

Evaluation Report on the Reconstructed Human Cornea-like Epithelium Test Method

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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 cytotoxicity induced in the RhCE tissue construct. This test method was adopted as a means for identifying chemicals not requiring classification and labeling under UN GHS by the OECD as Test Guideline No. 492 in 2015 after a joint validation by EURL ECVAM and Cosmetics Europe.

The JaCVAM Ocular Irritation Testing Editorial Committee has prepared a summary of the test itself and the opinions of the Committee, based on the validation report, peer review report, and other documentation related to the RhCE test method using EpiOcularTM, as described in TG 492.

The RhCE test using EpiOcularTM has an overall accuracy of 79.7%, false positive rate of 37.0% and false negative rate of 4.3%, when compared to the Draize rabbit eye test data. There were no significant concerns regarding transferability, and both within-laboratory and between-laboratory reproducibility were 90% or better. Each of these values satisfied the acceptance criteria established by the validation management team.

The Committee concluded that the RhCE test method is usable to identifying chemicals not requiring classification and labeling under UN GHS in a Bottom-Up approach.