

LONG TERM REPRODUCIBILITY OF EPIOCULAR™, A THREE-DIMENSIONAL TISSUE CULTURE MODEL OF THE HUMAN CORNEAL EPITHELIUMM. Klausner¹; J. Sheasgreen¹; J. Kubilus¹; P. Hayden¹

1. MatTek Corporation, Ashland, MA, USA.

The EpiOcular tissue model (OCL-200) is an organotypic model of the human corneal epithelium (HCE) cultured from normal human keratinocytes using serum free medium. Paraffin embedded, H & E stained histology cross-sections show the structure of EpiOcular closely parallels that of the HCE; large nucleated basal cells lie beneath 5-6 stratified cell layers which progressively flatten out, ending with a highly squamous, non-keratinized layer at the tissue's apical surface. Since commercial introduction in 1995, EpiOcular has been increasingly used by many personal care and household product companies to determine the ocular irritancy of their products without using animals. Currently, validation of the EpiOcular model as a replacement for the Draize rabbit eye test is underway in the US. In addition, a validation study sponsored by ECVAM is scheduled to begin in 2005. For commercial and regulatory purposes, it is very important to know that the model is reproducible both within a given lot and between lots, especially over extended periods. Quality control of weekly batches of EpiOcular is performed using the MTT assay, which historically has been the in vitro endpoint of choice for European and US regulators. The exposure time needed to reduce the viability to 50% (ET-50) for 0.3% Triton X-100 is determined. Yearly average ET-50 values have ranged from 20.6 minutes (2000) to 25.0 minutes (1998). The coefficients of variation (CV) for the negative control tissue (exposed to ultrapure H₂O) have averaged under 6% for every year since 1997. In addition, the yearly average CV for all tissues has never exceeded 6.5%. These results over the past 8 years of commercial production show EpiOcular to be a highly reproducible, stable toxicological model that is ideally suited for industrial and regulatory ocular irritancy studies.

ID# 2002**Location: Ballrooms A & B****Time of Presentation: Mar 10 8:30 AM - 11:30 AM****Category: Alternatives to Mammalian Models, (Safety Evaluation)**