In Vitro Dermal Irritation Assay

Need

Assessing the risk of dermal irritation, or the production of reversible 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 irritation testing combined with dermal corrosion testing can provide full UN GHS categorization of the chemical.

Solution

LifeNet Health offers chemical testing services with the validated EpiDerm™ Skin Irritation Test (SIT) for the assessment of potential dermal irritation of client's test articles, operating in full compliance with the OECD 439 guideline. The health of the dermal tissue is assessed by measuring tissue viability immediately following exposure and a post-treatment incubation period.

Accurate & reliable data

Fast turnaround times

OECD method-based studies

Collaborative approach

Testing Parameters

ASSAY PARAMETERS	PROTOCOL
Model	MatTek EpiDerm™ (EPI-200)
Replicates	3
Test Article Formulation	Liquid/Solid (tested neat or as provided)
Negative Control	DPBS
Positive Control	5% solution of sodium dodecyl sulfate (SDS)
Exposure Time	60 minutes (first ~35 minutes of the exposure at 37°C with 5% CO2 in a humidified incubator, and the final ~25 minutes at room temperature
Post Exposure Recovery	42 hours
Viability Assessment	MTT
Time to Complete	3-4 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 431)

LifeNet Health® LifeSciences

Talk with one of our experts for help with general inquiries, protocol details, or becoming a new client.

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TISSUE VIABILITY (% NEGATIVE CONTROL)	UN GHS CATEGORIZATION
≤ 50%	Requires Classification and labelling UN GHS (Category 2 or Category 1)
> 50%	Non-Irritant (UN GHS No Category)

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