

**JaCVAM statement
on two *in vitro* assays
for skin irritation testing**

At the meeting concerning the above method, held on 4 July 2012 at the National Institute of Health Sciences (NIHS), Tokyo, Japan, the members of the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board unanimously endorsed the following statement:

The *in vitro* assay using the reconstructed human epidermis models such as EpiDerm and SkinEthics is considered to have sufficient accuracy and reliability for prediction of skin irritating test substances applied for 4 hours under proper conditions.

Following the review of the results of the ECVAM (European Center for the Validation of Alternative Methods) statements and OECD (Organisation for Economic Co-operation and Development) Test Guideline revised No. 439, it is concluded that two *in vitro* assays using the reconstructed human epidermis models such as EpiDerm and SkinEthics for skin irritation testing are clearly beneficial.

The JaCVAM Regulatory Acceptance Board has been regularly kept informed of the progress of the study, and this endorsement is based on an assessment of various documents, including, in particular, the evaluation report prepared by the JaCVAM ad hoc peer review panel for skin irritation testing.



Takemi Yoshida
Chairperson
JaCVAM Regulatory Acceptance Board



Akiyoshi Nishikawa
Chairperson
JaCVAM Steering Committee

20 January, 2013