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Validation Status of the Isolated Chicken Eye (ICE) Test Method

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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, ICE, is an organotypic model that provides short-term maintenance of normal physiological and biochemical function of the eye in an isolated system. The ability of ICE to correctly identify ocular corrosives and severe irritants using available ICE and corresponding *in vivo* eye irritation data was evaluated according to current hazard classification schemes for the U.S. EPA (n=91), the European Union (n=121), and the UN Globally Harmonized System (n=93). Depending on the classification scheme used, ICE had a false positive rate of 8-10% and a false negative rate of 30-40%. In terms of reliability, the assay has acceptable interlaboratory reproducibility; intralaboratory reproducibility could not be assessed. 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 ICE for the detection of ocular corrosives/severe irritants. Investigators should consider using ICE prior to eye irritation testing in animals. When used in a tiered testing strategy, positive results could be used to classify and label a substance, while substances with negative results would undergo additional eye irritation 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. ILS staff supported by NIEHS contract N01-ES 35504.

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