Presse-Information

Press release ● Information de presse

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Statement
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Successful validation and acceptance of RHE based methods for regulatory toxicity testing

Reconstructed human skin (RhE) models are commercially available for two decades now and they have stimulated the development of alternatives safety test for topical toxicity. Due to the active cooperation and financial support of companies of the cosmetics and chemical industry on the one hand and of government institutions in Europe, Japan and the USA on the other hand RHE based test have been validated and accepted for regulatory purposes at the world-wide level (OECD) in this area of toxicology. As a consequence no testing in animals is required in this area of toxicology any more.

Skin corrosion was first and already ten year ago alternative methods have been validated and accepted for regulatory use in the EU (Annex V B.40) and at the OECD level (OECD TG 430 and TG 431). Therefore, no animal testing should be performed for this endpoint, either for hazard identification or for risk assessment purposes.

In the field of skin irritation, after several attempts an ECVAM validation study was finally successful in 2007 and in 2010 a RhE test methods has been accepted by the OECD entitled "In Vitro Skin Irritation: Reconstructed Human Epidermis (RhE) Test Method", which will allow to replace the current OECD TG 404 "Acute dermal irritation/corrosion". In 2010 the OECD is planning an expert meeting to accept RhE methods for classification and labelling of skin irritation/corrosion according to the UN Globally Harmonized System (GHS).

In the area of skin absorption and penetration, an alternative test has been accepted at the OECD level (TG 428), although it is based on has not passed through a formal prospective validation study but was based on a "weight of evidence" validation, in which data were provided on the testing of cosmetic ingredients and crop protection products. A successful

validation study on the use of RhE for skin absorption testing has recently been published by Schäfer-Korting et al. (2008).

In the area of acute phototoxicity, more than ten years ago an in vitro test (the 3T3 Neutral Red Uptake Phototoxicity Test(3T3-NRU-PT)) has been validated and adopted for regulatory use in the EU (Annex V B.41) and at the OECD level (OECD TG 432). This test is regarded as a basic screen for identifying acute phototoxic potential. A human RhE model phototoxicity test has undergone prevalidation and is an important adjunct tests for overcoming limitations of the 3T3-NRU-PT, namely, the fairly low UVB tolerance of the 3T3 fibroblasts, and its inability to model the bioavailability of test materials topically applied to the skin.

In the area of photo-genotoxicity, two tests (the Photo-Micronucleus Test and the Photo-Comet assay) are being evaluated in a formal validation study. It is expected that these in vitro photo-genotoxicity test methods will be validated and adopted at the EU level within the next three years.

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