



European Commission
Joint Research Centre
Institute for Health & Consumer Protection
ECVAM Unit
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 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)¹ 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.²

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,³ and a report on the study which has been accepted for publication.⁴

The validation study was conducted in accordance with the general principles laid down in the report of the CAAT⁵/ERGATT⁵ workshop held in 1990,⁶ guidelines contained in the report of an ECVAM/ERGATT workshop held in 1995,⁷ criteria laid down by ECVAM and the ECB,^{5,8} criteria recommended at an OECD⁵ workshop held in 1996,⁹ and the US ICCVAM report on validation and regulatory acceptance.¹⁰

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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)	Mr A Aguilar (DG RTD)
Dr P Botham (ECETOC)	Mr M Balls (ECVAM - Chairman)
Professor J Castell (Spain)	Mme F Drion (DG SANCO)
Dr D Clark (UK)	Ms S Louhimies (DG ENV)
Dr B Garthoff (EFPIA)	Mr L Nørgaard (DG ENTR)
Professor A Guillouzo (France)	Mr J Riego Sintes (ECB)
Dr C Hendriksen (The Netherlands)	Mr E Sabbioni (ECVAM)
Professor C Regan (Ireland)	Mr F Mc Sweeney (IHCP)
Professor V Rogiers (Belgium)	Mr A Worth (ECVAM)
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)	

2. As of 20 March 2000, the status of the draft guidelines referred to is as follows. The Competent Authorities of the EU Member States accepted the draft guideline on skin corrosivity testing¹¹ into the Annex V Testing Methods 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 guideline¹² has been circulated by the OECD Secretariat for consideration by the OECD Member Countries.
3. Botham P & Fentem J (1999) Statement on applicability of the EpiDermTM human skin model for skin corrosivity testing. 3pp. Ispra: ECVAM.
4. Liebsch M, Traue D, Spielmann H, Uphill P, Wilkins S, Wiemann C, Kaufmann T, Remmele M & Holzhütter H-G (2000) The ECVAM prevalidation study on the use of EpiDerm for skin corrosivity testing. *ATLA* **28**, 371-401.
5. CAAT: Center for Alternatives to Animal Testing, Baltimore, USA; ECB: European Chemicals Bureau, Ispra, Italy; ERGATT: European Research Group for Alternatives in Toxicity Testing, Utrecht, The Netherlands; ICCVAM; Interagency Coordinating Committee on the Validation of Alternative Methods, Research Triangle Park, USA; OECD: Organization for Economic Cooperation and Development, Paris, France.
6. Balls M, Blaauboer B, Brusick D, Frazier J, Lamb D, Pemberton M, Reinhardt C, Roberfroid M, Rosenkranz H, Schmid B, Spielmann H, Stamatii A-L. & Walum E (1990) Report and recommendations of the CAAT/ERGATT workshop on the validation of toxicity test procedures. *ATLA* **18**: 313-337.
7. Balls M, Blaauboer BJ, Fentem JH, Bruner L, Combes RD, Ekwall B, Fielder RJ, Guillouzo A, Lewis RW, Lovell DP, Reinhardt CA, Repetto G, Sladowski D, Spielmann H & Zucco F

- (1995) Practical Aspects of the Validation of Toxicity Test Procedures. The Report and Recommendations of ECVAM Workshop 5. *ATLA* **23**: 129-147.
8. Balls M & Karcher W (1995) The validation of alternative test methods. *ATLA* **23**: 884-886.
 9. OECD (1996) Final Report of the OECD Workshop on Harmonisation of Validation and Acceptance Criteria for Alternative Toxicological Test Methods. 60pp. Paris: OECD.
 10. NIEHS (1997) Validation and Regulatory Acceptance of Toxicological Test Methods. A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. 105pp. Research Triangle Park, NC: NIEHS.
 11. *Draft Commission Directive adapting to technical progress for the twenty-seventh time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.* Approved by the Committee for the Adaptation to Technical Progress of Directive 67/548/EEC on 4 February 2000.
 12. OECD Test Guidelines Programme. *In Vitro Skin Corrosion Tests. Draft of November 1999.* Circulated for comment on 21 February 2000.