JaCVAM statement on the SkinEthic™ HCE TTT, an alternative method for evaluating eye irritation

At a meeting held on 12 December, 2023 at National Institute of Health Sciences (NIHS) in Tokyo, Japan, the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

Proposal: This test method has high technological transferability and within- and between-laboratory reproducibility. Regarding predictive capacity, we believed that consideration of the applicability domain would enable the classification of a substance as United Nations Globally Harmonized System of Classification and Labeling of Chemicals (UN GHS) category 1 or 2 or determine no category. However, it was impossible to distinguish between UN GHS categories 2A and 2B. Moreover, regarding a solid, as the false negative rate for discriminating UN GHS category 2 and no category is high (28.9%; close to the standard set by the OECD of ≤30%), the classification of UN GHS category 2 for solids should be performed with caution.

This statement was released following a review prepared by the eye irritation test JaCVAM Editorial Committee to acknowledge that the results of the review and study by the JaCVAM Regulatory Acceptance Board have confirmed the usefulness of this assay.

Based on the above, we proposed the SkinEthic™ HCE TTT method as a useful means for assessing eye irritation potential during safety assessments by regulatory agencies.

Nishikawa Akiyoshi
Chairperson,
JaCVAM Regulatory Acceptance Board.

Hirabayashi Yoko
Chairperson,
JaCVAM Steering Committee.

February 26, 2024

The JaCVAM Regulatory Acceptance Board was established by the JaCVAM Steering Committee, and is composed of nominees from the industry and academia.

This statement was endorsed by the following members of the JaCVAM Regulatory Acceptance Board:

Nishikawa Akiyoshi (Division of Pathology, Center for Biological Safety and Research:CBSR, NIHS / Nagoya Tokushukai General Hospital) : Chairperson
Hirabayashi Yoko (CBSR, NIHS)
Kojima Koichi (Food and Drug Safety Center)
Matsumoto Kazuhiko (Nagoya City University)
Nakamura Ruriko (National Institute of Technology and Evaluation)
Nishimura Jihei (Pharmaceuticals and Medical Devices Agency)

Term: From 1st April 2022 to 31st March 2024

This statement was endorsed by the following members of the JaCVAM steering Committee after receiving the report from JaCVAM Regulatory Acceptance Board:

Hirabayashi Yoko (CBSR, NIHS): Chairperson
Hayashi Akiko (Ministry of Health, Labour and Welfare)
Honma Masamitsu (NIHS)
Inazumi Yoshihiko (Ministry of Health, Labour and Welfare)
Ishii Koji (National Institute of Infectious Diseases)
Kanda Yasunari (Division of Pharmacology, CBSR, NIHS)
Kitajima Satoshi (Division of Cellular and Molecular Toxicology, CBSR, NIHS)
Maki Kazushige (Pharmaceuticals and Medical Devices Agency)
Masumura Kenichi (Division of Risk Assessment, CBSR, NIHS)
Ogawa Kumiko (Division of Pathology, CBSR, NIHS)
Sugiyama Keiichi (Division of Genetics and Mutagenesis, CBSR, NIHS)
Taquahashi Yuhji (Animal Management Section of the Division of Toxicology, CBSR, NIHS)
Tsukano Masaaki (Ministry of Health, Labour and Welfare)
Yokota Masahiko (Pharmaceuticals and Medical Devices Agency)
Ashikaga Takao (Division of Risk Assessment, CBSR, NIHS): Secretary