IN VITRO METHODS FOR PREDICTING SKIN IRRITATION AND CORROSION

START here if you suspect your test substance is corrosive

TOP-DOWN APPROACH OECD TG 431 or 435 STOP testing: test substance Test substance using in vitro skin should be labelled as corrosive irritation assav: OECD TG 439 STOP testing: test substance should STOP testing: test substance is be labelled as an irritant not classified as an irritant

START here if you suspect your test substance is not corrosive **BOTTOM-UP APPROACH OECD TG 439** Test substance using *in vitro* skin STOP testing: test substance is not corrosion assay: OECD TG 431 or 435 classified as an irritant STOP testing: test substance STOP testing: test substance should should be labelled as corrosive be labelled as an irritant

METHOD	PRINCIPLE OF THE TEST	RHE MODEL (IF APPLICABLE)	APPLICABILITY DOMAIN	GHS CATEGORISATION
OECD TG 439: <i>In Vitro</i> Skin Irritation: Reconstructed Human Epidermis Test Method	The test substance is applied to a three-dimensional reconstructed human epidermis (RhE) model. Following exposure and a post-exposure incubation period, the vital dye MTT is added and cell viability determined. Optional histology may also be conducted to gain further information.	 EpiSkin™ (L'Oréal, France) EpiDerm™ (MatTek, US) SkinEthic™ (L'Oréal, France) LabCyte EPI-MODEL24 (J-TEC, Japan) epiCS® (Phenion, Germany) Skin+™ (Sterlab, France) KeraSkin™ SIT (Biosolution Co, Republic of Korea) 	Applicable to solids, semi-solids, liquids, waxes, and mixtures	Discriminates skin irritants (Cat 2) from substances not classified for skin irritation (No Cat). Materials that test positive should be tested for skin corrosion (bottom-up approach).
OECD TG 431: <i>In Vitro</i> Skin Corrosion: Reconstructed Human Epidermis Test Method	The test substance is applied topically to a three-dimensional RhE model. Corrosive chemicals are able to penetrate the tissue and are cytotoxic to cells in the underlying layers. Cell viability is measured using the vital dye MTT.	· EpiSkin™ (L'Oréal, France) · EpiDerm™ (MatTek, US) · SkinEthic™ (L'Oréal, France) · epiCS® (Phenion, Germany) · LabCyte EPI-MODEL24 (J-TEC, Japan)	Applicable to solids, semi-solids, liquids, waxes, and mixtures	Discriminates non-corrosive substances from corrosive substances (Cat 1) and allows subcategorisation into 1A or 1B and 1C together. Materials that test negative should be tested for skin irritation (top-down approach).
OECD TG 435: <i>In Vitro</i> Membrane Barrier Test Method for Skin Corrosion	The test substance is applied to the surface of an artificial membrane barrier designed to respond in a manner similar to skin <i>in vivo</i> . The time taken for the test substance to penetrate the barrier predicts corrosivity.	N/A	Applicable to solids, liquids, and emulsions. Aqueous chemicals with a pH in the range of 4.5 to 8.5 may not qualify for testing.	Discriminates non-corrosive substances from corrosive substances and allows full subcategorisation into 1A, 1B, and 1C.

Additional Reading

- Organisation for Economic Co-operation and Development. 2014. New guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation. Series on Testing and Assessment, No 203.
- European Chemicals Agency, 2017. Guidance on information requirements and chemical safety assessment. Chapter R.7a: Endpoint specific guidance. Version 6.0. See R.7.2.
- PETA Science Consortium International. In vitro methods for skin irritation and corrosion testing. Training tool.