Using Fewer Animals to Identify Chemical Eye Hazards: Revised Classification Criteria Necessary to Maintain Equivalent Hazard Labeling

W Stokes[1], J Haseman[2], E Lipscomb[3], J Truax[3], N Johnson[3], B. Jones[3], D Allen[3]

[1]NICEATM/NIEHS/NIH/DHHS, RTP, NC; [2]Consultant, Raleigh, NC; [3]ILS Inc., RTP, NC

U.S. Federal Hazardous Substances Act (FHSA) regulations specify eye safety testing procedures and hazard classification criteria for chemicals and products regulated by CPSC and OSHA. Current regulations require up to three sequential tests of six animals per test, with decisions on the need for subsequent tests based on the number of positive responses observed. Testing conducted in accordance with the OECD test guideline for eye irritation and corrosion can also be used, but current FHSA regulations do not provide criteria to classify results from this 3-animal test. Therefore, an analysis was conducted to determine classification criteria for results from a 3-animal test that would provide hazard labeling equivalent to that provided by current FHSA regulations. This analysis compared the frequency at which the current FHSA classification criteria would identify substances as ocular irritants with the frequency at which a classification criterion of either one or two positive animals out of three would identify these substances. The resulting classifications that would be assigned by each of the three criteria were also compared using four different underlying response rates (20, 40, 50, and 75%). For these response rates, current FHSA requirements would identify 20, 73, 88, and >99% of substances as irritants, respectively, while using a criterion of at least one out of three positive animals in a 3-animal test would identify 49, 78, 88, and 98% of substances as irritants, respectively. In contrast, using a criterion of at least two out of three positive animals in a 3-animal test would identify far fewer irritants, with detection rates of 10, 35, 50, and 84%, respectively. We conclude that using classification criteria of one or more positive animals in a 3-animal test will provide the same or greater level of eye hazard labeling as current FHSA requirements, while using up to 83% fewer animals. ILS Staff supported by NIEHS contract N01-ES-35504.

Keywords: eye irritant, hazard classification, ocular safety

Poster Session: Risk Assessment and Regulatory Policy Applications