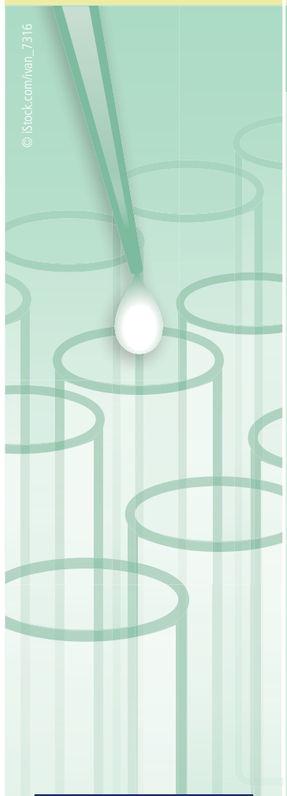
Alternative Approaches to Skin and Eye Testing

PETA SCIENCE CONSORTIUM INTERNATIONAL e.V.

	EYE IRRITATION AND CORROSION	SKIN IRRITATION AND CORROSION	SKIN SENSITISATION
REPLACEMENT STRATEGIES AND GUIDANCE	**Organisation for Economic Co-operation and Development (OECD). 2019. 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.**	**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.**	**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.**



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ALTERNATIVE TEST METHODS

Gather existing human, animal, and *in vitro* data; information on the substance's physiochemical 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.

EYE IRRITATION AND CORROSION

Defined Approaches

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

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

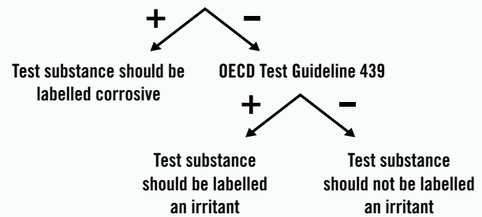
Macromolecular Matrix Assays

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

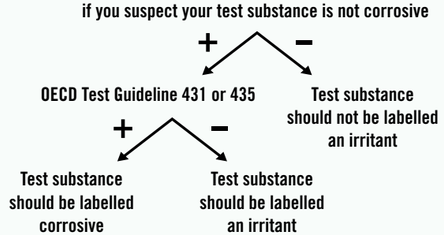
SKIN IRRITATION AND CORROSION

- 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



SKIN SENSITISATION

- OECD Guideline 497: Defined Approaches on Skin Sensitisation
- OECD Test Guideline 442C: *In Chemico* Skin Sensitisation Assays Addressing the Adverse Outcome Pathway (AOP) Key Event on Covalent Binding to Proteins
- OECD Test Guideline 442D: *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Keratinocyte Activation
- OECD Test Guideline 442E: *In Vitro* Skin Sensitisation Assays Addressing the AOP Key Event on Activation of Dendritic Cells

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For additional details on alternative testing methods and strategies, visit ThePSCI.eu/alternatives.

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