

JaCVAM Statement on the *In Vitro* Membrane Barrier Test Method for Skin Corrosion

At a meeting held on 25 July 2017 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: Corrositex[®] is a commercially available *in vitro* membrane barrier test method. We do not consider this test method to be suitable for predicting the skin corrosion potential of test chemicals due to a significant number of false negative test results and the limited applicability domain of the Chemical Detection System (CDS). Since a positive result from this test method can, however, be considered sufficient for predicting a test chemical to cause skin corrosion, this test could be useful when used within that limitation. We do not know of any other *in vitro* membrane barrier model, and if a new model is developed, its suitability for use in a regulatory context should be evaluated based on the results of a validation study.

This statement was prepared following a review of the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 435 *In Vitro* Membrane Barrier test method for skin corrosion 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 limited usefulness of this assay.

Based on the above, we propose the *In Vitro* Membrane Barrier test method as a useful means for assessing skin corrosion potential during safety assessments by regulatory agencies.



Yasuo Ohno
Chairperson
JaCVAM Regulatory Acceptance Board



Akiyoshi Nishikawa
Chairperson
JaCVAM Steering Committee

October 1, 2017

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. Naofumi Iizuka (Pharmaceuticals and Medical Devices Agency)*
- 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)
- Ms. Maki Noguchi (Pharmaceuticals and Medical Devices Agency)**
- Mr. Satoshi Numazawa (Japanese Society of Toxicology)
- Mr. Kazutoshi Shinoda (Pharmaceuticals and Medical Devices Agency)
- Ms. Mariko Sugiyama (Japan Cosmetic Industry Association)
- Mr. Hiroo Yokozeki (Japanese Society for Dermatoallergology and Contact Dermatitis)

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

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

Mr. Akiyoshi Nishikawa (BSRC, NIHS): Chairperson
Mr. Toru Kawanishi (NIHS)
Mr. Manabu Fuchioka (Ministry of Health, Labour and Welfare)
Ms. Yoko Hirabayashi (Division of Toxicology, BSRC, NIHS)
Mr. Akihiko Hirose (Division of Risk Assessment, BSRC, NIHS)
Ms. Mitsue Hirota (Pharmaceutical & Medical Devices Agency)
Mr. Masamitsu Honma (Division of Genetics and Mutagenesis, BSRC, NIHS)
Mr. Yasunari Kanda (Division of Pharmacology, BSRC, NIHS)
Mr. Atsushi Kato (National Institute of Infectious Diseases)
Mr. Kouichirou Koike (Ministry of Health, Labour and Welfare)
Ms. Kumiko Ogawa (Division of Pathology, BSRC, NIHS)
Mr. Taku Oohara (Ministry of Health, Labour and Welfare)
Mr. Kazutoshi Shinoda (Pharmaceuticals and Medical Devices Agency)
Mr. Atsuya Takagi (Animal Management Section of the Division of Toxicology, BSRC, NIHS)
Mr. Masaaki Tsukano (Ministry of Health, Labour and Welfare)
Mr. Shinichi Watanabe (Ministry of Health, Labour and Welfare)
Mr. Hajime Kojima (Division of Risk Assessment, BSRC, NIHS): Secretary