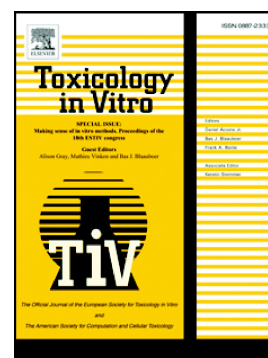


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SkinEthic™ HCE Eye Irritation Test: similar performance demonstrated after Long Distance Shipment and Extended Storage Conditions

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Abstract

Assessment of ocular irritation risk is an international regulatory requirement in the safety evaluation of products. In response to this need, L'Oréal developed the SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Test (EIT) that has been included in OECD Test Guideline 492. SkinEthic™ HCE EIT is able to correctly and reliably identify chemicals not requiring classification versus labelling for eye irritation or serious eye damage according to UN GHS. In an effort to promote its global use, the performance of the method was evaluated after long-distance shipment and compared to European shipment conditions. Results obtained by Cosmos Technical Center (Japan) after extended tissues transit were compared to results obtained in L'Oréal (France). Thirty-nine out of 40 blinded chemicals, representing different functional chemical classes, were consistently classified in both laboratories. The SkinEthic™ HCE EIT test method was also evaluated for its performance after extended storage of the tissues. The performance was in agreement with the values reported in OECD TG 492, with an overall accuracy of 87.1% (based on 119 chemicals), sensitivity of 95.5% and specificity of 73.5%. The reliability and relevance of SkinEthic™ HCE EIT test method after long-distance shipment and extended storage remain in agreement with regulatory validation criteria.

List of abbreviations

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