Classification of EPA Ocular Irritants and Non-Irritants by the OptiSafeTM Test Method of Mixtures

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The EPA eye irritation classification system is routinely used to categorize ocular toxicity. The EPA system classifies chemicals that damage the eye after 24 hours (Category III, II, or I) and those that do not cause damage (Category IV). This latter EPA classification is aligned with the standard definition of an "ocular non-irritant" and is appropriate for test substances routinely applied to the eye area. The OptiSafeTM ("Optimized for Safety") test is a novel, shelf-stable, test-tube based method that can be used to discriminate ocular irritants/corrosives from non-irritants and does not use animal tissues or cells. The OptiSafeTM test determines whether a substance is an ocular non-irritant by measuring damage via a proxy for the corneal stroma (water-soluble molecules), damage to phospholipid bilayers (water-insoluble molecules), and the potential to induce pH extremes in a system (pH buffering system of the eye). Chemicals in this study were selected based on a wide range of EPA classifications, chemical and physical properties, high quality in vivo reference data, and chemical stability. Selected chemicals (38) including surfactants not previously tested were aliquoted into coded vials and tested blind in triplicate. The coded vials were tested, and results were reported as either EPA Category IV (nonirritant) or not (EPA Category III, II, or I). The OptiSafeTM test method applied to these 38 test chemicals achieved a sensitivity of 100% (27/27), specificity was 81.8% (9/11), and overall accuracy was 94.7% (36/38). The better accuracy of OptiSafeTM (~ 95%) versus the OECD Test Guideline 492 EIT method (~ 86%) is best attributed to its higher sensitivity. These results suggest that OptiSafeTM may be an important tool in the complete classification of hazards, especially for surfactants, as well as cosmetics and other substances applied to or around the eye.