

COSMETICS

Skin Irritation according to OECD TG439

The SkinEthic™ reconstructed human tissue models RHE is a tissue construct featuring normal ultra-structure and functionality similar to human tissue *in vivo*. These models with a appropriate protocol are designed for regulatory purposes to classify and label chemicals regarding *in vitro* skin irritation assessment^{1,2}.

Test system: Reconstructed Human Epidermis (SkinEthic™).

Experimental number: Three tissues per group in duplicate.

Reference Item: Sodium lauryl sulfate (SDS).

Main Read-outs:

Absorbance of MTT (570 nm)³.

Validation Data

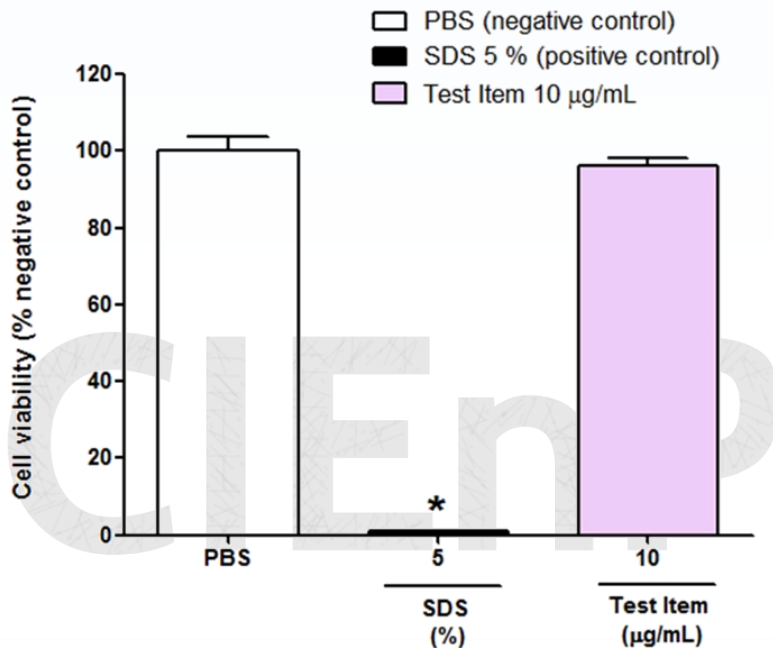


Figure: Skin irritation evaluation according to OECD TG439. The figure represents cell viability after SDS (5 %) incubation or Test item (10 µg/mL) incubation. Each column represents the mean ± SD of 3 tissues per group in duplicate. Statistical analyses used was one-way ANOVA with a post-hoc Newman-Keuls. *P < 0.05 versus negative control group (PBS).

To avoid bias and to allow reproducibility and reliability of all *in vitro* experiments we follow the “Guidance on Good Cell Culture Practice”⁴.

References:

- ¹A catch-up validation study on reconstructed human epidermis (SkinEthic™ RHE) for full replacement of the Draize skin irritation test. N. Alépée, N *et al.* Toxicology In Vitro, 24: 257-266, 2010.
- ²OECD Test N° 439: In vitro skin irritation reconstructed human epidermis Test method. 2015.
- ³Mosmann T. Rapid colorimetric assay for cellular growth and survival: application to proliferation and cytotoxicity assays. J Immunol Methods. 1983 Dec 16;65(1-2):55-63.
- ⁴Coecke S; Balls M; Bowe G; Davis J; Gstraunthaler G, Hartung T, Hay R, Merten OW, Price A, Schechtman L, Stacey G, Stokes W. Guidance on good cell culture practice: a report of the second ECVAM task force on good cell culture practice. Altern Lab Anim. 2005, 33(3):261-87.