

*Quality of Data
assessed by SCCP*

..... improving

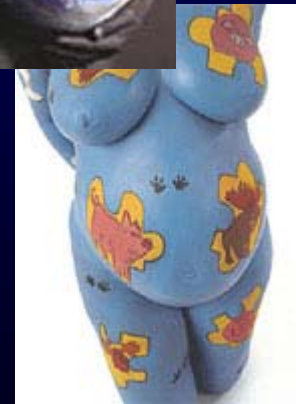
Safety

... a cosmetic product .. must not cause **damage** to human health .. under **normal or reasonably foreseeable** conditions of use

...

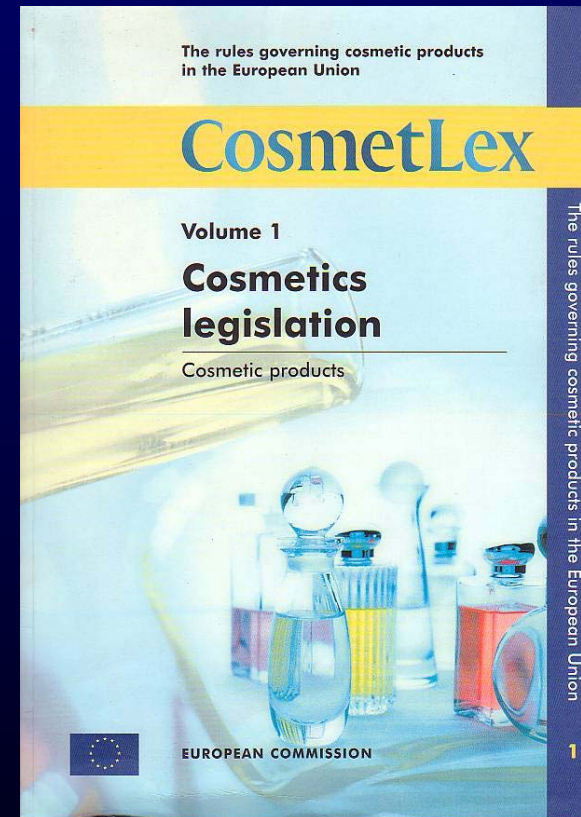


Normal or Reasonably foreseeable .. ?



Cosmetics Directive

- **Annexes**
 - annex 2
 - prohibited
 - annex 3
 - restricted / conditions of use
 - annex 6
 - preservatives
- **6th amendment**
 - ingredient labelling
- **7th amendment**
 - fragrance ingredient labelling
 - animal testing



What is required?

Notes of Guidance for the safety evaluation of cosmetic ingredients - 5th update

- Acute toxicity (oral / dermal / inhalation)
- Skin and eye irritation
- Skin sensitisation
- Dermal / percutaneous absorption
- Mutagenicity / genotoxicity
- Repeated dose toxicity
- Chronic toxicity
- Carcinogenicity
- Reproduction toxicity
- Toxicokinetics
- Photo-induced toxicity
- Human data

What could reasonably be asked from industry?

- Complete identification of the compound
- To provide high quality dossiers with special attention to :
 - amounts to be used in formulations
 - for each test, identification of the tested batch, its purity and concentration and representative of that to be used
 - justification when tested concentrations deviate from intended use levels
 - inclusion of all available studies

Zinc Oxide

- We recommend that industry submit the additional information on microfine zinc oxide that is required by the SCCNFP as soon as reasonably practicable so that the SCCNFP can deliver an opinion on its safety.
- The uncertainties about the safety of nanoparticles of zinc oxide are not just applicable to its use as a UV filter.
- until the safety dossier is provided to the SCCNFP the uncertainties remain.

Climbazole

- The dossier is an example of an inadequate and poor submission provided by industry.
- Due to the many shortcomings it is impossible for the SCCP to assess whether *Climbazole* is safe for use in rinse-off (2.0%) and leave-on (0.5%) anti-dandruff cosmetic products.
- The SCCP notes that *Climbazole* is in Annex VI and used as a preservative. In view of the poor quality of the toxicological data presented in the current dossier, the SCCP recommends a re-evaluation of the safety of this compound for preservative uses.

HAIR DYES STUDIED BY SCC(NF)P IN 2003-2005

52 opinions on website

SCCNFP/0695/03

SCCNFP/0792/04

SCCNFP/0681/03

SCCNFP/0697/03

SCCNFP/0803/04

SCCNFP/0676/03

SCCNFP/0732/03

SCCNFP/0793/04

SCCNFP/0680/03

22 dossiers contained dermal absorption studies
rejected by the SCC(NF)P !

SCCNFP/0735/03

SCCNFP/0665/03

SCCP/0876/05

SCCNFP/0730/03

SCCNFP/0661/03

SCCP/0683/03

SCCNFP/0785/04

SCCNFP/0668/03

SCCNFP/0789/04

SCCNFP/0786/04

SCCNFP/0710/03

SCCNFP/0782/04

SCCNFP/0787/04

SCCNFP/0689/03

SCCP/0875/05

SCCNFP/0788/04

SCCNFP/0678/03

SCCNFP/0795/04

SCCNFP/0790/04

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SCCNFP/0794/04

SCCNFP/0734/04

SCCNFP/0682/03

SCCNFP/0791/04

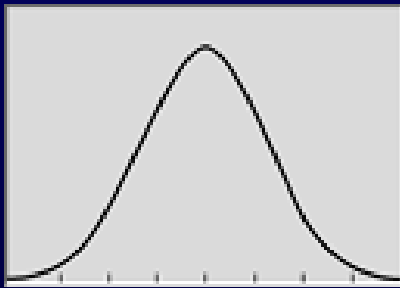
SCCNFP/0688/03

HAIR DYES STUDIED BY SCC(NF)P IN 2003-2005

Dermal / percutaneous absorption

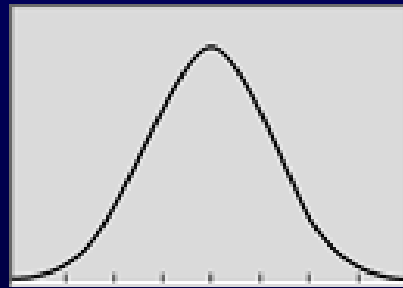
- Insufficient / inadequate information on test substance / dosage
- Insufficient / inadequate information on skin samples
- Inappropriate choice of receptor fluid
- Inadequacies in measurements and results
- For oxidative hair dyes : additional test mimicking *in vivo* situation

Colipa European study - cosmetics



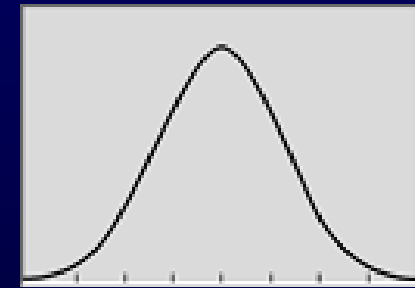
Frequency

x



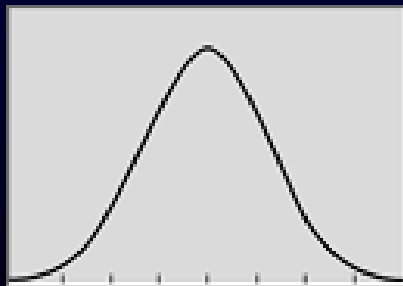
Amount

=



Exposure

Weight

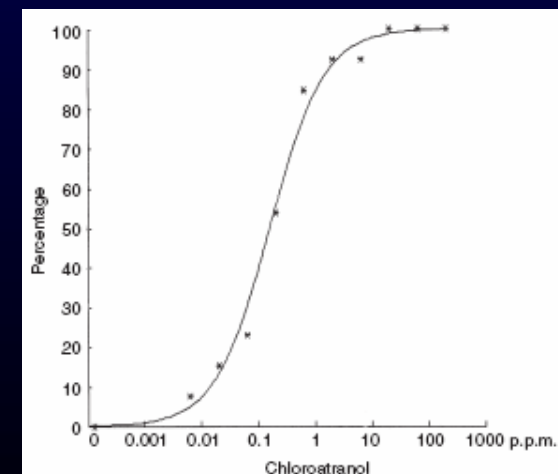
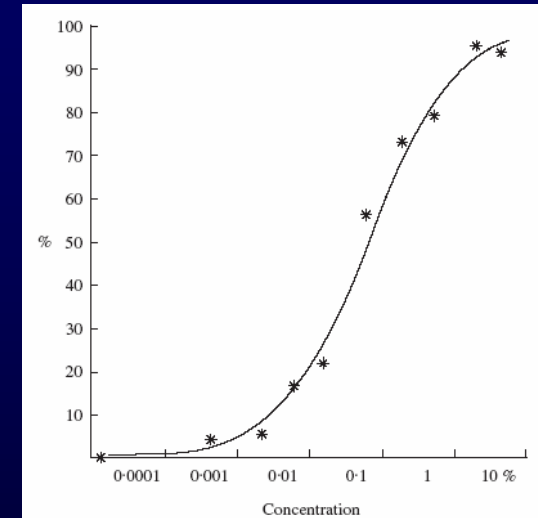


1. Body lotion
2. Deodorant - nonspray
3. Deodorant - spray
4. Lipstick
5. Facial moisturiser
6. Shampoo
7. Toothpaste

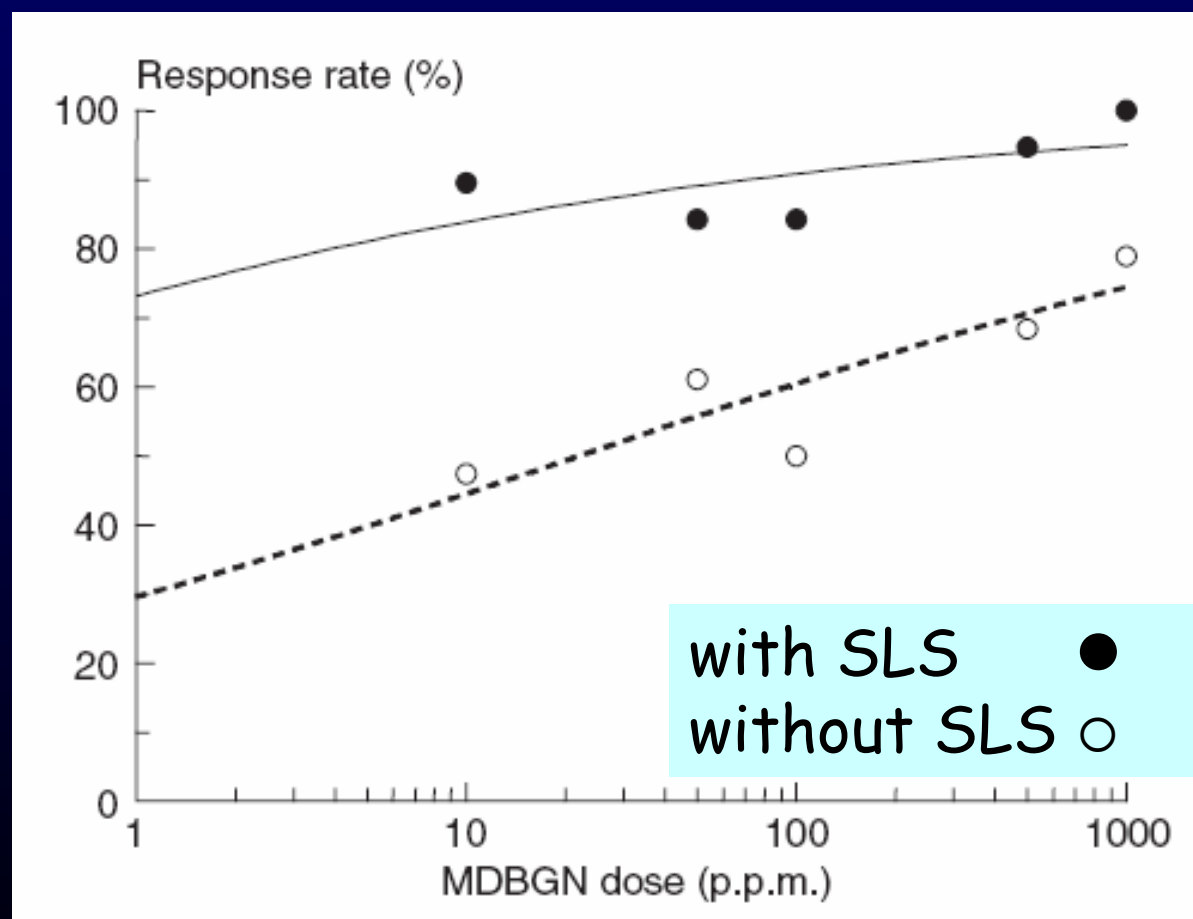
Dose elicitation studies

- *non industry data*

- Hydroxyisohexyl 3-cyclohexene carboxaldehyde
 - Lyrar
- Evernia prunastri
 - Oakmoss
 - chloratranol



Methyldibromo glutaronitrile elicitation - effects of surfactant *non-industry data*





SCIENTIFIC COMMITTEE ON CONSUMER PRODUCTS

SCCP

Opinion on

Methyldibromo glutaronitrile

(sensitisation only)

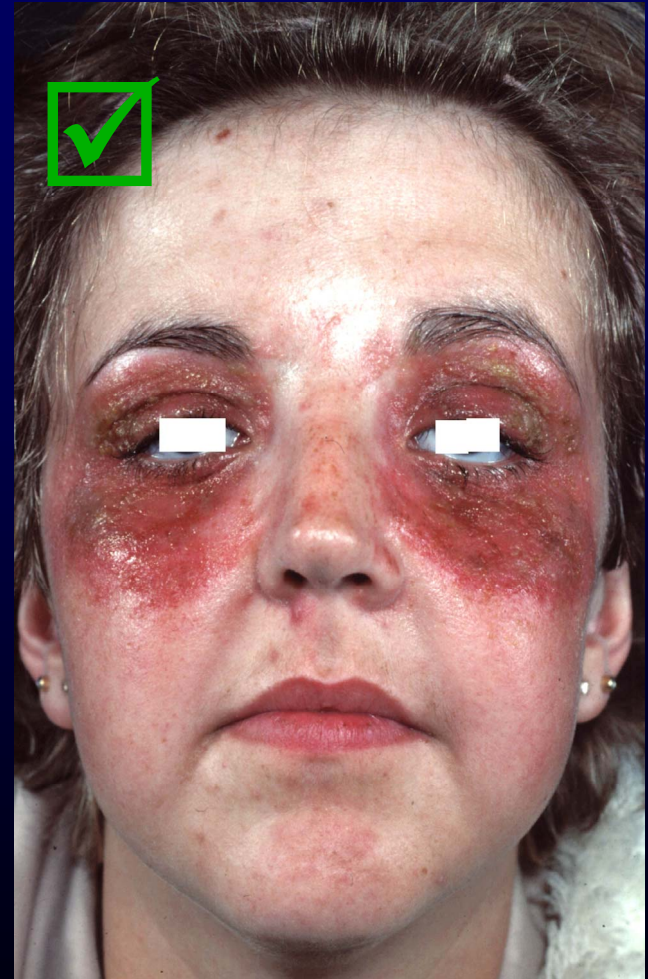
COLIPA n° P77

Adopted by the SCCP during the 3rd plenary meeting
of 15 March 2005

In response to the questions asked, the SCCP is of the opinion that:

- MDBGN was shown to cause elicitation of reactions by repeated open exposures with a rinse-off preparation at the maximum concentration allowed in rinse-off products (0.1%).
- No safe use-level for MDBGN in cosmetic leave-on or rinse-off products has been established.
- As no safe use-level for MDBGN in rinse-off products has been established, it is recommended that MDBGN should not be present in any cosmetic products.

The future?



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