



***In vitro* topical toxicity testing in line with requirements of EU and US regulators:  
reconstructed human tissue models**

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The potential for substances to cause effects such as corrosion or irritation to skin and eye is a concern of industrial toxicologists in their assessments of possible worker and consumer safety issues. Moreover, national and international regulatory agencies (e.g. ECA, EPA, US DOT), require that substances are labelled as to the toxicity potential to skin or eye. To prevent the unnecessary use of animals for the above-mentioned purposes, EU as well as US regulations recommend the use of alternative tests methods "whenever appropriate and feasible". Since reconstructed human tissue (RHT) models closely mimic native tissues, they can be used for reliable estimation of hazard (and in some cases also risk) related to human health. Tests with RHT models for topical toxicity testing are cost-effective and deliver faster and more reproducible results than many of the traditional *in vivo* assays. Another advantage of the commercially available RHT models is that their characteristics can be precisely controlled by established Quality Assurance procedures to insure long-term reproducibility, which is important in the regulatory toxicology (Rispin et al., 2006).

RHT-based assays for skin corrosion and skin irritation testing are validated, moreover, skin corrosion test with RHT models has reached full regulatory acceptance at the OECD level as OECD TG 431: The Human Skin Model Test. A number of *in vitro* RHT-based methods have completed pre-validation testing (photo-toxicity, eye irritation, genotoxicity) or are ready to enter the pre-validation process in the near future. They enable testing without excessive need for laboratory animals, which is of great importance for REACH as well as for EU cosmetic legislation. This presentation will describe currently available RHT-based assays for topical toxicity testing (with discrimination between risk and hazard). Approaches to the development, validation and implementation of these assays into regulatory systems and testing strategies will be discussed.

**References**

Rispin et al. (2006). *Regul. Toxicol. Pharmacol.* 45 (2), 97-103.

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