

Non-Animal Approaches to Skin and Eye Testing

EYE IRRITATION AND CORROSION

Organisation for Economic Co-operation and Development (OECD). 2019. Guidance document on an integrated approach on testing and assessment (IATA) for serious eye damage and eye irritation. No 263. Series on Testing and Assessment.

European Chemicals Agency. 2017. Guidance on information requirements and chemical safety assessment. Chapter R.7a: endpoint specific guidance. Version 6.0.

US Environmental Protection Agency (EPA) Office of Pesticide Programs. 2015. Use of an alternate testing framework for classification of eye irritation potential of EPA pesticide products.

SKIN IRRITATION AND CORROSION

European Chemicals Agency. 2017. Guidance on information requirements and chemical safety assessment. Chapter R.7a: endpoint specific guidance. Version 6.0.

OECD. 2014. Guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation. No 203. Series on Testing and Assessment.

SKIN SENSITISATION

US EPA. 2018. Interim science policy: use of alternative approaches for skin sensitization as a replacement for laboratory animal testing.

European Chemicals Agency. 2017. Guidance on information requirements and chemical safety assessment. Chapter R.7a: endpoint specific guidance. Version 6.0.

OECD. 2016. Guidance document on the reporting of defined approaches and individual information sources to be used within integrated approaches to testing and assessment (IATA) for skin sensitisation. No 256. Series on Testing and Assessment. Annex 1 and Annex 2.

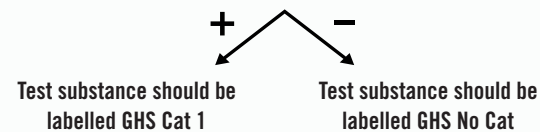
OECD. 2012. The adverse outcome pathway for skin sensitisation initiated by covalent binding to proteins. No 168. Series on Testing and Assessment. Part 1, Part 2.

REPLACEMENT STRATEGIES AND GUIDANCE

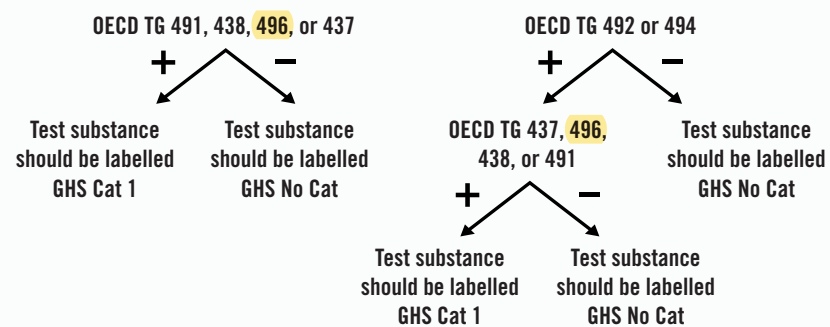
Gather existing human, animal, and *in vitro* data; information on the substance's physicochemical properties; and information from non-testing approaches, including quantitative structure-activity relationships (QSARs), read-across, grouping, bridging, and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) additivity approach when applicable. Determine if further testing can be waived.

- OECD TG 492: Reconstructed Human Cornea-like Epithelium (RhCE) Test Method
- OECD TG 491: Short Time Exposure In Vitro Test Method
- OECD TG 460: Fluorescein Leakage (FL) Test Method
- OECD TG 494: Vitrigel-Eye Irritancy Test (EIT) Method
- **OECD TG 496: In Vitro Macromolecular Test Method**
- OECD TG 437: Bovine Corneal Opacity and Permeability (BCOP) Test Method
- OECD TG 438: Isolated Chicken Eye (ICE) Test Method

Top-Down Approach: Start with OECD TG 437, 496, 438, or 491 if you suspect your test substance causes serious eye damage

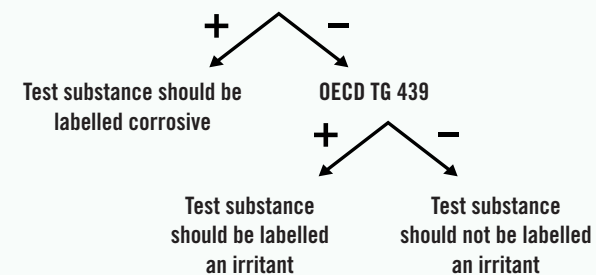


Bottom-Up Approach: Start with OECD TG 492, 494, 491, 438, 496, or 437 if you suspect your test substance is not an irritant

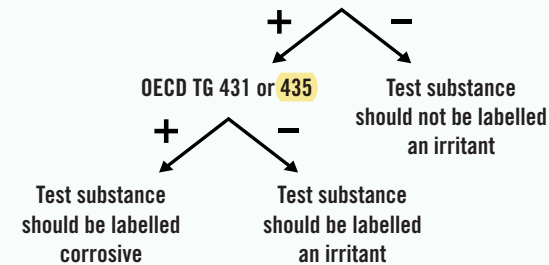


- OECD TG 439: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method
- OECD TG 431: In Vitro Skin Corrosion: Reconstructed Human Epidermis Test Method
- **OECD TG 435: In Vitro Membrane Barrier Test Method for Skin Corrosion**

Top-Down Approach: Start with OECD TG 431 or 435 if you suspect your test substance is corrosive



Bottom-Up Approach: Start with OECD TG 439 if you suspect your test substance is not corrosive



Support discrimination between skin sensitizers (GHS Cat 1) and non-sensitizers in the context of IATA using the following methods as appropriate:

- OECD TG 442C: *In Chemico* Skin Sensitisation Assays Addressing the Adverse Outcome Pathway (AOP) Key Event on Covalent Binding to Proteins
- OECD TG 442D: *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation
- OECD TG 442E: *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Activation of Dendritic Cells

NON-ANIMAL TEST METHODS

