# Applicability of EpiDerm<sup>™</sup> model to assess skin irritation potential of cosmetics

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#### Introduction

According to the recent legislation, the manufacturer of a cosmetic product is obliged to conduct a safety assessment of the product being introduced to the market. Evaluation of the skin irritancy potential of cosmetic formulations and ingredients is a necessity in the safety assessment of cosmetic products. *In vitro* tests for skin irritating properties are performed on models of the epidermis. EpiDerm<sup>TM</sup> – based skin irritation testing is formally validated as a alternative method in the European Union.

The objective of this work was to test EpiDerm<sup>™</sup> as *in vitro* screening model to characterize the irritancy of selected cosmetic formulation: a shampoo.

## Material and methods

*In vitro* skin irritation test on EpiDerm<sup>™</sup> -200 was performed using two different protocols: 1.IN VITRO EpiDerm<sup>™</sup> SKIN IRRITATION TEST (EPI-200-SIT) for use with MatTek Corporation's Reconstructed Human Epidermal Model EpiDerm (EPI-200) and 2. MTT Effective Time-50 (ET-50) protocol developed at MatTek Corporation. The major differences between protocols comprise: doses of test materials, exposure times and data interpretation procedure.



A rinse-off cosmetic formulation (shampoo) was tested in order to assess its in vitro skin irritation potential.



reflect their *in vivo* cosmetic application – the exposure time should be less than 60 minutes.



ET-50 = 4-12 hrs — moderate to mild ET-50 = 0,5-4 hrs — moderate ET-50 < 0,5 hrs— strong/severe, possible corrosive Our study showed that *in vitro* testing of the irritation potential over multiple time points (e.g. 2, 5, 18h) and ET-50 calcultation seems to be more sensitive tool than single time point (42hrs) protocol 1. Therefore MTT Effective Time-50 (ET-50) protocol is suitable for use in formulation development process.

### Conclusions

- EpiDerm<sup>TM</sup> in vitro tests can be utilized as a valuable tool in evaluating dermal irritation prior to dermatological tests.
- We are in line with recent MatTek recommendation which suggests that ECVAM-validated EpiDerm<sup>™</sup> SIT method is useful for hazard identification whereas MTT Effective Time-50 (ET-50) protocol is suitable for use in formulation development process.
- Further studies are required to adapt the human epidermis model EpiDerm™ to predict *in vivo* skin irritation of different cosmetic formulations.

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