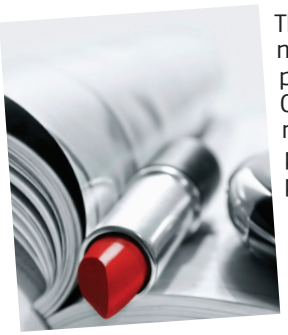
European Commission

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



The European Commission and its independent Scientific Committee on Consumer Safety (SCCS) provide guidance to public authorities and to the cosmetic industry to ensure compliance with the current cosmetic EU legislation, in particular regarding safety assessment of cosmetic ingredients.

## → WHAT ARE THE «SCCS NOTES OF GUIDANCE»?

The SCCS issues «Notes of Guidance» that provide relevant information on the different aspects of testing and safety assessment of cosmetic substances in the EU. The emphasis of the Guidance is on cosmetic ingredients, although some guidance is also given on the safety assessment of finished products.
The «Notes of Guidance» are regularly revised and updated in order to take account of up-to-date scientific and technological progress in relevant areas, including in the field of alternative methods aimed at replacing, reducing or refining animal experiments (3R principle).
A new revision of the «Notes of Guidance» has just been published, which updates the previous version issued in 2012.

## → WHAT HAS CHANGED SINCE THE LAST REVISION?

• The animal testing ban under the Cosmetics Regulation has remained a challenge in regard to strategies for the safety testing and assessment of cosmetic ingredients and for the development of alternative testing methods. Much of the progress achieved so far has been in the fields of local toxicity and mutagenicity testing. The current status of validated alternative methods is described, in particular in the area of skin and eye irritation and skin sensitisation. *In vivo* safety studies conducted for regulatory areas other than cosmetics may be used for the safety evaluation of cosmetics provided that the data were primarily generated for compliance with non-cosmetics related legislative frameworks and for substances that are not exclusively used in cosmetic products. For details, see the **2014 ECHA factsheet**.
Human clinical studies, for instance for the determination of dermal absorption of a cosmetic ingredient, are considered equivalent to alternative methods provided that risk assessment cannot adequately be performed by use of other data/methodologies, and that such human studies are ethically acceptable.

• Mutagenicity/genotoxicity testing: After long international discussions on *in vitro* test batteries, evidence shows that a combination of the bacterial reverse mutation test (Ames test, except for nano) and the *in vitro* micronucleus test allows the detection of all relevant genotoxic carcinogens for which *in vivo* data exist in the databases. Therefore, the **SCCS recommends** using these two *in vitro* tests for the base-level testing of the mutagenic potential of a cosmetic substance. In this regard, respective OECD testing guidelines should be followed.

• Dermal absorption of most cosmetic ingredients has been shown not to exceed 50% of the substance applied on skin. Therefore, this value may be used as a default in case of no or insufficient data instead of the previous default value of 100%.

• Cosmetic ingredients with very low dermal absorption are expected to be bioavailable in the systemic circulation only at negligible amounts. In proven cases of very low dermal absorption, studies on systemic toxicity may be waived and the required studies could only comprise local toxicity and mutagenicity/genotoxicity.

• The evaluation of substances with endocrine activity requires a distinction between endocrine modifying and endocrine disrupting properties. By definition, only in the latter case might there be a link between endocrine properties and toxic effects. Proven evidence for a mechanistic link between hormonal effects and toxic effects is necessary before a substance can be termed as an "endocrine disruptor". For details, see the **SCCS Memorandum** issued in 2015.

• Some chapters have been added, extended or revised. The chapter on toxicokinetics (describing the fate of a substance in the body) has been added with sections on metabolism and *in silico* methodology (PBPK modelling). Other chapters have been revised and/or rearranged in order to provide more clarity for the users.

## → 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 however 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 - 9th revision»
September, 2015

This Guidance is available at:
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf