

COLIPA program on optimization of existing *in vitro* eye irritation assays for entry into formal validation: technology transfer and intra/inter laboratory evaluation of an EpiOcular assay for chemicals

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The European Union will ban *in vivo* eye irritation tests on ingredients for cosmetic products after March 2009. COLIPA, (European Cosmetics Association) is actively working to bring *in vitro* eye irritation tests to formal validation with ECVAM. This poster details the Colipa program on technology transfer and reproducibility of MatTek's EpiOcular™ assay as one of the two human reconstructed tissue assays. This EpiOcular protocol differs from previous time-to-toxicity protocols in that it uses a single exposure period for each chemical and a prediction model based on a cut-off in relative survival (= 60% = irritant (I) (R36 and R41); >60% = non-classified (NC)). Test substance exposure time is 30 minutes with a 2-hour post-exposure incubation for liquids and 90 minutes with an 18-hour post-exposure incubation for solids. After the post-exposure, tissue viability is determined by tetrazolium dye reduction (MTT). Combinations of 20 coded chemicals were tested in 7 laboratories. A standardized protocol and laboratory documentation were used by all laboratories. MatTek provided initial training and then each laboratory operated independently during the technology transfer study. Twenty liquids (11 NC/9 I) by ECVAM plus 5 solids (3 NC/2 I) were selected so that both exposure regimens could be assessed. Concurrent positive (methyl acetate) and negative (water) controls were tested in each trial. Chemical decoding occurred only after study completion. In all, 298 independent trials were performed and demonstrated 99.7% agreement in prediction (NC/I) across the laboratories. Coefficients of variation for the % survival of tissues across laboratories was generally modest (<16%) except where tissue survival values were low. Using these data, a formal submission was sent to ECVAM in support the protocol's entry into a formal validation study.

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