vito

ENVIRONMENT
HEALTH & SAFETY

CON4EI

Consortium for in vitro Eye Irritation testing strategy

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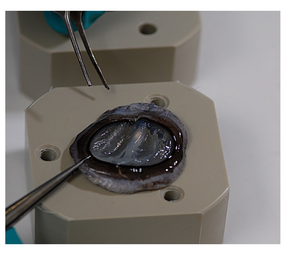
Background

Assessment of the acute **eye irritation** potential is part of the international **regulatory requirements** for testing of chemicals.
All ***in vitro* assays** have specific **strengths and limitations** whether this relates to ranges of irritancy, types of chemical classes or physical nature of the materials. Therefore, **combinations** of *in vitro* assays are **needed** for hazard identification and complex safety assessment. **Today**, these combinations of assays are used by individual companies as an integral part of their safety assessments, but often with **limited scientific knowledge** covering their own specific chemical properties/portfolio needs. This can contribute to a **lack of consistency** among *in vitro* test results within a battery approach or a **conflict** with available ***in vivo*** data.
Despite efforts to compare *in vitro* methods with *in vivo* data, the problem is that most of the so far proposed testing strategies for assessment of eye irritation were **not** evaluated with the **same** adequately **large set of chemicals**. This is consequently resulting in a **lack of information** on **predictive capacity** of the *in vitro* assays in a testing strategy. All available information confirms that the strategy is as strong as the weakest part of it.

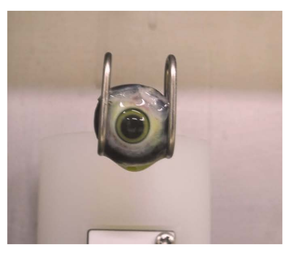
Cefic LRI-AIMT6-VITO CON4EI project goal

The main objective of this project is to develop tiered testing strategies for eye irritation assessment for all eye irritation drivers of classifications.
In this project the irritancy potency of a set of 80 chemicals, with good quality in vivo Draize eye data representing the most important drivers of in vivo classification, will be evaluated. Following **eight test methods** will be included in this project: **BCOP**[1] (Bovine Corneal Opacity and Permeability), **ICE**[1] (Isolated Chicken Eye) and **STE**[2] (Short Term Exposure), all of them can distinguish Category 1 versus No Category. **EpiOcular EIT**[2] (EpiOcular Eye Irritation Test) and **SkinEthicTM HCE**[3] (Human Corneal Epithelial) can distinguish between Not classified versus classified (Category 1/ Category 2). To distinguish between Category 1 and Category 2, the following methods are relevant to include: **histopathology** in association with the BCOP and ICE, **EpiOcular ET-50**[4] (EpiOcular time-to-toxicity test), **SMI** (Slug Mucosal Irritation), and **BCOP-LLBO** (BCOP-laser light-based opacitometer).

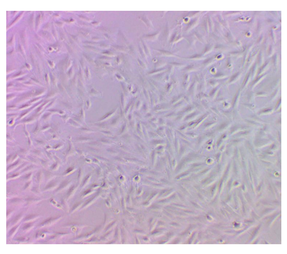
[1]regulatory accepted, [2]undergoing regulatory acceptance, [3]mature in development, [4]accepted by EPA for testing of antimicrobial cleaning products



BCOP

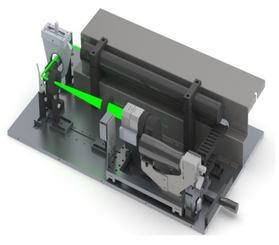


ICE

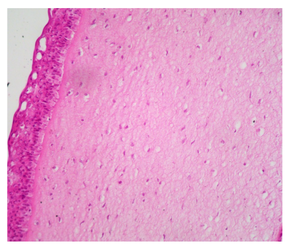


STE

SMI

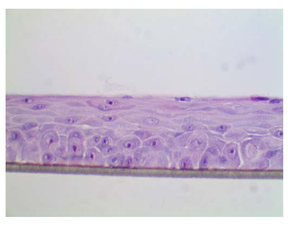


BCOP-LLBO



Histopatholog (BCOP-ICE)

SkinEthic HCE



EpiOcular EIT/ET50

This project will assess the **reliability** of these *in vitro* test methods, define **applicability domains** in terms of '**drivers of classification**', **strengths and limitations** of each method.
In this way, we will be able to identify methods that will fit in a **tiered approach** to distinguish UN GHS classified **Category 1** chemicals ***versus*** **No Category** chemicals and address the highest industrial gaps namely distinguish between **Category 2** versus **Category 1** chemicals.

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