JaCVAM Statement on the

In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method

(TER)

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: We consider the Transcutaneous Electrical Resistance Test Method (TER) to be

suitable for predicting the skin corrosion potential of a test chemical in a

regulatory context. We are concerned, however, that the use of isolated rat skin in

this test method for the safety evaluation of cosmetic ingredients and products

could be problematic due to the prohibition on animal testing for cosmetics that

are sold in the EU.

This statement was prepared following a review of the Organisation for Economic

Co-operation and Development (OECD) Test Guideline (TG) 430 In Vitro Skin Corrosion:

TER 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 TER 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

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October 1, 2017

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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

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

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

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