2nd IDEA Working Group meeting on the feasibility of a study to assess the effectiveness of QRA

Breakout group 1 – Intervention study

February 15th, 2017

Breakout group 1 – Intervention study

- General considerations
- Pilot study
- Material selection
- Consumer product selection
- Population selection
- Other considerations

Breakout group 1 – Intervention study Participants

- Cian O'Mahony
- Donald Belsito
- Maya Krusteva
- David Basketter
- Scott Schneider
- Hans Merk
- Magnus Bruze
- Petra Kern
- Anne Marie Api (Moderation)
- Cécile Gonzalez (Reporting)

Breakout group 1 – Intervention study

General considerations for the intervention study

- There is no absolute protection of consumers due to unforeseen misuse of consumer products. The success should be stated with the objective: there is a significant decrease of the skin sensitization rate in the QRA2 group over the pre-QRA group.
- We should exclude the exposure to the material for any participant.
- The patients could be given all the cosmetic products needed in order to better control exposure. If there is a reaction, the patient will have to undergo patch testing to define if the ingredient responsible of such reaction.

Breakout group 1 – Intervention study

General considerations for the intervention study

- The exposure levels set by QRA2 will be compared to the pre-QRA levels, unless the material used for the study is a strong sensitizer. The positive control will be used as pre-QRA baseline.
- Comparing to pre-QRA is taken in consideration for ethical review purposes.

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Pilot study

- A pilot study should be preliminarily performed in order to obtain approximate data on the study length and the size of population to be included in the study.
- Only the pre-QRA test group is needed in the pilot study.

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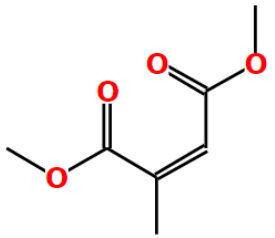
Material selection (1)

- Methyl citraconate is not appropriate for the intervention study as it is a too weak sensitizer.
  - As a consequence, a high number of participants would be required to run the study.



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Material selection (2)

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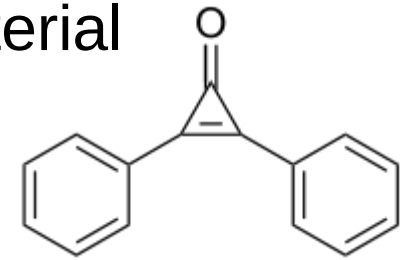
- Diphenylcyclopropenone: non fragrance material



  - EC3 value available – very strong/extreme sensitizer
  - Elicitation dose: 3 µg.cm^{-2}
  - Patch test data available (Danish study)
  - The allergy is observed in 100% in days with 2% solution
  - The positive group could be much smaller
  - Does not have a strong smell
  - Should ensure that Diphenylcyclopropenone is stable within the product formulation
  - The material is irritant - a patch test concentration should be found. The Danish study could provide valuable information.
  - An HRIPT will be needed

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Consumer product selection

Deodorants are the major source of sensitization, thus the studied area should be axillae.

In order to consider an aggregate exposure, several products should be considered in the studied area.

Breakout group 1 – Intervention study Population studies

If Diphenylciclopropenone is used, the intervention study would be carried on the general population.

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Further considerations

- The study needs to be reviewed and accepted in early stages by the people will participate to the review of the study's outcome. The success criteria of the study must be accepted in the beginning
- The risk of the study for participants is acquiring contact allergy. Treatment will be covered in the study (treated by corticosteroids). The material should not allow elicitation in the future.

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Thank you very much for your attention