

CONTACT DERMATITIS AND OCCUPATIONAL DERMATOSES

## **NEXT GENERATION RISK ASSESSMENT FOR CONTACT ALLERGY: A CASE STUDY**

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**Introduction:** Our Next Generation risk assessment (NGRA) for skin allergy incorporates a tiered approach, utilising information on product exposure, in silico predictions and in chemico/in vitro tests to prevent induction of contact allergy. The Skin Allergy Risk Assessment (SARA) model predicts human skin sensitiser potency from non-animal test methods, which can be used as part of a NGRA to prevent of induction of contact allergy.

**Objective:** To explore via a case study how the SARA model predictions can be used in a NGRA

**Materials and Methods:** The SARA model, a Bayesian probabilistic model, estimates the human sensitiser population threshold (defined as, the exposure level at which no individual in a population will experience induction of contact allergy) under the conditions of a human repeat insult patch test (HRIPT).

SARA model predictions using non-animal test method data (DPRA [OECD TG 442C], KeratinoSens<sup>TM</sup> [OECD TG 442D], h-CLAT [OECD TG 442E] and U-Sens<sup>TM</sup> [OECD TG 442E]) were compared to predictions using historical in vivo data.

A case study NGRA integrating the SARA model prediction was conducted for use of curcumin in a skin cream.

**Results:** SARA model estimates of human potency generated from in vitro data alone have at least the same level of accuracy, on average, as estimates generated from historically available In vivo data.

**Conclusions:** The SARA model provides a point of departure for use in NGRA.

The SARA model can predict the probability of sensitisation occurring under a given product use scenario.

Further evaluation of how NGRA outcomes compare to clinical outcome is required and collaboration with the dermatology community is essential to continue to evolve NGRA for skin allergy risk assessment.