

DRAFT

**Declaration on the assessment of packaging/packaging materials within
the framework of the safety assessment for cosmetic products**

**Supplier document
to confirm compliance with the requirements**

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Published by

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Foreword

In accordance with Article 3 of the Cosmetics Regulation (EC) No. 1223/2009, a cosmetic product made available on the market must be safe for human health when used under normal or reasonably foreseeable conditions of use. In accordance with Article 10 of the Regulation, the person responsible for the product (as a rule the manufacturer) is obliged to carry out a safety assessment in order to meet this requirement. In this connection the intended use of the cosmetic product and the anticipated systemic exposure to the individual ingredients has to be taken into account. This also includes an assessment in connection with the respective packaging (Annex I Part A Clause 4 of the Cosmetics Regulation). This concerns, more particularly, the packaging which comes into direct contact with the content.

It is important to ensure that as a result of the packaging and/or interactions between the packaging and the filling there are no health risks for the consumers. This refers, more particularly, to the potential migration of substances from the packaging into the filling. Packaging suppliers and, if necessary, their sub-contractors share the responsibility within the supply chain and should make available the necessary declarations and other relevant information.

Comparable rules have already been successfully applied for many years to foods and their packaging. These rules provide a sound basis in order to meet the above-mentioned requirements, because a large number of packaging and/or packaging materials used for cosmetic products are identical to the materials used for foodstuffs. At the same time cosmetic formulations have in many cases similar properties as food formulations. For that reason the document refers essentially to the standard practice of declarations of conformity with the relevant regulations for food packaging.

Furthermore, it is to be ensured that the packaging does not contain any substances which are excluded in accordance with the REACH Regulation 1907/2006, the Directive 94/62/EC on packaging and packaging waste as well as Annex VI of Regulation (EC) No. 1272/2008 about the classification, labelling and packaging of substances and mixtures. In addition, it may be necessary in special cases to assess certain substances more thoroughly in view of their safety in cosmetic products. This refers, more particularly, to additives which are added for specific purposes or new materials.

The supplier document is an important building block for the safety assessment by the cosmetics manufacturers. The departments of the cosmetics manufacturers in charge of the development and specification of the packaging are available for an exchange of information.

Further information on the assessment of the product packaging within the framework of the safety assessment is available on www.safetyassessor.info/information.

DECLARATION

This Declaration is used as a document for the assessment of the product safety of cosmetic products in accordance with the EC Cosmetics Regulation 1223/2009. It is used for packaging/packaging materials which are in direct contact with the filling.

Furthermore, this declaration serves for the documentation of compliance with the provisions of Directive 94/62/EC on packaging and packaging waste and the REACH Regulation 1907/2006.

1. Basic data

Date of the Declaration: _____ Version No.: _____

Author of the document (packaging manufacturer):

Recipient and user of the document (packaging user):

Description of the packaging/packaging part/packaging material:

Specification: _____

Data sheets: _____

2. Application history

The packaging/packaging part/packaging material specified above is already

- used for cosmetic products yes/ no
- used for foods yes/ no

If necessary, state the product categories (cosmetic products/foods):

3. Declarations of conformity

It is hereby declared that the packaging/packaging part/packaging material complies with the provisions of the following regulations, rules and/or recommendations:

Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food; in conjunction with Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

The specific migration limits stated in Regulation (EU) No. 10/2011 Annex I are complied with.

For metal packaging: Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food

German Commodities Regulation based on the Food, Commodities and Feed Code – Section 5

Recommendations of the Federal Institute for Risk Assessment (BfR) for materials in contact with food

For colorants: *CoE Resolution AP (89) 1 "On the use of colorants in plastic materials coming into contact with food"* and Recommendation No. IX of BfR "Colorants for the colouring of plastics and other polymers for commodities" (Status: 01.01.2010)

4. Declaration of substances/additives which are added for the purpose of special functions and/or during manufacturing (e.g. lubricants, antistatic agents)

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

5. Declaration about the use of biocidal active substances in accordance with Regulation (EU) No. 528/2012 (Biocidal Products Regulation)

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

6. Declaration about the use of CMR substances (substances which are classified as carcinogenic, mutagenic or toxic for reproduction in accordance with Annex VI of Regulation (EC) No. 1272/2008)

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

7. Declaration/exclusion of special substance groups

Does not contain / Contains

Substances of Very High Concern (SVHC in accordance with the REACH Regulation 1907/2006)
> 0.1 % per substance (if necessary, specify below).

Substance type: _____ CAS No.: _____

Substance amount: _____

Substance data sheet/safety data sheet as an Annex

Contains altogether < 100 ppm of the substances Pb, Cd, Hg, Cr (VI) and hence complies with the provisions of Directive 94/62/EC on packaging and packaging waste.

8. Exclusion/restriction of specially declared substances

For the packaging/packaging part/packaging material specified above it is hereby declared that no substances are contained in the packaging/packaging part/packaging material which appear in the following list and/or that their specific migration limit value is complied with:

Substance: _____ CAS No.: _____

Substance: _____ CAS No.: _____

Substance: _____ CAS No.: _____

Substance: _____ CAS No.: _____

Substance: _____ CAS No.: _____

Substance: _____ CAS No.: _____

SCHÖNHEITSPFLEGE"

KOMPETENZPARTNER IM IKW

Name of the author of the document: _____

Function of the author of the document: _____

Date: _____

Signature: _____