

Compatibility Testing *In Vitro*: A Comparison with *In Vivo* Patch Test Data

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Abstract

For safety reasons cosmetic formulations have to be assessed for putative side effects like skin irritation. The human patch test is an appropriate method for this type of assessment, but it cannot be used for the higher throughput needed for screening innovative formulations and a distinct assessment is often difficult.

The aim of this study was therefore to investigate the feasibility of using an *in vitro* approach for compatibility testing to determine the irritancy of surfactants. Test samples were provided by the German Society of Cosmetic Chemists (DGK), which conducted a human patch test study with the same set of samples in parallel. This gave us the unique opportunity to correlate *in vitro* with *in vivo* data.

To assess irritant effects *in vitro*, reconstructed human epidermis was exposed to seven coded test samples consisting of individual anionic surfactants, blends of surfactants, and controls. A *multiple endpoint analysis* was established comprising the viability, cytotoxicity, histology, cytokine release and differential gene expression. Using this test strategy, a very good correlation was determined for our *in vitro* assessment of compatibility with a theoretical ranking and the human patch test data.

Keywords: Alternatives to animal testing, compatibility testing, cytokine, human risk assessment, multiple endpoint analysis, reconstituted human epidermis, skin irritation

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