STATEMENT ON THE APPLICATION OF THE EPIDERM™
HUMAN SKIN MODEL FOR SKIN CORROSIVITY 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) unanimously endorsed the following statement:

Following the review of the results of the ECVAM-funded prevalidation study on the EpiDerm™ skin corrosivity 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 EU and draft OECD testing 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, and a report on the study which has been accepted for publication.

The validation study was conducted in accordance with the general principles laid down in the report of the CAAT/ERGATT workshop held in 1990, guidelines contained in the report of an ECVAM/ERGATT workshop held in 1995, criteria laid down by ECVAM and the ECB, criteria recommended at an OECD workshop held in 1996, and the US ICCVAM report on validation and regulatory acceptance.

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21 March 2000
1. The ESAC was established by the European Commission, and is composed of representatives of the EU Member States, industry, academia and animal welfare, together with representatives of the relevant Commission services. The following members of the ESAC were present at the meeting on 14-15 March 2000:

Dr B Blaauboer (ERGATT)  
Dr P Botham (ECETOC)  
Professor J Castell (Spain)  
Dr D Clark (UK)  
Dr B Garthoff (EFPIA)  
Professor A Guillouzo (France)  
Dr C Hendriksen (The Netherlands)  
Professor C Regan (Ireland)  
Professor V Rogiers (Belgium)  
Dr B Rusche (EUROGROUP for Animal Welfare)  
Dr O de Silva (COLIPA)  
Professor H Spielmann (Germany)  
Professor O Svendsen (Denmark)  
Professor H Tritthart (Austria)  
Dr M Viluksela (Finland)  
Professor E Walum (Sweden)  
Dr F Zucco (EUROGROUP for Animal Welfare)  
Mr A Aguilar (DG RTD)  
Mr M Balls (ECVAM - Chairman)  
Mme F Drion (DG SANCO)  
Ms S Louhimies (DG ENV)  
Mr L Nørgaard (DG ENTR)  
Mr J Riego Sintes (ECB)  
Mr E Sabbioni (ECVAM)  
Mr F Mc Sweeney (IHCP)  
Mr A Worth (ECVAM)  

2. As of 20 March 2000, the status of the draft guidelines referred to is as follows. The CompetentAuthorities of the EU Member States accepted the draft guideline on skin corrosivity testing\(^1\) into the Annex V Testing Methods at the 27\(^{th}\) Meeting on Adaptation to Technical Progress in relation to Directive 67/548/EEC, held in Brussels on 4 February 2000. An equivalent draft guideline\(^2\) has been circulated by the OECD Secretariat for consideration by the OECD Member Countries.


