

IDEA WS on Application of the RCPL Discussion

- **Which NAMs seem most suitable for evaluation by the RCPL in determining potency of fragrance materials?**
- **How are we going to encourage the systematic use of the RCPL for evaluation of NAMs to accurately measure skin sensitising potency ?**
- **Are there other aspects that should be considered for the effective assessment of skin sensitising potency with NAMs ?**

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Key Conclusions



- **The RCPL provides a new template for the evaluation of NAM* to measure the skin sensitizing potency of chemicals. The strength of the RCPL is in both, providing absolute dose per area values and ranking the potency of chemicals.**
- **The RCPL represents a step change in that it integrates human and animal data in a rigorous and transparent process, yet logically stays clear of any in vitro data for which it serves as reference. It provides 33 reference chemicals (i.e. mostly fragrance materials) on a continuous scale of potency values.**
- **The group concludes, based on initial assessments with the RCPL, that a point of departure for the risk assessment for skin sensitization for chemicals within a defined applicability domain, can be determined reliably with NAM.**
- **With a tendency towards hazard as opposed to risk-based decisions by regulators, scientific advocacy (publications, webinars, workshops, ...) on the importance and feasibility of risk assessment for dermal sensitization will be pursued. This should be started with a paper demonstrating the application of the RCPL combined with progress that has been made in the use of NAM for potency assessment.**

* 'NAM' includes NAM, combinations of NAM, Defined Approaches

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Key Conclusions



- **There is consensus to encourage the evaluation of NAM* for potency assessment with RCPL and have IDEA collate the data. This evaluation requires a base set of guidelines.**
- **For fragrance materials potency assessment based on NAM is expected to be used directly in the QRA given it is benchmarked against human data presented in the RCPL.**
- **The group felt that extension of the number beyond 33 reference chemicals could have merits and may be considered but is not a priority at this stage.**
- **The group felt that consideration should be given to submit the concept of the RCPL to the OECD test program. It is recognized that this might require an extension of the RCPL.**