



Commission of the European Union
Joint Research Centre
Institute for Health & Consumer Protection
21020 Ispra (VA)
Italy

ECVAM European Centre for the Validation of Alternative Methods

STATEMENT ON THE APPLICATION OF THE EPIDERM™ HUMAN SKIN MODEL FOR SKIN CORROSION TESTING

At its 14th meeting, held on 14-15 March 2000 at the European Centre for the Validation of Alternative Methods (ECVAM), Ispra, Italy, the ECVAM Scientific Advisory Committee (ESAC)¹ unanimously endorsed the following statement:

Following a review of the results of the ECVAM-funded prevalidation study on the EpiDerm™ skin corrosion test coordinated by ZEBET, it is concluded that the EpiDerm human skin model can be used for distinguishing between corrosive and non-corrosive chemicals within the context of the draft EU and OECD test guidelines on skin corrosion.

The ESAC has been regularly kept informed of the progress of the study, and this endorsement was based on an assessment of various documents, including, in particular; the report on the results and evaluation of the study prepared for the ESAC,² and a report on the study which has been accepted for publication.³

The validation study was conducted in accordance with the general principles laid down in the report of the CAAT⁴/ERGATT⁴ workshop held in 1990,⁵ guidelines contained in the report of an ECVAM/ERGATT workshop held in 1995,⁶ criteria laid down by ECVAM and the ECB,^{4,7} criteria recommended at an OECD⁴ workshop held in 1996,⁸ and the US ICCVAM⁴ report on validation and regulatory acceptance.⁹

The status of the draft guidelines referred to is as follows. The Competent Authorities of EU Member States accepted the draft guideline on skin corrosion testing¹⁰ into the Annex V guidelines at the 27th Meeting on Adaptation to Technical Progress in relation to *Directive 67/548/EEC*, held in Brussels on 4 February 2000. An equivalent draft guideline¹¹ has been circulated by the OECD Secretariat for consideration by the OECD Member Countries.

Michael Balls
Head of Unit
ECVAM
Institute for Health & Consumer Protection
Joint Research Centre
European Commission
Ispra

Eva Helisten
Head of Unit E.2
Environment Directorate General
European Commission
Brussels

20 March 2000

[This Page Intentionally Left Blank]