JaCVAM statement on the U937 Cell Line Activation Test (U-SENS™) Skin Sensitization Test Method

At a meeting held on 29 October 2018 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:

Proposal: Although it is possible to classify chemicals that yield positive results using the U-SENS™ test method as sensitizers, it is not possible to assess accurately their sensitization strength nor their subcategorization under the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (UN GHS). The U-SENS™ test method is not suitable for predicting skin sensitization potential on its own; in order to make a suitable assessment, the results of U-SENS™ testing must be used with a thorough understanding of the properties of each test chemical in combination with other information as part of an integrated approach to testing and assessment (IATA). 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) 442E: IN VITRO SKIN SENSITISATION ASSAYS ADDRESSING THE KEY EVENT ON ACTIVATION OF DENDRITIC CELLS ON THE ADVERSE OUTCOME PATHWAY FOR SKIN SENSITISATION, ESAC Opinion No. 2016-03 and EURL ECVAM U-SENS Test Submission Template 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 U-SENS™ skin sensitization test method as a useful means for safety assessment by regulatory agencies.

Yasuo Ohno
Chairperson
JaCVAM Regulatory Acceptance Board

Yoko Hirabayashi
Chairperson
JaCVAM Steering Committee

November 5, 2018

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. Yasuo Ohno (Kihara Memorial Yokohama Foundation for the Advancement of Life Sciences): Chairperson
Mr. Yoshiaki Ikarashi (National Institute of Health Sciences: NIHS)
Mr. Noriyasu Imai (Japanese Society for Alternatives to Animal Experiments)
Mr. Tomoaki Inoue (Japanese Society of Immunotoxicology)
Mr. Yuji Ishii (Biological Safety Research Center: BSRC, NIHS)
Ms. Yumiko Iwase (Japan Pharmaceutical Manufacturers Association)
Mr. Takeshi Morita (Japanese Environmental Mutagen Society)
Mr. Shunji Nakai (Japan Chemical Industry Association)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Akiyoshi Nishikawa (BSRC, NIHS)
Mr. Satoshi Numazawa (Japanese Society of Toxicology)
Ms. Maki Noguchi (Pharmaceuticals and Medical Devices Agency) *
Mr. Kazutoshi Shinoda (Pharmaceuticals and Medical Devices Agency)
Ms. Mariko Sugiyama (Japan Cosmetic Industry Association)
Mr. Hiroo Yokozeki (Japanese Society for Cutaneous Immunology and Allergy)

Term: From 1st April 2016 to 31st March 2018
*: From 1st April 2017 to 31st March 2018

Mr. Yasuo Ohno (Kihara Memorial Yokohama Foundation for the Advancement of Life Sciences): Chairperson
Ms. Yoko Hirabayashi (BSRC, NIHS)
Mr. Yoshiaki Ikarashi (NIHS)
Mr. Noriyasu Imai (Japanese Society for Alternatives to Animal Experiments)
Mr. Kunifumi Inawaka (Japan Chemical Industry Association)
Mr. Tomoaki Inoue (Japanese Society of Immunotoxicology)
Mr. Yuji Ishii (BSRC, NIHS)
Ms. Yumiko Iwase (Japan Pharmaceutical Manufacturers Association)
Mr. Fumihiro Kubo (Pharmaceuticals and Medical Devices Agency)
Mr. Kenichi Masumura (Japanese Environmental Mutagen Society)
Ms. Ruriko Nakamura (National Institute of Technology and Evaluation)
Mr. Akiyoshi Nishikawa (BSRC, NIHS/ Saiseikai Utsunomiya Hospital)
Mr. Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)
Mr. Satoshi Numazawa (Japanese Society of Toxicology)
Ms. Mariko Sugiyama (Japan Cosmetic Industry Association)
Mr. Hiroo Yokozeki (Japanese Society for Cutaneous Immunology and Allergy)

Term: From 1st April 2018 to 31st March 2020

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 (BSRC, NIHS): Chairperson
Mr. Manabu Fuchioka (Ministry of Health, Labour and Welfare)
Mr. Osamu Fueki (Pharmaceuticals and Medical Devices Agency)
Mr. Akihiko Hirose (Division of Risk Assessment, BSRC, NIHS)
Mr. Koichi Hiruta (Pharmaceuticals and Medical Devices Agency)
Mr. Masamitsu Honma (Division of Genetics and Mutagenesis, BSRC, NIHS)
Mr. Koji Ishii (National Institute of Infectious Diseases)
Mr. Yasunari Kanda (Division of Pharmacology, BSRC, NIHS)
Mr. Satoshi Kitajima (Division of Toxicology, BSRC, NIHS)
Mr. Kouichirou Koike (Ministry of Health, Labour and Welfare)
Ms. Kumiko Ogawa (Division of Pathology, BSRC, NIHS)
Mr. Haruhiro Okuda (NIHS)
Mr. Taku Oohara (Ministry of Health, Labour and Welfare)
Mr. Atsuya Takagi (Animal Management Section of the Division of Toxicology, BSRC, NIHS)
Mr. Masaaki Tsukano (Ministry of Health, Labour and Welfare)
Mr. Hajime Kojima (Division of Risk Assessment, BSRC, NIHS): Secretary