Evaluation report on a Reconstructed Human Cornea-Like Epithelium Test Method: The SkinEthic™ Human Corneal Epithelium Eye Irritation Test

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Abstract

The Reconstructed Human Cornea-like Epithelium (RhCE) test method is a means of evaluating the eye irritation potential of chemicals by measuring the cytotoxicity induced in a RhCE tissue construct and has been adopted as OECD (Organisation for Economic Co-operation and Development) TG (Test Guideline) No. 492 for use in a bottom-up approach to identifying chemicals not requiring classifica-tion and labelling for eye irritation or serious eye damage in accordance with UN GHS (United Na-tions Globally Harmonized System of Classification and Labelling of Chemicals).

The SkinEthic™ Human Corneal Epithelium Eye Irritation Test (SkinEthic™ HCE EIT) is a RhCE test method that has been included in TG 492 as the Validated Reference Method. This report includes an overview of the test method based on the SkinEthic™ HCE EIT validation study report, peer review report, and related documentation as well as an opinion from the JaCVAM Ocular Irrita-tion Testing Editorial Committee.

A validation study in which 60 liquid and 60 solid chemicals were tested at three laboratories was conducted to confirm the reliability and accuracy of the SkinEthic™ HCE EIT. The test chemicals were tested three times at each laboratory. The results showed a sensitivity of 98.3%, a specificity of 69.4%, and an overall accuracy of 84.8% for liquid test chemicals as well as a sensitivity of 92.2%, a specificity of 76.6%, and an overall accuracy of 84.4% for solid test chemicals. There were no signifi-cant concerns regarding transferability, and both within-laboratory and between-laboratory reproduci-bility were 85% or better. These values satisfied the criteria established by the validation management team for accuracy and reproducibility.

The Committee concluded that the SkinEthic™ HCE EIT is suitable for use in a bottom-up approach to identifying chemicals not requiring classification and labeling under UN GHS.