

TEST SERVICE FOR *in vitro* EYE IRRITATION ASSESSMENT OF CHEMICALS AND FINISHED PRODUCTS

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Toxicology assessment of chemicals are crucial in ensuring the safety of these chemical ingredients in consumer finished products. Human eyes are very sensitive when exposed to foreign particulates and the potential to cause eye irritancy is one of the very first and important subject in irritancy test. The toxicology assessment for eye irritancy potential need to go through the following protocols:

- Bovine corneal opacity and permeability test method to screen i) chemicals inducing serious eye damage and ii) chemicals not requiring classification for eye irritation or serious eye damage (OECD TG 437, 2017).
- Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage (OECD TG 492, 2017).

The test methods have been accepted by the Organisation for Economic Co-operation and Development (OECD) to classify eye corrosivity or irritancy of chemicals according to the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS, 2015).

BACKGROUND

Different materials and chemicals can result in different degree of damages to the cornea of the eye. The effects may vary from irritation and inflammation causing mild discomfort to tissue corrosion resulting in irreversible blindness. The materials include industrial, household, agricultural products, cosmetics, toiletries and certain ocular drugs and pharmaceuticals. To reduce the risk of exposure to dangerous substances, all manufactured consumer products and their ingredients must be tested and their eye irritation potential are assessed so that the public can be assured of their safety, or warned of the associated risk of exposure.

SERVICE

An *in vitro* testing strategy approach for eye irritation is proposed using a Bottom-Up (begin with test methods that can accurately identify non-irritants) or Top-Down (begin with test methods that can accurately identify severe irritants) progression of *in vitro* tests (Figure 1) (Scott *et al.*, 2010). In Top-Down approach testing, BCOP test is recommended to be used as initial testing to distinguish severe eye irritants (GHS Cat. 1) from other classes (GHS Cat.2 or not labelled). The second step in Top-Down approach involves testing using epithelial models such as the SkinEthic™ HCE. Both tests can be used to distinguish non-classified substances from irritants.

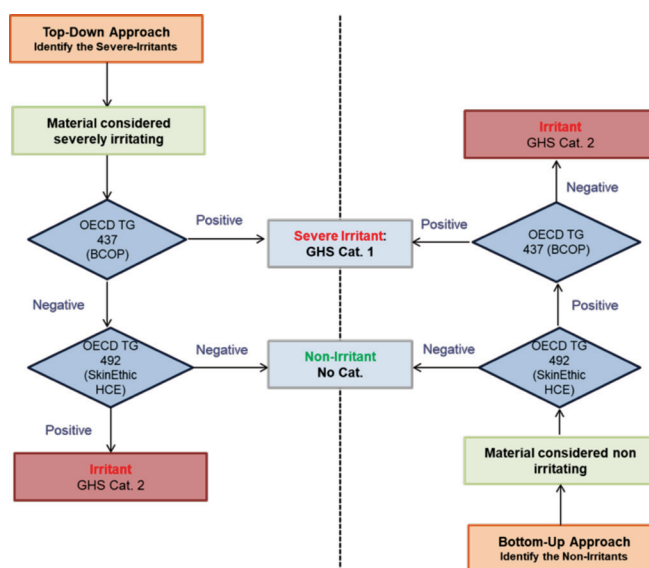
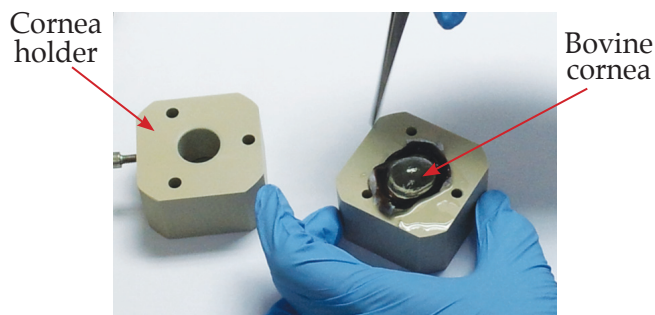


Figure 1. Top-Down and Bottom-Up *in vitro* testing strategies for eye irritation.

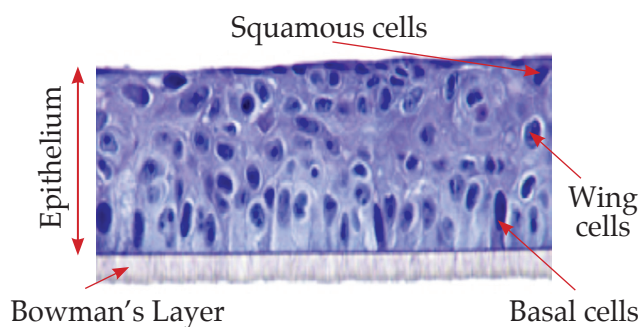
BENEFITS

In vitro eye irritation assessment service is an alternative methods for the assessment of hazards of substances. The service will help the palm oil and oleochemicals manufacturers in obtaining eye irritation data in the preparation of chemical safety data sheet.





(a)



(b)

Figure 2. (a) Mounting bovine's cornea for OECD TG 437 and (b) reconstructed human corneal epithelium (HCE) model for OECD TG 492.

SERVICES OFFERED

- OECD Test No. 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (OECD TG 437, 2017).
- OECD Test No. 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage (OECD TG 492, 2017).

COST OF SERVICES

The indicative price of the services offered is shown in Table 1.

TABLE 1. COST OF SERVICES

No.	Test	Charges per sample (RM)
1.	Bovine Corneal Opacity and Permeability Test (OECD TG437, 2017)	7 000*
2.	Reconstructed Human Cornea-like Epithelium Test (OECD TG492, 2017)	10 000*

Note: * Subject to change.

INNOVATION

- Request for analyses please contact Nor Zuliana Yusof at email: zuliana@mpob.gov.my
- The request will be registered through an online laboratory software information management for data traceability.
- You will get your data within seven working days.

REFERENCES

OECD TG 437 (2017). Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage. OECD, Paris, France.

OECD TG 492 (2017). Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage. OECD, Paris, France.

Scott, L; Eskes, C; Hoffman, S; Adriaens, E; Alepee, N; Bufo, M; Clothier, R; Facchini, D; Faller, C; Guest, R; Harbell, J; Hartung, T; Kamp, H; Varlet, B L; Meloni, M; McNamee, P; Osborne, R; Pape, W; Pfannenbecker, U; Prinsen, M; Seaman, C; Spielmann, H; Stokes, W; Trouba, K; Berghe, C V; Van Goethem, F; Vasallo, M; Vinardell, P and Zuang, V (2010). A proposed eye irritation testing strategy to reduce and replace in vivo studies using Bottom-Up and Top-Down approaches. *Toxicology in vitro*, 24: 1-9.

United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) (2015). Part 3 Health Hazards-Chapter 3.3 Serious Eye Damage/Eye Irritation. [Online] Available from: https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev06/English/03e_part3.pdf, accessed on 29 March 2018.

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