JaCVAM Statement on the *In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method, LabCyte EPI-MODEL24 SCT

At a meeting held on 7 December 2021 at the 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: Although a positive result in an *in vitro* skin corrosion test using human skin models such as LabCyte EPI-MODEL24 SCT is generally considered sufficient for predicting a test chemical to cause skin corrosion under the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) Category 1, this test as well as EpiSkin™ and EpiDerm™ SCT are considered sufficient for predicting a test chemical to cause skin corrosion under the UN GHS subcategories. Furthermore, thorough consideration must be given to the applicability domain when using this test.

This statement was prepared following a review of the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 431 *In Vitro* Skin Corrosion: Reconstructed Human Epidermis (RhE) Test Method together with other materials prepared by the Skin Corrosion Testing JaCVAM Editorial Committee to acknowledge that the results of a review and study by the JaCVAM Regulatory Acceptance Board have confirmed the usefulness of this assay.

Based on the above, we propose the *In Vitro* Skin Corrosion: RhE Test Method, LabCyte EPI-MODEL24 SCT as a useful means for assessing skin corrosion potential during safety assessments by regulatory agencies.

Akiyoshi Nishikawa
Chairperson
JaCVAM Regulatory Acceptance Board

Yoko Hirabayashi
Chairperson
JaCVAM Steering Committee

December 7, 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