

## **Evaluation report on the Fluorescein Leakage (FL) test for eye irritation testing**

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### **Summary**

An OECD (Organisation for Economic Co-operation and Development) test guideline (TG) has been proposed for a Fluorescein Leakage (FL) test as an initial step within a Top-Down approach and alternative to ocular irritation tests using animals for identifying ocular corrosives and severe irritants. This method is a cytotoxicity and cell-function based *in vitro* assay, in which damage caused by short time exposure to a test chemical is evaluated by measuring the amount of sodium fluorescein that passes through a monolayer of tubular epithelial cells. A validation study of the FL test has shown that, when the test chemicals are limited to water-soluble substances and mixtures, this method achieved false positive rates of 7% (7/103) per the United Nations (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and 9% (9/99) per the U.S. EPA (U.S. Environmental Protection Agency).