

NICEATM Poster Presentation

Society of Toxicology 44th Annual Meeting

March 6 - 10, 2005

New Orleans, LA

Validation Status of the Hen's Egg Test-Chorioallantoic Membrane (HET-CAM) Test Method

N. Choksi^{1,2}; D. Allen^{1,2}; C. Inhof^{1,2}; J. Truax^{1,2}; R. Tice^{1,2}; W. Stokes¹

1. NICEATM, NIEHS, Research Triangle Park, NC, USA.

2. ILS, Inc., Research Triangle Park, NC, USA.

Concerns about animal welfare and interest in higher throughput testing have led researchers to develop alternative *in vitro* test methods for the current rabbit eye test. NICEATM evaluated four *in vitro* ocular test methods for their ability to identify substances that cause irreversible or severe irritation or corrosion. One of these test methods, HET-CAM, is a model that is proposed to mimic the mucosal tissues of the eye. The ability of HET-CAM to correctly identify ocular corrosives and severe irritants using available HET-CAM data that evaluated the time to appearance of endpoints and corresponding *in vivo* eye irritation data was evaluated according to current hazard classification schemes for the U.S. EPA (n=54), the European Union (n=54), and the UN Globally Harmonized System (n=52). Depending on the classification scheme used, HET-CAM had a false positive rate of 20-27%, and a false negative rate of 0-7%. Lack of published intra- and interlaboratory data for this analysis method precluded an evaluation of test method reliability. A proposed standardized test method protocol and a proposed recommended list of reference substances have been developed for future validation and testing studies to further assess the accuracy, reliability, and the applicability domain of HET-CAM for the detection of ocular corrosives and severe irritants. HET-CAM may be useful in a tiered-testing strategy where positive results can be used to classify and label a substance, while substances with negative results would undergo additional testing to identify false negative ocular corrosives/severe irritants and to identify those chemicals with reversible ocular effects. This approach would reduce the number of animals used for eye irritation testing and reduce the number of animals experiencing pain and distress by identifying substances that are severe irritants/corrosives. ILS staff supported by NIEHS contract N01-ES 35504.

SOT Itinerary Information:

ID# 1997
Location: Ballrooms A & B
Date/Time: March 10, 2005 / 8:30 - 11:30 AM
Category: Alternatives to Mammalian Models