An Improved Version of the OptiSafe Test with High Specificity

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Most chemical and product safety testing for eye irritation and toxicity has historically used the Draize live rabbit eye test, in which the eyes of unanesthetized New Zealand White rabbits are exposed to the chemical or product, and the ocular responses are recorded over 21 days. There is a public movement against live animal testing, which has led to legislation limiting the use of animals for product testing in many countries, including the U.S., and proposals to ban the use of live animals for a wide range of testing applications. Current high sensitivity alternatives to live animal testing for ocular irritation have high false-positive rates and modest accuracy. Thus, the classification of products using these alternatives may desensitize consumers and manufacturers to the risks of handling hazardous materials because the high false-positive rate would result in many materials being classified as irritating. In addition, product manufacturers may resist adopting animal alternatives if too many products are falsely classified as irritants.

To address the need for better and more predictive nonanimal ocular irritation test, we have been developing and improving the chemical based, in vitro ocular irritation test, OptiSafe. This test can discriminate nonirritants from irritants/corrosives in fewer than 24 hours, with only an hour of hands-on time. Furthermore, multiple test samples can be evaluated simultaneously using standard laboratory techniques and equipment with a shelf life of at least 1 year. Recently, results from a validation study showed that OptiSafe has a very high sensitivity for nonirritant detection and provides a rapid, high-throughput screening method for nonirritants; however the false-positive rate was about 40%, which is similar to other available nonanimal eye safety tests.

The major goal of the current project was to further optimize the OptiSafe method and reduce the false positive rate. The updated version is now called OSII. We have successfully made the targeted improvements and tested them in house by retesting prior validation study chemicals (accuracy still needs to be confirmed by a blind validation study). Based on the in-house retest of the validation chemicals with the new formulation, protocol, and prediction model, the specificity of the GHS Cat. NC (Not classified by regulatory agencies) prediction improved from 58.3% to 80.6%. The sensitivity remained the same at 100%, and the overall accuracy improved from 78.9% to 90.0%. These new improvements position OSII to be a useful tool for the identification of nonirritant chemicals without using animals.