

NICEATM Poster Presentation

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Comparative Performance of Four *In Vitro* Test Methods for the Classification of Ocular Corrosives and Severe Irritants

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The Draize rabbit eye test is accepted by U.S. and international regulatory authorities for the assessment of ocular hazard potential. However, concerns about animal welfare and the reliability of the *in vivo* rabbit eye test have led researchers to develop *in vitro* test methods as alternatives to the currently used Draize rabbit eye test method. The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) evaluated the Isolated Rabbit Eye, Isolated Chicken Eye, Bovine Corneal Opacity and Permeability, and the Hens Egg Test-Chorioallantoic Membrane test methods for their ability to detect ocular corrosives or severe irritants. *In vivo* results were classified based on U. S. and international ocular hazard classification systems (i.e., U.S. Environmental Protection Agency [EPA], the European Union [EU], and the United Nations Globally Harmonized System [GHS]). Ocular corrosives and severe irritants were defined as Category 1 according to the GHS, as Category I according to the EPA, or as R41 according to the EU. *In vitro* results were classified as severe irritants based on decision criteria obtained from a literature review and/or personal communications with developers of the individual test methods. Accuracy of the four evaluated test methods ranged from 53% to 81% for the GHS classification system; and was similar across all three regulatory classification systems for each *in vitro* test method. Accuracy analyses based on the physicochemical characteristics of a test substance suggested limitations for each test method. Intralaboratory repeatability and reproducibility and interlaboratory reproducibility were evaluated using both quantitative and qualitative approaches. The analyses indicated that the test methods were generally reproducible within and between testing laboratories. Supported by NIEHS contract N01-ES-35504.

SOT Itinerary Information:

ID# 908
Location: Exhibit Hall (Convention Center)
Date/Time: March 7, 2006 / 9:00 am – 12:00 noon
Category: Regulatory/Policy, (Alternatives to Mammalian Models)