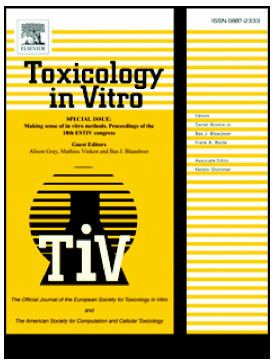

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Pre-validation of an in vitro Skin Irritation Test for Medical Devices Using the Reconstructed Human Tissue Model EpiDerm™

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ABSTRACT

Assessment of dermal irritation is an essential component of the safety evaluation of medical devices. Reconstructed human epidermis (RhE) models have replaced rabbit skin irritation testing for neat chemicals and their mixtures (OECD Test Guideline 439). However, this guideline cannot be directly applied to the area of medical devices (MD) since their non-toxicity assessment is largely based on the testing of MD extracts that may have very low irritation potential. Therefore, the RhE-methods previously validated with neat chemicals needed to be modified to reflect the needs for detection of low levels of potential irritants.

A protocol employing RhE EpiDerm was optimized in 2013 using known irritants and spiked polymers (Casas et al., TIV, 2013). In 2014 and 2015 MatTek In Vitro Life Science Laboratories (IVLSL) and RIVM assessed the transferability of the assay. After the successful transfer and standardization of the protocol, 17 laboratories were trained in the use of the protocol in the preparation for the validation. Laboratories produced data with 98 % agreement of predictions for the selected references and controls.

We conclude that a modified RhE skin irritation test has the potential to address the skin irritation potential of the medical devices. Standardization and focus on the technical issues is essential for accurate prediction.