Consumer Product Safety Commission

§ 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

(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.

§ 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