



EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
European Centre for the Validation of Alternative Methods (ECVAM)

STATEMENT ON THE APPLICATION OF THE SKINETHIC™ HUMAN SKIN MODEL FOR SKIN CORROSIVITY TESTING

At its 25th Meeting, held on 16-17 November 2006 at the European Centre for the Validation of Alternative Methods (ECVAM), Ispra, Italy, the non-Commission members of the ECVAM Scientific Advisory Committee (ESAC)¹ unanimously endorsed the following statement:

On the basis of a peer review² of the results of an inter-laboratory study³ with the SkinEthic™ reconstituted human epidermal (RHE) model, the Committee endorses the conclusion that the SkinEthic™ human skin model can be used for distinguishing between corrosive and non-corrosive chemicals within the context of the OECD test guideline, TG 431.

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

17 November 2006

1. The ESAC was established by the European Commission, and is composed of nominees from the EU Members States, industry, academia and animal welfare, together with representatives of the relevant Commission services.

This statement was endorsed by the following members of the ESAC:

Mr Walter Pfaller (Austria)
Ms Sonja Beken (Belgium)
Ms Dagmar Jírová (Czech Republic)
Ms Elisabeth Knudsen (Denmark)
Mr Tõnu Püssa (Estonia)
Mr Timo Ylikomi (Finland)
Mr Manfred Liebsch (Germany)
Mr Efstathios Nikolaidis (Greece)
Ms Katalin Horvath (Hungary)
Ms Annalaura Stammati (Italy)
Ms Maija Dambrova (Latvia)
Mr Jan van der Valk (The Netherlands)
Mr Dariusz Sladowski (Poland)
Mr Albert Breier (Slovakia)
Mr Jon Richmond (UK)
Ms Odile de Silva (COLIPA)
Ms Julia Fentem (ECETOC)
Ms Nathalie Alépée (EFPIA)
Mr Robert Combes (ESTIV)
Ms Maggy Jennings (Eurogroup for Animal Welfare)
Mr Roman Kolar (Eurogroup for Animal Welfare)

The following Commission Services and Observer Organisations were involved in the consultation process, but not in the endorsement process itself.

Mr Thomas Hartung (ECVAM; chairman)
Mr Jens Linge (ECVAM; ESAC secretary)
Ms Elke Anklam (Director of IHCP)
Mr Juan Riego Sintés (ECB)
Mr Siegfried Breier (DG Enterprise, Unit F.3)
Ms Susanna Louhimies (DG Environment, Unit C.3)
Ms Beatrice Lucaroni (DG Research, Unit F.5)
Mr Christian Wimmer (DG Research)
Mr Constantin Mircioiu (Romania)
Mr Len Schechtman (ICCVAM, USA)
Mr William Stokes (NICEATM, USA)
Ms Vera Rogiers (ECOPA)
Mr Hasso Seibert (European Science Foundation)

2. *ESAC Peer Review - Application of the SkinEthic™ human skin model for skin corrosivity testing. Summary & conclusions of the peer review panel, 6pp., October 2006.*
3. Helena Kandarova, Manfred Liebsch, Horst Spielmann, Elke Genschow, Elisabeth Schmidt, Dieter Traue, Robert Guest, Andrew Wittingham, Neil Warren, Armin O. Gamer, Marina Remmele, Tanja Kauffmann, Elke Wittmer, Bart De Wever, Martin Rosdy (2006): *Assessment of the human epidermis model SkinEthic RHE for in vitro*

skin corrosion testing of chemicals according to new OECD TG 431. Toxicology in Vitro **20**, 547-559.