



Long Term Reproducibility of EpiDerm™, an Epidermal Model for Dermal Testing and Research

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ABSTRACT

An in vitro model of human epidermis, EpiDerm (EPI-200), cultured from normal human epidermal keratinocytes has been sold by MatTek Corporation since 1993. Weekly lots of EpiDerm are produced for dermal irritancy, product efficacy, percutaneous absorption, pharmacological, and basic skin research studies.

In 2000 and 2002, respectively, European and US regulators approved the use of EpiDerm to assess the skin corrosivity of chemicals. Validation studies utilizing EpiDerm for phototoxicity and skin irritation are currently underway.

For commercial and regulatory purposes, models must be reproducible within a given lot and between lots, especially over extended periods. Regulators and end users need assurance that the in vitro models will provide consistent, good quality data during the validation process and over time.

To address tissue reproducibility, quality control (QC) testing of each EpiDerm lot involves both a positive (1% Triton X-100) and a negative control (water). Using the MTT assay, which historically has been the endpoint of choice for European and US regulators, a dose response curve is constructed and the exposure time that reduces the tissue viability to 50% (ET-50) is interpolated.

The yearly average ET-50 since 1996 has varied from 6.2 hr (2003) to 7.5 hr (1998). The coefficients of variation (CV) for the negative control averaged under 7%; the average CV for all tissues has never exceeded 12%.

Over the past 10+ years of commercial production, EpiDerm has remained a highly reproducible, stable toxicological model that is ideally suited for industrial and regulatory toxicology and other skin related studies.

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