

# Recap on Day 1

*LRI-Workshop*

*"Applicability of sensitization testing methods for regulatory purposes"*

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LRI Workshop  
*"Applicability of skin sensitization testing methods for regulatory purposes"*

European Committee of  
Organic Surfactants and  
their Intermediates



# Recap Day 1 - I

**Aim of the Workshop:** Ensure a common understanding of the applicability of the current animal tests (OECD 404 and OECD 429) and to promote a flexible testing strategy.

- Scientific background of the LLNA was presented
- LLNA has brought us forward but there are still some areas of concern (Industry data: irritation, chemical structure and conformation, MW).
- LLNA gives a holistic view of skin sensitization process
- Promising developments in-vitro. Battery of test approach.



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# Recap Day 1 - II

- ❁ No holistic view in vitro. Warning and Challenge: put the pieces of the puzzle back together. Interpretation of the data?
- ❁ In vitro methods should help us understand the limitations of the LLNA (and explain the inconsistent results?)
- ❁ Still a long time until in vitro methods will affect regulation
- ❁ Till then work and understand what we have (GP and LLNA)

# Recap Day 1 - III

- ❁ Discussion “melange”, risk and hazard (remember C&L is hazard based)
- ❁ Two different aspects. Regulatory issue → classify or not to classify (pass fail concept) → severe consequences
- ❁ Hazard is based on the intrinsic properties of the material

# Recap Day 1 - IV

Questions that are still unresolved:

- To better define the applicability domain of GPMT and LLNA
- To clarify what to do with discordant results
- To identify the next steps needed to investigate possible pathways → integrate modifications and endpoints to improve the methodology
- To evaluate how and if human experience can be integrated in the assessment of sensitisation potential
- To evaluate how false negative or false positive results should be integrated into the validation of alternative methods
- Incorporating test limitations into intelligent testing strategies

# Out look of day 2

Break out groups:

- ☼ Is there a “Gold Standard”
- ☼ Applicability Domains: What can we do about it?
- ☼ The use of LLNA for the development of next generation tests

# Out look of day 2

## GOAL

- To openly discuss the key question.
- Share your thoughts and exchange information

## DELIVERABLE

- Identify set of actions (ownership of the issue)
- To come up with a set of recommendations