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ECVAM European Centre for the Validation of Alternative Methods

STATEMENT ON THE APPLICATION OF THE 3T3 NRU PT TEST TO UV FILTER CHEMICALS

At its 10th meeting, held on 31 March 1998 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:

The outcome of the study with UV filter chemicals further confirms the validity of the 3T3 NRU PT test, which has now been demonstrated to be applicable for testing these types of chemicals for their phototoxic potential.

The ESAC has been regularly kept informed of the progress of the special study, and this endorsement was based on the assessment of various documents and a verbal report to the ESAC by Professor Horst Spielmann, Chairman of the Management Team for the study.

This special study was conducted in accordance with the general principles for validation laid down in the report of the CAAT²/ERGATT² workshop held in 1990,³ guidelines contained in the report of an ECVAM/ERGATT workshop held in 1995,⁴ criteria laid down by ECVAM and the ECB,^{2,5} criteria recommended at an OECD² workshop held in 1996,⁶ and the US ICCVAM² report on validation and regulatory acceptance.⁷

A detailed report on the study will be published in *ATLA* during 1998,⁸ and the report on Phase II of the EU/COLIPA validation study on the 3T3 NRU PT test will shortly be published in *Toxicology in Vitro*.⁹ The ESAC formally endorsed the method as a scientifically validated test at its meeting on 1-2 October 1997.¹⁰

The experience and results obtained during the study on UV filters have been taken into account in the drafting of a proposed test guideline on the *in vitro* 3T3 NRU PT test.

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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 31 March 1998:

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)	Dr R Lorenzini (Italy)
Professor G Papadopoulos (Greece)	Professor V Rogiers (Belgium)
Dr B Rusche (Eurogroup for Animal Welfare)	Dr O de Silva (COLIPA)
Professor H Spielmann (Germany)	Dr O Svendsen (Denmark)
Professor H. Tritthart (Austria)	Dr M Viluksela (Finland)
Professor E Walum (Sweden)	
Professor M Balls (ECVAM)	Mr G Corcelle (DGXI)
Dr J Fentem (ECVAM)	Dr G Fracchia (DGXII)
Ms S Louhimies (DGXI)	Dr M Robert (DGIII)
Mr A Van Elst (DGXXIV)	

2. 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: *ad hoc* Interagency Coordinating Committee on the Validation of Alternative Methods, Research Triangle Park, USA; OECD: Organization for Economic Cooperation and Development, Paris, France.
3. Balls M, Blaauboer B, Brusick D, Frazier J, Lamb D, Pemberton M, Reinhardt C, Robertfroid M, Rosenkranz H, Schimid B, Spielmann H, Stamatii AL & Walum E (1990). Report and recommendations of the CAAT/ERGATT workshop on the validation of toxicity test procedures. *ATLA* 18: 303-337.
4. 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.
5. Balls M & Karcher W (1995). The validation of alternative test methods. *ATLA* 23: 884-886.
6. Anon. (1996). Final Report of the OECD Workshop on Harmonization of Validation and Acceptance Criteria for Alternative Toxicological Test Methods. 60pp. Paris: OECD.
7. Anon. (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.

8. Spielmann H, Balls M, Dupuis J, Pape WJW, de Silva O, Holzhütter HG, Gerberick F, Liebsch M, Lovell WW & Pfannenbecker U (1998). A special study on UV filter chemicals from Annex VII of the EU Cosmetics Directive 76/768 in the *in vitro* 3T3 NRU phototoxicity test. *ATLA* 26, in press.
9. Spielmann H, Balls M, Dupuis J, Pape WJW, Pechovitch G, de Silva O, Holzhütter HG, Clothier R, Desolle P, Gerberick F, Liebsch M, Lovell WW, Maurer T, Pfannenbecker U, Polthast JM, Csato M, Sladowski D, Steiling W & Brantom P (1998). The international EU/COLIPA *in vitro* phototoxicity validation study: results of phase II (blind trial). Part 1: the 3T3 NRU phototoxicity test. *Toxicology in Vitro* 12, in press.
10. Anon (1998). Statement on the scientific validation of the 3T3 NRU PT test (an *in vitro* test for phototoxic potential). *ATLA* 26, 7-8.