

ECVAM Feasibility Study: Can the Pre-validated *In Vitro* Skin Model Phototoxicity Assay be Upgraded to Quantify Phototoxic Potency of Topical Phototoxins

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ABSTRACT/ INTRODUCTION

The determination of phototoxicity of a chemical in the 3T3-NRU-PT according to OECD Test Guideline 432 (1) is often the first step in the sequential phototoxicity testing strategy. If the chemical provides a negative result in the 3T3-NRU-PT, in most instances no further testing is required. However, if the result is positive, the chemical may be still applied topically at safe concentrations, depending on the absorption and accumulation of the chemical in the skin. Thus, in addition to the information on inherent phototoxicity potential assessed by the 3T3-NRU-PT, additional testing may be required to obtain combined information on the *phototoxicity* and *bioavailability* of the chemical in the skin. Ideally, confirmatory tests should be performed *in vivo* on human volunteers, but for ethical reasons, this is not acceptable, if the 3T3-NRU-PT has provided a positive result. Thus, to avoid confirmatory testing *in vivo* in animals, reconstructed human 3-D skin models are offering an attractive *in vitro* alternative for testing, since such models are characterized by both skin barrier function and viable primary skin cells. In the current study several substances (mostly cosmetic ingredients) which are known to be safely used in humans and which provided positive results in the 3T3 NRU PT were evaluated using the cells. study, humans, 3T3-NRU-PT, reconstructed human skin model EpiDerm and the pre-validated EpiDerm Phototoxicity test (2). In order to clarify the situation in man, human data were generated using a standard photopatch test on a limited group of human volunteers.

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