

SCHÖNHEITSPFLEGE"

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**Considerations on product packaging
within the framework of the safety assessment of cosmetic products**

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The EU Cosmetics Regulation stipulates in Annex I (Part A) that within the framework of the safety assessment of cosmetic products "the relevant characteristics of packaging material, in particular purity and stability" have to be taken into account as well.

Packaging, containers and other wrappings, which are intended to come into contact with cosmetic products, are classified in Germany as commodities within the meaning of the German Food, Commodities and Feed Act (LFGB, § 2.6.2). Consequently, the packaging of cosmetic products is subject to the requirements of § 30 LFGB (prohibitions in view of health protection in dealing with other commodities) as well as indirectly also to § 26 LFGB (prohibitions in view of the protection of health in dealing with cosmetic products).

The selection of the type (e.g. jar, tube or dispenser), the materials and the quality of the packaging of a cosmetic product is particularly important in view of ensuring the stability and safety of a product across its entire life cycle. The selection of the appropriate material is frequently based on empirical values and/or recommendations by the packaging manufacturers. A distinction needs to be made between primary packaging in direct contact with the cosmetic filling and secondary packaging (e.g. outer packaging such as cardboard packaging) which is not in direct contact with the filling. For the primary packaging higher requirements have to be met, since in this case interactions between the filling and the packaging have to be assumed as probable. The safety assessor must individually assess and ensure the suitability of the packaging material for the intended formulation in terms of safety of use of the product. Frequently packaging materials designed for foods are used. In this case the cosmetic manufacturers should comply with the applicable requirements governing food packaging, confirmed by the packaging manufacturer.

A possible impairment of the quality, efficacy, safety, tolerance, microbiological quality or stability of the product by the packaging material must be controlled through appropriate measures and must be limited to an acceptable extent – taking into account the indications on application and storage conditions as well as the shelf life of the product. As a rule, a storage test in the respective original packaging or a representative packaging is carried out for each product in order to confirm the stability of the product. The issue of a possible migration of ingredients of cosmetic products into the packaging material and/or a migration of substances from the packaging materials into the product must be considered on top in each individual case. In this connection it is, more particularly, necessary to consider toxicologically relevant substances (e.g. CMR substances or SVHC substances) if they can migrate in relevant amounts into the filling.

For enquiries concerning essential information to be supplied on the packaging material by the packaging manufacturer and/or supplier, IKW makes available an exemplary supplier document under <http://www.safetyassessor.info/information>.

Other possible issues such as the adsorption of ingredients of the cosmetic product at the wall of the container, the instability of the packaging material vis a vis the product or the possibility that the packaging material protects the content only insufficiently from surrounding influences (e.g. light for transparent packaging), may have to be considered as well within the framework of the safety assessment. If the data available to the cosmetic manufacturer and other findings do not permit any sufficiently reliable statements on the qualification of a certain packaging material, it may be necessary to conduct or contract out additional tests with the respective formulation.

The experience made so far by the different manufacturers with their market products have confirmed that the assessment criteria and test methods outlined here are sufficient in order to meet the requirements concerning the quality and safety of the products. The existing practice is, therefore, also in conformity with the current requirements of the SCCS (SCCS's Notes of Guidance, 8th Revision, 2012): *"Relevant stability tests, adapted to the type of cosmetic product and its intended use, should be carried out. To make sure that no stability problems are induced by the type of container and packaging used, physical stability tests are currently carried out with inert containers and those intended to be used on the market."*

The following regulatory provisions should be applied in assessing packaging for cosmetic products (insofar as relevant for the safety of the cosmetic product):

- Directive 94/62/EC of the European Parliament and Council of 20 December 1994 on packaging and packaging waste
- Regulation (EC) No. 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation)
- Regulation (EC) No. 1907/2006 of the European Parliament and Council of 18 December 2006 concerning the registration, evaluation, authorisation and restrictions of chemicals (REACH Regulation)
- Directive 2002/72/EC of the Commission of 6 August 2002 relating to plastic materials and articles intended to come into contact with food
- Regulation (EC) No. 1935/2004 of the European Parliament and Council of 27 October 2004 on materials and articles intended to come into contact with food

Against the backdrop described above, the requirements referred to in Annex I (Part A, item 4; in conjunction with Article 10) of the EC Cosmetics Regulation No. 1223/2009 (taking into account the "relevant characteristics of packaging material, in particular purity and stability") have to be considered as fulfilled.
