

IDEA: NAM HAZARD ASSESSMENT OF FMs

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DRIVERS FOR NAM HAZARD ASSESSMENT OF CHEMICALS

• Ethical/political pressures in the EU as e.g. indicated by the Cosmetics Regulation

 Benefits of reduced resource needs and costs along with improved sustainability

 Increase in availability of expertise as simpler endpoints used for assessment purposes



REQUIREMENTS FOR NAMs TO REPLACE ANIMAL USE

- Understanding of how (modes of action) adverse effects of concern caused by chemicals are initiated and progressed
- Suitable means of replicating the modes of action in vitro or in silico and readily measured, validated end point(s)
- Regulatory and other stakeholder acceptance of weight of evidence for replacement



WHY NAM SKIN SENZITISATION HAZARD AND RISK ASSESSMENT IS AN IDEA PRIORITY

- EU Cosmetics Regulation requires new FMs, intended to be used in cosmetics, to be safety assessed using NAMs
- Early stages of the mode of action that may result in dermal allergy are well established. This resulted in the LLNA mouse test that has wide regulatory acceptance.
- The same mode of action can be replicated in vitro.

TODAYS AIM

- Update of IDEA progress to date and current priorities in order to facilitate discussion of participants comments and suggestions
- Plan to follow up with another WS in 2025 and submission of dossier to SCCS

