

### **Testing of the EpiOcular™ Tissue Model Following Extended Shipping Times**

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The EpiOcular tissue model has been commercially available since 1996 and is used extensively by companies to evaluate the ocular irritancy of new formulations and products. Functional quality control (QC) tests involve determination of the exposure time that reduces tissue viability to 50% (ET-50) following exposure to Triton X-100 (0.3%). These QC tests show a high level of intra-lot reproducibility and long term inter-lot stability of the tissue model. Coefficients of variation (CV) in the standardized QC assay average < 7% and the yearly average ET-50 has ranged from 22.0 – 27.3 minutes over the period 1996-2007. Recently, a new ocular irritancy protocol has been developed which extends the domain of applicability to a broad variety of organic chemicals. The assay protocol was tested extensively in a European Cosmetic, Toiletry and Perfumery Association (Colipa) sponsored pre-validation study and will enter formal validation early in 2009. The current study investigated QC testing results following the extended times required for shipment of the tissue from the US to Japan.

Over a 12-month period, 22 independent lots of EpiOcular tissue were shipped to Kurabo Industries (Osaka, Japan), an EpiOcular distributor. Standardized QC testing was performed 4-6 days later by Kurabo with the following results: ET-50 = 23.2 +/- 4.1 min (n = 22 tissue lots). All tissue lots tested within the QC acceptance range of 12.2 min < ET-50 < 37.5 min and compared favorably with the 1996 average ET = 24.9 +/- 6.3 minutes (upon which QC acceptance criteria are based). These results demonstrate successful shipment of EpiOcular and establish the feasibility of transfer of the in vitro ocular irritation assay to Japan and other venues requiring elongated shipping times.

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