IDEA WORKSHOP

Skin Sensitisation Potency Measurement and Risk Assessment without a Requirement for Animals

July 1 2025

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IDEA

International Dialogue for the Evaluation of Allergens

OVERARCHING OBJECTIVES

- Foster engagement with all relevant scientific, industry and regulatory stakeholders
- Provision of high quality aggregate exposure and use data
- Surveillance data - providing early insights into fragrance allergy: Extended Fragrance Ingredients Surveillance Study (EFISS)
- Integrating New Approach Methodologies (NAMs) into QRA – deriving reliable NESILs without recourse to animal data

RCPL

Reference Chemical Potency List

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Reference Chemical Potency List (RCPL): A new tool for evaluating the accuracy of skin sensitisation potency measurements by New Approach Methodologies (NAMs)

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ABSTRACT

Considerable progress has been made in the design of New Approach Methodologies (NAMs) for the hazard identification of skin sensitising chemicals. However, effective risk assessment requires accurate measurement of sensitising potency, and this has proven more difficult to achieve without recourse to animal tests.

One important requirement for the development and adoption of novel approaches for this purpose is the availability of reliable databases for determining the accuracy with which sensitising potency can be predicted. Some previous approaches have relied on comparisons with potency estimates based on either human or animal (local lymph node assay) data. In contrast, we here describe the development of a carefully curated Reference Chemical Potency List (RCPL) which is based on consideration of the best available human and animal data.

The RCPL is comprised of 33 readily available chemicals that span a wide range of chemistry and sensitising potency, and contain examples of both direct and indirect (pre- and pro-) haptens. For each chemical a potency

Recent Previous Meetings: a Summary

October 7 2022: Introduction to the RCPL: development, roll-out, features and purpose

September 22 2023: (a) Initial evaluation of selected NAMs to measure potency using the RCPL; (b) Consideration of requirements for assessment of weak/very weak skin sensitisers; (c) Initial consideration of additional uncertainty when using NAMs

October 19 2024: (a) Plans for extension of the RCPL; (b) Initial evaluation of 2 NAMs (GARDskin Dose-Response; Linear regression); (c) Considerations of uncertainty

Workshop: July 1 2025

- RCPL: original development, recent extension and benefits
- Brief introduction to selected NAMs: (a) regression model, (b) GARD-DR, (c) SARA-ICE
- Overview of NAMs and potency assessment: progress, achievements, limitations
- Addressing a NAM-based QRA
    - Maintaining a QRA approach based on derivation of a NESIL
    - Retaining SAFs (but possibly with additions)
- Variability and uncertainty: defining a way forward