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 CORROSITEX® ASSAY FOR SKIN CORROSIVITY TESTING

At its 15th meeting, held on 5-6 December 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 scientific reports and publications on the CORROSITEX assay[2-7], it is concluded that the CORROSITEX assay is a scientifically validated test, but only for those acids, bases and their derivatives which meet the technical requirements of the assay.

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6 December 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 5-6 December 2000:

Dr B Blaauboer (ERGATT)
Professor J Castell (Spain)
Dr D Clark (UK)
Dr B Garthoff (EFPIA)
Professor A Guillouzo (France)
Professor C Hendriksen (The Netherlands)
Professor G Koptopoulos (Greece)
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 M Balls (ECVAM - Chairman)
Ms B Lucaroni (DG RTD)
Mr L Nørgaard (DG ENTR)
Mr J Riego Sintes (ECB)
Mr E Sabbioni (ECVAM)
Mr F Mc Sweeney (IHCP)
Mr G Willmott (DG ENV)
Mr A Worth (ECVAM)

2. NIH (1999). Corrositex: an *in vitro* test method for assessing dermal corrosivity potential of chemicals. NIH Publication No. 99-4495. National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), NC, USA.

3. Botham, P.A., Chamberlain, M., Barratt, M.D., Curren, R.D., Esdaile, D.J., Gardner, J.R., Gordon, V.C., Hildebrand, B., Lewis, R.W., Liebsch, M., Logemann, P., Osborne, R., Ponec, M., Régnier, J-F., Steiling, W., Walker, A.P. & Balls, M. (1995). A prevalidation study on *in vitro* skin corrosivity testing. The report and recommendations of ECVAM Workshop 6. *ATLA* **23**, 219-255.

4. Fentem, J.H., Archer, G.E.B., Balls, M., Botham, P.A., Curren, R.D., Earl, L.K., Esdaile, D.J., Holzhütter, H.G. & Liebsch, M. (1998). The ECVAM international validation study on *in vitro* tests for skin corrosivity. 2. Results and evaluation by the management team. *Toxicology in Vitro* **12**, 483-524.

5. Gordon, V.C., Harvell, J.D. & Maibach, H.I. (1994). Dermal corrosion, the CORROSITEX™ system: a DOT accepted method to predict corrosivity potential of test materials. In *In Vitro Skin Toxicology - Irritation, Phototoxicity, Sensitization.* Alternative Methods in Toxicology, Volume 10 (ed. A. Rougier, A.M. Goldberg & H.I. Maibach). pp. 37-45. Mary Ann Liebert, New York.

6. Scala, R., Stokes, W., Hill, R., Goldsworthy, T., Tice, R. & Haneke, K. The results of an independent peer review panel evaluation of the validation status of CORROSITEX. Abstracts of the 3rd World Congress on Alternatives and Animal use in the Life Sciences. *ATLA* **27**, p.334.

7. Comments on the NIH report[2] from the Agency for Toxic Substances and Disease Registry (ATSDR), the Environmental Protection Agency (EPA), and the National Institute for Occupational Safety and Health (NIOSH).