

Poster: skin models as alternatives to animal testing

## ***In vitro* acute skin irritancy of 184 cosmetic ingredients using the validated EPISKIN model protocol**

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Following considerable interest in the development of *in vitro* model substitutes, reconstructed human skin or epidermis available as standardized kits, allow the measurement of parameters linked to the safety of topically applied products. Able to mimic *in vivo* situation, the reconstructed human epidermis EPISKIN was involved in the ECVAM acute skin irritancy validation and has been officially validated as full replacement method by the ESAC in May 2007 (ESAC statement, 2007).

The validated protocol is based on a short treatment time (15 minutes) followed by an extended 42 hours post treatment incubation period. Using viability measurement (MTT assay) (Mosmann et al., 1983) and IL1 alpha release, appropriate cut-off value allowed the drawing up of 2 chemical classes: Irritants (R38 EU risk phrases) and Non Irritant (EU Risk phrases: Non Classified) (Spielmann et al., 2007; Cotovio et al., 2005). Applied to a set of 184 industrial ingredients of diverse physical-chemical categories, sensitivity, specificity and accuracy of the defined predictive model were 85%, 86% and 86%, respectively. These results confirmed the validation performances and demonstrated the usefulness of the tiered strategy MTT + IL1 alpha as a decision making tool for skin irritancy hazard identification. The EPISKIN model is currently used in basic and screening studies of large number of chemical ingredients. The aim is to assess the real performances and usefulness of the *in vitro* methods in order to concretely determine the applicability domains and the remaining gaps acknowledging the fact that the industry is facing a wide chemical-physical diversity of ingredients.

### **References**

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