



## **Expanded Applicability Domain for Assessing Ocular Irritation Using EpiOcular™ human corneal tissue model**

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The EpiOcular tissue model (OCL-200) is an organotypic model of the human corneal epithelium (HCE) cultured from normal human keratinocytes. Paraffin embedded, histological cross-sections show the structure of EpiOcular closely parallels that of the HCE. Quality control of weekly EpiOcular batches 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. Since 1997, yearly average ET-50 values have ranged from 20.6 minutes to 25.0 minutes with average coefficients of variation under 7%. Thus, EpiOcular has demonstrated long term reproducibility over the past 10 years. This is important since regulators require that test methods provide consistent data during and after the validation process.

EpiOcular has been increasingly used by many personal care and household product companies to determine the ocular irritancy of their products without using animals. In particular, EpiOcular has been very useful for evaluating water soluble and low irritancy materials. Currently, a new protocol to handle industrial chemicals spanning a range of chemical categories and irritancies has been developed. 41 materials including alcohols, hydrocarbons, amines, esters, and ketones have been evaluated. Using a straightforward MTT tissue viability protocol, a prediction model for discriminating between ocular irritants and non-irritants was developed which resulted in 100% sensitivity and 63% specificity. This new protocol will prove very useful in fulfilling the provisions of REACH (Registration, Evaluation, and Authorization of Chemicals) in the EU.

**Keywords:** EpiOcular, ocular irritation, REACH, MTT

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