Performance Standards for the Use of In Vitro Tissues in a Regulated Environment

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In vitro skin models are being proposed as alternatives to animal testing for safety evaluation of cosmetics, consumer products, and Pharmaceuticals. Methods currently validated or in the validation process utilizing the EpiDerm™ skin model (EPI-200) include protocols for skin corrosion, irritation, and genotoxicity. For instance, EpiDerm skin irritation data utilizing the MTT assay resulted in 100% sensitivity and 60% specificity versus human patch test (HPT) results while rabbit tests gave 100% sensitivity and 50% specificity versus HPT results (n=25 materials). Likewise, data from the EpiDerm micronucleus assay for genotoxicity correctly predicted 13 genotoxins and 4 non-genotoxins. However, for these and other assays to be used in a regulated environment, it is important to know that the tissues models are reproducible both during and following the validation process (K. Gupta et al., Regul Toxicol Pharmacol. 2005 Dec;43(3):219-24). The current poster summarizes the long-term reproducibility and performance of EpiDerm (EPI-200) against benchmark chemical treatment. Quality control testing of weekly batches of EpiDerm was performed using the MTT assay. The exposure time needed to reduce the viabilityto 50% (ET-50) for 1% Triton X-100 was determined. The coefficients of variation (CV) for the negative control tissue (exposed to ultrapure H2O) have averaged below 7.5% for every year since 1997. In addition, the yearly average ET-50 values have ranged from 6.0 hrs to 7.5 hrs. A reproducible ET-50 is indicative of constant barrier properties which are important in determining the exposure of a chemical following dermal exposure. These results over the past 11 years of commercial production are designed to address regulatory concerns regarding performance standards over time.

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