JaCVAM statement on the SIRC-CVS: TEA method for evaluating ocular irritation

At a meeting held on July 23, 2021 at the National Institute of Health Sciences (NIHS) in Kanagawa, Japan, the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

The SIRC-CVS: TEA test method assesses cytotoxicity by exposing SIRC cells to a test chemical, then staining the exposed SIRC cells with crystal violet to measure their viability. As the test method does not use living animals, it is in accordance with the spirit of 3Rs. In addition, this test method is inexpensive, can be completed easily, and does not include special components, equipment, or other scientific procedures. Therefore, no requirement of practical training is a good indication of the robustness of the test method, and it has high reproducibility. However, this method could not assess the ocular irritation potential of chemicals, which when used in a bottom-up approach to identifying chemical substances that do not require classification and labeling under the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) is suitable for use in a regulatory context. The applicability domain of the test method was adjusted without providing clear mechanistic insights and justification of the proposed domain restrictions.

This statement was prepared, following the review prepared by the eye irritation test JaCVAM Editorial Committee, to acknowledge that the results of a review and study by the JaCVAM Regulatory Acceptance Board have confirmed the value of the test method for regulatory acceptance.

July 30, 2021

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:

Mr. Akiyoshi Nishikawa (Center for Biological Safety and Research: CBSR, National Institute of Health Sciences: NIHS / Saiseikai Utsunomiya Hospital) : Chairperson
Ms. Yoko Hirabayashi (CBSR, NIHS)
Mr. Hiroshi Itagaki (ITACS Consulting)
Mr. Kazuhiko Matsumoto (Nagoya City University)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)

Term: From 1st April 2020 to 31st March 2022

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

Ms. Yoko Hirabayashi (CBSR, NIHS): Chairperson
Mr. Osamu Fueki (Pharmaceuticals and Medical Devices Agency)
Mr. Yukihiro Goda (NIHS)
Mr. Akihiko Hirose (Division of Risk Assessment, CBSR, NIHS)
Mr. Koji Ishii (National Institute of Infectious Diseases)
Mr. Yasunari Kanda (Division of Pharmacology, CBSR, NIHS)
Mr. Satoshi Kitajima (Division of Toxicology, CBSR, NIHS)
Ms. Kumiko Ogawa (Division of Pathology, CBSR, NIHS)
Mr. Takayuki Okubo (Ministry of Health, Labour and Welfare)
Mr. Keiichi Sugiyama (Division of Genetics and Mutagenesis, CBSR, NIHS)
Mr. Masahiro Takahata (Ministry of Health, Labour and Welfare)
Mr. Yuhji Taquahashi (Animal Management Section of the Division of Toxicology, CBSR, NIHS)
Mr. Masaaki Tsukano (Ministry of Health, Labour and Welfare)
Mr. Masahiko Yokota (Pharmaceuticals and Medical Devices Agency)
Mr. Takao Ashikaga (Division of Risk Assessment, CBSR, NIHS): Secretary
Mr. Hajime Kojima (Division of Risk Assessment, CBSR, NIHS): Secretary