# EpiDerm<sup>TM</sup> model for dermal irritancy testing of cosmetics - comparison of two skin irritation protocols

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## Introduction

A model of the human epidermis, EpiDerm<sup>TM</sup>, developed at MatTek Corporation, is based on neonatal, foreskin-derived normal human epidermal keratinocytes (NHEK). EpiDerm<sup>TM</sup> allows application of cosmetic products (liquid and solid) directly to the *stratum corneum* of this air-lifted, highly differentiated culture. The objective of this work was to evaluate EpiDerm<sup>TM</sup> as a preclinical screening model to characterize the irritancy of cosmetic formulation.

## Material and methods

*In vitro* skin irritation test on EpiDerm<sup>™</sup> -200 was performed using two different protocols. Both tests are based on the measuring of the reduction of tissue viability using MTT endpoint. The differences between these two methods comprises: doses of test materials, exposure times and data interpretation procedure.

## Protocol I

Standard Operating Procedure evaluated in European Centre of the Validation of Alternative Methods (ECVAM) Skin Irritation Validation Study - *In vitro Skin Irritation Test: Human Skin Model, EpiDerm-200; version 5:0, Oct 2004* 



## Protocol 2

MTT Effective Time-50 (ET-50) protocol for use with EpiDerm<sup>TM</sup> (EPI-200) MTT kit (MTT-100), MK-24-007-0001 09/06/05) developed at MatTek Corporation.



ET-50 (hours) = 12-24 – very mild ET-50 (hours) = 24 – non-irritating

ET-50 (hours) = 4-12 – moderate to mild

% viability = 100 x [OD (sample)/OD(negative control) ET-50 (hours) – the time at which the % viability has dropped to 50%

#### **Tested dermocosmetics:**

I. Kids Gentle Face Cream. 2. Kids Soothing Creamy Cleansing Gel. 3. Gentle Cleasing Foam

### Results

Our results of the studies performed according to ECVAM protocol demonstrated that this protocol could be useful in the preliminary study of the potential of dermal irritation.

Fig.2. Evaluation of the irritation potential of dermocosmetics



% viability = 100 x [OD (sample)/OD(negative control)

Tested dermocosmetics: I. Kids Gentle Face Cream. 2.Kids Soothing Creamy Cleansing Gel. 3. Gentle Cleasing Foam

## Results

Our preliminary results showed that the method developed by MatTek Corporation is a sensitive tool to predict skin irritancy after skin care products application.

Fig.1. Evaluation of the irritation potential of dermocosmetics



product number

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Tested dermocosmetics: Product I – tissue viability = 95% - non irritating Product 2 – tissue viability = 99% - non irritating Product 3 – tissue viability = 103% - non irritating Tested dermocosmetics: Product I – ET-50 > 24h - non irritating Product 2 – ET-50 = 9h - moderate to mild Product 3 – 7,5h = 7,5h - moderate to mild

## Conclusions

EpiDerm<sup>TM</sup> in vitro tests can be utilized as an alternative to the use of animals in evaluating dermal irritation prior to clinical tests. Further studies are required to adapt the human epidermis model EpiDerm<sup>TM</sup> to predict *in vivo* skin irritation of cosmetics. According to ECVAM protocol the sensitivity of this method could be increased by measuring the interleukin-I $\alpha$  release.

