

# SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation

- 10th revision -



## → WHAT ARE THE "SCCS NOTES OF GUIDANCE"?

The Scientific Committee on Consumer Safety (SCCS) is a group of independent scientists that provides advice to the European Commission on consumer products.

Emphasis is on the safety evaluation of cosmetic ingredients for which some concern has been expressed with respect to human health.

Depending on the testing results obtained, these ingredients are taken up in the Annexes of the Cosmetic Regulation (EU) 1223/2009. Using substances under consideration in cosmetics can be prohibited (Annex II), restricted (Annex III) or allowed in the case of colourants (Annex IV), preservatives (Annex V) and UV-filters (Annex VI).

The SCCS Notes of Guidance provide relevant information about the safety evaluation process for the Annex substances and the testing procedures that can be applied. They are regularly updated according to the latest scientific and technological advances.

## → WHAT HAS CHANGED SINCE THE LAST REVISION?

The last revision took place in April 2016. While attention was then given to the general requirements of the new Cosmetic Regulation and the use of alternative methods, the focus is now entirely on non-animal methodologies and strategies.

Indeed, in the light of the full implementation of the animal testing and marketing bans, only non-animal replacement methods are legally allowed for the testing of cosmetics and their ingredients. Non-animal techniques, termed New Approach Methods (NAMs), are thus increasingly being used. Therefore, the general structure of the Notes of Guidance, as well as the content, has been updated in the 10th Revision.

Priority has been given to the updated non-animal methods, followed by the older *in vivo* techniques.

A section on Weight of Evidence (WoE) and the use of a 'toolbox' strategy for genotoxicity testing has been included.

As the safety assessment of cosmetic ingredients is exposure-driven, the section on exposure has been significantly extended.

External and internal exposure, a tiered approach and aggregate exposure have been considered separately and a literature overview of consumer exposure data has been included in the Appendix.

More guidance has also been provided for the submission of a safety dossier to the SCCS and re-submission in case of rejection.

## → USING THE «SCCS NOTES OF GUIDANCE»

The "Notes of Guidance" are mainly concerned with testing and the safety evaluation of the cosmetic substances listed in the cosmetic EU legislation and those for which safety concerns have been expressed. They are also of interest for all substances intended to be incorporated in a cosmetic product. They can indeed be of practical use in making a product information file for a finished cosmetic product, which is required by the cosmetic regulation.

The "Notes of Guidance" should not be seen as a mere checklist, but rather as a general guide that should be adapted on a case-by-case basis when evaluating the safety of a finished cosmetic product.

This fact sheet is based on the "SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation - 10th revision"

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