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EVALUATING & MEASURING THE 6 HAZARDS IN THE FEDERAL HAZARDOUS SUBSTANCES ACT

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Overview

Six (6) unique hazards each are given a specific definition and evaluation under the Federal Hazardous Substances Act ("FHSA"). A product requires labeling under the FHSA if two (2) events occur. First, a product is toxic, corrosive, flammable or combustible, an irritant, or a strong sensitizer, or it must generate pressure through decomposition or heat. Second, the product has the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonable foreseeable handling or use, including reasonably foreseeable ingestion by children.¹ Regulations issued under FHSA specify the tests a manufacturer must perform to evaluate a product for a specific hazard.

Evaluating Exposure and Risk under FHSA

- (1) **TOXICITY.** A product is toxic if it can produce personal injury or illness to humans when it is inhaled, swallowed, or absorbed through any bodily surface.²

Acute Dermal Toxicity. 16 CFR § 1500.4 contains the test on animals (rabbits) to determine whether a product can cause immediate injury by acute toxicity. The acute dermal toxicity test specifies that in the acute exposures, an 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.³

The procedure for testing is specified in the regulation and is as follows: A 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. 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 two weeks.⁴

Chronic Toxicity. In addition, a product is toxic if it can cause long-term chronic effects like cancer, birth defects, or neurotoxicity. 16 CFR § 1500.135 is guidance for evaluating products for chronic hazards. However, this regulation does not specify tests to determine chronic toxicity, but rather it provides guidelines to determine if a substance falls into the cancer-causing, reproductive toxicant, or neurotoxicity categories by meeting specific criteria.⁵

(2) **CORROSIVITY.** A product is corrosive if it destroys living tissue such as skin or eyes by chemical action.⁶ Tests for corrosivity are the same for Methods of Testing for Primary Skin Irritants and Eye Irritants discussed below.

(3) **IRRITANT.** A product is an irritant if it is not corrosive and causes a substantial injury to the area of the body that it comes in contact with. Irritation can occur after immediate, prolonged, or repeated contact.⁷ Tests for skin and eye irritation are at §§ 16 CFR 1500.41 and 1500.42, respectively.

Method of Testing for Primary Skin Irritants. 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

\1\ The "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 skin irritation score.⁸

Method of Testing for Eye Irritants. Six albino rabbits are used for each test substance in testing for eye irritants. Both eyes of each animal in the test group must be examined before testing. 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 other eye serves as the control eye. The eyes are examined and the grade of ocular reaction is recorded at 24, 48, and 72 hours. An animal will be considered as exhibiting a positive reaction if the test substance produces at any of the readings ulceration of the cornea, opacity of the cornea (other than a slight dulling of the normal luster) inflammation of the iris (other than a slight Deeping of the folds 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 aversion of the lids or a diffuse crimson-red with individual vessels not easily discernible.⁹

The test is 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 is regarded as negative. If two or three animals exhibit a positive reaction, the test is repeated using a different group of six animals. The second test is 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 should 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.¹⁰

- (4) **STRONG SENSITIZERS.** A strong sensitizer is a substance that will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance.¹¹ Additionally, the Commission must declare by regulation that the substance has a significant potential to cause hypersensitivity.¹² 16 CFR § 1500.13 lists the products that the Commission has classified as strong sensitizers.¹³
- (5) **FLAMMABILITY.** The flammability of a product depends on the results of testing. 16 CFR § 1500.3(c)(6) defines the terms “extremely flammable,” “flammable,” and “combustible” as they apply to liquids, solids, and the contents of self-pressurized containers like aerosol cans.

“Extremely flammable” means any substance which has a flashpoint at or below 20 F (-6.7C) as determined by the test method described at 16 CFR § 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.¹⁴

“Flammable” means 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 16 CFR §1500.43a, except that: (1) 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 (2) any mixture containing 24 percent or less of water miscible alcohols, by volume, in an aqueous solution is not considered to be flammable if the mixture does not present a significant flammability hazard when used by consumers.¹⁵

“Combustible” means 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 16 CFR §1500.43a, except that: (1) 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 (2) 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.¹⁶

Solid and self-pressurized products can be either extremely flammable or flammable. 16 CFR §§ 1500.43 and 43a contain the basic tests for the flammability of liquids and similar products. The procedure for testing the contents of self-pressurized containers is found at 16 CFR § 1500.45 and 46.

Method of Test for Flashpoint of Volatile Flammable Materials. This method describes the test procedure which the Commission will use for the determination of the flashpoint of volatile flammable materials, using a Setaflash \1\ low-range closed tester, or an apparatus producing equivalent results. Manufacturers and labelers of products subject to labeling and other requirements under the FHSA may use

other apparatus and/or test methods which produce equivalent results. The regulation provides a summary of the test methods.

(i) 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 16 CFR § 1500.43(i).¹⁷

(ii) Method B- Finite (or Actual Flashpoint). A specified volume of sample is introduced into the cup of 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. The specimen is then 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). The procedure is then repeated at 1 C (2 F) intervals until the flashpoint is Determined to the nearest 1 C (2 F). If improved accuracy is desired, the procedure is repeated at 0.5 C (1 F). Test procedures are set forth in detail at 16 CFR § 1500.43a(j).¹⁸

(iii) Definition of Flashpoint. The lowest temperature of the sample corrected to a barometric pressure of 202.3 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 enlarged flame; this is not a flash and should be ignored.¹⁹

(iv) Test Apparatus. The test apparatus is an equilibrium closed-cup tester with a range up to 100 C (212 F). Closed-cup flashpoint testers and accessories meeting the following requirements in Table 3 are available from commercial suppliers and distributors of laboratory equipment.

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.²⁰

(v) Preparation of Samples. 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 store samples in plastic (polyethylene, polypropylene, etc.) bottles since volatile materials may diffuse through the walls of the bottle. A 2-mil 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.²¹

Method of Determining Extremely Flammable and Flammable Contents of Self-Pressurized Containers. The test equipment required 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.²² 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. Three readings should be taken for each test, and an average. As a precaution, large quantities should not be sprayed in a small, confined space.²³

Method of Determining Flashpoint of Extremely Flammable Contents of Self-Pressurized Containers. The apparatus described in Table 3 of 16 CFR § 1500.43a should be used.²⁴ Some means such as dry ice in an open container to chill the pressurized container should be used. 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 formation to the test apparatus and test in accordance with the method described in 16 CFR § 1500.43a.²⁵

- (6) **PRODUCTS THAT GENERATE PRESSURE THROUGH DECOMPOSITION OR HEAT.** This hazard includes aerosols, fireworks that contain explosive powder, and certain pool chemicals. The FHSA does not mandate specific tests to determine the amount of pressure that these types of products might generate.²⁶

Conclusion

There are no formal guidelines under the FHSA or its regulations to evaluate exposure to a product and its risk of injury. However, a manufacturer should consider: (1) how the contents and form of the product might cause an injury, (2) the product's intended handling, use, and storage, and (3) any accidents that might foreseeably happen during handling, use, or storage that could hurt the purchaser, user, or others, including young children who might get into the package of the product. In evaluating a product, it is essential that the manufacturer evaluate the finished product, rather than its individual ingredients.²⁷

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***OF NOTE:** Mark A. Kinzie is a lawyer who has defended chemical manufacturers in product liability lawsuits and currently represents them in regulatory compliance, product warnings, and product recall matters. Patricia A. Hietter is a lawyer who has worked extensively in product liability, regulations, and warnings required in the supply chain of chemical goods.*

NOTE: This White Paper is for informational purpose only and has not been prepared to evaluate any claim, application, product, product line, methodology, regulation, compliance, or manufacturing operation. Consult a lawyer when deciding whether the FHSA applies to your product.



¹ U.S. Consumer Product Safety Commission: Office of Compliance, *Requirements Under the Federal Hazardous Substances Act: Labeling and Banning Requirements for Chemicals and Other Hazardous Substances* (August 2002); see also 16 CFR § 1500.3 Definitions.

² 16 CFR § 1500.3(b)(5) Definitions.

³ 16 CFR § 1500.40(a) Method of Testing Toxic Substances.

⁴ 16 CFR § 1500.40(c) Method of Testing Toxic Substances.

⁵ 16 CFR § 1500.135 Summary of Guidelines for Determining Chronic Toxicity.

⁶ 16 CFR § 1500.3(b)(7) Definitions.

⁷ 16 CFR § 1500.3(b)(8) Definitions.

⁸ 16 CFR § 1500.41 Method of Testing Primary Irritant Substances.

⁹ 16 CFR § 1500.42(a),(b)(1) Test for Eye Irritants.

¹⁰ 16 CFR § 1500.42(b)(2) Test for Eye Irritants.

¹¹ 16 CFR § 1500.3(b)(9) Definitions.

¹² *Id.*

¹³ (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. 16 CFR § 1500.13

Listing of “Strong Sensitizer” Substances.

¹⁴ 16 CFR § 1500.3(c)(6)(i) Definitions.

¹⁵ 16 CFR § 1500.3(c)(6)(ii)(A)-(B) Definitions.

¹⁶ 16 CFR § 1500.3(c)(6)(iii)(A)-(B) Definitions.

¹⁷ 16 CFR § 1500.43a(fb)(1) Method of Test of Flashpoint for Volatile Flammable Materials.

¹⁸ 16 CFR § 1500.43a(fb)(2) Method of Test of Flashpoint for Volatile Flammable Materials.

¹⁹ 16 CFR § 1500.43a(c).

²⁰ 16 CFR § 1500.43a(d) Method of Test of Flashpoint for Volatile Flammable Materials.

²¹ 16 CFR § 1500.43a(f) Method of Test of Flashpoint for Volatile Flammable Materials.

²² 16 CFR § 1500.45(a) Method for Determining Extremely Flammable and Flammable Contents of Self-Pressurized Containers.

²³ 16 CFR § 1500.45(b) Method for Determining Extremely Flammable and Flammable Contents of Self-Pressurized Containers.

²⁴ 16 CFR §1500.46 Method for Determining Flashpoint of Extremely Flammable Contents of Self-Pressurized Containers.

²⁵ *Id.*

²⁶ U.S. Consumer Product Safety Commission: Office of Compliance, *Requirements Under the Federal Hazardous Substances Act: Labeling and Banning Requirements for Chemicals and Other Hazardous Substances* (August 2002).

²⁷ *Id.*