

## **Classification of agrochemicals for eye irritancy potential using the IVD EIT (In Vitro Depth of Injury Eye Irritation Test)**

Stewart J. Lebrun<sup>1</sup>, Linda Nguyen<sup>1</sup>, Sara Chavez<sup>1</sup>, and James V. Jester<sup>2</sup>

<sup>1</sup>Lebrun Labs LLC, Anaheim, CA, United States,

<sup>2</sup>Department of Ophthalmology and Biomedical Engineering, University of California Irvine, Irvine, CA

### **Abstract**

The IVD EIT method uses food source animal or human cadaver eyes incubated under tissue culture conditions for 24 hours. To improve accuracy, the method has been updated to include a "metabolic" procedure to be used in addition to the "direct" procedure. Globally Harmonized System of classification and labeling of chemicals (GHS) and Environmental Protection Agency (EPA) prediction models were established with 32 non-agrochemicals distributed between all classes. The purpose of this study was to evaluate the method for detection of 16 coded agrochemicals provided by the National Toxicology Program (NTP). For the GHS Not Classified (NC) vs. 2, 1 prediction, the accuracy was 93.8%, the sensitivity was 100.0%, and the specificity was 87.5%. For the GHS category 1 prediction, the accuracy was 100.0%, the sensitivity was 100.0%, and the specificity was 100.0%. For the EPA IV vs. III, II, I prediction, the accuracy was 87.5%, the sensitivity was 88.9%, and the specificity was 85.7%. There was one false negative chemical which was an EPA Category III. For the EPA IV/III vs. II/I prediction, the accuracy was 93.8%, the sensitivity was 100.0%, and the specificity was 87.5%. For the I vs. IV, III, II prediction, the accuracy was 93.8%, the sensitivity was 85.7%, and the specificity was 100.0%. There was one false negative that was a borderline Category I (Depth of Injury = 23.6%); if the result was >25% then it would be predicted as an EPA Category I. Results suggest that the IVD EIT test method may be a highly accurate, in vitro test method that can be used to classify agrochemicals for the least and most irritating classifications. Further studies with more middle classification agrochemicals are needed to determine if the method detects the full range of agrochemical related ocular irritancies and to establish human relevance by comparing food source animal eyes with human cadaver eyes.

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