**Background**

Assessment of **ocular irritation** is an international regulatory requirement in the **safety evaluation** of products. Although a number of **in vitro** assays exist, none are capable of fully categorizing chemicals as stand-alone assays. In **CON4EI** (2015-2016) the reliability of **8 in vitro test methods** and computational models for **80 reference chemicals** was assessed and an **integrated testing strategy** for eye irritation was established. **Results will be published in ATLA.**

**Results**

**Concordance in prediction:** in terms of the classification I versus NI, a **100% agreement** in prediction between VITO and L’Oréal was obtained.

**Reproducibility of the viability**

The **high reproducibility** between the runs between VITO and L’Oréal was reflected in the correlation plots.

**The predictive capacity**

The predictive capacity was calculated for each laboratory and for the cumulative results of the laboratories. A **sensitivity of 96.9%** and **specificity of 100%** with an **accuracy of 97.5%** was obtained overall and in both laboratories separately.

Overall, **four false negatives** were reported, the following **in vivo** Cat 2 chemicals (both solids) were consistently predicted NI by the two laboratories: (2R,3R)-3-[(R)-1-(Tert-butyldimethylsiloxy)ethyl]-4-oxazetidin-2-yl acetate (**in vivo** Cat 2A with CO mean ≥ 1 as driver) and m-Dinitrobenzene (**in vivo** Cat 2B with Conj mean ≥ 2 as driver).

**CON4EI:**

One of the 8 assays was the **Reconstructed Human Corneal Epithelium model (SkinEthic™ HCE).** The test method consists of a topical exposure of the chemical onto the SkinEthic™ HCE test system followed by cell viability assessment with MTT. This method **discriminates** between **No Cat and Cat 1/Cat2.** The 80 blind-coded chemicals were tested by the **laboratories VITO and L’Oréal.**

**Goals for SkinEthic™ HCE:**

- Evaluate the **Performance** to discriminate Cat1/Cat2 from No Cat.
- Investigate the **Predictive capacity** in terms of **in vivo** drivers of classification.
- Test if it can be **part of the tiered-testing strategy.**

**CON4EI:** IS **SKINETHIC™ HCE** INCLUDED IN AN INTEGRATED TESTING STRATEGY FOR **EYE IRRITATION** ASSESSMENT?


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**YES, THE RESULTS SEEM PROMISING WITH REGARD TO INCLUSION OF SKINETHIC™ HCE IN AN INTEGRATED TESTING STRATEGY FOR EYE IRRITATION.**