



**Use of the EpiOcular tissue model for testing of ultra-mild eye care cosmetics.**

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Eye care cosmetics (ECC) need to be non-irritating in order to be successful in the marketplace. In addition, in order to avoid complaints by customers with sensitive eyes, many ECCs are formulated to be ultra-mild. However, testing of, and discrimination between ultra-mild formulations is difficult since traditional Draize rabbit eye testing is insensitive to the low levels of irritation caused by ECCs. Furthermore, animal testing is not possible due to animal rights concerns and due to current European legislation banning cosmetics that have been tested using animals. Human clinical testing can be performed but because only a low level response is expected, large numbers of subjects would be necessary and hence testing costs would be high if not prohibitive. Cells in monolayer culture could be used for testing however the test materials would need to be dissolved in aqueous media which for many non-water soluble cosmetics is not possible. The current study investigated use of the organotypic EpiOcular tissue model as a means of discriminating between ultra-mild formulations.

Ten (10) commercially available mascara products were purchased and tested using EpiOcular with an extended time exposure protocol. Because the tissue model is cultured at the air-liquid interface (apical tissue surface left dry), both water soluble and water insoluble test materials could be applied neat to the apical tissue surface. Exposure times between 8 and 24 hours were used after which the tissue viability was determined using the MTT assay. Dose response curves were constructed and the exposure time that reduces tissue viability to 50% (ET-50) was determined by mathematical interpolation. For the 10 mascaras tested, a broad range of ET-50s was obtained from 8.7 hours to > 24 hours. Other studies with low levels of surfactants known to be irritating at higher concentrations could also be discriminated by ET-50s. As such, the extended time exposure protocol appears to be a facile, cost effective means to screen ultra-mild ECCs and other materials.

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