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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.

(d) 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 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.

§ 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.

§ 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.

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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]