



1 **ESAC STATEMENT ON THE SCIENTIFIC VALIDITY OF AN IN-VITRO TEST**
2 **METHOD FOR SKIN CORROSIVITY TESTING**

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4 Following its 30th meeting, held on 9 and 10 March 2009, the non-Commission members of
5 the ECVAM Scientific Advisory Committee (ESAC) endorsed on 12 June 2009 by consensus
6 and written procedure the following statement:

7 ***The EST-1000 method for skin corrosion testing can be used for reliably predicting the***
8 ***corrosive potential of chemical substances. It is considered meeting the Performance***
9 ***Standards as determined in the OECD test guideline TG 431 on in vitro skin corrosion***
10 ***testing using human skin model tests (Ref 1).***

11 This conclusion is based on the results of an inter-laboratory study of the EST-1000 human
12 reconstructed epidermis (RhE) model that was reviewed by an independent ESAC Peer
13 Review (Ref 2).

14 This study showed that 11 out of 12 Reference Substances of the OECD TG 431 were
15 correctly predicted by EST-1000 when considering the final prediction derived from the mode
16 of the individual predictions of the four participating testing laboratories. On the basis of the
17 median of the laboratory predictions for the 12 Reference Substances, the following predictive
18 values were observed:

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Specificity (%)	91.7
Sensitivity (%)	100
Overall Accuracy (%)	95.8

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23 In the study, only one substance, *Tetrachloroethylene*, was incorrectly predicted by three
24 laboratories as a skin corrosive (false positive prediction). Predictions were also variable
25 within and between laboratories for the substance *Eugenol* without however affecting the final
26 decision based on the mode of individual laboratory predictions.

27 However, all human skin models for skin corrosion assessment (EpiSkin, Ref 3; EpiDerm,
28 Ref 4; and SkinEthic, Ref. 5) that were previously validated by ECAVM and that are
29 considered meeting the OECD Performance Standards also displayed a higher extent of
30 variability for these two substances in comparison to the other 10 Reference Substances.
31 Therefore the false positive prediction obtained for *Tetrachloroethylene* was regarded as
32 acceptable.

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34 Joachim Kreysa

35 Head of Unit

36 In-Vitro Methods Unit

37 European Centre for the Validation of Alternative Methods

38 Ispra, 12 June 2009



39 REFERENCES

- 40 1. OECD Test Guideline (Nr. 431) for the testing of chemicals – In vitro skin Corrosion:
41 human skin model test. OECD 2004.
- 42 2. ESAC Peer Review Panel Consensus Report on the EST-1000 in vitro test method for
43 assessing skin corrosion in vitro. 2009
- 44 3. ESAC Statement on the scientific validity of the EpiSkin test (an in vitro test fro skin
45 corrosivity). 1998. <http://ecvam.jrc.it/>
- 46 4. ESAC Statement on the application of the EpiDerm human skin model fro skin
47 corrosivity testing. 2000. <http://ecvam.jrc.it/>
- 48 5. ESAC Statement on the application of the SkinEthic human skin model for skin
49 corrosivity testing. 2006. <http://ecvam.jrc.it/>



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51 The ESAC was established by the European Commission, and is composed of experts
52 nominated by the EU Member States, and by industry, academia and animal welfare
53 organisations. Representatives of the relevant Commission services, other international
54 organisations, and partner validation bodies participate in its meetings.

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

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58 Ms Argelia Castaño (Spain)
59 Ms Maija Dambrova (Latvia)
60 Ms Alison Gray (ESTIV)
61 Ms Katalin Horvath (Hungary)
62 Ms Maggy Jennings (Eurogroup for Animals)
63 Ms Dagmar Jírová (Czech Republic)
64 Mr Roman Kolar (Eurogroup for Animals)
65 Ms Elisabeth Knudsen (Denmark)
66 Mr Manfred Liebsch (Germany)
67 Mr Gianni Dal Negro (EFPIA)
68 Mr. Walter Pfaller (Austria)
69 Mr Tõnu Püssa (Estonia)
70 Mr Jon Richmond (UK)
71 Ms Vera Rogiers (ECOPA)
72 Mr Hasso Seibert (ESF, acting as co-moderator at the meeting)
73 Ms Annalaura Stamatì (Italy)
74 Mr Jan van der Valk (The Netherlands)
75 Mr Carl Westmoreland (COLIPA, acting as moderator at the meeting)

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77 The following Commission employees and observers were involved in the consultation
78 process, both during the meeting and the following written procedure, but not in the
79 endorsement itself:

80 **Commission services**

81 Mr Joachim Kreysa (DG JRC, Head of In Vitro Methods Unit/ECVAM, chairman)
82 Mr Claudius Griesinger (DG JRC, ESAC secretariat)
83 Ms Eimear Kelleher (DG JRC)
84 Ms Karin Kilian (DG SANCO)
85 Mr Juan Riego Sintès (DG JRC)

86

87 **Observers**

88 Mr Patric Amcoff (OECD)
89 Mr Hajime Kojima (JaCVAM, Japan)
90 Mr William Stokes (NICEATM/ICCVAM, USA)
91 Ms Marilyn Wind (ICCVAM/ U.S. Consumer Product Safety Commission, USA)