

SCHÖNHEITSPFLEGE"

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**Safety Assessment and Safety Report
in the EC Cosmetics Regulation
(Regulation (EC) No 1223/2009)**

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Background

The safety requirements to be met by cosmetic products are reformulated in Article 3 of Chapter II of Regulation (EC) No 1223/2009 (Safety, Responsibility, Free Movement). This article now stipulates – with a slightly different wording compared to the former EC Cosmetics Directive – that cosmetic products must be safe when used under normal or reasonably foreseeable conditions of use. In comparison to the former Cosmetics Directive (Directive 76/768/EEC), two aspects are essential:

1. The formulation that a product must be “safe” initially sounds stricter compared to the existing provision which stipulates that a cosmetic product must not cause damage to human health. In practice, the difference in formulation will not, however, have any consequences, since the responsible person had already so far to be able to prove in case of doubt the health safety of the cosmetic product.
2. The requirement as to the safety of cosmetic products includes – as was already basically the case before, but not explicitly mentioned in the Cosmetics Directive – the detailed provisions concerning products which can be confused with foodstuffs in accordance with Directive 87/357/EEC.

In addition, the labelling of the products as well as the instructions for use and disposal have to be taken into account to ensure the safety for human health. The provision of warnings does not, however, exempt the persons responsible for cosmetic products in accordance with Article 4 of the Regulation from compliance with the other requirements laid down in this Regulation.

The requirements to be met by the format and contents of a safety assessment are described in detail in Article 10 of Chapter III (Safety Assessment, Product Information File, Notification) as well as in the new Annex 1 of the Regulation. The safety assessment is prepared on the basis of the relevant information referred to in Annex I and documented together with the latter in the so-called Safety Report. The Safety Report, in turn, is an integral part of the product information file (Article 11, Clause 2).

When setting up a safety assessment first of all the requirements in Article 10.1 have to be complied with. According to these provisions, the intended use of the cosmetic product and the anticipated systemic exposure to the individual ingredients in a final formulation are to be assessed. Furthermore, the safety assessment is to include an appropriate weight of evidence approach for reviewing data from all existing sources. The safety report on a cosmetic product must, if necessary, be updated in view of additional relevant information generated after placing the product on the market. Of course a safety assessment can only refer to a concrete formulation and presentation of the product so that every reformulation of the cosmetic product, including for instance a change in packaging (technical execution/design and/or material) and presentation (labelling elements, claims, information on use and warnings)

requires regularly a further review and possible update of the safety assessment. This is of course also the case if the data situation changes for the substances used (consideration of the state of science).

Helpful literature as well as data sources for safety information on cosmetic products as well as their ingredients are available for safety assessors under the following link:

<http://www.safetyassessor.info/information.html>.

Moreover, the European Commission has published [Guidelines](#) in order to permit small and medium sized enterprises compliance with the requirements specified in Annex I to the EC Cosmetics Regulation.

Article 10.2 includes also the requirements to be met in terms of the **qualification of the safety assessor**:

"The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a member state."

When appointing a safety assessor it must, however, be taken into account that the latter not only fulfils the formal requirements in terms of the university course but also has actually the necessary experience, in particular in the fields of experimental/clinical toxicology and dermatology, cosmetic chemistry and cosmetic law. At the same time it has to be taken into account that the safety assessor is always informed about the most recent state of science and technology through corresponding continuing education. Information on appropriate continuing education programmes can be found by interested parties under <http://www.safetyassessor.info/training.html> (in English) or at <http://www.sicherheitsbewerter.info/fortbildung.html> (in German language).

Appointment of the Safety Assessor

In order to avoid at the appointment of an employed safety assessor an overloading of the employment contract and in order to facilitate a possible later revocation of the appointment, it is recommended to use a separate document. The appointment should be made (subject to revocability) directly by the executive management of the company. In the appointment document the tasks of the safety assessor should once more be outlined by referring to the provisions of the Cosmetics Regulation to be complied with.

In order to document the freedom of instructions and independence of the person appointed, it should be stipulated in the appointment document that the latter reports – in his capacity as safety assessor – exclusively and directly to the executive management and/or the board of directors of the company. If the safety assessor has to fulfil other tasks within the company, this privilege only refers to his activity as a safety assessor.

The executive management must ensure that the work of the safety assessor does not fail due to insufficient equipment in organisational, technical or personnel terms. In this connection the appointment document can stipulate that the safety assessor has all necessary resources available that he needs to fulfil his task. It must be ensured that he is granted access to all necessary information. The decision about the consequences of his assessment lies, however, with the executive management which decides, on the basis of his report, at the end of the day alone about possible remedial and/or improvement measures, such as the use of a warning or in the extreme case the initiation of a recall.

Although the responsibility for the definition of the possibly necessary information on use and warnings of the cosmetic products can be transferred to the safety assessor, this is not at all mandatory, since the Cosmetics Regulation does not prescribe such a distribution of duties. The safety assessor may, however, in all cases supplement his assessment by a corresponding proposal if a positive safety assessment can only be made in individual cases subject to the use of warnings.

The safety assessor may not be responsible at the same time for the field of product monitoring. In order to prevent product liability claims it is, however, advisable to ensure that he is, if necessary, constantly informed about all complaints referring to health impairments which could under certain circumstances require a revision of the assessment made by him.

The activities of an employed safety assessor can be included into the coverage of employers and product liability insurance of the company.

In particular when an external person is appointed to carry out the safety assessment of whom there are so far hardly any experiences available, a certain regular checking of his work by the executive management of the instructing company within its duty of care will be necessary. Such a checking of the instructions given to a renowned external assessor already known for some time to the company will as a rule not be necessary to the same extent. As for the rest, the securing of access to all necessary information is equally important for the appointment of an external as for the appointment of an employed safety assessor.

Below you will find an example for a cover letter to appoint a responsible person for safety assessment. This text only serves for illustration purposes. It has to be adjusted to the individual requirements of each single company and under certain circumstances additional details will have to be added. In view of different corporate structures, it must be taken into account that deviations from the recommenda-

tions given here for the form of appointment of the safety assessor are possible provided that the requirements of cosmetics law and product liability law are complied with.

Example for an appointment of a safety assessor for cosmetic products

"Dear Mrs / Mr . . . ,

We hereby appoint you as responsible safety assessor for the assessment of all cosmetic products of our company in view of their safety for human health in accordance with Article 10 of the EC Cosmetics Regulation [Regulation (EC) No. 1223/2009].

In this capacity you are responsible for the drafting and signing of safety reports for the products of our company based on Article 10 and Annex I of the EC Cosmetics Regulation.

In your capacity as safety assessor you report directly to the executive management of our company (Mr / Mrs ...). You have to report the results of your assessments directly to it. In your capacity as safety assessor you have access to all information you need for the assessment of the safety of our products, in particular the information referred to in Annex I Part A of the EC Cosmetics Regulation.

We assure you that we will take out insurance cover for you within the framework of our employers and product liability insurance in respect of any claims which can be asserted against you for damage caused as a result of your safety assessments, unless your behaviour in this respect is based on intent or gross negligence.

In order to acknowledge your agreement with your appointment as safety assessor, we kindly ask you to return the enclosed copy of this letter after having signed it, to us.

Yours sincerely"