



The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation

12th Revision (SCCS/1647/22)

NOVEMBER 2023

WHAT ARE THE «NOTES OF GUIDANCE»?

The EU has some of the strongest consumer protection laws in the world, and that includes regulations about the safety of cosmetics and their ingredients. Cosmetic ingredients must be proven to be safe to the consumer before they are allowed on the EU market and this safety is based on safe ingredients. But how do cosmetic companies prove the safety of cosmetic ingredients? And how do authorities know which standards to apply, and which laws must be complied with?

The Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation provide information about current [EU legislation](#) to public authorities and the cosmetic industry, so that they can ensure to be in compliance. This saves time, money and effort to everyone filing safety dossiers, but it also warrants that EU citizens continue to benefit from the most stringent cosmetic safety legislation in the world and can feel confident about using products available on the EU market.

The Notes, which mainly focus on cosmetic ingredients for which there are some concerns for human health, have been drafted and are regularly updated by the European Commission's independent Scientific Committee on Consumer Safety (SCCS) to take into account the most up-to-date scientific and technological advances.

WHAT HAS CHANGED SINCE THE LAST REVISION?

The SCCS – and the cosmetic industry – have both continually adapted to the changing landscape of cosmetic testing and safety evaluation after the EU Cosmetic Regulation's [ban on animal testing](#) entry into force progressively between 2004 and 2013. Without recourse to animal testing for the safety of cosmetics, scientists needed to find alternative testing methods and ways to reliably evaluate the safety of cosmetic ingredients.



It's a quickly evolving field, and there has been progress since the last SCCS Notes of Guidance were published in 2021. The newly revised Notes of Guidance focus on Replacement Methods and animal-free New Approach Methodologies (NAMs) for the safety testing of cosmetic substances. Also, Next-Generation Risk Assessment (NGRA) is seen as a promising framework for the safety evaluation of cosmetic ingredients.

Safety assessment of cosmetics and their ingredients is shifting towards a strategic combination of NAMs and other newly emergent technologies, with historical animal data, when available, to obtain a Weight of Evidence approach to decision making.

The revised Notes of Guidance (SCCS/1647/22) also include new in vitro tools (outside of a living organism) for genotoxicity testing. In addition, they suggest criteria for Integrated Approaches to Testing and Assessment (IATA) and defined Approaches (DAs), the Threshold of Toxicological Concern (TTC) is re-established and an update of in silico prediction possibilities is provided.

The section on exposure has been reworked and extended as the safety of cosmetics and their ingredients is exposure driven. The exposure of children to different cosmetic product categories according to age has been addressed and a clear rationale behind the exposure data used for the protection offered by sunscreen products has been included.

The SCCS Notes of Guidance are technical as they are intended for a specialised audience, but the document is freely available to everyone online, and the [list of changes](#) provides a good overview.

USING THE SCCS NOTES OF GUIDANCE

The EU Cosmetic Regulation requires cosmetic companies to supply a Product Information File (PIF) for each finished cosmetic product, and the Notes of Guidance can be of great practical use when completing such file. The Notes pertain to all substances intended to be incorporated in a cosmetic product.

The «SCCS Notes of Guidance» should be thought of as a general guide rather than a checklist. They should be adapted on a case-by-case basis when evaluating the safety of a cosmetic ingredient.

This factsheet is based on the “SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation - 12th revision (SCCS/1647/22)” – May 2023

This Guidance is available under 'statements' at:

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf
https://health.ec.europa.eu/scientific-committees/scientific-committee-consumer-safety-sccs/sccs-opinions_en#final-opinions

Checklists for Applicants can be found here:

https://health.ec.europa.eu/publications/checklists-applicants-submitting-dossiers-cosmetic-ingredients-be-evaluated-sccs_en

