inch) are covered or otherwise designed to prevent injuries; and

(iii) All holes larger than one-eighth inch (0.125 inch) in diameter and slots, cracks, or hinged components in any portion of the article through which a child could insert, in whole or in part a finger, toe, or any other part of the anatomy are guarded or otherwise designed to prevent injuries; and

(iv) The articles are designed and constructed to prevent accidental collapse while in use; and

(v) The articles are designed and constructed in a manner that eliminates from any portion of the article the possibility of presenting a mechanical hazard through pinching, bruising, lacerating, crushing, breaking, amputating, or otherwise injuring portions of the human body when in normal use or when subjected to reasonably foreseeable damage or abuse; and

(vi) Any article which is introduced into interstate commerce after the effective date of this subparagraph is labeled:

(A) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller; and

(B) With a code mark on the article itself and on the package containing the article or on the shipping container, in addition to the invoice(s) or shipping document(s), which code mark will permit future identification by the manufacturer of any given model (the manufacturer shall change the model number whenever the article undergoes a significant structural or design modification); and

(vii) The manufacturer or importer of the article shall make, keep, and maintain for 3 years records of sale, distribution, and results of inspections and tests conducted in accordance with this subparagraph and shall make such records available at all reasonable hours upon request by any officer or employee of the Consumer Product Safety Commission and shall permit such officer or employee to inspect and copy such records, to make such stock inventories as he deems necessary, and to otherwise check the correctness of such records.

(5) Clacker balls described in §1500.18(a)(7) that have been designed, manufactured, assembled, labeled, and tested in accordance with the following requirements, and when tested at the point of production or while in interstate commerce or while held for sale after shipment in interstate commerce do not exceed the failure rate requirements of the table in paragraph (a)(5)(vi) of this section:

(i) The toy shall be so designed and fabricated that:

(A) Each ball: Weighs less than 50 grams; will not shatter, crack, or chip; is free of cracks, flash (ridges due to imperfect molding), and crazing (tiny surface cracks); and is free of rough or sharp edges around any hole where the cord enters or over any surface with which the cord may make contact. Each ball is free of internal voids (holes, cavities, or air bubbles) if the balls are made of materials other than those materials (such as ABS (acrylonitrile butadiene styrene), nylon, and high-impact polystyrene) that are injection-molded and possess high-impact characteristics.

(B) The cord: Is of high tensile strength, synthetic fibers that are braided or woven, having a breaking strength in excess of 445 Newtons (100 pounds); is free of fraying or any other defect that might tend to reduce its strength in use; is not molded in balls made of casting resins which tend to wick up or run up on the outside of the cord; and is affixed to a ball at the center of the horizontal plane of the ball when it is suspended by the cord. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may have a minimum cord breaking strength of less than 445 Newtons (100 pounds), as computed by the following formula:

Adjusted Cord Breaking Strength in Newtons = $0.1382(m_b)(R_p)$, where m_b = mass of a single ball in grams and

R_p = pivot length in mm.

(C) When the cord is attached to the ball by means of a knot, the end beneath the knot is chemically fused or otherwise treated to prevent the knot from slipping out or untying in use.

(ii) The toy shall be tested at the time of production:

(A) By using the sampling procedure described in the table in subdivision (vi) of this subparagraph to determine the number of units to be tested.

(B) By subjecting each ball tested to 10 drops of a 2.25 kg (5-pound) steel impact rod or weight (57-mm (2¼-inch) diameter with a flat head) dropped 1220 mm (48 inches) in a vented steel or aluminum tube (60-mm (2⅜-inch) inside diameter) when the ball is placed on a steel or cast iron mount. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may be tested by dropping the impact weight from a height of less than 1220 mm (48 in.), where the height is computed as follows:

Adjusted drop height in mm = $179 \times 10^{-5}(m_b)$ ($R_p/2$), where m_b = mass of a single ball in grams and

R_p = pivot length in mm.

Any ball showing any chipping, cracking, or shattering shall be counted as a failure within the meaning of the third column of the table in paragraph (a)(5)(vi) of this section.

(C) By inspecting each ball tested for smoothness of finish on any surface of the ball which may come in contact with the cord during use. A cotton swab shall be rubbed vigorously over each such surface or area of the ball; if any cotton fibers are removed, the ball shall be counted as a failure within the meaning of the fourth column of the table in subdivision (vi) of this paragraph. The toy shall also be checked to ascertain that there is no visibly perceptible "wicking up" or "running up" of the casting resins on the outside of the cord in the vicinity where the ball is attached.

(D) By fully assembling the toy and testing the cord in such a manner as to test both the strength of the cord and the adequacy with which the cord is attached to the ball and any holding device such as a tab or ring included in the assembly. The fully assembled article shall be vertically suspended by one ball and a 445-Newton (100-pound) test applied to the bottom ball. Clacker balls where the mass of each ball is less

than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may be tested with a force of under 445 Newtons (100 pounds). The test force for these clacker balls shall be the same as the cord breaking strength calculated in §1500.86(a)(5)(i)(B). Any breaking, fraying, or unraveling of the cord or any sign of slipping, loosening, or unfastening shall be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section.

(E) By additionally subjecting any ring or other holding device to a 222-Newton (50-pound) test load applied to both cords; the holding device is to be securely fixed horizontally in a suitable clamp in such a manner as to support 50 percent of the area of such holding device and the balls are suspended freely. Clacker balls where the mass of each ball is less than 12 grams (0.42 oz.) and the distance between the center of the pivot and the center of the ball cannot exceed 180 mm (7.1 inches) may have their holding device tested with a force of less than 222 Newtons (50 pounds). The holding device test force for these clacker balls shall be half of the cord breaking strength calculated in §1500.86(a)(5)(i)(B). Any breaking, cracking, or crazing of the ring or other holding device shall be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section.

(F) By cutting each ball tested in half and then cutting each half perpendicularly to the first cut into three or more pieces of approximately equal thickness. Each portion is to be inspected before and after cutting, and any ball showing any flash, crack, crazing, or internal voids on such inspection is to be counted as a failure within the meaning of the fourth column of the table in paragraph (a)(5)(vi) of this section. Balls that are injection-molded and possess high-impact characteristics (such as injection-molded balls made of ABS, nylon, or high-impact polystyrene) though exempt from the requirements that there be no internal voids, must be tested to determine the presence of any flash, crack or crazing. A transparent ball shall be subjected to

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the same requirements except that it may be visually inspected without cutting.

(iii) The toy shall be fully assembled for use at time of sale, including the proper attachments of balls, cords, knots, loops, or other holding devices.

(iv) The toy shall be labeled:

(A) With a conspicuous statement of the name and address of the manufacturer, packer, distributor, or seller.

(B) To bear on the toy itself and/or the package containing the toy and/or the shipping container, in addition to the invoice(s) and shipping document(s), a code or mark in a form and manner that will permit future identification of any given batch, lot, or shipment by the manufacturer.

(C) To bear a conspicuous warning statement on the main panel of the retail container and display carton and on any accompanying literature: That if cracks develop in a ball or if the cord becomes frayed or loose or unfastened, use of the toy should be discontinued; and if a ring or loop or other holding device is present, the statement "In use, the ring or loop must be placed around the middle finger and the two cords positioned over the forefinger

and held securely between the thumb and forefinger," or words to that effect which will provide adequate instructions and warnings to prevent the holding device from accidentally slipping out of the hand. Such statements shall be printed in sharply contrasting color within a borderline and in letters at least 6 mm (¼ inch) high on the main panel of the container and at least 3 mm (⅙) high on all accompanying literature.

(v) The manufacturer of the toy shall make, keep, and maintain for 3 years records of sale, distribution, and results of inspections and tests conducted in accordance with this subparagraph and shall make such records available upon request at all reasonable hours by any officer or employee of the Consumer Product Safety Commission, and shall permit such officer or employee to inspect and copy such records and to make such inventories of stock as he deems necessary and otherwise to check the correctness of such records.

(vi) The lot size, sample size, and failure rate for testing clacker balls are as follows:

| Number of units in batch, shipment, delivery, lot, or retail stock | Number of units in random sample | Failure rate constituting rejection when testing per § 1500.86(a)(5)(ii)(B) | Failure rate constituting rejection when testing per § 1500.86(a)(5)(ii)(C), (D), (E), and (F) |
|--|----------------------------------|---|--|
| 50 or less | 8 | 1 | 1 |
| 51 to 90 | 13 | 1 | 1 |
| 91 to 150 | 20 | 1 | 1 |
| 151 to 280 | 32 | 1 | 2 |
| 281 to 500 | 50 | 1 | 2 |
| 501 to 1,200 | 80 | 2 | 4 |
| 1,201 to 3,200 | 125 | 2 | 6 |
| 3,201 to 10,000 | 200 | 3 | 10 |
| 10,001 to 35,000 | 315 | 4 | 16 |
| 35,001 to 150,000 | 500 | 6 | 25 |
| 150,001 to 500,000 | 800 | 8 | 40 |
| 500,001 and over | 1,250 | 11 | 62 |

(vii) Applicability of the exemption provided by this paragraph shall be determined through use of the table in paragraph (a)(5)(vi) of this section. A random sample of the number of articles as specified in the second column of the table shall be selected according to the number of articles in a particular batch, shipment, delivery, lot, or retail stock per the first column. A failure rate as shown in either the third or fourth column shall indicate

that the entire batch, shipment, delivery, lot, or retail stock has failed and thus is not exempted under this paragraph from classification as a banned hazardous substance.

(6) [Reserved]

(7) Dive sticks and similar articles described in §1500.18(a)(19) that come to rest at the bottom of a container of water in a position in which the long axis of the article is greater than 45 degrees from vertical when measured in

accordance with the following test method:

(i) Test equipment.

(A) A container that is filled with tap water to a depth at least 3 inches [76 mm] greater than the longest dimension of the dive stick. The container shall:

(1) Be sufficiently wide to allow the dive stick to lie along the bottom with its long axis in a horizontal position,

(2) Have clear side walls to permit observation of the dive stick under water, and

(3) Be placed on a level surface and have a flat bottom.

(B) A protractor or other suitable angle measurement device that has an indicator for 45 degrees from vertical.

(ii) Testing procedure

(A) If the dive stick is sold such that the consumer is required to attach an additional component(s) to the dive stick, then the product shall be tested both with and without the attachment(s).

(B) From just above the water surface, drop the dive stick into the container.

(C) Let the dive stick sink and come to rest at the bottom of the container. If the dive stick is designed so that the weight can be adjusted by adding water or other substance, adjust the weight so that the dive stick sinks and comes to rest with its long axis positioned as close to vertical as possible.

(D) Align the angle measurement device alongside the dive stick underwater and wait for the dive stick to come to rest if there is any water disturbance. Determine whether the long axis of the dive stick is greater than or less than 45 degrees from vertical.

(8) Dive sticks and similar articles described in §1500.18(a)(19) in which the maximum force measured in the following test method is less than 5-lbf [22N]. The test shall be conducted in the ambient environment of the laboratory and not under water.

(i) Test equipment.

(A) A compression rig that has a force gauge or equivalent device that is calibrated for force measurements within a minimum range of 0 to 5 lbf [0–22 N] and with an accuracy of ± 0.1 lbf [± 0.44 N] or better. The test rig shall have a system to guide this force appli-

cation in the vertical direction and shall have a means to adjust the rate of load application.

(B) Compression disk—the loading device that is attached to the force gauge shall be a rigid metal disk with a minimum diameter of 1.125 inches [29 mm].

(C) Vise or other clamping device.

(ii) Testing procedure

(A) Position the bottom of the dive stick in the clamping device so that the longest axis of the dive stick is vertical. The bottom end of the dive stick is the end that sinks to the bottom of a pool of water. Secure the bottom of the dive stick in the clamp such that the clamping mechanism covers no more than the bottom $\frac{1}{2}$ inch [13 mm] of the dive stick.

(B) Apply a downward force at a rate of 0.05 in/sec (± 0.01 in/sec) [1.3 mm/sec ± 0.3 mm/sec] at the top of the dive stick with the compression disk positioned so that the plane of the disk contact surface is perpendicular to the long axis of the dive stick.

(C) Apply the load for a period of 40 seconds or until the maximum recorded force exceeds 5-lbf [22 N].

(D) Record the maximum force that was measured during the test.

(b) [Reserved]

(9) Boston Billow Nursing Pillow and substantially similar nursing pillows that are designed to be used only as a nursing aide for breastfeeding mothers. For example, are tubular in form, C- or crescent-shaped to fit around a nursing mother's waist, round in circumference and filled with granular material.

[38 FR 27012, Sept. 27, 1973, as amended at 53 FR 46839, Nov. 18, 1988; 59 FR 9076, 9077, Feb. 25, 1994; 66 FR 13651, Mar. 7, 2001; 68 FR 70140, Dec. 17, 2003; 73 FR 77495, Dec. 19, 2008; 75 FR 35282, June 21, 2010; 78 FR 66841, Nov. 7, 2013]

§1500.87 Children's products containing lead: inaccessible component parts.

(a) The Consumer Product Safety Improvement Act (CPSIA) provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or

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intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm after three years, unless the Commission determines that it is not technologically feasible to have this lower limit.

(b) Section 101 (b)(2) of the CPSIA provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child.

(c) Section 101(b)(2)(B) of the CPSIA directs the Commission to promulgate by August 14, 2009, this interpretative rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible.

(d) The accessibility probes specified for sharp points or edges under the Commission's regulations at 16 CFR 1500.48–1500.49 will be used to assess the accessibility of lead-component parts of a children's product. A lead-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A lead-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For products intended for children that are 18 months of age or less, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of §1500.51(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For products intended for children that are over 18 months but not over 36 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of §1500.52(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For products intended for children that are over 36 months but not over 96 months of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of §1500.53(c)), will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For products intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission's regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of §1500.53(c)) intended for children aged 37–96 months will be used to evaluate accessibility of lead-containing component parts of a children's product as a result of normal and reasonably foreseeable use and abuse of the product.

(i) A children's product that is or contains a lead-containing part which is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child unless the product or part of the product in one dimension is smaller than 5 centimeters.

(j) The intentional disassembly or destruction of products by children older than age 8 years by means or knowledge not generally available to younger children, including use of tools, will not be considered in evaluating products for accessibility of lead-containing components.

[74 FR 39540, Aug. 7, 2009]

§ 1500.88 Exemptions from lead limits under section 101 of the Consumer Product Safety Improvement Act for certain electronic devices.

(a) The Consumer Product Safety Improvement Act (CPSIA) provides for

specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to meet this lower limit. Section 101(b)(2) of the CPSIA further provides that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission. Paint, coatings, or electroplating may not be considered to be a barrier that would render lead in the substrate to be inaccessible to a child.

(b) Section 101(b)(4) of the CPSIA provides that if the Commission determines that it is not technologically feasible for certain electronic devices to comply with the lead limits, the Commission must issue requirements by regulation to eliminate or minimize the potential for exposure to and accessibility of lead in such electronic devices and establish a compliance schedule unless the Commission determines that full compliance is not technologically feasible within a schedule set by the Commission.

(c) Certain accessible lead-containing component parts in children's electronic devices unable to meet the lead limits set forth in paragraph (a) of this section due to technological infeasibility are granted the exemptions that follow in paragraph (d) of this section below, provided that use of lead is necessary for the proper electronic functioning of the component part and it is not technologically feasible for the component part to meet the lead con-

tent limits set forth in paragraph (a) of this section.

(d) Exemptions for lead as used in certain electronic components parts in children's electronic devices include:

(1) Lead blended into the glass of cathode ray tubes, electronic components, and fluorescent tubes.

(2) Lead used as an alloying element in steel. The maximum amount of lead shall be less than 0.35% by weight (3,500 ppm).

(3) Lead used in the manufacture of aluminum. The maximum amount of lead shall be less than 0.4% by weight (4,000 ppm).

(4) Lead used in copper-based alloys. The maximum amount of lead shall be less than 4% by weight (40,000 ppm).

(5) Lead used in lead-bronze bearing shells and bushings.

(6) Lead used in compliant pin connector systems.

(7) Lead used in optical and filter glass.

(8) Lead oxide in plasma display panels (PDP) and surface conduction electron emitter displays (SED) used in structural elements; notably in the front and rear glass dielectric layer, the bus electrode, the black stripe, the address electrode, the barrier ribs, the seal frit and frit ring, as well as in print pastes.

(9) Lead oxide in the glass envelope of Black Light Blue (BLB) lamps.

(e) Components of electronic devices that are removable or replaceable, such as battery packs and light bulbs that are inaccessible when the product is assembled in functional form or are otherwise granted an exemption, are not subject to the lead limits in paragraph (a) of this section.

(f) Commission staff is directed to re-evaluate and report to the Commission on the technological feasibility of compliance with the lead limits in paragraph (a) of this section for children's electronic devices, including the technological feasibility of making accessible component parts inaccessible, and the status of the exemptions, no less than every five years after publication of a final rule in the FEDERAL REGISTER on children's electronic devices.

[75 FR 3158, Jan. 20, 2010]

§ 1500.89 Procedures and requirements for determinations regarding lead content of materials or products under section 101(a) of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

(b) The Commission may, either on its own initiative or upon the request of any interested person, make a determination that a material or product does not contain leads levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable.

(c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section.

(d) To request a determination under paragraph (b) of this section, the request must:

(1) Be e-mailed to *cpsc-os@cpsc.gov*, and titled "Section 101 Request for Lead Content Determination." Requests may also be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, Maryland 20814, or delivered to the same address.

(2) Be written in the English language.

(3) Contain the name and address, and e-mail address or telephone number, of the requestor.

(4) Provide documentation including:

(i) A detailed description of the product or material and how it is used by a child;

(ii) Representative data on the lead content of parts of the product or materials used in the production of a product;

(iii) All relevant data or information on manufacturing processes through which lead may be introduced into the material or product;

(iv) An assessment of the likelihood or lack thereof that the manufacturing processes will result in lead contamination of a material or product that ordinarily does not contain lead;

(v) All relevant data or information on the facilities used to manufacture the material or product, and any other materials used in the product;

(vi) An assessment of the likelihood or lack thereof that the use of leaded materials in a facility will result in lead contamination of a material or product that ordinarily does not contain lead;

(vii) Any other information relevant to the potential for lead content of the product or material to exceed the statutory lead limit specified in the request, that is 600 ppm, 300 ppm, or 100 ppm, as applicable;

(viii) Detailed information on the relied upon test methods for measuring lead content of products or materials including the type of equipment used or any other techniques employed and a statement as to why the data is representative of the lead content of such products or materials generally; and

(ix) Any data or information that is unfavorable to the request that is reasonably available to the requestor.

(e) Where a submission fails to meet all of the requirements of paragraph (d) of this section, the Office of the Secretary shall notify the person submitting it, describe the deficiency, and explain that the request may be resubmitted when the deficiency is corrected.

(f) Upon receipt of a complete request for a determination, the Office of Hazard Identification and Reduction

(EXHR) will assess the request to determine whether the product or material is one that does not contain lead in excess of the limits as provided under paragraph (a) of this section. EXHR will make an initial recommendation within thirty (30) calendar days, to the extent practicable. EXHR may request an extension from the Executive Director of the CPSC, if necessary, to make its initial determination. A complete request is one that does not require additional information from the requestor for EXHR to make an initial recommendation to the Commission.

(g) Where the Office of Hazard Identification and Reduction's (EXHR) initial recommendation is to deny the request for a lead content determination, it will provide, in a staff memorandum to the Commission, submitted to the Commission for ballot vote, the basis for the denial with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are not presented. The Commission, by ballot vote, will render a decision on the staff's recommendation. The ballot vote and the staff memorandum will be posted on the CPSC Web site. Any determination by the Commission to grant a request will be published in the FEDERAL REGISTER for comment. If the Commission concludes that the request shall be denied, the requestor shall be notified in writing of the denial from the Office of the Secretary along with the official ballot results and the EXHR staff's memorandum of recommendation.

(h) Where the Office of Hazard Identification and Reduction's (EXHR) initial recommendation is to grant the request for a lead content determination, it will submit the basis for that recommendation to the Commission in a memorandum to be voted on by ballot, with sufficient detail for the Commission to make an informed decision that reasonable grounds for a determination are presented. If the notice of proposed rulemaking (NPR) is published, it will invite public comment in the FEDERAL REGISTER. EXHR will review and evaluate any comments and supporting documentation before making its final recommendation to the Commission for final agency action, by staff memorandum submitted to the Commission.

If the Commission, after review of the staff's final recommendation, determines that a material or product does not and would not exceed the lead content limits, it will decide by ballot vote, on whether to publish a final rule in the FEDERAL REGISTER.

(i) The filing of a request for a determination does not have the effect of staying the effect of any provision or limit under the statutes and regulations enforced by the Commission. Even though a request for a determination has been filed, unless a Commission determination is issued in final form after notice and comment, materials or products subject to the lead limits under section 101 of the CPSIA must be tested in accordance with section 102 of the CPSIA, unless the testing requirement is otherwise stayed by the Commission.

[74 FR 10480, Mar. 11, 2009]

§ 1500.90 Procedures and requirements for exclusions from lead limits under section 101(b) of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

(b) *Exclusion of certain materials or products and inaccessible component parts.* The CPSIA provides the following functional purpose exception from the lead limits stated in section 101(a) of the CPSIA.

(1) *Functional purpose exception*—(i) *In general.* The Commission, on its own initiative or upon petition by an interested party, shall grant an exception to the limit under paragraph (a) of this section for a specific product, class of product, material, or component part if the Commission, after notice and a hearing, determines that:

(A) The product, class of product, material, or component part requires the inclusion of lead because it is not practicable or not technologically feasible to manufacture such product, class of product, material, or component part, as the case may be, in accordance with paragraph (a) of this section by removing the excessive lead or by making the lead inaccessible;

(B) The product, class of product, material, or component part is not likely to be placed in the mouth or ingested, taking into account normal and reasonably foreseeable use and abuse of such product, class of product, material, or component part by a child; and

(C) An exception for the product, class of product, material, or component part will have no measurable adverse effect on public health or safety, taking into account normal and reasonably foreseeable use and abuse.

(ii) *Measurement.* For purposes of paragraph (b)(1)(i)(C) of this section, there is no measurable adverse effect on public health or safety if the exception described in paragraph (b)(1)(i) of this section will result in no measurable increase in blood lead levels of a child. The Commission may adopt an alternative method of measurement other than blood lead levels if it determines, after notice and a hearing, that such alternative method is a better scientific method for measuring adverse effect on public health and safety.

(iii) *Procedures for granting exception*—(A) *Burden of proof.* A party seeking an exception under paragraph (b)(1)(i) of this section has the burden of demonstrating that it meets the requirements of such paragraph.

(B) *Grounds for decision.* In the case where a party has petitioned for an exception, in determining whether to grant the exception, the Commission may base its decision solely on the materials presented by the party seeking

the exception and any materials received through notice and a hearing.

(C) *Admissible evidence.* In demonstrating that it meets the requirements of paragraph (b)(1)(i) of this section, a party seeking an exception under such paragraph may rely on any nonproprietary information submitted by any other party seeking such an exception and such information shall be considered part of the record presented by the party that relies on that information.

(D) *Scope of exception.* If an exception is sought for an entire product, the burden is on the petitioning party to demonstrate that the criteria in paragraph (b)(1)(i) of this section are met with respect to every accessible component or accessible material of the product.

(iv) *Limitation on exception.* If the Commission grants an exception for a product, class of product, material, or component part under paragraph (b)(1)(i) of this section, the Commission may, as necessary to protect public health or safety:

(A) Establish a lead limit that such product, class of product, material, or component part may not exceed; or

(B) Place a manufacturing expiration date on such exception or establish a schedule after which the manufacturer of such product, class of product, material, or component part shall be in full compliance with the limit established under paragraph (b)(1)(iv)(A) of this section or the limit set forth under paragraph (a) of this section.

(v) *Application of exception.* An exception under paragraph (b)(1)(i) of this section for a product, class of product, material, or component part shall apply regardless of the date of manufacture unless the Commission expressly provides otherwise.

(vi) *Previously submitted petitions.* A party seeking an exception under this paragraph may rely on materials previously submitted in connection with a petition for exclusion under this section. In such cases, petitioners must notify the Commission of their intent to rely on materials previously submitted. Such reliance does not affect petitioners' obligation to demonstrate that they meet all requirements of this

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paragraph as required by paragraph (b)(1)(iii)(A) of this section.

(2) [Reserved]

[74 FR 10480, Mar. 11, 2009, as amended at 78 FR 41298, July 10, 2013]

§ 1500.91 Determinations regarding lead content for certain materials or products under section 101 of the Consumer Product Safety Improvement Act.

(a) The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 and younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 and younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit may be further reduced to 100 ppm, unless the Commission determines that it is not technologically feasible to have this lower limit. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child. Materials used in products intended primarily for children 12 and younger that are treated or coated with paint or similar surface-coating materials that are subject to 16 CFR part 1303, must comply with the requirements for lead paint under section 14(a) of the Consumer Product Safety Act (CPSA), as amended by section 102(a) of the CPSIA.

(b) Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, either on its own initiative or upon the request of any interested person, to make a determination that a material or product does not exceed the lead limits as provided under paragraph (a) of this section.

(c) A determination by the Commission under paragraph (b) of this section that a material or product does not contain lead levels that exceed 600 ppm, 300 ppm, or 100 ppm, as applicable, does not relieve the material or product from complying with the applicable lead limit as provided under paragraph (a) of this section if the product or ma-

terial is changed or altered so that it exceeds the lead content limits.

(d) The following materials do not exceed the lead content limits under section 101(a) of the CPSIA provided that these materials have neither been treated or adulterated with the addition of materials that could result in the addition of lead into the product or material:

(1) Precious gemstones: diamond, ruby, sapphire, emerald.

(2) Semiprecious gemstones and other minerals, provided that the mineral or material is not based on lead or lead compounds and is not associated in nature with any mineral based on lead or lead compounds (excluding any mineral that is based on lead or lead compounds including, but not limited to, the following: aragonite, bayldonite, boleite, cerussite, crocoite, galena, linarite, mimetite, phosgenite, vanadinite, and wulfenite).

(3) Natural or cultured pearls.

(4) Wood.

(5) Paper and similar materials made from wood or other cellulosic fiber, including, but not limited to, paperboard, linerboard and medium, and coatings on such paper which become part of the substrate.

(6) CMYK process printing inks (excluding spot colors, other inks that are not used in CMYK process, inks that do not become part of the substrate under 16 CFR part 1303, and inks used in after-treatment applications, including screen prints, transfers, decals, or other prints).

(7) Textiles (excluding any textiles that contain treatments or applications that do not consist entirely of dyes) consisting of:

(i) Natural fibers (dyed or undyed) including, but not limited to, cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco;

(ii) Manufactured fibers (dyed or undyed) including, but not limited to, rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, spandex.

(8) Other plant-derived and animal-derived materials including, but not

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limited to, animal glue, bee's wax, seeds, nut shells, flowers, bone, sea shell, coral, amber, feathers, fur, leather.

(e) The following metals and alloys do not exceed the lead content limits under section 101(a) of the CPSIA, provided that no lead or lead-containing metal is intentionally added but does not include the non-steel or non-precious metal components of a product, such as solder or base metals in electroplate, clad, or fill applications:

(1) Surgical steel and other stainless steel within the designations of Unified Numbering System, UNS S13800–S66286, not including the stainless steel designated as 303Pb (UNS S30360).

(2) Precious metals: Gold (at least 10 karat); sterling silver (at least 925/1000); platinum; palladium; rhodium; osmium; iridium; ruthenium, titanium.

[74 FR 43041, Aug. 26, 2009, as amended at 80 FR 61732, Oct. 14, 2015]

§ 1500.121 Labeling requirements; prominence, placement, and conspicuousness.

(a)(1) *Background and scope.* Section 2(p)(1) of the Federal Hazardous Substances Act (FHSA) or “the Act”), 15 U.S.C. 1261(p)(1), requires that hazardous substances bear certain cautionary statements on their labels. These statements include: signal words; affirmative statements of the principal hazard(s) associated with a hazardous substance; the common or usual name, or chemical name, of the hazardous substance; the name and place of business of the manufacturer, packer, distributor, or seller; statements of precautionary measures to follow; instructions, when appropriate, for special handling and storage; the statement “Keep Out of the Reach of Children” or its practical equivalent; and, when appropriate, first-aid instructions. Section 2(p)(2) of the Act specifies that all such statements shall be located prominently on the label of such a substance and shall appear in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label. This regulation contains the Commission's interpretations and policies for the type size and placement of cautionary material on the labels of haz-

ardous substances and contains other criteria for such cautionary statements that are acceptable to the Commission as satisfying section 2(p)(2) of the Act. Labels that do not comply with this regulation may be considered misbranded.

(2) *Definitions.* For the purposes of this section:

(i) *Container* means the immediate package from which a hazardous substance may be dispensed and also any article, package or wrapping, such as a tube or cone used for a firework or a wet cell battery casing containing sulfuric acid, which is necessary for the substance to function during actual use.

(ii) *Cautionary material, cautionary labeling, and cautionary labeling required by the Act* mean all items of labeling information required by sections 2(p)(1) of the FHSA (repeated in 16 CFR 1500.3(b)(14)(i) or by the regulations which require additional labeling under section 3(b) of the Act.

(iii) *Display panel* means any surface of the immediate container, and of any outer container or wrapping, which bears labeling.

(iv) *Principal display panel* means the portion(s) of the surface of the immediate container, and of any outer container or wrapping, which bear(s) the labeling designed to be most prominently displayed, shown, presented, or examined under conditions of retail sale. (See paragraph (c)(1) of this section.)

(v) *Type size* means the actual height of the printed image of each upper case or capital letter as it appears on the label of a hazardous substance. (See paragraph (c)(2) of this section.)

(vi) *Signal word* means the appropriate word “DANGER,” “WARNING,” or “CAUTION,” as required by sections 2(p)(1) (C) or (D) of the Act.

(vii) *Statement of principal hazard(s)* means that wording descriptive of the principal or primary hazard(s) associated with a hazardous substance required by section 2(p)(1)(E) of the Act. Some examples of such statements are “HARMFUL OR FATAL IF SWALLOWED,” “VAPOR HARMFUL,” “FLAMMABLE,” and “SKIN AND EYE IRRITANT.”

(viii) *Other cautionary material* means all labeling statements, other than “signal words” or “statement(s) of principal hazard(s),” required by the Act or by regulations issued under the Act.

(b) *Prominent label placement.* To satisfy the requirement of the Act that cautionary labeling statements shall appear “prominently” on the label of a hazardous substance, all such statements shall be placed on the label as follows:

(1) *Horizontal placement of labeling statements.* Except for the name and place of business of the manufacturer, packer, distributor, or seller, all cautionary material required by the Act shall appear in lines that are generally parallel to any base on which the package rests as it is designed to be displayed for sale or, on display panels other than the principal display panel, in lines generally parallel to all other labeling on that panel. This requirement does not apply to labeling on collapsible tubes, cylindrical containers with a narrow diameter, or F-type containers where both the “front” and “back” of the container are principal display panels. (See paragraph (e) of this section.)

(2) *Principal display panel labeling.* (i) All items of cautionary labeling required by the Act may appear on the principal display panel on the immediate container and, if appropriate, on any other container or wrapper. See paragraph (b)(4) of this section for requirements and exceptions for labeling outer containers and wrappings.

(ii) The signal word, the statement of principal hazard(s), and, if appropriate, instructions to read carefully any cautionary material that may be placed elsewhere on the label shall be blocked together within a square or rectangular area, with or without a border, on the principal display panel on the immediate container and, where required by paragraph (b)(4) of this section, on any outer container or wrapping. All cautionary statements placed on the principal display panel shall be separated on all sides from other printed or graphic matter, with the exception of the declaration of net contents required under the Fair Packaging and Labeling Act, 15 U.S.C. 1453(a) (2) and

(3), by a border line or by a space no smaller than the minimum allowable height of the type size for cautionary material required by the Act (exclusive of signal words and statements of hazard) on the principal display panel.

(iii) Depending on the design of the package or the configuration of the label, or both, a package may have more than one principal display panel. If so, each principal display panel must bear, at a minimum, the signal word, statement of principal hazard or hazards, and, if appropriate, instructions to read carefully any cautionary material that may be placed elsewhere on the label.

(A) Where the principal display panel of the immediate container consists of a lid, cap, or other item which may be separated from the immediate container and discarded, the container shall be deemed to have a second principal display panel elsewhere on the immediate container which must bear, at a minimum, the signal word, statement of principal hazard(s), and instructions, if appropriate, to read any cautionary material which may be placed elsewhere on the label.

(3) *Prominent label placement—other display panel labeling.* All items of cautionary labeling required by the Act which do not appear on the principal display panel shall be placed together on a display panel elsewhere on the container. The name and place of business of the manufacturer, packer, distributor, or seller may appear separately on any display panel. Where cautionary material appears on a display panel other than the principal display panel, the principal display panel shall bear the statement “Read carefully other cautions on the ___ panel,” or its practical equivalent. [A description of the location of the other panel is to be inserted in the blank space.]

(4) *Outer container or wrappings.* All cautionary labeling appearing on the immediate container of a hazardous substance shall also appear on any outer container or wrapping used in the retail display of the substance, in the same manner as required for the immediate container. Those cautionary labeling statements appearing on the immediate container which are

clearly legible through any outer container or wrapper used in retail display need not appear on the outer container or wrapping itself. (See section 2(n)(1) of the Act.)

(5) *Placement of the word “Poison” and the skull and crossbones symbol.* The word “poison” and, when appropriate, the skull and crossbones symbol shall appear on the label of a hazardous substance as follows:

(i) If a hazardous substance is “highly toxic,” as defined in §1500.3(c)(i) and section 2(h)(1) of the FHSA, the label must bear the word “poison” in accordance with section 2(p)(1)(H) of the Act, in addition to the signal word “DANGER,” and must also bear the skull and crossbones symbol. Some products, under §1500.14(b) of the regulations, may, in addition to any required signal word, be required to bear the word “poison” and the skull and crossbones symbol because of the special hazard associated with their ingredients. In both instances, the word “poison” and the skull and crossbones symbol need not appear on the principal display panel on the container, unless all other cautionary labeling required by the Act appears on the principal display panel. The word “poison” and the skull and crossbones symbol, when required, must appear either together with other cautionary labeling on a display panel other than the principal display panel or together with the signal word and statement(s) of principal hazard on the principal display panel.

(ii) Where, pursuant to a regulation issued under section 3(b) of the Act, the label of a hazardous substance requires the word “poison” instead of a signal word, the word, “POISON” shall appear in capital letters on the principal display panel, together with the statement(s) of the principal hazard. Certain substances for which the word “poison” is required instead of any signal word are listed in §1500.129.

(c) *Conspicuousness—type size and style.* To satisfy the requirement that cautionary labeling statements under the Act be conspicuous and legible, such statements shall conform to the following requirements:

(1) *Area of principal display panel.* The area of the principal display panel is the area of the side or surface of the

immediate container, or of the side or surface of any outer container or wrapping, that bears the labeling designed to be most prominently displayed, shown, presented, or examined under conditions of retail sale. This area is not limited to the portion of the surface covered with labeling; rather, it includes the entire surface. Flanges at the tops and bottoms of cans, conical shoulders of cans, handles, and shoulders and necks of bottles and jars are excluded in measuring the area. For the purposes of determining the proper type size for cautionary labeling, the area of the principal display panel (or other panel bearing cautionary labeling, under paragraph (c)(2)(ii) of this section) is to be computed as follows:

(i) In the case of a rectangular package, where one entire side is the principal display panel, the product of the height times the width of that side shall be the area of the principal display panel.

(ii) In the case of a cylindrical or nearly cylindrical container or tube on which the principal display panel appears on the side, the area of the principal display panel shall be 40 percent of the product of the height of the container times its circumference.

(iii) In the case of any other shape of container, the area of the principal display panel shall be 40 percent of the total surface of the container, excluding those areas, such as flanges at tops and bottoms, specified in paragraph (c)(1) above. However, if such a container presents an obvious principal display panel (such as an oval or hourglass shaped area on the side of a container for dishwashing detergent), the area to be measured shall be the entire area of the obvious principal display panel.

(2) *Type-size requirements.* (i) The term *type size* refers to the height of the actual printed image of each upper case or capital letter as it appears on the label. The size of cautionary labeling shall be reasonably related to the type size of any other printing appearing on the same panel, but in any case must meet the minimum size requirements in table 1.

(ii) When an item of labeling is required to be in a specified type size, all upper case, or capital, letters must be

at least equal in height to the required type size, and all other letters must be the same style as the upper case or capital letters. Unless otherwise specified in the regulations (examples appear at §§1500.14(b)(6), 1512.19, 1508.9,

and part 1505), the type size of all cautionary statements appearing on any display panel shall comply with the specifications in table 1 when the area of the display panel is measured by the method in paragraph (c)(1) above:

TABLE 1

| Area of principal display panel in square inches | 0-2 | >2-5 | >5-10 | >10-15 | >15-30 | >30 |
|--|------|------|-------|--------|--------|------|
| Type size in inches* | | | | | | |
| Signal word** | 3/64 | 1/16 | 3/32 | 7/64 | 1/8 | 5/32 |
| Statement of hazard | 3/64 | 3/64 | 1/16 | 3/32 | 3/32 | 7/64 |
| Other cautionary material*** | 1/32 | 3/64 | 1/16 | 1/16 | 5/64 | 3/32 |

> means "greater than."
 * minimum height of printed image of capital or upper case letters.
 ** including the word "poison" when required instead of a signal word by Section 3(b) of the Act (§ 1500.129).
 *** size of lettering for other cautionary material is based on the area of the display panel on which such cautionary material appears.

(iii) If all of the required cautionary labeling does not appear on the principal display panel, the statement to "Read carefully other cautions on the ___ panel," or its practical equivalent, must appear in, as a minimum, the same type size as that required in table 1 for the other cautionary material which appears elsewhere on the label of a hazardous substance. The size of the cautionary labeling that does not appear on the principal display panel is determined by the area of the panel on which it does appear.

(3) *Type style—proportion.* The ratio of the height of a capital or uppercase letter to its width shall be such that the height of the letter is no more than 3 times its width.

(4) *Signal word and statements of hazard—capital letters.* The signal word, the word "poison" if required instead of a signal word (see §1500.129), and the statement of principal hazard or hazards shall be in capital letters.

(5) *Multiple statement of hazard—type size and style.* All statements of principal hazard or hazards on a label shall appear in the same size and style of type, and shall appear in the same color or have the same degree of boldness.

(6) *Accompanying literature containing directions for use.* Where literature accompanying the package of a hazardous substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling.

(i) All such cautionary labeling shall be in reasonable proximity to any di-

rection for use and shall be placed together within the same general area.

(ii) The type size of such cautionary labeling shall be reasonably related to the type size of any other printed matter in the accompanying literature and must be in conspicuous and legible type by typography, layout, or color with other printed matter on the label. The signal word and statement of principal hazard or hazards shall appear in capital letters.

(d) *Conspicuousness—contrast.* To satisfy the requirement that cautionary labeling statements appear in conspicuous and legible type which is in contrast by typography, layout, or color with the other printed matter on the label, such statements shall conform to the following requirements:

(1) *Color.* Where color is the primary method used to achieve appropriate contrast, the color of any cautionary labeling statement shall be in sharp contrast with the color of the background upon which such a statement appears. Examples of combinations of colors which may not satisfy the requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(2) *Interference with conspicuousness—labeling design, vignettes, or other printed material.* For cautionary information appearing on panels other than the

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principal display panel, the label design, the use of vignettes, or the proximity of other labeling or lettering shall not be such that any cautionary labeling statement is obscured or rendered inconspicuous.

(e) *Collapsible metal tubes.* Collapsible metal tubes containing hazardous substances shall be labeled so that all cautionary labeling required by the Act appears as close to the dispensing end of the container as possible. The placement and conspicuousness of these statements shall conform to the provisions of paragraphs (b), (c), and (d) of this section.

(f) *Unpackaged hazardous substances.* Where practicable, unpackaged hazardous substances intended, or distributed in a form suitable, for use in or around a household or by children shall be labeled so that all items of information required by the Act appear upon the article itself. In instances where this is impracticable (for example, because of the size or nature of the article), the required cautionary labeling must be displayed by means of a tag or other suitable material that is no less than five square inches in area and is securely affixed to the article so that the labeling will remain attached throughout conditions of merchandising and distribution to the ultimate consumer. The placement and conspicuousness of all cautionary labeling appearing on such a tag or material, or on an unpackaged article, shall conform to the provisions of paragraphs (b), (c), and (d) of this section. For the purposes of determining the proper type size to use on a tag or other material, the area of one side of the tag or other material shall be the area of the principal display panel.

(g) *Exemptions.* All requirements of the Act are satisfied by compliance with this §1500.121. However, exemptions can be granted under section 3(c) of the Act and §1500.83, or under the provisions of another statute should this section be incorporated in regulations under another statute. Section 1500.82 contains the requirements for exemption requests under the Federal Hazardous Substances Act.

(h) *Effective date.* The provisions of this rule apply to hazardous substances bearing labels printed after December

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30, 1985. Labels printed prior to the effective date of this rule may be applied until not later than December 28, 1987. This rule applies to all hazardous substances to which labels are applied after December 28, 1987.

[49 FR 50383, Dec. 28, 1984]

§ 1500.122 Deceptive use of disclaimers.

A hazardous substance shall not be deemed to have met the requirements of section 2(p) (1) and (2) of the act (repeated in §1500.3(b)(14) (i) and (ii)) if there appears in or on the label (or in any accompanying literature; words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the act; for example, the statement “Harmless” or “Safe around pets” on a toxic or irritant substance.

§ 1500.123 Condensation of label information.

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p)(1) (E) and (F) of the act (repeated in §1500.3(b)(14)(i) (E) and (F)). When the statement of precautionary measures in effect provides instruction for first-aid treatment, the statement of the precautionary measures will satisfy the requirements of section 2(p)(1) (F) and (G) of the act (repeated in §1500.3(b)(14)(i) (F) and (G)).

§ 1500.125 Labeling requirements for accompanying literature.

When any accompanying literature includes or bears any directions for use (by printed word, picture, design, or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act (repeated in §1500.3(b)(14)).

§ 1500.126 Substances determined to be “special hazards.”

Whenever the Commission determines that for a particular hazardous substance intended or packaged in a

form suitable for use in the household or by children, the requirements of section 2(p) of the act (repeated in §1500.3(b)(14)) are not adequate for the protection of the public health and safety because of some special hazard, the Commission, by an appropriate order in the FEDERAL REGISTER, shall specify such reasonable variations or additional label requirements that it finds are necessary for the protection of the public health and safety. Such order shall specify a date that is not less than 90 days after the order is published (unless emergency conditions stated in the order specify an earlier date) after which any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children that fails to bear a label in accordance with such order shall be deemed to be a misbranded hazardous substance.

§ 1500.127 Substances with multiple hazards.

(a) Any article that presents more than one type of hazard (for example, if the article is both toxic and flammable) must be labeled with: An affirmative statement of each such hazard; the precautionary measures describing the action to be followed or avoided for each such hazard; instructions, when necessary or appropriate, for first-aid treatment of persons suffering from the ill effects that may result from each such hazard; instructions for handling and storage of articles that require special care in handling and storage because of more than one type of hazard presented by the article; and the common or usual name (or the chemical name if there is no common or usual name) for each hazardous component present in the article.

(b) Label information referring to the possibility of one hazard may be combined with parallel information concerning any additional hazards presented by the article if the resulting condensed statement contains all of the information needed for dealing with each type of hazard presented by the article.

[38 FR 27012, Sept. 27, 1973; 38 FR 30105, Nov. 1, 1973]

§ 1500.128 Label comment.

The Commission will offer informal comment on any proposed label and accompanying literature involving a hazardous substance if furnished with:

- (a) Complete labeling or proposed labeling, which may be in draft form.
- (b) Complete quantitative formula.
- (c) Adequate clinical pharmacological, toxicological, physical, and chemical data applicable to the possible hazard of the substance.
- (d) Any other information available that would facilitate preparation of a suitable label, such as complaints of injuries resulting from the product's use or other evidence that would furnish human-experience data.

§ 1500.129 Substances named in the Federal Caustic Poison Act.

The Commission finds that for those substances covered by the Federal Caustic Poison Act (44 Stat. 1406), the requirements of section 2(p)(1) of the Federal Hazardous Substances Act (repeated in §1500.3(b)(14)(i)) are not adequate for the protection of the public health. Labeling for those substances, in the concentrations listed in the Federal Caustic Poison Act, were required to bear the signal word "poison." The Commission concludes that the lack of the designation "poison" would indicate to the consumer a lesser hazard and that such would not be in the interest of the public health. Under the authority granted in section 3(b) of the act, the Commission therefore finds that for the following substances, and at the following concentrations, the word "poison" is necessary instead of any signal word:

- (a) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid (HCl) in a concentration of 10 percent or more.
- (b) Sulfuric acid and any preparation containing free or chemically unneutralized sulfuric acid (H₂SO₄) in a concentration of 10 percent or more.
- (c) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO₃) in a concentration of 5 percent or more.
- (d) Carboic acid (C₆H₅OH), also known as phenol, and any preparation

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containing carbolic acid in a concentration of 5 percent or more.

(e) Oxalic acid and any preparation containing free or chemically unneutralized oxalic acid (H₂ C₂ O₄) in a concentration of 10 percent or more.

(f) Any salt of oxalic acid and any preparation containing any such salt in a concentration of 10 percent or more.

(g) Acetic acid or any preparation containing free or chemically unneutralized acetic acid (HC₂ H₂ O₂) in a concentration of 20 percent or more.

(h) Hypochlorous acid, either free or combined, and any preparation containing the same in a concentration that will yield 10 percent or more by weight of available chlorine.

(i) Potassium hydroxide and any preparation containing free or chemically unneutralized potassium hydroxide (KOH), including caustic potash and vienna paste (vienna caustic), in a concentration of 10 percent or more.

(j) Sodium hydroxide and any preparation containing free or chemically unneutralized sodium hydroxide (NaOH), including caustic soda and lye in a concentration of 10 percent or more.

(k) Silver nitrate, sometimes known as lunar caustic, and any preparation containing silver nitrate (AgNO₃) in a concentration of 5 percent or more.

(l) Ammonia water and any preparation containing free or chemically uncombined ammonia (NH₃), including ammonium hydroxide and "hartshorn," in a concentration of 5 percent or more.

§ 1500.130 Self-pressurized containers: labeling.

(a) Self-pressurized containers that fail to bear a warning statement adequate for the protection of the public health and safety may be misbranded under the act, except as otherwise provided pursuant to section 3 of the act.

(b) The following warning statement will be considered as meeting the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) if the only hazard associated with an article is that the contents are under pressure:

WARNING—CONTENTS UNDER PRESSURE

Do not puncture or incinerate container. Do not expose to heat or store at tempera-

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tures above 120 °F. Keep out of the reach of children.

The word "CAUTION" may be substituted for the word "WARNING". A practical equivalent may be substituted for the statement "Keep out of the reach of children."

(c) That portion of the warning statement set forth in paragraph (b) of this section in capital letters should be printed on the main (front) panel of the container in capital letters of the type size specified in §1500.121(c). The balance of the cautionary statements may appear together on another panel if the front panel also bears a statement such as "Read carefully other cautions on panel."

(d) If an article has additional hazards, such as skin or eye irritancy, toxicity, or flammability, appropriate additional front and rear panel precautionary labeling is required.

§ 1500.133 Extremely flammable contact adhesives; labeling.

(a) Extremely flammable contact adhesives, also known as contact bonding cements, when distributed in containers intended or suitable for household use may be misbranded under the act if the containers fail to bear a warning statement adequate for the protection of the public health and safety.

(b) The following warning statement is considered as the minimum cautionary labeling adequate to meet the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) with respect to containers of more than one-half pint of contact adhesive and similar liquid or semiliquid articles having a flashpoint at or below 20 °F. as determined by the method in §1500.43, when the only hazard foreseeable is that caused by the extreme flammability of the mixture:

DANGER

EXTREMELY FLAMMABLE

VAPORS MAY CAUSE FLASH FIRE

Vapors may ignite explosively.

Prevent buildup of vapors—open all windows and doors—use only with cross-ventilation.

Keep away from heat, sparks, and open flame.

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Do not smoke, extinguish all flames and pilot lights, and turn off stoves, heaters, electric motors, and other sources of ignition during use and until all vapors are gone.

Close container after use.

Keep out of the reach of children.

(c) The words that are in capital letters in the warning statement set forth in paragraph (b) of this section should be printed on the main (front) panel or panels of the container in capital letters of the type size specified in §1500.121(c). The balance of the cautionary information may appear together on another panel provided the front panel bears a statement such as "Read carefully other cautions on ___ panel," the blank being filled in with the identification of the specific label panel bearing the balance of the cautionary labeling. It is recommended that a borderline be used in conjunction with the cautionary labeling.

(d) If an article has additional hazards, or contains ingredients listed in §1500.14 as requiring special labeling, appropriate additional front and rear panel precautionary labeling is required.

(e) Since the Commission has issued a regulation banning under the Consumer Product Safety Act extremely flammable contact adhesives covered by this labeling regulation (sec. 16 CFR part 1302), paragraphs (a), (b), (c) and (d) of this section are revoked as to the subject products after June 13, 1978.

[38 FR 27012, Sept. 27, 1973, as amended at 42 FR 63742, Dec. 19, 1977]

§ 1500.134 Policy on first aid labeling for saline emesis.

(a) This section states the Consumer Product Safety Commission's policy concerning first aid instructions for the use of a salt solution to induce vomiting (saline emesis) in the event of ingestion of hazardous substances.

(b) In many cases where hazardous substances are ingested, the recommended first aid instructions for inducing vomiting have contained a statement that this should be accomplished by drinking a solution of salt (sodium chloride) in warm water. At one time, this direction was considered medically acceptable. However, the Commission has obtained information showing that the instruction to per-

form saline emesis is no longer appropriate. This is because the use of salt to induce vomiting can cause severe hypernatremia (salt poisoning) with potentially toxic effects, particularly in children 5 years old or younger, the age group most often involved in accidental poisonings. In view of the availability of safer and more effective emetics such as ipecac syrup, the Commission no longer recommends a direction to perform saline emesis as a first aid direction for inducing vomiting.

(c) The Commission believes that, for products for which directions for saline emesis have been given in the past, ipecac syrup, U.S.P., is the most appropriate emetic, unless a particular contraindication exists in connection with any particular hazardous substance.

(d) The Commission wishes to emphasize that this policy does not require that any specific first aid instruction or wording be used. Where appropriate, the label may include directions (1) that the victim immediately contact a doctor or poison control center and/or (2) that vomiting be induced using methods other than salt. It is, of course, the manufacturer's responsibility to insure that the label provides enough information in addition to first aid instructions to fulfill all other labeling required by statute or regulation.

(Sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)))

[43 FR 33704, Aug. 1, 1978]

§ 1500.135 Summary of guidelines for determining chronic toxicity.

A substance may be toxic due to a risk of a chronic hazard. (A regulatory definition of "toxic" that pertains to chronic toxicity may be found at 16 CFR 1500.3(c)(2).) The following discussions are intended to help clarify the complex issues involved in assessing risk from substances that may potentially cause chronic hazards and, where possible, to describe conditions under which substances should be considered toxic due to a risk of the specified chronic hazards. The guidelines are not intended to be a static classification system, but should be considered along with available data and with expert judgment. They are not mandatory. Rather, the guidelines are intended as

an aid to manufacturers in determining whether a product subject to the FHSA presents a chronic hazard. All default assumptions contained in the guidelines on hazard and risk determination are subject to replacement when alternatives which are supported by appropriate data become available. The following are brief summaries of more extensive discussions contained in the guidelines. Thus, the guidelines should be consulted in conjunction with these summaries. Copies of the guidelines may be obtained from the Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207. (In addition to the chronic hazards discussed below, issues relating to the chronic hazard of sensitization are discussed in 16 CFR 1500.3(c)(5).)

(a) *Carcinogenicity*. Substances are toxic by reason of their potential carcinogenicity in humans when they are known or probable human carcinogenic substances as defined below. Substances that are possible human carcinogenic substances or for which there is no evidence of carcinogenic effect under the following categories lack sufficient evidence to be considered toxic by virtue of their potential carcinogenicity.

(1) *Known Human carcinogenic Substances* (“sufficient evidence” in humans). Substances are toxic by reason of their carcinogenicity when they meet the “sufficient evidence” criteria of carcinogenicity from studies in humans, which require that a causal relationship between exposure to an agent and cancer be established. This category is similar to the Environmental Protection Agency’s (EPA) Group A, the International Agency for Research on Cancer’s (IARC) Group 1, or the American National Standards Institute’s (ANSI) Category 1. A causal relationship is established if one or more epidemiological investigations that meet the following criteria show an association between cancer and exposure to the agent.

(i) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(ii) All possible confounding factors which could account for the observed

association can be ruled out with reasonable confidence.

(iii) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(2) *Probable Human Carcinogenic Substances*. Substances are also toxic by reason of their probable carcinogenicity when they meet the “limited evidence” criteria of carcinogenicity in humans or the “sufficient evidence” criteria of carcinogenicity in animals described below. This category is similar to EPA’s Group B, IARC’s Group 2, or ANSI’s Categories 2 and 3. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. For example, such evidence would result when there was an identified mechanism of action for a chemical that causes cancer in animals that has been shown not to apply to the human situation. It is reasonable, for practical purposes, to regard an agent for which there is “sufficient” evidence of carcinogenicity in animals as if it presented a carcinogenic risk to humans.

(i) *“Limited evidence” of carcinogenicity in humans*. The evidence is considered limited for establishing a causal relationship between exposure to the agent and cancer when a causal interpretation is credible, but chance, bias, or other confounding factors could not be ruled out with reasonable confidence.

(ii) *“Sufficient evidence” of carcinogenicity in animals*. Sufficient evidence of carcinogenicity requires that the substance has been tested in well-designed and -conducted studies (e.g., as conducted by National Toxicology Program (NTP), or consistent with the Office of Science Technology Assessment and Policy (OSTP) guidelines) and has been found to elicit a statistically significant ($p < 0.05$) exposure-related increase in the incidence of malignant tumors, combined malignant and benign tumors, or benign tumors if there is an indication of the ability of such benign tumors to progress to malignancy:

(A) In one or both sexes of multiple species, strains, or sites of independent origin; or experiments using different routes of administration or dose levels; or

(B) To an unusual degree in a single experiment (one species/strain/sex) with regard to unusual tumor type, unusual tumor site, or early age at onset of the tumor.

The presence of positive effects in short-term tests, dose-response effects data, or structure-activity relationship are considered additional evidence.

(3) *Possible Human Carcinogenic Substance* (“limited evidence” animal carcinogen). In the absence of “sufficient” or “limited” human data, agents with “limited” evidence of carcinogenicity from animal studies fall into this category. Such substances, and those that do not fall into any other group, are not considered “toxic.” This does not imply that the substances are or are not carcinogens, only that the evidence is too uncertain to provide for a determination. This category is similar to EPA’s Group C, IARC’s Group 3, or ANSI’s category 4.

(b) *Neurotoxicity*. Substances are toxic by reason of their potential neurotoxicity in humans when they meet the “sufficient evidence” or “limited evidence” criteria of neurotoxicity in humans, or when they meet the “sufficient evidence” criteria of neurotoxicity in animals.

(1) *Known Neurotoxic Substances* (“sufficient evidence in humans”). Substances are toxic by reason of their neurotoxicity and are considered “known neurotoxic substances” when they meet the “sufficient evidence” criteria of neurotoxicity derived from studies in humans which require that a causal association between exposure to an agent and neurotoxicity be established with a reasonable degree of certainty. Substances in this category meet the definition of “neurotoxic” as stated above. “Sufficient evidence,” derived from human studies, for a causal association between exposure to a chemical and neurotoxicity is considered to exist if the studies meet the following criteria.

(i) A consistent pattern of neurological dysfunction is observed.

(ii) The adverse effects/lesions account for the neurobehavioral dysfunction with reasonable certainty.

(iii) All identifiable bias and confounding factors are reasonably discounted after consideration.

(iv) The association has been shown unlikely to be due to chance, based on statistical analysis.

(2) *Probable Neurotoxic Substances*. Substances are also toxic by reason of their probable neurotoxicity when they meet the “limited evidence” criteria of neurotoxicity in humans, or the “sufficient evidence” criteria derived from animal studies. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. Such evidence would result, for example, when there was an identified mechanism of action for a chemical that causes neurotoxicity in animals that has been shown not to apply to the human situation.

(i) *“Limited evidence” of neurotoxicity in humans*. The evidence derived from human studies is considered limited for neurotoxicity when the evidence is less than convincing, i.e., one of the criteria of “sufficient evidence” of neurotoxicity for establishing a causal association between exposure to the agent and neurotoxicity is not met, leaving some uncertainties in establishing a causal association.

(ii) *“Sufficient evidence” of neurotoxicity in animals*. Sufficient evidence of neurotoxicity derived from animal studies for a causal association between exposure to a chemical and neurotoxicity requires that:

(A) The substance has been tested in well-designed and -conducted studies (e.g., NTP’s neurobehavioral battery, or conforming to EPA’s neurotoxicity test guidelines); and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) increase in any neurotoxic effect in one or both sexes of multiple species, strains, or experiments using different routes of administration and dose-levels.

(3) *Possible Neurotoxic Substances*. “Possible neurotoxic substances” are the substances which meet the “limited evidence” criteria of neurotoxicity evidence derived from animal studies in the absence of human data, or in the presence of inadequate human data, or data which do not fall into any other group. Substances in this category are not considered “toxic.”

(c) *Developmental and Reproductive Toxicity—(1) Definitions of “Sufficient”*

and “*Limited*” Evidence. The following definitions apply to all categories stated below.

(i) “Sufficient evidence” from human studies for a causal association between human exposure and the subsequent occurrence of developmental or reproductive toxicity is considered to exist if the studies meet the following criteria:

(A) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(B) All possible confounding factors which could account for the observed association can be ruled out with reasonable confidence.

(C) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(ii) “Limited evidence” from human studies exists when the human epidemiology meets all but one of the criteria for “sufficient evidence”; i.e., the statistical evidence is borderline as opposed to clear-cut, there is a source of bias, or there are confounding factors that have not been and cannot be accounted for.

(iii) “Sufficient evidence” from animal studies exists when

(A) Obtained from a good quality animal study; and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) treatment-related increase in multiple endpoints in a single species/strain, or in the incidence of a single endpoint at multiple dose levels or with multiple routes of administration in a single species/strain, or increase in the incidence of a single endpoint in multiple species/strains/ experiments.

(iv) “Limited evidence” from animal studies exists when:

(A) Obtained from a good quality study and there is a statistically significant ($p < 0.05$) treatment-related increase in the incidence of a single endpoint in a single species/strain/experiment at a single dose level administered through only one route and such evidence otherwise does not meet the criteria for “sufficient evidence”; or

(B) The evidence is derived from studies which can be interpreted to show positive effects but have some qualitative or quantitative limitations

with respect to experimental procedures (e.g., doses, exposure, follow-up, number of animals/group, reporting of the data, etc.) which would prevent classification of the evidence in the group of “sufficient evidence.”

(2) *Developmental Toxicants*. Substances are toxic by reason of their potential developmental or reproductive toxicity when they meet the “sufficient evidence” or “limited evidence” criteria of developmental or reproductive toxicity in humans, or when they meet the “sufficient evidence” criteria of developmental or reproductive toxicity in animals. The Food and Drug Administration (FDA) and the European Economic Community (EEC) have developed categories for teratogens but not other developmental toxicants. The teratogen guidelines limit the information only to structural birth defects and do not include other hazards of developmental toxicity such as embryonal death, fetal death, or functional deficiencies which are also important in assessing the overall toxicity of a substance when administered during pregnancy. Recently, EPA has proposed a system for classifying developmental toxicity. The Occupational Safety and Health Administration (OSHA) has not yet developed any classification for developmental toxicity. The commission has established the following categories for determination of developmental toxicity according to the available evidence.

(1) *Known Human Developmental Toxicant* (“sufficient evidence in humans”). A substance is considered a “known human developmental toxicant” if there is “sufficient” human evidence to establish a causal association between human exposure and the subsequent occurrence of developmental toxicity manifested by death of the conceptus (embryo or fetus), or structural or functional birth defects. This category (Human Developmental Toxicant) is comparable to category 1 of the EEC and categories D and X of FDA, except that these guidelines are limited to teratogens. This category is also comparable to the category “definitive evidence for human developmental toxicity” proposed by EPA.

(ii) *Probable Human Developmental Toxicant*. A substance is considered a

“probable human developmental toxicant” if there is “limited” human evidence or “sufficient” animal evidence to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. This group (Probable Human Developmental Toxicant) is comparable to the category “adequate evidence for human developmental toxicity” proposed by EPA. This category is also comparable to category 2 of the EEC and category A1 of FDA, except that these guidelines are limited to teratogens.

(iii) *Possible Human Developmental Toxicant*. A substance is considered a “possible human developmental toxicant” if there is “limited” animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. EEC, FDA, and EPA have not developed a category comparable to this group. The Commission believes that data from well planned animal studies are important to consider even though they may provide only limited evidence of developmental toxicity.

(3) *Male Reproductive Toxicants*. Male reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies.

(i) *Known Human Male Reproductive Toxicant*. A substance is considered a “known human male reproductive toxicant” if there is “sufficient” human evidence to establish a causal association between human exposure and the adverse effects on male reproductive main endpoints which are mating ability, fertility, and prenatal and postnatal development of the conceptus. This category is comparable to the one termed “Known Positive” in the EPA guidelines on male reproductive risk assessment.

(ii) *Probable Human Male Reproductive Toxicant*. A substance is considered a “probable human male reproductive toxicant” if there is “limited” human evidence or “sufficient” animal evidence to establish a causal association between human exposure and the ad-

verse effects on male reproductive main endpoints. This category is comparable to the one termed “Probable Positive” in the EPA guidelines on male reproductive risk assessment. However, the EPA category is based only on sufficient animal evidence. CPSC believes that limited human evidence is also sufficient for a chemical to be placed in this category.

(iii) *Possible Human Male Reproductive Toxicant*. A substance is considered a “possible human male reproductive toxicant” if there is limited animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on male reproductive main endpoints. This category is comparable to the one termed “Possible Positive A” in the EPA guidelines on male reproductive risk assessment. EPA proposes to use either limited human or limited animal evidence data to classify a toxicant as a “Possible Positive A” toxicant. As described above, CPSC would elevate limited human evidence to the category “Probable Human Male Reproductive Toxicant.”

(4) *Female Reproductive Toxicants*. Female reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies. EPA has proposed guidelines for assessing female reproductive risk but has not yet proposed a specific system for categorization of female reproductive toxicants.

(i) *Known Human Female Reproductive Toxicant*. A substance is considered a “known human female reproductive toxicant” if there is “sufficient” human evidence to establish a causal association between human exposure and adverse effects on female reproductive function such as mating ability, fertility, and prenatal and postnatal development of the conceptus.

(ii) *Probable Human Female Reproductive Toxicant*. A substance is considered a “probable human female reproductive toxicant” if there is “limited” human evidence or “sufficient” animal

evidence to establish a causal association between human exposure and adverse effects on female reproductive function.

(iii) *Possible Human Female Reproductive Toxicant.* A substance is considered a “possible human female reproductive toxicant” if there is “limited” animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on female reproductive function.

(d) *Other Subjects Related to the Determination that a Substance is Toxic.* Under the FHSA, for a toxic substance to be considered hazardous, it must not only have the potential to be hazardous but there must also be the potential that persons are exposed to the substance, that the substance can enter the body, and that there is a significant risk of an adverse health effect associated with the customary handling and use of the substance. Under these guidelines, existence of an adverse health effect means that such exposure is above the “acceptable daily intake” (“ADI”). The ADI is based on the risks posed by the substance, and whether they are acceptable under the FHSA. This section addresses those issues by providing guidelines concerning assessment of exposure, assessment of bio-availability, determination of acceptable risks and the ADI to children and adults, and assessment of risk.

(1) *Assessment of Exposure.* An exposure assessment may comprise a single exposure scenario or a distribution of exposures. Reasonably foreseeable use, as well as accidental exposure, should be taken into consideration when designing exposure studies. The following guidelines should be used in the assessment of exposure.

(i) *Inhalation.* Inhalation studies to assess exposure should be reliable studies using direct monitoring of populations, predictions of exposure through modeling, or surrogate data.

(A) *Direct Monitoring.* Populations to be monitored should be selected randomly to be representative of the general population, unless the exposure of a particular subset population is the desired goal of the assessment. The

monitoring technique should be appropriate for the health effect of interest.

(B) *Modeling.* Predictions of exposure to a chemical using mathematical models can be based on physical and chemical principles, such as mass balance principles. Mass balance models should consider the source strength of the product of interest, housing characteristics, and ambient conditions likely to be encountered by the studied population.

(C) *Surrogate Data.* Surrogate data should only be used when data concerning the chemical of interest are sparse or unavailable and when there is a reasonable assurance that the surrogate data will accurately represent the chemical of interest.

(ii) *Oral Ingestion.* Oral ingestion studies may involve direct monitoring of sources of chemicals as well as laboratory simulations. The estimation of exposure from ingestion of chemicals present in consumer products is predicted based upon estimates of use of the product and absorption of the chemical from the gastrointestinal tract. The following criteria should be established for laboratory simulations to estimate exposure:

(A) A simulant or range of simulants should be carefully selected to mimic the possible range of conditions which occur in humans, such as full and empty stomachs, or various saliva compositions at different times of the day.

(B) The mechanical action to which a product is submitted must be chosen to represent some range of realistic conditions to which a human may subject the product.

(iii) *Dermal Exposure.* (A) Dermal exposure involves estimating the amount of substance contacting the skin. This may involve experiments measuring the amount of material leached from a product contacting a liquid layer which interfaces with the skin, or the amount of substance which migrates from a product (in solid or liquid form) which is in contact with the skin.

(B) Parameters to be considered include: Surface area of the skin contacted, duration of contact, frequency of contact, and thickness of a liquid interfacial layer.

(2) *Assessment of Bioavailability.* (i) The need to consider bioavailability in estimating the risk from use of a product containing a toxic substance only arises when it is anticipated that the absorption characteristics of a substance to which there is human exposure will differ from those characteristics for the substance tested in the studies used to define the dose-response relationship.

(ii) In determining the need to assess bioavailability, the factors to be examined include:

(A) The physical or chemical form of the substance,

(B) The route of exposure (inhalation, ingestion, or through the skin),

(C) The presence of other constituents in the product which interfere with or alter absorption of the toxic substance, and

(D) Dose.

(3) *Assessment of Risk.* This section on quantitative risk assessment applies to estimates of risk for substances that are toxic by reason of their carcinogenicity.

(i) Generally, the study leading to the highest risk should be used in the risk assessment; however, other factors may influence the choice of study.

(ii) Risk should be based on the maximum likelihood estimate from a multistage model (such as Global83 or later version) unless the maximum likelihood estimate is not linear at low dose, in which case the 95% upper confidence limit on risk should be used.

(iii) For systemic carcinogens, if estimates of human risk are made based on animal data, a factor derived from dividing the assumed human weight (70 kg) by the average animal weight during the study and taking that to the $\frac{1}{3}$ power should be used. There is the possibility that this factor may be changed, using the $\frac{1}{4}$ power instead of the $\frac{1}{3}$ power, as part of a unified Federal regulatory approach. If such an approach is adopted, it will apply here.

(iv) When dose is expressed as parts per million, and the carcinogen acts at the site of contact, humans and animals exposed to the same amount for the same proportion of lifetime should be assumed to be equally sensitive.

(v) If no experimental study having the same route of exposure as that an-

anticipated for human use of a substance is available, a study by another route of exposure may be used. Pharmacokinetic methods may be used if sufficient data are available.

(vi) When exposure scenarios are different from those used in the underlying study upon which estimates of risk are based, proportionality should be applied. If pharmacokinetic methods are used to adjust for risks at high versus low exposure levels, level-time measures should not be combined without taking the non-linearity into account.

(4) *Acceptable Risks—(i) ADI for Carcinogens.* The maximum acceptable daily intake (“ADI”) is that exposure of a toxic (by virtue of its carcinogenicity) substance that is estimated 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.

[57 FR 46665, Oct. 9, 1992]

§ 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.

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§ 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 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 Commission 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 that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are “hazardous substances.” A household product that is not intended for children but which creates such a risk of injury because it contains lead requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children which contains a hazardous amount of lead that is accessible for children to ingest is a banned hazardous substance. 15 U.S.C. 1261(q)(1)(B). In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: the total amount of lead contained in a product, the bio-availability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.

(2) Paint and similar surface coatings containing lead have historically been the most commonly-recognized sources of lead poisoning among the products within the Commission’s jurisdiction. The Commission has, by regulation, banned paint and other similar surface coatings that contain more than 0.06% lead (“lead-containing paint”), toys and other articles intended for use by children that bear lead-containing paint, and furniture articles for consumer use that bear lead-containing paint. 16 CFR Part 1303. In recent

¹This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

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years, however, the Commission staff has identified a number of disparate products—some intended for use by children and others simply used in or around the household or in recreation—that presented a risk of lead poisoning from sources other than paint. These products included vinyl miniblinds, crayons, figurines used as game pieces, and children’s jewelry.

(3) In several of these cases, the staff’s determination that the products presented a risk of lead poisoning resulted in recalls or in the replacement of those products with substitutes, in addition to an agreement to discontinue the use of lead in future production. The Commission believes that, had the manufacturers of these lead-containing products acted with prudence and foresight before introducing the products into commerce, they would not have used lead at all. This in turn would have eliminated both the risk to young children and the costs and other consequences associated with the corrective actions.

(4) The Commission urges manufacturers to eliminate lead in consumer products to avoid similar occurrences in the future. However, to avoid the possibility of a Commission enforcement action, a manufacturer who believes it necessary to use lead in a consumer product should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a “hazardous substance.” If the product is a hazardous substance and is also a children’s product, it is banned. If it is a hazardous household substance but is not intended for use by children, it requires precautionary labeling. This same type of analysis also should be performed on materials substituted for lead.

(5) The Commission also notes that, under the FHSA, any firm that purchases a product for resale is responsible for determining whether that product contains lead and, if so, whether it is a “hazardous substance.” The Commission, therefore, recommends that, prior to the acquisition or distribution of such products, importers, distributors, and retailers obtain information and data, such as analyses of chemical composition or accessibility,

relevant to this determination from manufacturers, or have such evaluations conducted themselves.

[63 FR 70649, Dec. 22, 1998]

§ 1500.231 Guidance for hazardous liquid chemicals in children’s products.

(a) *Summary.* The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from exposure to hazardous chemicals found in liquid-filled children’s products, such as rolling balls, bubble watches, necklaces, pens, paperweights, keychains, liquid timers, and mazes.¹ The Commission identifies the major factors that it considers when evaluating liquid-filled children’s products that contain hazardous chemicals, and informs the public of its experience with exposure to these hazardous chemicals to children. To reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, methylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children’s products. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that liquid-filled children’s products do not contain hazardous liquid chemicals.

(b) *Hazard.* During reasonably foreseeable handling or use of liquid-filled children’s products, hazardous chemicals may become accessible to young children in a manner that places children at risk. Young children are exposed to the chemicals from directly mouthing them or from handling such objects and subsequent hand-to-mouth or hand-to-eye 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

¹This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

the product. The adverse health effects of these chemicals to children include chemical poisoning from ingestion of the chemicals, pneumonia from aspiration of the chemicals into the lungs, and skin and eye irritation from exposure to the chemicals. The chemicals may also be combustible.

(c) *Guidance.* (1) Under the Federal Hazardous Substances Act (FHSA), products that are toxic or irritants and that may cause substantial injury or illness under reasonably foreseeable conditions of handling or use, including reasonably foreseeable ingestion by children, are "hazardous substances." 15 U.S.C. 1261(f)(1). A product that is not intended for children, but that creates a risk of substantial injury or illness because it contains hazardous chemicals, requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children that contains an accessible and harmful amount of a hazardous chemical is banned. 15 U.S.C. 1261(q)(1)(A). In evaluating the potential hazard associated with children's products that contain hazardous chemicals, the Commission's staff considers certain factors on a case-by-case basis, including: the total amount of the hazardous chemical in a product, the accessibility of the hazardous chemicals to children, the risk presented by that accessibility, the age and foreseeable behavior of the children exposed to the product, and the marketing, patterns of use, and life cycle of the product.

(2) The Commission's staff has identified a number of liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, maze toys, liquid timers, and keychains, that contain hazardous chemicals. In several of these cases, the staff determined that these products violated the FHSA because they presented a risk of chemical poisoning and/or chemical pneumonia from aspiration. This determination resulted in recalls or in the replacement of those products with substitutes, as well as in agreements with the manufacturers to discontinue the use of hazardous chemicals in liquid-filled children's products in future production. The Commission believes that these haz-

ardous substances pose a risk to young children and, consequently, manufacturers should not have included them in the product design or manufacturing process.

(3) Therefore, the Commission considers the use of hazardous chemicals in children's products such as those described above to be ill-advised and encourages manufacturers to avoid using them in such products. Further, the Commission recommends that, before purchasing such products for resale, importers, distributors, and retailers obtain assurances from the manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

[63 FR 70648, Dec. 22, 1998]

§ 1500.232 Statement on animal testing policy.

(a) *Summary.* (1) The U.S. Consumer Product Safety Commission issues this statement of policy on animal testing and alternatives to animal testing of hazardous substances regulated under the Federal Hazardous Substances Act (FHSA). The FHSA requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazard(s) that the products may present. Among the hazards addressed by the FHSA are toxicity, corrosivity, sensitization, and irritation.

(2) In order to determine the appropriate cautionary labeling, it is necessary to have objective criteria by which the existence of each hazard can be determined. Hazards such as toxicity, tissue corrosiveness, eye irritancy, and skin irritancy result from the biological response of living tissue and organs to the presence of the hazardous substance. One means of characterizing these hazards is to use animal testing as a proxy for the human reaction. In fact, the FHSA defines the hazard category of "highly toxic" in terms of animal toxicity when groups of 10 or more rats are exposed to specified amounts of the substance. The Commission's regulations under the FHSA concerning toxicity and irritancy allow the use of animal tests to determine the presence of the hazard when human data or existing animal data are not available.

(3) Neither the FHSA nor the Commission's regulations requires animal testing. The FHSA and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. If animal testing is conducted, Commission policy supports limiting such tests to a minimum number of animals and advocates measures that eliminate or reduce the pain or discomfort to animals that can be associated with such tests. The Commission has prepared this statement of policy with respect to animal testing to encourage the manufacturers subject to the FHSA to follow a similar policy.

(4) In making the appropriate hazard determinations, manufacturers of products subject to the FHSA should use existing alternatives to animal testing whenever possible. These include: prior human experience (*e.g.*, published case studies), *in vitro* or *in silico* test methods that have been approved by the Commission, literature sources containing the results of prior animal testing or limited human tests (*e.g.*, clinical trials, dermal patch testing), and expert opinion (*e.g.*, hazard assessment, structure-activity analysis). If a manufacturer or other entity performs a hazard test for FHSA labeling purposes that has not been previously approved by the Commission, CPSC staff will consider the data on a case-by-case basis and, upon review, determine whether to post the test method on the animal testing Web site. The Commission recommends resorting to animal testing only when the other information sources have been exhausted. At this time, the Commission recommends use of the most humane procedures with the fewest animals possible to achieve reliable results. Recommended procedures are summarized in the following statement and can be accessed on the Commission's Web page at: <http://www.cpsc.gov/library/animaltesting.html>. If a manufacturer or other entity performs a hazard test for FHSA labeling purposes that has not been previously approved by the Commission (*e.g.*, an ICCVAM-recommended test method or one of the tests described in the current version of the FHSA), CPSC staff will consider the data on a case-by-case basis and,

upon review, determine whether to post the test method on the animal testing Web site.

(b) *Statement of policy on animal testing.* (1) Neither the FHSA nor the Commission's regulations requires animal testing. Reliable human experience always takes precedence over results from animal data. In the cases where animal tests are conducted, the Commission prefers test methods that reduce stress and suffering in test animals and that use fewer animals while maintaining scientific integrity. To this end, the Commission reviews recommendations on alternative test methods developed by the scientific and regulatory communities. Current descriptions of test method recommendations approved by or known to the Commission can be accessed via the Internet at: <http://www.cpsc.gov/library/animaltesting.html>. The Commission strongly supports the use of scientifically sound alternatives to animal testing. The following parts of this section outline some of these alternatives. Testing laboratories and other interested persons requiring assistance interpreting the results obtained when a substance is tested in accordance with the methods described here, or in following the testing strategies outlined in the section, should refer to the Commission's animal testing Web page at: <http://www.cpsc.gov/library/animaltesting.html>.

(i) *Acute toxicity.* The traditional FHSA animal test for acute toxicity determines the median lethal dose (LD50) or lethal concentration (LC50), the dose or concentration that is expected to kill half the test animals. Procedures for determining the median LD50/LC50 are described in section 2(h)(1) of the Act and supplemented in §1500.3(c)(1) and (2) and the test method outlined in §1500.40. The Commission recommends *in vitro* alternatives over *in vivo* LD50/LC50 tests, or using modifications of the traditional LD50/LC50 test during toxicity testing that reduce the number of animals tested whenever possible. Data from *in vitro* or *in silico* test methods that have not been approved by the Commission may be submitted to the Commission for consideration of their acceptability. Commission-approved testing alternatives are

identified on the Web site at: <http://www.cpsc.gov/library/animaltesting.html> and include:

(A) *In vitro* and *in vivo* test methods that have been scientifically validated and approved for use in toxicity testing by the Commission;

(B) Valid *in vitro* methods to estimate a starting dose for an acute *in vivo* test;

(C) A sequential version of the traditional LD50/LC50 tests described in §1500.3(c)(1) and (2) and the test method described in §1500.40, in which dose groups are run successively rather than simultaneously;

(D) A limit-dose test where the LD50/LC50 is determined as a point estimate, which can still be used to categorize a hazard, although it gives no information on hazard dose-response. In the limit test, animals (10 rats) each receive a single dose of product at 5g per kilogram of body weight. If not more than one animal dies in 14 days, the product is considered to have an LD50 of greater than 5g/kg, and thus, deemed to be nontoxic. Only if two or more animals die is a second group of 10 rats tested (at a lower dose). This procedure reduces the number of animals tested from the 80 to 100 animals involved in a full LD50 test to, typically, 10 to 20 rats per product. This reduction in the number of animals tested is justified because an exact LD50 is not required by either the FHSA or the regulations. The FHSA requires only a categorical determination that the toxicity is greater than 5g/kg, between 50 mg/kg and 5g/kg, or less than 50 mg/kg.

(ii) *Dermal irritation/corrosivity*. An acceptable *in vitro* test method or weight-of-evidence analysis is recommended before *in vivo* dermal irritation testing is considered to determine appropriate cautionary labeling. The weight-of-evidence analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test results (valid tests are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), the substance's dermal toxicity, evidence of corrosivity/irritation of one or more structurally related substances or mixtures of such substances, data demonstrating low or high pH (≤ 2 or ≥ 11.5) of the substance, and any other relevant physico-

chemical properties that indicate the substance might be a dermal corrosive or irritant. If there is any indication from this analysis that the substance is either corrosive or irritating to the skin, the substance should be labeled appropriately. If the substance is not corrosive *in vitro*, but no data exist regarding its irritation potential, human patch testing should be considered. If *in vitro* data are unavailable, human patch testing is not an option, and there are insufficient data to determine the weight-of-evidence, a tiered *in vivo* animal test is recommended.

(A) In a tiered *in vivo* dermal study, a single rabbit is tested initially. If the outcome is positive for corrosivity, testing is stopped, and the substance is labeled appropriately. If the substance is not corrosive, two more rabbits should be patch-tested to complete the assessment of skin irritation potential.

(B) If a tiered test is not feasible, the Commission recommends the test method described in §1500.41. Note that in any *in vivo* dermal irritation test method, the Commission recommends using a semioclusive patch to cover the animal's test site and eliminating the use of stocks for restraint during the exposure period, thereby allowing the animal free mobility and access to food and water.

(iii) *Ocular irritation*. A weight-of-evidence analysis is recommended to evaluate existing information before any *in vivo* ocular irritation testing is considered. This analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test data (identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), the substance's dermal corrosivity/irritation (primary skin irritants and corrosives are also usually eye irritants and therefore do not need to be tested in the eye), evidence of ocular irritation of one or more structurally related substances or mixtures of such substances, data demonstrating high acidity or alkalinity of the substance, and any other relevant physicochemical properties that indicate the substance might be a dermal corrosive or irritant or ocular irritant.

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(A) When the weight-of-evidence is insufficient to determine a substance's ocular irritation, a Commission-approved *in vitro* or *in silico* assay for ocular irritancy should be run to assess eye irritation potential and determine labeling. Examples of Commission-validated *in vitro* assays are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>). If no valid *in vitro* test exists, the test strategy for determining dermal corrosion/irritation outlined in paragraph (b)(1)(ii)(B) of this section can be followed to determine ocular irritation.

(B) If the dermal test strategy outlined in section paragraph (b)(1)(ii)(B) of this section leads to a conclusion of not corrosive, a tiered *in vivo* ocular irritation test should be performed, in which a single rabbit is exposed to the substance initially. If the outcome of this initial test is positive, testing is stopped, and the substance is labeled an eye irritant. If the outcome of this initial test is negative, one to two more rabbits are tested for ocular irritation, and the outcome of this test will determine the label. If a tiered test is not feasible, the Commission recommends the test method described in §1500.42.

(C) When any ocular irritancy testing on animals is conducted, including the method described in §1500.42, the Commission recommends a threefold plan to reduce animal suffering: The use of preemptive pain management, including topical anesthetics and systemic analgesics that eliminate or reduce suffering that may occur as a result of the application process or from the test substance itself (an example of a typical preemptive pain treatment is two applications of tetracaine ophthalmic anesthetic, 10–15 minutes apart, prior to instilling the test material to the eye); post-treatment with systemic analgesics for pain relief; and implementation of humane endpoints, including scheduled observations, monitoring, and recording of clinical signs of distress and pain, and recording the nature, severity, and progression of eye injuries. The specific techniques that have been approved by the Commission can be found at: <http://www.cpsc.gov/library/animaltesting.html>.

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(iv) *Dermal sensitization*. An acceptable *in vitro* test method (examples of valid *in vitro* tests are identified on the Commission's animal testing Web site at: <http://www.cpsc.gov/library/animaltesting.html>), or weight-of-evidence analysis is recommended before *in vivo* animal sensitization testing is considered to determine appropriate cautionary labeling. The weight-of-evidence analysis should incorporate any existing data on humans and animals, validated *in vitro* or *in silico* test results, and any relevant physicochemical properties that indicate the substance might be a dermal sensitizer. If there is any indication from this analysis that the substance is sensitizing to the skin, the substance should be labeled appropriately.

(2) [Reserved]

[77 FR 73288, Dec. 10, 2012]

IMPORTS

§ 1500.265 Imports; definitions.

For the purposes of the regulations prescribed under section 14 of the act:

(a) The term *owner or consignee* means the person who has the rights of a consignee under the provisions of the Tariff Act of 1930 (secs. 483, 484, 485, 46 Stat. 721 as amended; 19 U.S.C. 1483, 1484, 1485).

(b) The term *area office director* means the director of the area office of the Consumer Product Safety Commission having jurisdiction over the port of entry through which a hazardous substance is imported or offered for import, or such officer of the area office as he may designate to act in his behalf in administering and enforcing the provisions of section 14 of the act.

§ 1500.266 Notice of sampling.

When a sample of a hazardous substance offered for import has been requested by the director of the area office, the collector of customs having jurisdiction over the hazardous substance shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon

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receipt of the notice, the owner or consignee shall hold such hazardous substance and not distribute it until further notice from the area office director or the collector of customs of the results of the examination of the sample.

§ 1500.267 Payment for samples.

The Consumer Product Safety Commission will pay for all import samples that are found to be in compliance with the requirements of the act. Billing for reimbursement should be made by the owner or consignee to the Commission area office headquarters in the territory of which the shipment was offered for import. Payment for samples will not be made if the hazardous substance is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance.

§ 1500.268 Hearing.

(a) If it appears that the hazardous substance may be subject to refusal of admission, the area office director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the hazardous substance, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the hazardous substance into compliance with the act, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the area office director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1500.269 Application for authorization.

Application for authorization to relabel or perform other action to

bring the hazardous substance into compliance with the act may be filed only by the owner or consignee and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1500.270 Granting of authorization.

(a) When authorization contemplated by § 1500.269 is granted, the area office director shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) That the operations are to be carried out under the supervision of an officer of the Consumer Product Safety Commission or the Bureau of Customs, as the case may be;

(3) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(4) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the area office director may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the area office director.

(d) If ownership of a hazardous substance covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 1500.271 Bonds.

(a) The bonds required under section 14(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part

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thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the hazardous substance into compliance with the act in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the area office director is in full agreement with the action.

§ 1500.272 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

The cost of supervising the relabeling or other action necessary in connection with an import of a hazardous substance that fails to comply with the act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 14(b) of the act. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station as provided by law.

(c) Services of the supervising officer, to be calculated at the rate of a GS 11, step 1 employee, except that such services performed by a customs officer and subject to the provisions of the Act of February 13, 1911, as amended (sec. 5, 36 Stat. 901 as amended; 19 U.S.C. 267), shall be calculated as provided in that Act.

(d) Services of the analyst, to be calculated at the rate of a GS 12, step 1 employee (which shall include the use of the chemical laboratories and equipment of the Consumer Product Safety Commission).

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(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

[38 FR 27012, Sept. 27, 1973, as amended at 57 FR 28605, June 26, 1992]

PART 1501—METHOD FOR IDENTIFYING TOYS AND OTHER ARTICLES INTENDED FOR USE BY CHILDREN UNDER 3 YEARS OF AGE WHICH PRESENT CHOKING, ASPIRATION, OR INGESTION HAZARDS BECAUSE OF SMALL PARTS

Sec.

1501.1 Purpose.

1501.2 Scope.

1501.3 Exemptions.

1501.4 Size requirements and test procedure.

1501.5 Enforcement procedure.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), and 10; 74 Stat. 372, 374, 375 as amended; 80 Stat. 1304-05, 83 Stat. 187-89 (15 U.S.C. 1261, 1262, 1269).

SOURCE: 44 FR 34903, June 15, 1979, unless otherwise noted.

§ 1501.1 Purpose.

Section 1500.18(a)(9) of this chapter classifies as a banned hazardous substance any toy or other article intended for use by children under 3 years of age that presents a choking, aspiration, or ingestion hazard because of small parts. This part 1501 describes certain articles that are subject to § 1500.18(a)(9); lists certain articles that are specifically exempted; and provides a test method for determining whether an article is hazardous to children under 3 because it, or one of its components that can be detached or broken off during normal or reasonable foreseeable use, is too small.

§ 1501.2 Scope.

(a) This regulation (§ 1500.18(a)(9) and the criteria described in § 1501.4 below) applies to all toys and other articles intended for use by children under 3 years (36 months) of age that are introduced into interstate commerce after