

Prevalidation of the OptiSafe Ocular Irritation Assay for the Detection of Ocular Corrosives

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Abstract

OptiSafe™ is a novel, shelf stable, test tube-based assay that can discriminate ocular irritants/corrosives from nonirritants and does not use animal tissues or cells. It can determine whether an unknown substance is an ocular nonirritant by measuring and comparing chemical models for three variables: damage to the corneal stroma, damage to phospholipid bilayers, and the potential to induce pH extremes in a system. A substance can be evaluated in less than 2 hours, and results can be obtained in fewer than 24 hours. Previous studies indicated that predictions of EPA Category IV or GHS category NC (not classified) by the OptiSafe ocular irritation assay had high sensitivity, suggesting that it may represent a new tool for the *in vitro* assessment of the ocular toxicity potential of chemicals in a tiered-testing strategy. While a limited number of ocular corrosives have been tested, the initial analyses of retrospective and prospective OptiSafe data suggest that the test method is also sensitive for the detection of ocular corrosives. Overall, for the GHS Category 1 prediction, the sensitivity was 87.5% and the specificity was 70%. The EPA Category I prediction yielded a sensitivity of 85.7% and a specificity of 67.6%. OptiSafe had a higher sensitivity for the detection of ocular corrosives and similar or lower specificity compared to other *in vitro* test methods: Bovine Cornea Opacity/Permeability, Isolated Chicken Eye, Short-Time Exposure, and Irritection™. To confirm the results of these initial studies, additional ocular corrosives will be assessed to provide a more complete description of the sensitivity and accuracy for the detection of ocular corrosives. If the prevalidation results are confirmed, then OptiSafe may represent a new approach that moves closer to a multiple category test paradigm, NC/IV classification results can be accepted with a higher level of confidence, and noncorrosive results can be accepted with an above-average level of confidence. While positives may require confirmation by other methods, nonirritant and noncorrosive results may be acceptable. This approach may find applications in scenarios where there is a time-sensitive need to determine whether a substance is safe for eye area exposure.

This project was funded in whole or in part with federal funds from the NIEHS, NIH under Contract No. HHSN273201500010C