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Abstract-Title:

EpiOcular tissue model protocols for 1) REACH ocular irritation screening and 2) ultra-mild eye care cosmetics

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Abstract-Text:

Purpose: In vitro tests for assessing ocular irritancy of consumer/household product chemical ingredients are urgently needed to comply with EU legislation such as the 7th amendment of the Cosmetics directive and the Reach directive. Eye care cosmetics (ECC) also need to be non-irritating (i.e. "ultra-mild") in order to be successful in the marketplace. This poster summarizes 2 different protocols that have been developed for use with the in vitro EpiOcular tissue model in order to accommodate both purposes

Methods: For Reach irritation testing, a single exposure period is used: 30 minutes with a 2-hour post-exposure incubation (liquids) or 90 minutes with 18-hour post-exposure incubation (solids). A single cut-off in relative survival is used for classification: $\leq 60\%$ = irritant (I) (R36 and R41); $>60\%$ = non-classified (NC). Tissue viability is determined by MTT assay. For ultra-mild testing, exposure times between 8 and 24 hours are used, and tissue viability (ET-50) is also determined by MTT assay. **Results:** For irritation screening of chemicals, 99.7% agreement in prediction (NC/I) was obtained from 298 independent trials across seven laboratories (Harbell et al, *The Toxicologist* 108(1), 2009). For ultra-mild testing of 10 mascaras, a range of ET-50s was obtained from 8.7 hours to > 24 hours. Other formulations with low levels of surfactants known to be irritating at higher concentrations could also be discriminated by ET-50s. Thus, the EpiOcular model appears to function well for both chemical testing for REACH purposes, as well as ultra-mild screening of ECCs and other materials.