Evaluation Report on an Alternative Test Method for Ocular Irritation: Short Time Exposure *In Vitro* Test Method

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Abstract

The Short Time Exposure In Vitro Test Method (STE) is a means of assessing eye irritation potential by measuring the cytotoxicity of chemical substances applied to cultured rabbit corneal epithelial cells. Based on the results of a validation study that assessed the usefulness of the STE for identifying UN (United Nations) GHS（Globally Harmonized System of Classification and Labelling of Chemicals）Category 1 chemicals in a top-down approach as well as for identifying UN GHS Not classified chemicals in a bottom-up approach, the STE was formally adopted by the OECD in 2015 as Test Guideline 491. This report provides a brief summary on the STE and presents the opinions of the JaCVAM Ocular Irritation Testing Editorial Committee based on published documentation, including the ICCVAM/NICEAT^{M}

When compared with results obtained using the Draize rabbit eye test, results from the STE yielded a concordance of 83.2%, a false-positive rate of 1.2%, and a false-negative rate of 51.3% in a top-down approach as well as a concordance of 84.6%, a false-positive rate of 19.3%, and a false-negative rate of 12.3% in a bottom-up approach. When the results from test chemicals that fall outside its applicability domain are excluded, the STE yields a concordance of 90.2%, a false-positive rate of 18.8%, and a false-negative rate of 1.9% in a bottom-up approach. There were no concerns regarding method transfer or intra- and inter-laboratory reproducibility.

When used in conformance with TG 491, we consider the STE to be a useful means of identifying UN GHS Category 1 chemicals in a top-down approach as well as for identifying UN GHS No Category chemicals in a bottom-up approach.

Keywords*: alternative method, GHS, ocular irritation, SIRC cell, STE*