

ECVAM Feasibility Study: Can the Pre-validated EpiDerm In Vitro Phototoxicity Test be Upgraded to Quantify Phototoxic Potency of Topical Phototoxins?

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The determination of phototoxicity of a chemical in the 3T3 NRU-PT according to OECD Test Guideline 432 is often the first step in the sequential phototoxicity testing strategy. If the chemical provides a negative result in the 3T3NRU-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 3T3NRU-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 3T3NRU-PT has provided a positive result. Thus, to avoid confirmatory testing *in vivo* in animals, reconstituted 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 on the reconstructed human skin model EpiDerm and if the result was negative, tested in a limited group of human volunteers. First results we obtained show that the human skin model phototoxicity test represents a useful step in the sequential strategy for phototoxicity testing.