



# Dermal Corrosion Services



Leading the Field of *In Vitro* Toxicology

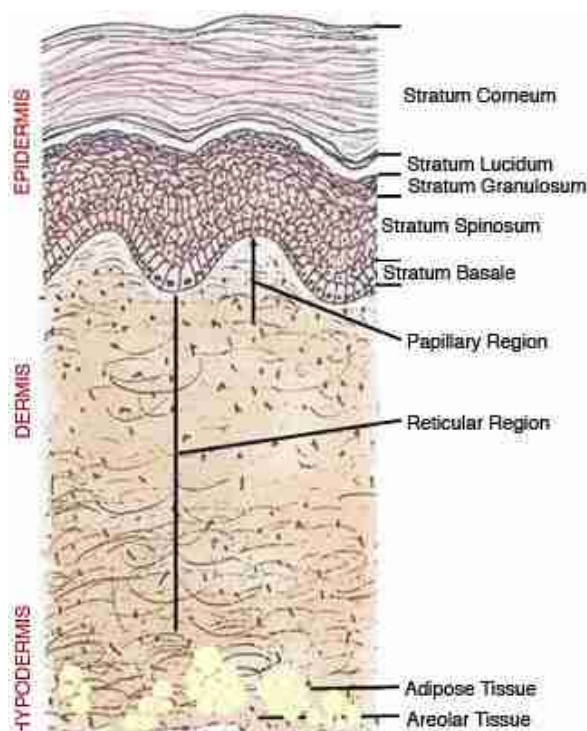
CeeTox is pleased to offer a series of assays to test for skin corrosion. These assays use 3-dimensional epithelial cell models that allow for testing of both individual ingredients and finished products. They work well for nearly all liquids, solids, semi-solids, pastes, gels, creams and waxes.

CeeTox routinely uses the SkinEthic RHE™ (SkinEthic Corporation) model and the EpiDerm™ EPI-200 (MatTek Corporation) model for dermal corrosion testing. However, we have also used many other cell models and are able to use any other model required by our clients.

As CeeTox is a GLP compliant laboratory, assays may be performed and reported in a GLP compliant manner if desired by the client.

These *in vitro* skin corrosion tests offered by CeeTox allow you to rapidly meet your regulatory and safety testing needs. These assays comply with the European Union Cosmetic Directive Amendment 7 and REACH requirements.

**Dermal corrosion** refers to localized toxic effect resulting from a topical exposure of the skin to a substance. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) defines skin corrosion as "the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance (UNECE, 2004).



Source: <http://www.lionden.com/SkinLayers.jpg>  
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The two major mechanisms of skin corrosion are the destruction (erosion or solubilization) of the skin penetration barrier (stratum corneum) including the viable skin cells underneath, and the rapid penetration of highly cytotoxic chemicals through the skin barrier without involving its destruction.

The *in vitro* skin corrosion assay uses cell viability as the primary endpoint to measure skin corrosion. It is based on the experience that corrosive chemicals show cytotoxic effects following short-term exposure of the stratum corneum of the epidermis. The test predicts and classifies the skin corrosivity potential of a chemical by assessment of its effect on a reconstituted three-dimensional human epidermis model.

Cytotoxicity of the skin cells after application of the potential corrosive is determined by the MTT assay, which measures the total activity of a cell population as determined by the ability of cellular mitochondrial dehydrogenases to reduce the vital dye MTT ([3-(4,5-Dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide, Thiazolyl blue). This correlates with the total number and/or vitality of the living cells. This colorimetric cell viability assay measures the reduction of soluble-MTT (yellow) to formazan-MTT (purple). Viable cells have the greatest amount of MTT reduction and thus the highest absorbance values.

The corrosivity potential of the test material is predicted from the relative mean tissue viabilities obtained after exposure compared to the negative control tissues concurrently treated with H<sub>2</sub>O. A chemical is classified "corrosive" if the relative tissue viability after 3 minutes exposure to a test material is decreased below 50%. In addition, those materials classified "non corrosive" after 3 minutes are classified "corrosive" if the relative tissue viability after 1 hour treatment with a test material is decreased below 15%.

In addition, an optional histology service is available to visualize the morphological changes to the models caused by the test compounds. The histological evaluation improves interpretations and reduces false negatives.

Result reporting may take three basic forms. Our standard reporting includes data charts and graphs detailing results of the assays run. A detailed report is optionally available as well. This report includes:

- Executive Summary
- Objective
- Experimental Design
- Results
- Tables and Figures
- Materials and Methods
- Appendix (if necessary)

Finally, a report complying to GLP requirements is available for those studies performed according to GLP regulations.

CeeTox has a number of corrosion assays for you to choose from.

MODEL	EpiSkin™ Skin Corrosivity Test	EpiDerm™ Skin Corrosivity Test	EpiDerm™ Combined Skin Irritation and Corrosion Test
<b>Purpose of Assay</b>	This assay assesses the corrosion resulting from a topical exposure of the skin to a substance.	This assay assesses the corrosion resulting from a topical exposure of the skin to a substance.	This assay assesses both irritation and corrosion of a test article.
<b>Cell Model</b>	The EpiSkin (SkinEthic Corporation)	The EpiDerm SIT (MatTek Corporation)	EPI-200 (MatTek Corporation)
<b>Assays Performed</b>	Solubility Assay MTT IL-1α release (optional) Histology	Solubility Assay MTT IL-1α release (optional) Histology	Solubility Assay MTT IL-1α release (optional) H&E stained histology slide (optional)
<b>Controls</b>	MTT direct reduction, water-killed (if needed), no application, 1 positive for irritation, 1 positive for corrosion, negative	MTT direct reduction, water-killed (if needed), no application, 1 positive for irritation, 1 positive for corrosion, negative	MTT direct reduction, water-killed (if needed), no application, 1 positive for irritation, 1 positive for corrosion, negative
<b>Exposure</b>	3 minutes, 1 hour, 4 hours (optional)	3 minutes, 1 hour	1 hour
<b>Incubation</b>	42 hours	42 hours	42 hours
<b>Number of Replicates</b>	3	3	3
<b>Standard Turn Around Time</b>	4 weeks from sample and tissue receipt	4 weeks from sample and tissue receipt	4 weeks from sample and tissue receipt
<b>Scientific Endorsement</b>	ECVAM	ECVAM	ECVAM
<b>International Regulatory Acceptance</b>	OECD Test Guideline 431	OECD Test Guideline 431	Draft OECD Test Guideline OECD for irritation and Test Guideline 431 for corrosion
<b>National Regional Regulatory Acceptance</b>			EU test method B.46 in COM regulation 440/2008/EC for irritation

Criteria for Corrosion

Classification	Packing Group	Criteria for <i>In Vitro</i> Interpretation
EU	Corrosive Class R35	If cell viability < 35% after 3 min exposure
	Corrosive Class R34	If cell viability > or equal to 35% after 3 min exposure and < 35% after 4 hours
	Non-Corrosive	If cell viability > or equal to 35% after 4 hours

References:

NIH Publication No: 02-4502. (2004) ICCVAM Review of *In Vitro* Dermal Corrosivity Methods, p. 59. from <http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg430.pdf>

United Nations-Economic Commission for Europe (UNECE) (2004). Globally Harmonised System of Classification and Labelling of Chemicals (GHS). UN, New York and Geneva, from <http://www.unece.org/trans/danger/publi/ghs/ghs.html>

