In Vitro Dermal Corrosion Assay

Need

Assessing the risk of dermal corrosion, or the production of irreversible damage of the skin following the exposure to a substance or mixture, is a primary consideration in determining the safety of topical drugs, chemicals or cosmetics as well as in the cases of accidental exposures to chemicals, formulations, and other products.

Dermal corrosion testing combined with dermal irritation testing can provide full UN GHS categorization of the chemical.

Solution

LifeNet Health offers chemical testing services with the validated EpiDerm™ Skin Corrosion Test (SCT) for the assessment of potential dermal corrosion of client's test articles, operating in full compliance with the OECD 431 guideline. The health of the dermal tissue is assessed by measuring tissue viability immediately following exposure.





times





Testing Parameters

ASSAY PARAMETERS	PROTOCOL
Model	MatTek EpiDerm™ (EPI-200)
Replicates	3
Test Article Formulation	Liquid/Solid (tested neat or as provided)
Negative Control	Deionized sterile water
Positive Control	8N Potassium hydroxide (KOH)
Exposure Time	30 minutes (liquid test articles) and/or 6 hours (solid test articles)
Post Exposure Recovery	none
Viability Assessment	MTT
Time to Complete	4 weeks from study initiation
Regulatory	Non-GLP or GLP
Deliverables	Full Report including Tissue Viability, UN GHS classification (full classification may only be possible with follow-up study (OECD 439)



Additional Information

TISSUE VIABILITY (% NEGATIVE CONTROL)	UN GHS CATEGORIZATION
< 25% after 3 min exposure	Corrosive (Subcategory 1A)
< 50% after 3 min exposure	Corrosive (Subcategory 1B or 1C)
≥ 50% after 3 min exposure AND < 15% after 60 min exposure	Corrosive (Subcategory 1B or 1C)
≥ 50% after 3 min exposure AND ≥ 15% after 60 min exposure	Non-corrosive

Table 1. Irritancy categorization based on tissue viability after exposures and post-exposure recovery.