

Alternative Approaches to Skin and Eye Testing

EYE IRRITATION AND CORROSION

Organisation for Economic Co-operation and Development (OECD). 2024. Guidance document on integrated approaches to 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. 2017. Guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation. No 203. Series on Testing and Assessment.

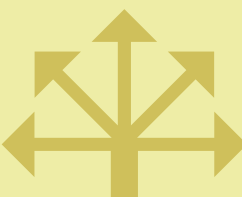
SKIN SENSITISATION

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. 2017. 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.

OECD. 2014. The adverse outcome pathway for skin sensitisation initiated by covalent binding to proteins. No 168. Series on Testing and Assessment.



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.

Defined Approaches

- OECD Test Guideline 467: Defined Approaches for Serious Eye Damage and Eye Irritation (comprising two defined approaches for liquids, a defined approach for solids, and a defined approach for surfactants)

Reconstructed Human Corneal Epithelium Models

- OECD Test Guideline 492: Reconstructed Human Cornea-Like Epithelium (RhCE) Test Method
- OECD Test Guideline 492B: Reconstructed Human Cornea-Like Epithelium Test Method for Eye Hazard Identification (SkinEthic™)
- OECD Test Guideline 494: Vitrigel-Eye Irritancy Test (EIT) Method

Organotypic *Ex Vivo* Assays

- OECD Test Guideline 437: Bovine Corneal Opacity and Permeability (BCOP) Test Method
- OECD Test Guideline 438: Isolated Chicken Eye (ICE) Test Method

Cytotoxicity and Cell Function Based *In Vitro* Assays

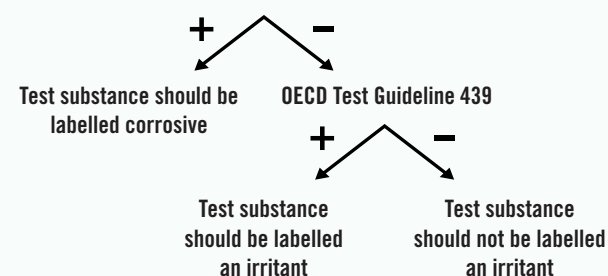
- OECD Test Guideline 460: Fluorescein Leakage (FL) Test Method
- OECD Test Guideline 491: Short Time Exposure *In Vitro* Test Method

Macromolecular Matrix Assays

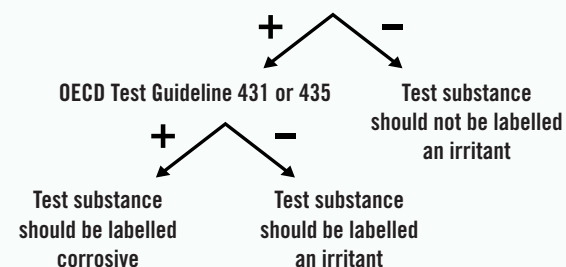
- OECD Test Guideline 496: *In Vitro* Macromolecular Test Method

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

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



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



ALTERNATIVE
TEST METHODS

