Repeatability of a Depth of Injury Test Method for the Classification of Eye Irritants

Priya Mistry¹, James V. Jester², Debby Le¹, Stewart Lebrun¹

¹Lebrun Labs LLC, Anaheim, California

²Department of Ophthalmology and Biomedical Engineering, University of California Irvine, Irvine, California

The purpose of this study is to evaluate variability in the newly developed Globally Harmonized System (GHS) prediction model for classifying ocular irritant materials based on depth of injury (DoI) measurements. Previously, 16 different materials were tested, representing all classes of toxicity, according to the GHS classification systems. The new study used a subset of these chemicals to determine the reproducibility of the method. For this method, food-source rabbit eyes were used. Tissues were exposed to test material for 1 min, and corneas were collected 24 hours after exposure. Tissues were then fixed and processed for live/dead biomarker fluorescent staining using phalloidin. Dol was then measured, and the percent Dol values for the stroma were compared to the prediction model. The GHS not classified (NC) irritant, n-hexyl bromide (CASRN 111-25-1), caused no damage to the stroma with an average depth of injury of 0% and a standard deviation of 0%. The GHS category 2 material, n-octanol (CASRN 111-87-5), caused damage to the stroma with an average depth of injury of 12.7% with a standard deviation of 5.0%, whereas the GHS corrosive, cyclohexanol (CASRN 108-93-0), caused significantly greater damage to the stroma with an average depth of injury of 44.4% with a standard deviation of 4.3%. The data from ongoing independent replicates for the same chemicals demonstrate that the method is statistically reproducible with low variability.