



How to approach the eye irritation testing strategy

Sometimes the classification for eye damage/irritation obtained by calculation is over predictive, leading to a classification too harsh for your products.

Eurofins BioPharma Product Testing Italy, can help you to design the best testing strategy for the eye irritation and/or damage classification, of your products, allowing you to save time and resources. Our experts will support you on the product classification also when the tests do not provide conclusive results.

Methods employed to determine in vitro eye irritation, often provide non definitive results. It is generally acknowledged that a single in vitro test method is not able to cover the criteria for injury and inflammation addressed by the regulatory adopted in vivo animal test method (the in vivo rabbit eye test - Draize test OECD TG 405). Therefore, in order to replace or to reduce the use of the in vivo rabbit eye test, it is recommended to make use of testing strategies that combine the strengths of individual in vitro test methods to address the required ranges of irritation potential and/or chemical classes.

In particular, two tiered testing approaches are recommended for serious eye damage and eye irritation hazard identification:

- A Top-Down approach, starting with in vitro test methods that can identify test chemicals causing serious and/or irreversible eye damage (UN GHS Cat. 1) and proceeding with test methods that can identify test chemicals not requiring classification for eye hazard (UN GHS No Cat.)
- A Bottom-Up approach, starting with in vitro test methods that can identify test chemicals not requiring classification for eye hazard (UN GHS No Cat.) and proceeding with test methods that can identify test chemicals causing serious and/or irreversible eye damage (UN GHS Cat. 1).

This tiered approach can sometimes provide non conclusive results and an expert judgment is necessary to interpret the data. Eurofins BioPharma Product Testing Italy can provide you with this support and lead you to the correct classification of your products.

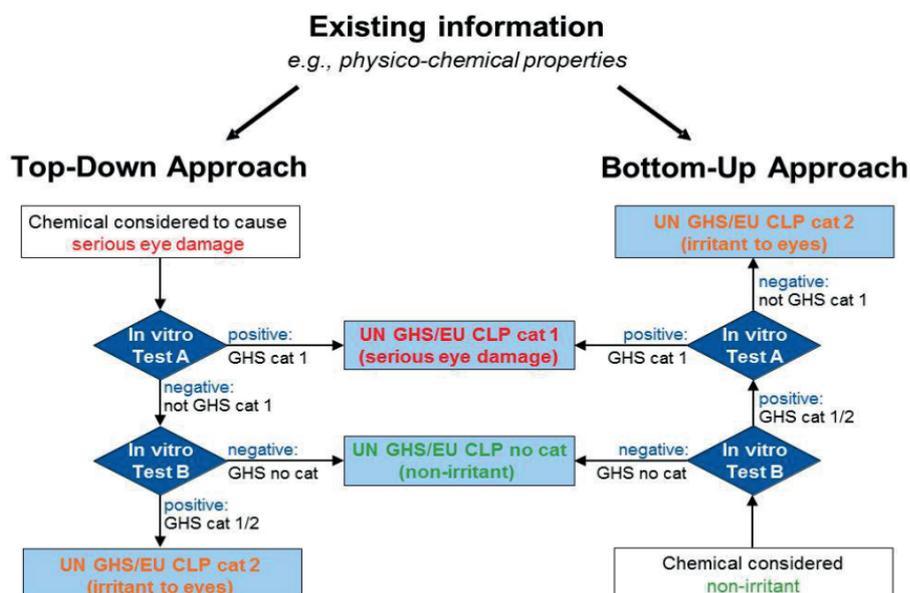


Figure 4.1. Bottom-Up and Top-Down approaches for serious eye damage/eye irritation (after Scott *et al.*, 2010)