

IN VITRO MODELS FOR ASSESSING SKIN IRRITATION POTENTIAL

Hayden, Patrick J.¹; Kubilus, Joseph¹; Ayehunie, Seyoum¹; Kaluzhny, Yulia¹; Klausner, Mitchell¹

1. MatTek Corp., Ashland, MA, USA.

In vitro models for assessing skin irritation include submerged monolayer cell cultures (e.g. mouse 3T3 cells or human keratinocytes), as well as differentiated 3-D human epidermal (partial-thickness) or epidermal/dermal (full-thickness) skin equivalents cultured at the air-liquid interface. Submerged monolayer cultures may be useful for irritation screening in some instances, and have been validated for applications such as phototoxicity. However, submerged cultures do not adequately model the physiologic and biochemical properties of differentiated epithelial tissues, and do not allow for topical application of water insoluble materials. Endpoints for submerged monolayer culture assays include cell viability (e.g. neutral red assay) or cytokine release (e.g. IL-1a, IL-8, TNFa). 3-D human skin equivalents cultured at the air-liquid interface offer differentiated properties including barrier function (i.e. stratum corneum) and Phase I/II drug metabolizing enzyme activity, and allow for more realistic in vivo-like treatment options, including topical application of creams, lotions and other water insoluble treatments. Endpoints may be culture viability, cytokine release or histological evaluation as well as more recent genomic and proteomic technologies. Ongoing validation programs for skin irritation with 3-D skin equivalents have shown promising correlation with in vivo results.

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