

**General Guidance
for Manufacturers and Distributors of Cosmetic Products in
Germany**

Status: 02 December 2015

Published by

The German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW)

Department Beauty Care

Mainzer Landstrasse 55

60329 Frankfurt am Main

Germany

Fax: +49 69 237631

info@ikw.org

www.ikw.org

The information compiled below represents a short version which can serve as a support. In legal terms the original text of the corresponding regulations are binding. This information relates only to the EC Cosmetics Regulation and the directly related national legislation. Apart from that, there are further regulations, such as chemicals and hazardous substances law (in particular REACH), the Animal Protection Act, the Detergent and Cleaning Product Act, the Prepackage Regulation, the Aerosol Packaging Regulation and others which need to be taken into account (see literature list).

Since 11 July 2013 cosmetic products have been subject within the EU to a uniform regulation: the EC Cosmetics Regulation – [Regulation \(EC\) No. 1223/2009](#). The latter applies directly in all Member States. Furthermore, German cosmetics law includes several additional and/or specific requirements concerning the placing on the market of cosmetic products in the Foods, Commodities and Feeds Code (LFGB) as well as in the German Cosmetics Ordinance.

Essential contents of the EC Cosmetics Regulation

Article 2: Definitions

Definitions, amongst others for cosmetic products, manufacturers, distributors, the making available on the market, the placing on the market, importers, nanomaterials, substances, (serious) undesirable effects.

Link to more detailed information: [Definition of cosmetic products](#) (in German)

Only products which are in conformity with the definition of cosmetic products described here, can be assessed and marketed as such.

Article 3: Safety requirement

Obligation to make only cosmetic products available on the market which when used under normal or reasonable foreseeable conditions of use, are safe for human health.

Further information, see Article 10: Safety assessment.

Articles 4/5: Responsible persons and their obligations

For each cosmetic product placed on the market, a responsible person established within the EU must be designated. This person must be disclosed on the packaging of the products and is responsible for ensuring that only products which are safe for human health are placed on the market. There is no mandatory approval. Compliance with the legal provisions by the responsible person is subject to verification by the competent surveillance authorities.

In the event of contract manufacturing or imports from countries outside the EU the responsible person indicated on the packaging is responsible for the product vis a vis the legislator and more particularly for the presentation and composition as well as compliance with duties of notification. In the event of imports from third countries it is also necessary to ensure the availability of labelling elements which are relevant for safety on the packaging in German language.

Link to more detailed information: [Cosmetics Europe Guide on the roles and responsibilities along the supply chain](#) (German translation: [Cosmetics-Europe-Leitfaden zu Verantwortlichkeiten innerhalb der Lieferkette](#))

Article 6: Obligations of the distributors

The EC Cosmetics Regulation also defines the different obligations for distributors of cosmetic products.

Link to more detailed information: [Cosmetics Europe Guide on the roles and responsibilities along the supply chain](#) (German translation: [Cosmetics-Europe-Leitfaden zu Verantwortlichkeiten innerhalb der Lieferkette](#))

Link to more detailed information: [Letter to the editor](#) by IKW to *Pharmazeutische Zeitung* of 24.05.2013.

Article 8: Good manufacturing practice

Requirements to be met by the manufacturing process (Cosmetics GMP) as well as reference to the relevant harmonised standards:

There are currently no legal texts with validity throughout the EU for the manufacturing in accordance to Cosmetics GMP. The recommendation of IKW on this topic is compiled in the brochure "[Cosmetics GMP – Guidance for the manufacturing of cosmetic products](#)" (1999, in German). Since 2008 the Standard DIN EN ISO 22716 – "Cosmetics GMP – Guidelines on good manufacturing practices" has been available. This international Standard becomes increasingly important because in the meantime it has also been referred to in a "[Commission Communication](#) in the framework of the implementation of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products (publication of titles and references of harmonised standards; 2011/C123/04)". IKW has published an explanatory brochure on this Standard: "[Cosmetics GMP – the Standard DIN EN ISO 22716, commented by the German Cosmetic, Toiletry, Perfumery and Detergent Association](#)" (in German) and has also published, by way of supplement, a GMP Checklist ([in German](#)/[in English](#)) for internal reviews.

The Standard [ISO 22716:2007](#) "Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices"; EN ISO 22716, DIN EN ISO 22716, can be obtained subject to a charge in different language versions from [Beuth Verlag](#) in Berlin.

Previous English guidelines on Cosmetics GMP:

- COLIPA (now Cosmetics Europe): "Cosmetic Good Manufacturing Practices, Guidelines for the Manufacturer of Cosmetic Products" (1994)
- Council of Europe: "[Guidelines for good manufacturing practice of cosmetic products \(GMPC\)](#)" (1995)

Article 10: Safety assessment

Obligation to conduct a safety assessment and set up a product safety report prior to the placing on the market of any cosmetic product in accordance with Annex I of the Regulation. The safety report is an integral part of the product information file (cf. Article 11).

Link to more detailed information: [Cosmetics Europe – Guidelines on the product information file \(PIF\) requirement](#) (German translation: [Cosmetics-Europe-Leitlinien zu den Anforderungen an die Produktinformationsdatei](#))

Data sources for the safety assessment and continuing education offers for safety assessors: www.sicherheitsbewerter.info (in German)/www.safetyassessor.info (in English)

Article 11: Product information file

Keeping available of information on every cosmetic product placed on the market in view of surveillance at the registered office of the responsible person (under the address stated on the packaging):

1. Description of the cosmetic product
2. Safety report (cf. Article 10)
3. Manufacturing method and statement on compliance with good manufacturing practice (Cosmetics GMP, cf. Article 8)
4. Proof of the effect claimed
5. Data on certain animal testing

Link to more detailed information: [Cosmetics Europe – Guidelines on the product information file \(PIF\) requirement](#) (German translation: [Cosmetics-Europe-Leitlinien zu den Anforderungen an die Produktinformationsdatei](#))

Article 13: Notification

Obligation in view of the central recording of all cosmetic products prior to their placing on the market in the CPNP database.

Link to more detailed information: [Website of the EU Commission](#)

Article 14: Restrictions for substances

Concrete regulations on ingredients – reference to the Annexes II to VI of the Regulation (substance lists):

Annex II: Prohibited substances

Annex III: Substances whose use is restricted

Annexes IV to VI: Substances subject to approval (colorants, preservatives and UV filters)

The requirements to be met by substances subject to approval are described in the [Notes of Guidance of the SCCS](#) (previously SCCP/SCCNFP), the advisory body of the EU Commission in charge of the safety assessment of cosmetic raw materials, of December 2012.

Any substances not expressly regulated by the substance lists are subject to the general safety requirement in accordance with Article 3 (to be documented within the framework of the safety assessment in accordance with Article 10).

Article 15: Substances classified as CMR substances

Regulations on the use of substances which are classified as CMR substances in accordance with Annex VI of Regulation (EC) No. 1272/2008.

Link to more detailed information: [Website of the EU Commission](#)

Article 16: Nanomaterials

Obligation in respect of a separate notification of products which contain nanomaterials (six months prior to being placed on the market). This requirement does not apply to nanomaterials subject to approval (colorants, preservatives, UV filters).

Link to more detailed information: [Website of the EU Commission](#)

Article 17: Traces of prohibited substances

Toleration of the unintended presence of small quantities of a prohibited substance provided that this cannot be avoided in good manufacturing practice and the product is safe in accordance with Article 3.

Article 18: Animal testing

Prohibition to conduct animal testing for cosmetic products and their ingredients and to market cosmetic products, if the products or the ingredients have been tested by performing animal testing.

Link to more detailed information: [Website of the EU Commission/Questions & Answers on animal testing](#) (in German)

Article 19: Labelling

Specific cosmetics labelling provisions for packages and containers:

- Name/company name and address of the responsible person (cf. Article 4)
- Nominal content at the time of packaging
- Date of minimum durability (for a durability of ≤ 30 months) or period after opening (for a durability of > 30 months)
- Precautions to be observed in use, special precautionary information
- Batch identification
- Function (unless it is clear from the presentation)
- List of ingredients (only on outer packaging)

The inventory of ingredients employed in cosmetic products, which serves as a basis for the INCI labelling, was published for the first time in the Official Journal of the EC on 01.06.1996 (ISSN 0376-9453). A first updated version was published in the Official Journal of the EU in April 2006. Since 2008 the ingredients of cosmetic products and their INCI names can also be searched in the freely accessible (and continuously updated) [CosIng database](#) of the EU Commission.

26 perfume ingredients listed in Annex III to the EU Cosmetics Regulation must be labelled – regardless of their integration into the cosmetic product – above the threshold values of 0.01 % for

products which are rinsed off and 0.001 % for other products separately on the packages within the framework of the INCI declaration.

Link to more detailed information: Cosmetics Europe – [Guidelines on cosmetic product labelling](#) (German translation: [Cosmetics-Europe-Leitlinien für die Kennzeichnung von kosmetischen Mitteln](#))

Article 20: Product claims

The Regulation stipulates that claims on cosmetic products must always be truthful, supported by verifiable evidence, honest and fair (see also Article 11/Clause 4: Evidence for claimed effects).

Links to more detailed information: [Commission Regulation \(EU\) No 655/2013](#) laying down common criteria for the justification of claims used in relation to cosmetic products/[Guidelines to Commission Regulation \(EU\) No 655/2013](#)

Article 21: Access to information for the public

Certain elements of the product information file (cf. Article 11) must be made easily accessible to the public on request.

Link to more detailed information: [Cosmetics Europe – Guidelines on the product information file \(PIF\) requirement](#), Section V (German translation: [Cosmetics-Europe-Leitlinien zu den Anforderungen an die Produktinformationsdatei](#))

Article 23: Communication of serious undesirable effects

Serious undesirable effects (cf. Article 2: Definitions) which are attributable to the normal, reasonably foreseeable use of a cosmetic product must be notified.

Link to more detailed information: [Website of the EU Commission](#)

Link to more detailed information: Cosmetics Europe Guidelines on the Management of Undesirable Effects and reporting of Serious Undesirable Effects in the European Union ([German translation](#))

More detailed information on the EC Cosmetics Regulation:

[EC Cosmetics Regulation 1223/2009 – Explanations and comments](#)

[Information of the Federal Office for Consumer Protection and Food Safety \(BVL\) for persons placing cosmetic products on the market](#) (in German language)

German Cosmetics Ordinance (KVO) of 16.07.2014 (Federal Law Gazette I, p. 1054)

Essential contents:

§ 3

Duties of notification (notification of the manufacturing site and/or the import site in Germany – [list of competent authorities](#))

§ 4

Obligation to label in accordance with Article 19.1 b/c/d/f EC Cosmetics Regulation in German

§ 8

Criminal offences

§ 9

Administrative offences

Existing regulations under the **German Foods, Commodities and Feeds Code (LFGB)**¹ on cosmetic products (will be adapted to the new EC Cosmetics Regulation in the near future)

¹As published on 03.06.2013 (Federal Law Gazette I, p. 1426)

Some essential contents:

§ 2 para 5

Definition of cosmetic products

§ 5 para 2 No. 2 in conjunction with § 3 No. 8

Prohibition to place products on the market which can be confused with foods

§ 26

Prohibition to place cosmetic products on the market which can damage consumer health in the event of proper or foreseeable use.

§ 27

Prohibition of misleading

§ 38

Competence for surveillance measures in accordance with regional law

The inspection of cosmetic products and their manufacturing is subject to official food surveillance. The implementation of the official food surveillance lies within the sphere of responsibility of the Federal States. The food surveillance is carried out by the “Food investigation offices” or “Chemical and veterinary investigation offices” of the lower administrative authorities by civil servants with a specialist training. The superior supervision lies with the superior regional public authority. This is normally the Federal State Minister or Senator in charge of food safety and/or consumer protection.

§ 39

Duty and measures of the competent authorities

§ 42

Execution of the surveillance

§ 43

Sampling

§ 64

Analytical methods

Recommendations

In addition to the afore-mentioned legal texts, there are various recommendations which have been published by the EU Commission, national authorities as well as industry, which are also checked by the competent surveillance in terms of compliance.

The IKW Recommendations are available on the website of the Competence Partner Beauty Care within IKW ([in German](#)/[in English](#)). The recommendations by Cosmetics Europe can be consulted [here](#).

The reports and recommendations of the Federal Institute for Risk Assessment (BfR) are available on the Internet under www.bfr.bund.de (in German) or www.bfr.bund.de/en/ (in English).

Additional information

More extensive advice e.g. on product-specific issues is offered by private experts, if needed. Chemical and/or microbiological analyses are offered by different commercial laboratories (see also "Chemical/Microbiological Laboratories" in the local classified directories). Any references to advisors and/or experts which specialise in the drafting of product information files and/or safety reports or issues relating to "Good Manufacturing Practice" (Cosmetics GMP) can for instance be found in the relevant journals for cosmetics, on the Internet or can be obtained, on request, from IKW (info@ikw.org).

Literature/Sources

Status: December 2015. The most recent version of the following Regulations is valid in each case.

European Union/International:

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30.11.2009 on cosmetic products (<http://eur-lex.europa.eu/homepage.html?locale=en>).

Council Directive 75/324/EEC of 20.05.1975 on the approximation of the laws of the Member States relating to aerosol dispensers (<http://eur-lex.europa.eu/homepage.html?locale=en>).

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18.12.2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) (<http://eur-lex.europa.eu/homepage.html?locale=en>).

Regulation (EC) No. 1272/2008 of the European Parliament and Council on the classification, labelling and packaging of substances and mixtures (<http://eur-lex.europa.eu/homepage.html?locale=en>).

Websites of the EU Commission on cosmetic products:
http://ec.europa.eu/growth/sectors/cosmetics/index_en.htm

CosIng database of the European Commission (INCI names of cosmetic ingredients):
http://ec.europa.eu/growth/sectors/cosmetics/cosing/index_en.htm

EU notification portal for cosmetic products (Cosmetic Products Notification Portal, CPNP):
http://ec.europa.eu/growth/sectors/cosmetics/cpnp/index_en.htm

International Cosmetic Ingredient Dictionary and Handbook, 15th ed. (2014), Personal Care Products Council (previously CTFA), Washington DC, <http://www.personalcarecouncil.org>

Germany:

Foods, Commodities and Feeds Code (LFGB) as published on 03.06.2013 (Federal Law Gazette I, p. 1426): <http://bundesrecht.juris.de/lfgb/index.html>

German Cosmetics Ordinance of 16.07.2014 (BGBl. I, p. 1054):
http://www.gesetze-im-internet.de/bundesrecht/kosmetikv_2014/gesamt.pdf

Chemicals Act: Act on the protection against hazardous substances as published on 28.08.2013 (Federal Law Gazette I, p. 3498, 3991): <http://bundesrecht.juris.de/chemg/index.html>

Hazardous Substances Ordinance: Ordinance for the Protection Against Hazardous Substances of 26.11.2010 (BGBl. I, p. 1643, 1644): http://www.gesetze-im-internet.de/gefstoffv_2010/index.html

Act on the Implementation of Regulation (EC) No. 1907/2006 (REACH Amendment Act) of 20.05.2008 (BGBl. I, p. 922).

Animal Protection Act as published on 18.05.2006 (BGBl. I, p. 1206, 1313):
<http://gesetze-im-internet.de/tierschg/index.html>

Detergent and Cleaning Product Act: Act on the Environmental Compatibility of Detergents and Cleaning Products as published on 17.07.2013 (Federal Law Gazette I, p. 2538):
<http://gesetze-im-internet.de/wrmg/index.html>

Pre-package Ordinance: Ordinance on Pre-packages as published on 08.03.1994 (Federal Law Gazette I, p. 451, 1307): http://gesetze-im-internet.de/fertigpackv_1981/index.html

Thirteenth Ordinance concerning the Product Safety Act (Aerosol Packaging Ordinance) of 27.02.2002 (Federal Law Gazette I, p. 3777, 3805):
http://www.gesetze-im-internet.de/bundesrecht/gsgv_13/gesamt.pdf