

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Requirements for all cosmetic substances**

Article No.:

req. no.	Statutory requirement	Law	Article
5214	<p>The import and marketing of products and devices containing chlorofluorocarbons, other perhalogenated chlorofluorocarbons, halons, carbontetrachlorides, 1,1,1-trichloroethane, partly halogenated bromofluoride hydrocarbons and chlorobromomethane are prohibited. The following are affected:</p> <ul style="list-style-type: none"> <li>- Aerosol products</li> <li>- Dyes and paints</li> <li>- Cosmetics</li> <li>- Lubricants</li> <li>- Cleaning materials</li> <li>- Pressurised gas containers</li> <li>- Fire extinguishers</li> <li>- Insulation materials</li> <li>- Refrigerators</li> <li>- Air conditioning units</li> <li>- Mattresses</li> <li>- Foam material</li> <li>- Adhesives</li> </ul>	ChemOzonSchi chtV	Art.4
160006	<p>For cosmetic products only colorants allowed in Annex IV may be used. The use of colorants not listed in Annex IV is strictly prohibited. Exceptions to these are hair dyeing and hair colouring substances.</p> <p>For the colorants in Annex IV RE (EC) No 1223/2009 the highest concentration levels and conditions to which cosmetic finished products must adhere, are listed.</p> <p>The purity criterias for the colorants must be fulfilled. Exceptions to these are hair dyeing and hair colouring substances.</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang IV_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160248	<p>Cosmetic applications that could be easily inhaled should not contain the dyes listed in Annex IV RE (EC) No 1223/2009:</p> <p>No. 126a: Carbon black (nano) (INCI: 77266 (nano) Carbon black (nano); CAS No 1333-86-4, 7440-44-0) No. 144: Zinc oxide (INCI: 77947; CAS No 1314-13-2)</p> <p>From 24 May 2018 only cosmetic products which comply with the new requirements on zinc oxide shall be made available on the Union market.</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160014	<p>Preservatives listed in Annex V RE (EC) No 1223/2009 are allowed for cosmetic products within the limits and the conditions laid down (as purity criteria, limits of concentration, warnings) The use of all other preservative is definitely prohibited.</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

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Article No.:

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160016	<p>The following conservation substances listed in Annex V of RE (EC) No 1223/2009 may be added for other purposes than conservation as long as they are allowed for that particular cosmetic product. These are conservation substances marked in Annex V of RE (EC) No 1223/2009 with a number (#). In this case the concentration in the product may be higher. It must, however, be clear from the labelling for what purpose the substance was added.</p> <p>No 3: Salicylic acid and its salts (CAS No 69-72-7, 824-35-1, 18917-89-0, 59866-70-5, 54-21-7, 578-36-9, 2174-16-5) (see Annex III No 98)</p> <p>No 5: Formaldehyde paraformaldehyde (INCI: Formaldehyde Paraformaldehyde, CAS No 50-00-0, 30525-89-4) (see Annex III No 13)</p> <p>No 8: Pyrithione zinc (INCI: Zinc pyrithione, CAS No 13463-41-7) (see Annex III No 101)</p> <p>No 9: Inorganic sulphites and hydrogen-sulphites (CAS No 7757-83-7, 10192-30-0, 10196-04-0, 10117-38-1, 7773-03-7, 7631-90-5, 7681-57-4, 16731-55-8) (see Annex III No 99)</p> <p>No 23: 1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl) urea (INCI: Triclocarban, CAS No 101-20-2) (see Annex III No 100)</p> <p>No 34: Benzyl alcohol (INCI: Benzyl Alcohol, CAS No 100-51-6) (see Annex III No 45)</p> <p>No 43: 1-Phenoxypropan-2-ol (INCI: Phenoxyisopropanol, CAS No 770-35-4) (see Annex III No 54)</p> <p>No 44: Alkyl(C12-22)trimethyl-ammoniumbromide and -chloride, thereof are behentrimonium chloride, cetrimonium chloride, steartrimonium chloride (CAS No 17301-53-0, 112-02-7, 112-03-8) listed in Annex III No 286 and 287 (see RE (EU) No. 866/2014)</p> <p>No 54: Benzalkonium chloride, bromide and saccharinate (CAS No 8001-54-5, 63449-41-2, 91080-29-4, 68989-01-5, 68424-85-1, 68391-01-5, 61789-71-7, 85409-22-9) (see Annex III No 65)</p> <p>No 58: Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2) (see Annex III No 197)</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160064	For bio or natural cosmetics no legal regulations exist. However, the use of various private legal seals or logos is possible, if for the seal in question laid down requirements are fulfilled.	Zusatzinfo	
160066	It is prohibited to place cosmetic products on the market under a misleading designation, information statement or presentation.	LFGB	§ 27

Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - Requirements for all cosmetic substances**

Article No.:

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160123	<p>In all cosmetic products the following substances listed in Annex III RE (EC) No 1223/2009 are allowed if the various limitations ( purity requirements, highest concentrations, additional labelling elements etc.,) laid down in the annex are observed:</p> <p>No 4: Ammonia (INCI: Ammonia, CAS No 7664-41-7/ 1336-21-6)</p> <p>No 5: Tosylchloramide sodium (INCI: Chloramine-T, CAS No 127-65-1)</p> <p>No 6: Chlorates of alkali metals (INCI: Sodium chlorate, CAS No 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9)</p> <p>No 7: Dichloromethane (INCI: Dichloromethane, CAS No 75-09-2)</p> <p>No 11: Dichlorophene (INCI: Dichlorophene, CAS No 97-23-4)</p> <p>No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2)</p> <p>No 15c: Calcium hydroxide (INCI: Calcium hydroxide; CAS No 1305-62-0)</p> <p>No 17: Sodium nitrite (INCI: Sodium nitrite, CAS Nr. 7632-00-0)</p> <p>No 18: Nitromethane (INCI: Nitromethane, CAS No 75-52-5)</p> <p>No 24: Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrithione (INCI: Zinc acetate, zinc chloride, zinc gluconate, zinc glutamate, CAS No - )</p> <p>No 45: Benzyl alcohol (INCI: Benzyl Alcohol, CAS No 100-51-6)</p> <p>No 52: Methanol (INCI: Methyl alcohol, CAS No 67-56-1)</p> <p>No 60: Fatty acid dialkylamides and dialkanolamides (INCI: -, CAS No -)</p> <p>No 61: Monoalkylamines, monoalkanolamines and their salts (INCI: -, CAS No -)</p> <p>No 66: Polyacrylamides (INCI: -, CAS No -)</p> <p>No 152: Allyl heptine carbonate (allyl oct-2-ynoate) (INCI: Allyl heptine carbonate, CAS No 73157-43-4)</p> <p>No 153: Amylcyclopentenone; 2-Pentylcyclopent-2-en-1-one (INCI: Amylcyclopentenone, CAS No 25564-22-1)</p> <p>No 154: Myroxylon balsamum var. pereirae; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru) (INCI: -, CAS No 8007-00-9)</p> <p>No 155: 4-tert.-Butyldihydrocinnamaldehyde; 3-(4-tert-Butylphenyl)propionaldehyde (INCI: 4-tert.-Butyldihydrocinnamaldehyde, CAS No 18127-01-0)</p> <p>No 159: trans-Rose ketone-5; (E)-1-(2,4,4- Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (Isodamascone) (INCI: trans-Rose ketone-5, CAS No 39872-57-6)</p> <p>No 167: l-Limonene; (S)-p-Mentha-1,8-dien (INCI: Limonene, CAS No 5989-54-8)</p> <p>No 168: dl-Limonene (racemic); 1,8-p-Menthadiene; p-Mentha-1,8-diene (Dipentene) (INCI: Limonene, CAS No 138-86-3)</p> <p>No 170: Isobergamate; Menthadiene-7- methyl formate (INCI: Isobergamate, CAS No 68683-20-5)</p> <p>No 171: Methoxy dicyclopentadiene carboxaldehyde; Octahydro-5- methoxy-4,7- Methano-1H-indene-2-carboxaldehyde (INCI: Scentenal, CAS No 86803-90-9)</p> <p>No 172: 3-Methylnon-2- enenitrile (INCI: 3-methylnon-2-enenitrile, CAS No 53153-66-5)</p> <p>No 176: Isocyclogeraniol; 2,4,6-Trimethyl-3- cyclohexene-1-methanol (INCI: Isocyclogeraniol, CAS No 68527-77-5)</p> <p>No 179: p-methylhydrocinnamic aldehyde;</p> <p>Cresylpropionaldehyde; p-Methyldihydrocinnamaldehyde (INCI: p-methylhydrocinnamic aldehyde, CAS No 5406-12-2)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



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**Cosmetic products - Requirements for all cosmetic substances**

Article No.:

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160124	<p>The following substances, in cosmetic materials, must adhere to the limitations listed in Annex III RE (EC) No 1223/2009 (highest amounts, purity requirements, additional labelling elements etc. For a few cosmetic products the regulations deviate or the material is totally prohibited for a particular product. This information is given in the requisite actions for each product affected:</p> <p>No 1a: Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex 1 (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1)</p> <p>No 6: Chlorates of alkali metals (INCI: Sodium chlorate, CAS No 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9)</p> <p>No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2)</p> <p>No 15c: Calcium hydroxide (INCI: Calcium hydroxide, CAS No 1305-62-0)</p> <p>No 59: Talc: Hydrated magnesium silicat (INCI: Talc, CAS No 14807-96-6)</p> <p>No 62: Trialkylamines, trialkanolamines and their salts (INCI: -, CAS No -)</p> <p>No 65: Benzalkonium Chloride, bromide and saccharinate (INCI: Benzalkonium bromide, CAS No 91080-29-4; INCI: Benzalkonium chloride, CAS No 63449-41-2/ 68391-01-5/ 68424-85-1/ 85409-22-9; INCI: Benzalkonium saccharinate, CAS No 68989-01-5)</p> <p>No 66: Polyacrylamides (INCI: -, CAS No -)</p> <p>No 72: 7-Hydroxycitronellal (INCI: Hydroxycitronellal, CAS No 107-75-5)</p> <p>No 73: Phenol, 2-methoxy4-(1-propenyl) (INCI: Isoeugenol, CAS No 97-54-1)</p> <p>No 89: Methyl Oct-2-ynoate; Methyl heptene carbonate (INCI: Methyl 2-octynoate, CAS No 111-12-6)</p> <p>No 96: 5-tert-Butyl-2,4,6- trinitro-m-xylene (INCI: Musk xylene, CAS No 81-15-2)</p> <p>No 97: 4'-tert-Butyl-2',6'- dimethyl-3',5'-dinitroacetophenone (INCI: Musk ketone, CAS No 81-14-1)</p> <p>No 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7)</p> <p>No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS-No 93-15-2)</p> <p>No 157: cis-Rose ketone-1; (Z)-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (cis-alpha-Damascone) (INCI: Alpha-Damascone, CAS No 23726-94-5 / 43052-87-5)</p> <p>No 158: trans-Rose ketone-2; (E)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (trans-beta-Damascone) (INCI: trans-Rose ketone-2, CAS No 23726-91-2)</p> <p>No 160: Rose ketone-4; 1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one (Damasconone) (INCI: Rose ketone-4; CAS No 23696-85-7)</p> <p>No 161: Rose ketone-3; 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (Delta-Damascone) (INCI: Delta-Damascone, CAS No 57378-68-4)</p> <p>No 162: cis-Rose ketone-2; (Z)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (cis-beta-Damascone) (INCI: cis-Rose ketone-2, CAS No 23726-92-3)</p> <p>No 163: trans-Rose ketone-1; (E)-1-(2,6,6- Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (trans-alpha-Damascone) (INCI: trans-Rose ketone-1, CAS-Nr, 24720-09-0)</p> <p>No 165: trans-Rose ketone-3; 1-(2,6,6- Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (trans-gamma-Damascone) (INCI: trans-gamma-Damascone, CAS No 23726-93-4)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
S. 4			



Category: Cosmetics

18-05

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Article No.:

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160146	<p>Cosmetics strongly contaminated by germs are fundamentally not safe and should not find their way onto the market. The limit value lies according to "The SCFP's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation" at 10<sup>3</sup> KBE/g or ml for the me-sophile, aerobe total germ count for cosmetic substances in general use .</p> <p><b>Additional information:</b> BfR Kosmetik-Keime_17-11</p>	BfR Kosmetik-Keime	

Category: Cosmetics

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Article No.:

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160147	<p>The question whether a product is a cosmetic substance in the sense of RE (EC) No 1223/2009 is answered in the guidelines (LL borderline-products) for the following products:</p> <ol style="list-style-type: none"> <li>1.1. Tongue brushes releasing a preparation or a mixture</li> <li>1.2. Clothes releasing cosmetic substances</li> <li>1.3. Tooth picks and tooth floss</li> <li>1.4. Patches</li> <li>1.5. Washable, temporary "tattoos"</li> <li>1.6. Wipes</li> <li>1.7. Wig</li> <li>1.8. Tattoo removal devices</li> <li>1.9. Wet razors releasing substances/mixtures</li> <li>2. Application Site               <ol style="list-style-type: none"> <li>2.1. Vagina</li> <li>2.2. Ingestion (tablets)</li> <li>2.3. Ingestion (Chewing gum)</li> <li>2.4. Nasal Spray</li> </ol> </li> <li>3. Intended Cosmetic Purpose               <ol style="list-style-type: none"> <li>3.1. Borderline with toys                   <ol style="list-style-type: none"> <li>3.1.1. Products which, according to their presentation, are destined to be used as make-up on dolls</li> <li>3.1.2. Products which, according to their presentation, are destined to be used as make-up on children</li> <li>3.1.3. Bath Products for Children with a Play Value</li> <li>3.1.4. Face paints, body paints, aerography</li> </ol> </li> <li>3.2. Borderline with Biocides                   <ol style="list-style-type: none"> <li>3.2.1. Leave-on products presented as "antiseptic" or "antibacterial"</li> <li>3.2.2. "Antiseptic" or "Anti-bacterial" Mouthwash</li> </ol> </li> <li>3.3. Borderline with Pharmaceutical Products                   <ol style="list-style-type: none"> <li>3.3.1. Products which, according to their presentation, are intended to exclusively or mainly relieve joint pain</li> <li>3.3.2. Products which, according to their presentation, are intended to address "itching"</li> <li>3.3.3. Product containing substances which restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action</li> <li>3.3.4. Products containing substances stimulating hair growth or reducing hair loss</li> <li>3.3.5. Products that make eyelashes grow</li> <li>3.3.6. Products for in-grown hairs</li> <li>3.3.7. Products that make the lips swell</li> <li>3.3.8. Products reducing cellulite</li> <li>3.3.9. Substances applied with skin-patches</li> <li>3.3.10. Products delivered through</li> <li>3.3.11. Products delivered through invasive techniques, such as needle roller</li> <li>3.3.12. Product to treat dry mouth</li> <li>3.3.13. Products for superficial moisturizing of female genital organ in cases of extreme mucosal dryness</li> <li>3.3.14. Topical breast augmentation products</li> <li>3.3.15. Products claiming aromatherapy</li> <li>3.3.16. Products for atopic skin</li> <li>3.3.17. Products to reduce dark circle under the eyes, bruises or blue spots</li> <li>3.3.18. Products with claims related to bruises, bumps and similar</li> </ol> </li> </ol> </li> </ol>	LL Borderline-products	
S. 6			

Category: Cosmetics

18-05

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**Cosmetic products - Requirements for all cosmetic substances**

Article No.:

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160153	In order to distinguish a cosmetic substance from a medicinal product the following guidance document may be consulted: GUIDANCE DOCUMENT ON THE DEMARCATION BETWEEN THE COSMETIC PRODUCTS DIRECTIVE 76/768 AND THE MEDICINAL PRODUCTS DIRECTIVE 2001/83 AS AGREED BETWEEN THE COMMISSION SERVICES AND THE COMPETENT AUTHORITIES OF MEMBER STATES. Please take account of the next instruction. <b>Additional information:</b> LL Borderline Kosm-MedPr_18-05	LL Borderline Kosm-MedPr	
160245	Cosmetic products equally used as toys must bear the CE marking.	ALS	2015/56
160154	The Federal Institute for Risk Analysis (BfR) recommends for tea tree oil (Oil from <i>Melaleuca alternifolia</i> ) the limitation use of 1% in cosmetic products. The products should be in a light-proof packaging and should contain antioxidants. To prevent health risks it is recommended to affix warning and application notes. <b>Additional information:</b> 7-Sitzung-der-BfR-Kommission-fuer-kosmetische-Mittel_13-04 BfR Teebaumöl_13-04	BfR Teebaumöl	
160156	The use of substances classified as CMR in cosmetic products is prohibited. In exceptional cases substances classified as CMR 1A and CMR 1B may be used if - they fulfil the requirements of food safety according to RE (EC) Nr. 178/2002 - no suitable substitutes are available - they are used for a particular application of known effect - if they have been evaluated and found safe by the SCCS (Scientific Committee for Consumer Safety). The substances must be specially labelled.	VO (EG) Nr. 1223/2009	Art. 15 Abs. 1, 2
160157	Cosmetic products shall be safe for human health when used under normal or reasonably foreseeable conditions of use. This applies particularly to the presentation, labelling, instructions for use and disposal and other indication or information.	VO (EG) Nr. 1223/2009	Art. 3
160158	The restrictions for certain materials which are listed in Annex III RE (EU) No 1223/2009 must be adhered to. <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

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**Cosmetic products - Requirements for all cosmetic substances**

Article No.:

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160159	<p>The substances listed in Annex II of RE (EC) No 1223/2009 must not be used in cosmetic materials. These substances may, however, be used as aids if they are completely removed or removed to such an extent that only technically unavoidable and technologically inactive residues remain in amounts completely harmless to health.</p> <p>From 23 August 2019 cosmetic products containing HICC, Atranol or Chloratranol shall not be placed on the Union market. From 23 August 2021 cosmetic products containing HICC, Atranol or Chloratranol shall be not be made available on the Union market. Until 23 August 2021 HICC can be used according to Annex III RE 1223/2009.</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang II_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe a)
160239	<p>2-(2-ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS No 111-90-0) is only allowed for cosmetic products listed in the annex adhere the limitations and requirements. The substance must not be used for oral or eye products.</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160160	<p>The non-intended presence of a small quantity of prohibited substance stemming from impurity of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable shall be permitted as long as the cosmetic product is considered to be safe.</p>	VO (EG) Nr. 1223/2009	Art. 17
160185	<p>The responsible person provides on demand access for the public regarding certain information. This is :</p> <ul style="list-style-type: none"> <li>- the composition (qualitative and quantitative for substances considered dangerous according to RE (EEU) Nr. 1272/2008),</li> <li>- in case of perfume and aromatics the name and code number of the composition as well as the identity of the supplier</li> <li>- Data on undesirable effects and serious undesirable effects.</li> </ul>	VO (EG) Nr. 1223/2009	Art. 21
160186	<p>All serious undesirable effects must be notified to the competent authority by responsible person and distributors. Documents in German language are available under the following link:</p> <p><a href="http://www.bvl.bund.de/DE/03_Verbraucherprodukte/03_AntragstellerUnternehmen/02_Kosmetik/02_SUE/bgs_fuerAntragsteller_kosmetik_SUE_node.html">http://www.bvl.bund.de/DE/03_Verbraucherprodukte/03_AntragstellerUnternehmen/02_Kosmetik/02_SUE/bgs_fuerAntragsteller_kosmetik_SUE_node.html</a></p>	VO (EG) Nr. 1223/2009	Art. 23
160187	<p>In case of serious doubt regarding the safety of any substance contained in cosmetic products, the competent authority of a Member State can require a list of all cosmetic products containing this substance from the responsible person (highlighted address on the label). The concentration of this substance is to be stated.</p>	VO (EG) Nr. 1223/2009	Art. 24



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160198	The European court of Justice delivered a final judgement on the definition of "pharmaceutical effect". This judgment shall be used to differentiate cosmetic products from pharmaceutical products. <b>Additional information:</b> Urteil EuGH Definition pharmakologische Wirkung	Urteil EuGH Definition pharmakologische Wirkung	
160201	Information and clarifications about undesirable effects and serious undesirable effects might be provided by the guidelines from Cosmetics Europe. <b>Additional information:</b> LL Unerwünschte Wirkungen 0213_13-04	LL UW und EUW	
160209	The manufacturer must indicate the place of manufacturing of a cosmetic product to the competent authorities responsible for controls before placing a product on the market. Amendments must be indicated.	KosmetikV	§ 3 Satz 1,3,4
160210	The importer of a cosmetic product must indicate the first place of import of a cosmetic product to the competent authorities responsible for controls before the import takes place the first time. Amendments must be indicated.	KosmetikV	§ 3 Satz 2,3,4
160224	Fluorescent dyes are not classified as dyes in accordance to RE (EC) 1223/2009. If fluorescent dyes are used in cosmetic products, the harmlessness must be stated in the safety assessment.	ALS	2013/25
160252	Traces of forbidden heavy metals are considered as technically avoidable if they exceed the BVL's orientation values.	ALS	2017/39

Category: Cosmetics

18-05

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**Cosmetic products - Prepacked Cosmetics**

Article No.:

Prepackages need a labelling of their nominal weight or nominal volume.

req. no.	Statutory requirement	Law	Article
40173	The requirements of FPackV do not apply to free samples which are marked as such.	FertigPackV	§ 33a Abs. 1
160082	Finished packs of cosmetic substances with a content amount of less than 5g or mL or with a contents amount of more than 10kg or L may be put on the market without a contents statement and are not subject to the FPackV	FertigPackV	§ 30 + § 31 Abs.1
10622	For finished packs with the same nominal capacity which are labeled according to weight or volume, the actual capacity of the finished pack may only vary in the range laid down in §22 of FpackV and must not be below the nominal capacity in the middle. Hereby the reference temperatures from §26 of FpackV are to be observed.	FertigPackV	§ 22, § 26
20431	For the statement of nominal filling quantity and its unit and for the statement of the number of pieces in individual packs, the following script sizes are prescribed: nominal filling quantity script size in g or ml in mm 5 to 50, 2 mm, more than 50 up to 200 3 mm, more than 200 up to 1000 4 mm, more than 1000 6 mm.  For collected packs the content amount of the individual finished packs must be stated in the following script sizes: nominal filling quantity of the individual packs up to 50 g or 50 ml: 3mm; nominal filling quantity of the individual packs 50 g or 50 ml and more: 6 mm.  For finished packs of uneven nominal filling quantity, for whose manufacture scales are used with a print-out of the weight, there is an exception in the regulation: here the script size is aligned according to the calibration regulations.	FertigPackV	§ 20
40141	If products are filled in bottles which are measured containers then these measured containers must conform to the requirements of § 2, 3 and 4 of FpackV. The measuring container must write the mark according to FPackV Annex 8. <b>Additional information:</b> FPackV Anlage 8	FertigPackV	§ 2,3, 4+§ 20 Abs.1
40172	The requirements of FPackV do not apply to finished packs with food which may be marked according to the number of items or for which the unit of the amount (volume, weight, number of items) may be selected at will, as long as this statement is solely destined for bulk consumers.	FertigPackV	§ 33a Abs. 1
40142	On finished packs the contents must be given according to weight, volume, or number of pieces or other sizes. The statement must be given in the prescribed size; if there is no prescribed size for this product, then the contents statement must conform to generally accepted standards. A statement of uncertain contents, range of possible contents or the addition of a gross weight statement is forbidden.	FertigPackV	§ 6 Abs. 1,2

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Prepacked Cosmetics**

Article No.:

Prepackages need a labelling of their nominal weight or nominal volume.

req. no.	Statutory requirement	Law	Article
160077	For finished packs with liquid or paste cosmetic substances, the contents amount must be labelled according to volume. For solid cosmetic substances or cosmetic substances in powder form the contents amount must be labelled according to weight. Exceptions to this are: 1. soft soaps, these must be labelled according to weight 2. solid deodorants and freshening up sticks, these must be labelled according to volume 3. cosmetic substances in portion packs; here the number of pieces may be stated 4. cosmetic substances for which the statements of weight or volume have no meaning (e.g. make-up sticks, cotton wool balls, bathsalt tablets, bathsalt balls, mouthwash balls) here the piece-number may be stated.	FertigPackV	§ 7 Abs.3 + § 9
160079	For finished packs of cosmetic substances, which consist of an inner and an outer packing, the contents amount must be provided on the inner packaging and the outer packaging.	FertigPackV	§ 18 Abs. 1
40143	Finished packs which consist of several particular packs of goods, not intended for retail, must bear a statement of the total contents and of the packs contained. If all the packs are clearly visible and easy to count, then the statement of the number of packs may be dispensed with.	FertigPackV	§ 6 Abs. 3
40145	Finished packs which consist of several individual packs of goods (finished, not intended for retail, must bear a statement of the total contents and of the packs contained (finished multi-packs) must bear the number and contents-amount of individual packs on the outside packaging of the multi-pack e. g. "5 packs à 50g". This statement can be dispensed with if all the finished packs are visible and easily countable and the statement of contents on all finished packs can be recognised; if all the finished packs have the same contents amount it is enough for the exemption if the contents amount on one of the finished packs is recognisable. A statement of the contents of the finished multi-pack is not required.	FertigPackV	§ 6 Abs. 5
40160	The statement of contents on the finished pack must be easily recognisable, clearly legible and non-eradicable. The following units are prescribed for the statement: - weight in grams or kilograms - volume in millilitres, centilitres or litres. The name of the unit or unit sign must be supplied.	FertigPackV	§ 18 Abs. 1,4, 5
40163	Finished packs of the same contents amount may bear the EWG sign shown in Annex 9 of the FPackV, if the following conditions are met: The contents amount lies in the region of 5g or ml to 10kg or L; the contents amount is given according to volume or weight; the form and type of the contents amount statement conforms to the FPackV (size of script, easily visible etc) Statement as to the manufacturer must be present. The stated contents amount must be adhered to according to the regulations of the FPackV. Also the EWG-sign must be attached in easily recognisable, clearly legible and non-eradicable form and in the same field of view as the contents amount statement. <b>Additional information:</b> FPackV Anlage 9	FertigPackV	§ 21



Category: Cosmetics

18-05

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**Cosmetic products - Prepacked Cosmetics**

Article No.:

Prepackages need a labelling of their nominal weight or nominal volume.

req. no.	Statutory requirement	Law	Article
40168	A manufacturer of finished packs must perform and document the controls and tests prescribed by FPackV in order to ensure that the contents amount adheres to the requirements. Control scales and control measuring equipment which satisfy the requirements of FPackV must be used.	FertigPackV	§ 27+§ 28
40166	Finished packs with the same contents amount, marked according to the number of items, up to the number of 30 items, must contain at least this number of items in the finished pack. If the number exceeds 30 items the variance in number must conform to the regulation as stated in §24 of the FpackV.	FertigPackV	§ 24
40167	Finished packs with different contents amount, marked according to weight, must conform to the minus variance as stated in §25 of the FpackV	FertigPackV	§ 25 Abs. 1

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Materials used in the manufacture of cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160253	The intake of Vitamin A via cosmetic products should be limited.  The BfR recommends limiting the concentration of vitamin A in cosmetic products for facial care and hand care. In contrast, vitamin A should not be used in lip and body care products. <b>Additional information:</b> BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160161	The manufacture of a cosmetic product must comply with good manufacturing practice (GMP). The requirements of the harmonized standards are to be adhered to.	VO (EG) Nr. 1223/2009	Art. 8
160163	When a cosmetic product is placed on the market the responsible person shall keep a product information file for it. This should contain the following; description of the product, safety report, method of manufacturing, where justified proof of the effect claimed on the product and data on animal testing. The product information file shall be kept for a period of ten years following the date the last batch of the cosmetic product was placed on the market.	VO (EG) Nr. 1223/2009	Art. 11 Abs. 1, Abs. 2
160208	In order to assist to create a product information file, the guideline of Cosmetics Europe (formerly known as Colipa) can be used. <b>Additional information:</b> LL PID Kosmetik_13-11	LL PID	
160164	The responsible person shall make the product information file readily accessible at his address indicated on the label to the competent authority of the Member State in which the file is kept. If there were several addresses indicated, the place of the product information file must be underlined. In case of Subcontractors, those Subcontractors must make available the information and documents.	VO (EG) Nr. 1223/2009	Art. 11 Abs. 3
160165	Prior to placing the product on the market the responsible person shall notify the following information to the Commission: category and name of the product, responsible person, country of origin if imported, member state in which the product is placed on the market, contact details of a natural person, presence of substances in form of nano materials, name of CMR-substances if present and the frame formulation. When the product is placed on the market, the original labelling, and, where reasonably legible, a photograph of the corresponding packaging shall be notified by the responsible person.	VO (EG) Nr. 1223/2009	Art. 13

Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - Materials used in the manufacture of cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160167	<p>Cosmetic products which contain nanomaterials must conform to a high level of protection of human health. These cosmetic substances must be notified 6 months prior to they were placed on the market, except for nanomaterials which contains colouring, UV-filter and preserving agents. The notification must contain at least the following information: identification of the nanomaterial, specifications, estimated quantity that will be placed on the market, toxicological profile, safety data and reasonably foreseeable exposure.</p> <p>A notification is not necessary for products which have already been placed on the market by the same responsible person before 11 January 2013.</p>	VO (EG) Nr. 1223/2009	Art. 16
160168	<p>Animal testing with the final formulation of the product and with ingredients or combination of ingredients is prohibited. Tests in relation to repeated-dose toxicity, reproductive toxicity and toxicokinetics for which there are no alternatives shall be limited to 11. March 2013.</p> <p>The general prohibition on animal testing is in force for new cosmetic substances and their constituent parts not tested by 11.03.2013. Cosmetic substances and constituent parts which have been tested on animals before 11.03.2013 may continue to be circulated and used in the manufacture of cosmetic substances.</p> <p>This also applies for cosmetic products from third countries.</p>	VO (EG) Nr. 1223/2009	Art. 18 Abs. 1 und Abs. 2
160189	<p>An overview of the responsibilities and the labelling of cosmetic substances is provided by the Colipa- Guideline "Responsibilities".</p> <p><b>Additional information:</b> LL Verantwortlichkeiten_11-11</p>	LL Verantwortlichkeiten	
160162	<p>Prior to placing the product on the market a safety report according to Annex I of Re (EU) Nr 1223/2009 must be set up. The product safety assessment shall be carried out by a person with the appropriate qualification according to Part B of Annex I.</p> <p><b>Additional information:</b> VO (EG) Nr. 1223/2009 Anhang I_11-11</p>	VO (EG) Nr. 1223/2009	Art. 10 in Verb. mit Anhang I
160207	<p>In order to assist of the creation of a safety report, the guidelines of the European Commission can be used.</p> <p><b>Additional information:</b> Beschl 2013/674/EU_13-11</p>	Beschl 2013/674/EU	Artikel 1

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Materials used in the manufacture of cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160159	<p>The substances listed in Annex II of RE (EC) No 1223/2009 must not be used in cosmetic materials. These substances may, however, be used as aids if they are completely removed or removed to such an extent that only technically unavoidable and technologically inactive residues remain in amounts completely harmless to health.</p> <p>From 23 August 2019 cosmetic products containing HICC, Atranol or Chloratranol shall not be placed on the Union market. From 23 August 2021 cosmetic products containing HICC, Atranol or Chloratranol shall be not be made available on the Union market. Untill 23 August 2021 HICC can be used according to Annex III RE 1223/2009.</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang II_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe a)
160160	The non-intended presence of a small quantity of prohibited substance stemming from impurity of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable shall be permitted as long as the cosmetic product is considered to be safe.	VO (EG) Nr. 1223/2009	Art. 17
160065	Substances or preparations may not be placed on the market as cosmetic products if their intended or predictable use is likely to impair health.	LFGB	§ 26
160157	Cosmetic products shall be safe for human health when used under normal or reasonably foreseeable conditions of use. This applies particularly to the presentation, labelling, instructions for use and disposal and other indication or information.	VO (EG) Nr. 1223/2009	Art. 3



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Materials used in the manufacture of cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160128	<p>The following substances listed in Annex III RE (EC) No 1223/2009 must at the manufacturing stage of the cosmetic material fulfil the purity requirements listed in Column g and Column h of the Annex. If the purity requirements are not adhered to, the cosmetic substance is prohibited from being placed on the market:</p> <p>No 60: Fatty acid dialkylamides and dialkanolamides (INCI: -, CAS No -)</p> <p>No 61: Monoalkylamines, monoalkanolamines and their salts (INCI: -, CAS No -)</p> <p>No 88: d-Limonene(4R)-1- Methyl-4-(1-methylethenyl) cyclohexene (INCI: Limonene CAS No 5989-27-5)</p> <p>No 103: Abies alba cone oil and extract (INCI: Abies Alba Cone Oil; Abies Alba Cone Extract; Abies Alba Leaf Oil; Abies Alba Leaf Cera; Abies Alba Needle Extract; Abies Alba Needle Oil, CAS No 90028-76-5)</p> <p>No 105: Abies pectinata needle oil and extract CAS No 92128-34-2 (INCI: Abies Pectinata Oil; Abies Pectinata Leaf Extract; Abies Pectinata Needle Extract Abies Pectinata Needle Oil, CAS No 92128-34-2)</p> <p>No 106: Abies sibirica needle oil and extract CAS No 91697-89-1 (INCI: Abies Sibirica Oil; Abies Sibirica Needle Extract Abies Sibirica Needle Oil, CAS No 91697-89-1)</p> <p>No 107: Abies balsamea needle oil and extract CAS No 85085-34-3 (INCI: Abies Balsamea Needle Oil; Abies Balsamea Needle Extract Abies Balsamea Resin; Abies Balsamea Extract; Abies Balsamea Balsam Extract, CAS No 85085-34-3)</p> <p>No 108: Pinus mugo pumilio leaf and twig oil and extract CAS No 90082-73-8 (INCI: Pinus Mugo Pumilio Twig Leaf Extract; Pinus Mugo Pumilio Twig Leaf Oil, CAS No 90082-73-8)</p> <p>No 109: Pinus mugo leaf and twig oil and extract CAS No 90082-72-7 (INCI: Pinus Mugo Leaf Oil Pinus Mugo Twig Leaf Extract Pinus Mugo Twig Oil, CAS No 90082-72-7)</p> <p>No 110: Pinus sylvestris leaf and twig oil and extract CAS No 84012-35-1 (INCI: Pinus Sylvestris Oil; Pinus Sylvestris Leaf extract; Pinus Sylvestris Leaf Oil; Pinus Sylvestris Leaf Water; Pinus Sylvestris Cone Extract; Pinus Sylvestris Bark Extract; Pinus Sylvestris Bud Extract Pinus Sylvestris Twig Leaf Extract Pinus Sylvestris twig, CAS No 84012-35-1)</p> <p>No 111: Pinus nigra leaf and twig oil and extract CAS No 90082-74-9 (INCI: Pinus Nigra Bud/Needle Extract Pinus Nigra Twig Leaf Extract Pinus Nigra Twig Leaf Oil, CAS No 90082-74-9)</p> <p>No 112: Pinus palustris leaf and twig oil and extract CAS No (INCI: Pinus Palustris Leaf Extract; Pinus Palustris Oil; Pinus Palustris Twig Leaf Extract Pinus Palustris Twig Leaf Oil, CAS No 97435-14-8)</p> <p>No 113: Pinus pinaster leaf and twig oil and extract (INCI: Pinus Pinaster Twig Leaf Oil; Pinus Pinaster Twig Leaf Extract, CAS No 90082-75-0)</p> <p>No 114: Pinus pumila leaf and twig oil and extract CAS (INCI: Pinus Pumila Twig Leaf Extract Pinus Pumila Twig Leaf Oil, CAS No 97676-05-6)</p> <p>No 115: Pinus species leaf and twig oil and extract (INCI: Pinus Strobilus Bark Extract; Pinus Strobilus Cone Extract; Pinus Strobilus Twig Oil Pinus Species Twig Leaf Extract Pinus Species Twig Leaf Oil, CAS No 94266-48-5)</p> <p>No 116: Pinus cembra leaf and twig oil and extract (INCI: Pinus Cembra Twig Leaf Oil Pinus Cembra Twig Leaf Extract, CAS No 92202-04-5)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
S. 16			

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Materials used in the manufacture of cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160142	The following preservative have to fulfill the purity criteria listed in Annex V RE (EC) No 1223/2009:  No 23: 1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea (INCI: Triclocarban, CAS No 101-20-2) <b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang V_17-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160252	Traces of forbidden heavy metals are considered as technically avoidable if they exceed the BVL's orientation values.	ALS	2017/39



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Labelling**

Article No.:

req. no.	Statutory requirement	Law	Article
160172	For imported cosmetic products the country of origin must be stated.	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 a)
160227	Two-sided labels:  The specification of mandatory labeling elements - especially the ingredient list - on the inside of a two-sided label is a non-conforming use of the labeling rules. For small containers exceptions are laid down in art. 19 (2) RE (EC) No. 1223/2009. Is a container so large that the details are clearly legible to install, an exception is not it reasonable.	ALS	2013/22
160228	Stating the internet address does not replace the required information of the name or registered name and address of the responsible person.	ALS	2013/21
160237	The labelling elements nominal content, best before date, particular precautions to be observed in use and the function of a cosmetic product must be in the German language for cosmetic products.	KosmetikV	§ 4
160063	Cosmetics do not have to be labelled with the dangerous substances symbols.	ChemG	§2 Abs. 1 i.V mit VO (EG) Nr. 1272/2008 Artikel 1
160067	Advertising statements regarding cosmetic substances which are concerned with the recognition, elimination or relief of illnesses, suffering, bodily injury or complaints of sickness whether of humans or animals must be in conformity with the guidelines of the Medicament Advertising Laws. <b>Additional information:</b> HWG_17-05	HWG	
160170	An indication that no animal testing has been performed is only permitted if the manufacturer and his suppliers have not been carried out or commissioned any animal testing on the finished cosmetic product, prototype or ingredients, - no ingredients are used that have been tested on animals	VO (EG) Nr. 1223/2009	Art. 20 Abs. 3
160189	An overview of the responsibilities and the labelling of cosmetic substances is provided by the Colipa- Guideline "Responsibilities". <b>Additional information:</b> LL Verantwortlichkeiten_11-11	LL Verantwortlichkeiten	
160177	The batch number for the identification of cosmetic products must be indicated on the container and the packaging. If the container is too small then the statement on the packaging is sufficient.	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 e)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Labelling**

Article No.:

req. no.	Statutory requirement	Law	Article
160171	<p>Container and packaging shall bear the following information indelible, easily legible and visible lettering:</p> <ul style="list-style-type: none"> <li>- Name or registered name and Address of the responsible person</li> <li>- nominal contents at the time of packaging</li> <li>- the date of minimum durability / use-by date</li> <li>- precaution to be observed in use</li> <li>- the batch number</li> <li>- the function unless it is clear from its presentation</li> <li>- list of ingredients</li> </ul> <p>The statements as to amount of the content, use-by date, precautions and intended purpose of use must appear in an easily understandable language.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1
160202	<p>In order to assist for the labeling of cosmetic products, the guideline of Cosmetics Europe can be used.</p> <p><b>Additional information:</b> LL Kennzeichnung Kosmetik_13-11</p>	LL Kennzeichnung Kosmetik	
160173	<p>The indication of the responsible persons may be abbreviated, must however be clearly identifiable. With the statement of many addresses, the address at which the product information file is accessible must be underlined. This shall be stated on container and packaging.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 a)
160029	<p>If a cosmetic substance contains more free formaldehyde in the final product than 0,05%, then the following warning notice must be attached to the outer packaging.</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160174	<p>The indication of nominal content is given by weight or volume. Exception:</p> <ul style="list-style-type: none"> <li>- in case of nominal content is less than 5g respectively 5 ml</li> <li>- free samples</li> <li>- single-application packs</li> <li>- pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the number of items appears on the packaging. This need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually.</li> </ul> <p>These information must be stated on container and packaging.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 b)
160175	<p>The date of minimum durability must be stated as follows:</p> <ul style="list-style-type: none"> <li>- shall be preceded by the words "Mindestens haltbar bis: ("best used before the end of)" or by the symbol Nr. 3 in Annex VII RE (EU) Nr. 1223/2009</li> <li>- followed by date or notice where the date is to be found</li> <li>- the date is stated with month and year or day month and year in this order</li> <li>- If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability</li> <li>- for cosmetic products with a minimum durability of more than 30 months this does not have to be stated.</li> </ul> <p>Must be stated on containers and packaging.</p> <p><b>Additional information:</b> VO (EG) Nr. 1223/2009 Anhang VII_11-11</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 c)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Labelling**

Article No.:

req. no.	Statutory requirement	Law	Article
160178	The function of the cosmetic product must be indicated if this is not clear from the product description. The indication shall appear on containers and packaging.	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 f)
160176	The indication of the period of durability after opening for which the product is safe and can be used without any harm to the consumer for cosmetic products with minimum durability of more than 30 months must be stated as follows: - with the symbol Nr. 2 in Annex VII RE (EU) Nr. 1223/2009 followed by the time period (Months and 7 or years). The statement may be dropped, if the concept of durability after opening is not relevant. <b>Additional information:</b> VO (EG) Nr. 1223/2009 Anhang VII_11-11	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 c)
160181	Where it is impossible for practical reasons to label the particular precautions and the list of ingredients, then the information can be - mentioned on an enclosed or attached leaflet, label, tape, tag or card - unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex VII of the RE (EU) Nr. 1223/2009 . For the particular precautions this notice must appear on the packaging and the container, for the list of ingredients on the packaging. <b>Additional information:</b> VO (EG) Nr. 1223/2009 Anhang VII_11-11	VO (EG) Nr. 1223/2009	Art. 19 Abs. 2

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Labelling**

Article No.:

req. no.	Statutory requirement	Law	Article
160183	<p>Perfume and aromatic compositions and their raw materials shall be referred to by the term "parfume" or "aroma". If it concerns the following substances from Annex III of RE (EU) Nr. 1223/2009 then these must be additionally stated with their names in the list of ingredients:</p> <p>Nr. 45 - Benzylalkohol (CAS-Nr. 100-51-6)            Nr. 67 - Amylcinnamal (CAS-Nr. 122-40-7)            Nr. 69 - Cinnamylalcohol (CAS-Nr. 104-54-1)            Nr. 70 - Citral (CAS-Nr. 5392-40-5)            Nr. 71- Eugenol (CAS-Nr. 97-53-0)            Nr. 72 - Hydroxycitronellal (CAS-Nr. 107-75-5)            Nr. 73 - Isoeugenol (CAS-Nr. 97-54-1)            Nr. 74 - Amylcinnamylalkohol (CAS-Nr. 101-85-9)            Nr. 75 - Benzylsalicylat (CAS-Nr. 118-58-1)            Nr. 76 - Cinnamal (CAS-Nr. 104-55-2)            Nr. 77 - Coumarin (CAS-Nr. 91-64-5)            Nr. 78 - Geraniol (CAS-Nr. 106-24-1)            Nr. 79 - Hydroxymethylpentylcyclohexencarboxaldehyd (CAS-Nr. 31906-04-4)            Nr. 80 - Anisylalkohol (CAS-Nr. 105-13-5)            Nr. 81 - Benzylcinnamat (CAS-Nr. 103-41-3)            Nr. 82 - Farnesol (CAS-Nr. 4602-84-0)            Nr. 83 - 2-(4-tert-Butylbenzyl)propionaldehyd (CAS-Nr. 80-54-6)            Nr. 84 - Linalool (CAS-Nr. 78-70-6)            Nr. 85 - Benzylbenzoat (CAS-Nr. 120-51-4)            Nr. 86 - Citronellol (CAS-Nr. 106-22-9)            Nr. 87 - Hexylcinnamaldehyd (CAS-Nr. 101-86-0)            Nr. 88 - d-Limonen (CAS-Nr. 5989-27-5)            Nr. 89 - Methylheptincarboxat (CAS-Nr. 111-12-6)            Nr. 90 - 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on (CAS-Nr. 127-51-5)            Nr. 91 - Evernia prunastri extract (CAS-Nr. 90028-68-5)            Nr. 92 - Evernia furfuracea extract (CAS-Nr. 90028-67-4)</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g) + VO (EU) Nr. 344/2013
160184	It is not allowed to imply characteristics or functions to the cosmetic products which they do not have in the labelling, presentation, advertising etc .	VO (EG) Nr. 1223/2009	Art. 20 Abs. 1
160203	<p>For the labeling of cosmetic products regarding advertising claims, these must meet certain criteria. The responsible person shall ensure, that the wording of the claim is in compliance. <b>Additional information:</b> VO (EU) Nr. 655/2013_13-11</p>	VO (EU) Nr. 655/2013	Artikel 1 und 2

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Labelling**

Article No.:

req. no.	Statutory requirement	Law	Article
160251	<p>In order to evaluate the advertising claims, the technical document on cosmetic claims can be used.</p> <p>The technical document contains the following Annexes: Annex 1 - Common criteria for claims used in relation to cosmetic products Annex 2 - Best practice for claim substantiation evidence Annex 3 - Free from claims Annex 4 - Hypoallergenic claim</p> <p>The requirements of Annex III and Annex IV shall apply from 1 July 2019. <b>Additional information:</b> Technisches Dokument Werbeaussagen Kosmetik_18-05</p>	Technisches Dokument Werbeaussagen Kosmetik	
160179	<p>The indication of the list of ingredients must appear as follows:</p> <ul style="list-style-type: none"> <li>- the term „Ingredients“ be preceded</li> <li>- all intentionally used substances or mixtures must be listed except for impurities or additives which are no longer present in the finished product,</li> <li>- the ingredients are listed in descending order of the weight at the time they were added</li> <li>- ingredients in concentrations less than 1% may be listed in no order</li> <li>- colorants other than colorants intended to colour the hair, can be listed in any order</li> <li>- for the statement of colorants CI (Colour Index) nomenclature shall be used</li> <li>- for the designation of the ingredients the INCI nomenclature, or if none available, a designation out of a generally recognised nomenclature must be used.</li> </ul> <p>The complete designations of INCI-Nomenklatur can be found in the database of the EU under the following link <a href="http://ec.europa.eu/growth/tools-databases/cosing/">http://ec.europa.eu/growth/tools-databases/cosing/</a></p> <ul style="list-style-type: none"> <li>- all ingredients, which are contained in the form of nanomaterials, the name of such ingredients shall be followed by the word “nano” in brackets.</li> </ul> <p>The list of the ingredients must be indicated on the packaging and on the container.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g) und Abs. 6
160046	<p>The following substances are not classified as ingredients of cosmetic product and therefore do not have to be stated on the list of ingredients:</p> <ol style="list-style-type: none"> <li>1. Impurities of used ingredients</li> <li>2. technical Additives</li> </ol>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g) Buchstaben
160195	<p>If allergenic scent substances or other content substances subject to registration occur during production or storage, which are not added as such during the production process, these must be declared with a warning notice (for example, "May, as a result of production, contain ...").</p>	ALS	2011/32
160196	<p>Plant juice, e.g. aloe barbadensis leaf juice, received from plant juice powder and water may be mentioned with the INCI name (aloe barbadensis leaf juice) in an ingredient list only when the powder did not contain any further ingredients, e.g. additives and the product is chemically identical. If there are further ingredients present, all ingredients as well as “aqua” and “...juice powder” must be mentioned.</p>	ALS	2013/29





Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Animal experiments**

Article No.:

req. no.	Statutory requirement	Law	Article
160094	If cosmetic materials are advertised as with "No animal experiments" or similar expression, then the guidelines 2006/406/EU are to be observed. <b>Additional information:</b> Kom Empf 2006/406/EG_10-05	Kom Empf 2006/406/EG	
160169	Cosmetic products where the final formulation respectively whose ingredients or combinations of ingredients has been the subject of animal testing using a method other than alternative after such alternative methods has been validated and adopted are not allowed to be placed on the market.	VO (EG) Nr. 1223/2009	Art. 18 Abs. 1
160170	An indication that no animal testing has been performed is only permitted if the manufacturer and his suppliers have not been carried out or commissioned any animal testing on the finished cosmetic product, prototype or ingredients, - no ingredients are used that have been tested on animals	VO (EG) Nr. 1223/2009	Art. 20 Abs. 3
160168	Animal testing with the final formulation of the product and with ingredients or combination of ingredients is prohibited. Tests in relation to repeated-dose toxicity, reproductive toxicity and toxicokinetics for which there are no alternatives shall be limited to 11. March 2013. The general prohibition on animal testing is in force for new cosmetic substances and their constituent parts not tested by 11.03.2013. Cosmetic substances and constituent parts which have been tested on animals before 11.03.2013 may continue to be circulated and used in the manufacture of cosmetic substances. This also applies for cosmetic products from third countries.	VO (EG) Nr. 1223/2009	Art. 18 Abs. 1 und Abs. 2

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Applicable documents in English**

Article No.:

req. no.	Statutory requirement	Law	Article
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Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Applicable documents in English**

Article No.:

req. no.	Statutory requirement	Law	Article
150000	<p>The following legal requirements are also available in the English language:</p> <p><b>Additional information:</b></p> <p>853/2004 Guidance englisch_13-11</p> <p>AG AL-EU_10-11</p> <p>AG AU-EU_10-11</p> <p>AG BA-EU_10-11</p> <p>AG CAM-EU_15-11</p> <p>AG CL-EU_10-11</p> <p>AG KR-EU_14-11.pdf</p> <p>AG MA-EU_12-11</p> <p>AG SADC-EPA_17-11</p> <p>AG UA-EU_16-11</p> <p>AG US-EU_12-11</p> <p>AG_CA-EU_17-05</p> <p>AG_GE-EU_18-05.pdf</p> <p>AG_MD-EU_17-05</p> <p>AG_ME-EU_17-05</p> <p>AG_PE-CO-EC-EU_18-05</p> <p>AG_RS-EU_17-05</p> <p>Beauty Claims Guidance food supplements_14-11</p> <p>BfR Energy shots en_10-05</p> <p>BfR opinion - Formaldehyde in hair straighteners</p> <p>BfR opinion - Allergic peanut oil</p> <p>BfR opinion - Boric Acid in lip care products</p> <p>BfR opinion - High Methyl-methacrylate contents</p> <p>BfR opinion - Zinc oxide as uv-filter</p> <p>Codex Salz</p> <p>Com Rec 2010/307/EU_11-04</p> <p>Com Rec 2010/9861 final_11-04</p> <p>COP Brühe en_10-05</p> <p>COP Brühe_16-11</p> <p>COP Fruchtwein &amp; Cidre_10-11</p> <p>COP Gemüse in Essig_18-05</p> <p>COP Mayo_16-11</p> <p>COP Senf englisch_10-11</p> <p>COP Senf_16-11</p> <p>COP Speiseeis edible ices_18-05</p> <p>COP Tomatenketchup_16-11</p> <p>Cosmetic product labelling_13-11</p> <p>CR 2006/406/EC</p> <p>DEC (EU) 2015/1735_15-11</p> <p>DEC (EU) 2015/1842_15-11</p> <p>DEC 2008/911/EU_18-05</p> <p>DEC 2010/791/EU_11-04</p> <p>DEC 2013/674/EU_13-11</p> <p>DEC 2014/237/EU_16-05</p> <p>DIR 2002/46/EC_17-11</p> <p>DIR 2008/38/EC_15-11</p> <p>DIR 2014/40/EU_15-11</p> <p>Directive 76/768/EEC_12-11</p> <p>DR 2002/32/EC_18-05</p> <p>EFFA_Guidance_Document_15-11</p> <p>FDE_Guidelines_on_Flavourings_15-11</p> <p>F-Gase VO 842/2006</p> <p>Flexibility Health Claims_13-04</p> <p>Guid. Doc. Borderline cosm/biocidal_12-11</p> <p>Guid.Doc Borderline cosm/medicinal_12-11</p> <p>Guid.Doc. Borderlines_12-11</p> <p>Guidance Flavourings_14-11</p> <p>Guidance food categories VO (EG) Nr. 1333 2008_17-11</p>	Zusatzinfo	
S. 25	<p>HCV guidance food supplements englisch_13-11</p> <p>Import Guidelines Organic</p>		



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Aerosol dispensers**

Article No.:

Aerosol dispensers are one-way vessels which are filled with pressure gases (materials with a critical temperature  $< 50^{\circ}$  or a steam pressure of  $50^{\circ} \text{C} > 3$  bar or cyanogen hydrogen) with a volume of over 50 ml to 1,000 ml for vessels made of metal or up to 220 ml for vessels made of protected glass or plastic which does not splinter or up to 150 ml for vessels made of glass or splintering plastic. Product examples: aerosol packaging, paint sprays/deodorants with propellant, one-way gas cartridges, mounting foam, spray cream.

req. no.	Statutory requirement	Law	Article
5019	<p>Aerosol packages (spray tins), the container of which has a total capacity of 50 millilitres or more, may be put on the market only if they fulfil the safety requirements of the directive 75/324/EEC in respective version.</p> <p>Exceptions to this are:</p> <ol style="list-style-type: none"> <li>1. Aerosol packages with metal containers, the total capacity of which exceeds 1000 millilitres;</li> <li>2. Aerosol packages with glass containers, the total capacity of which a) exceeds 220 millilitres, provided the container is fitted with a permanent protective covering, b) exceeds 150 millilitres, provided the container consists of unprotected glass.</li> <li>3. Aerosol packages with plastic containers, the total capacity of which a) exceeds 220 millilitres provided the container can form no fragments when broken, b) exceeds 150 millilitres if the container forms fragments when broken.</li> </ol> <p>In addition the affected aerosol packages must be labelled, and the text of the labelling must be written in German.</p> <p>The conformity mark consists of a reversed epsilon "3".</p> <p><b>Additional information:</b> CD 75-324-EEC_15-04 RL 75-324-EWG_15-04</p>	13. ProdSV	§ 1
40146	<p>For products in aerosol foam (these are in the pack under pressure and are released by the action of a valve) the filling amount must be given by volume, even if otherwise for the product a label according to weight is prescribed. The volume of the liquid phase is authoritative. Furthermore the total volume capacity of the pack (maximum volume as a right angle) is to be stated and in such a manner that it cannot be confused with the statement of the nominal volume of the contents.</p>	FertigPackV	§ 7 Abs.1
5215	The use of partly halogenated CFCs in aerosols is prohibited.	ChemOzonSchi chtV	Art.6
5300	Pressure gas packs with fluorinated greenhouse gases must not be placed on the market.	VO (EU) Nr. 517/2014	Art.11 Anh.III



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18-05

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**Aerosol dispensers**

Article No.:

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req. no.	Statutory requirement	Law	Article
5214	<p>The import and marketing of products and devices containing chlorofluorocarbons, other perhalogenated chlorofluorocarbons, halons, carbontetrachlorides, 1,1,1-trichloroethane, partly halogenated bromofluoride hydrocarbons and chlorobromomethane are prohibited. The following are affected:</p> <ul style="list-style-type: none"> <li>- Aerosol products</li> <li>- Dyes and paints</li> <li>- Cosmetics</li> <li>- Lubricants</li> <li>- Cleaning materials</li> <li>- Pressurised gas containers</li> <li>- Fire extinguishers</li> <li>- Insulation materials</li> <li>- Refrigerators</li> <li>- Air conditioning units</li> <li>- Mattresses</li> <li>- Foam material</li> <li>- Adhesives</li> </ul>	ChemOzonSchi chtV	Art.4

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - aerosols (sprays)**

Article No.:

req. no.	Statutory requirement	Law	Article
160126	<p>In aerosol dispensers (sprays) with cosmetic products, the following substances listed in Annex III RE (EC) No 1223/2009 are prohibited:</p> <p>for hair-care mixtures: No 44 - 1,3-Bis (hydroxymethyl) imidazolidine-2-thione</p> <p>for antiperspirants: No 50 - Aluminium zirconium chloride hydroxyde complexes Al<sub>x</sub>Zr(OH)<sub>y</sub>Cl<sub>z</sub> and the aluminium zirconium chloride sydroxide glycine complexes (INCI: -, CAS-Nr. -)</p> <p>for hair dye products: No 187: diethylene glycol monobutyl ether (DEGBE) (INCI: Butoxydiglykol, CAS-Nr. 112-34-5) No 188: ethylene glycol monobutyl ether (EGBE) (INCI: Butoxyethanol, CAS-Nr. 111-76-2)</p> <p>for deodorants: No 197: Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160133	<p>Aerosol dispensers (sprays) with cosmetic products are prohibited from containing the following conservation substances from Annex V RE (EC) No 1223/2009:</p> <p>No 5: Formaldehyde, paraformaldehyde (INCI: Formaldehyde Paraformaldehyde, CAS-Nr. 50-00-0, 30525-89-4) No 11: Chlorobutanol (INCI: Chlorobutanol, CAS No 57-15-8) No 13: 3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts (INCI: Dehydroacetic acid, sodium dehydroacetate, CAS No 520-45-6, 4418-26-2, 16807-48-0) No 48: Glutaraldehyde (Pentane-1,5-dial) (INCI: Glutaral, CAS No 111-30-8) No 58: Ethyl-Na-dodecanoyl-L-argininhydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160248	<p>Cosmetic applications that could be easily inhaled should not contain the dyes listed in Annex IV RE (EC) No 1223/2009:</p> <p>No. 126a: Carbon black (nano) (INCI: 77266 (nano) Carbon black (nano); CAS No 1333-86-4, 7440-44-0) No. 144: Zinc oxide (INCI: 77947; CAS No 1314-13-2)</p> <p>From 24 May 2018 only cosmetic products which comply with the new requirements on zinc oxide shall be made available on the Union market.</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - for children and babies**

Article No.:

req. no.	Statutory requirement	Law	Article
160095	<p>The following substances listed in Annex III RE (EC) No 1223/2009 are not allowed to be used for cosmetic products for children under 3 years of age:</p> <p>No 1a: Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex I (INCI: Boric acid, CAS No 10043-35-3 / 11113-50-1)</p> <p>No 1b: Tetraborates (INCI: -, CAS-Nr. -)</p> <p>No 98: Salicylic acid (INCI: Salicylic acid, CAS No 69-72-7) (but as a preservative within limitation allowed for baby shampoo).</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160102	<p>In cosmetic products for children and babies (powdery products) the following substance listed in Annex III RE (EC) No 1223/2009 is allowed if the stated limitations and additional labelling requirements are observed:</p> <p>No 59: Talc: Hydrated magnesium silicate (INCI: Talc, CAS No 14807-96-6)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160134	<p>In mixtures for children under three years of age the following preservatives listed in Annex V RE (EC) No 1223/2009 are not allowed to be used:</p> <p>No 3: Salicylic acid and its salts (INCI: Salicylic acid, calcium salicylate, magnesium salicylate, MEA-salicylate, sodium salicylate, potassium salicylate, TEA-salicylate, CAS No 69-72-7, 824-35-1, 18917-89-0, 59866-70-5, 54-21-7, 578-36-9, 2174-16-5) (except for shampoos within the limit for maximum amount)</p> <p>No 52: Silver chloride deposited on titanium dioxide (INCI: Silver chloride, CAS No 7783-90-6)</p> <p>No 56: 3-iodo-2-propynylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No 55406-53-6) ( except in bath products/shower gels and shampoo. adhere the limitations)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160093	<p>Cosmetics for children should not contain any allergy-inducing peanut-oil (INCI-Name "ARACHIS HYPOGAEA OIL")</p> <p><b>Additional information:</b> BfR Erdnussöl_10-05</p>	BfR Erdnussöl	



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - for children and babies**

Article No.:

req. no.	Statutory requirement	Law	Article
160145	<p>For child and baby cosmetics the Industrieverband Körperpflege- und Waschmittel e.V. (IKW) recommends in its brochure baby-cosmetics over and above the legal requirements:</p> <ul style="list-style-type: none"> <li>-minimal use of dyes, perfumed and conservation substances; -dispensing with ethereal oils such as eucalyptus-oil, menthol, tea-tree oil; -microbiologie:max. 100 KBE/g bz. Max. 100 KBE/ml; -absence of pathogenic micro-organisms;</li> <li>- residues of heavy metals and pesticides only in extremely minimal trace concentrations which are toxicologically unobjectionable/harmless</li> <li>- use of particularly mild tenside combinations</li> <li>- taking into account various assessments of the SCCFNP (see the applicable documentation "Babykosmetik")</li> <li>- At the safety evaluation stage, particularly close scrutiny of predictable application/use and possible misuse</li> </ul> <p><b>Additional information:</b> Babykosmetik_10-05</p>	Babykosmetik	



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - Leave-on-Products**

Article No.:

req. no.	Statutory requirement	Law	Article
160136	<p>In leave-on products the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1: Benzoic acid (INCI: Benzoic acid, CAS-Nr. 65-85-0) and its sodium salt (INCI: Sodium Benzoate, CAS No 532-32-1)                      No 35: 1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt (INCI: Piroctone Olamine , CAS No 50650-76-5, 68890-66-4)                      No 53: Benzenemethanaminium, N,Ndimethyl-N-[2-[2-[4-(1,1,3,3,-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride (INCI: Benzethonium Chloride, CAS No 121-54-0)                      No 56: 3-iodo-2-propynylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No: 55406-53-6)  <b>Additional information:</b>                      VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160253	<p>The intake of Vitamin A via cosmetic products should be limited.</p> <p>The BfR recommends limiting the concentration of vitamin A in cosmetic products for facial care and hand care. In contrast, vitamin A should not be used in lip and body care products.  <b>Additional information:</b>                      BfR Vitamin A_18-05</p>	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014

Category: Cosmetics

18-05

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**Cosmetic products - Leave-on-Products**

Article No.:

req. no.	Statutory requirement	Law	Article
160043	<p>If cosmetic products which are not rinsed out contain more than 0,001% of one of the following substances from Annex III No 1223/2009, then the name of the substances must be stated in the list of ingredients.</p> <p>No 45: Benzyl alcohol(CAS No 100-51-6) (if used as solvent no indication is needed) No 67: Amyl cinnamal (CAS No 122-40-7) No 69: Cinnamyl alcohol (CAS No 104-54-1) No 70: Citral (CAS No 5392-40-5) No 71: Eugenol (CAS No 97-53-0) No 72: Hydroxycitronellal CAS No 107-75-5 No 73: Isoeugenol CAS No 97-54-1 No 74: Amylcinnamyl alcohol (CAS No 101-85-9) No 75: Benzyl salicylate (CAS No 118-58-1) No 76: Cinnamal (CAS No 104-55-2) No 77: Coumarin (CAS No 91-64-5) No 78: Geraniol (CAS No 106-24-1) No 80: Anise alcohol (CAS No 105-13-5) No 81: Benzyl cinnamate (CAS No 103-41-3) No 82: Farnesol (CAS No 4602-84-0) No 83: 2-(4-tert-Butylbenzyl) propionaldehyde (CAS No 80-54-6) No 84: Linalool (CAS No 78-70-6) No 85: Benzyl benzoate (CAS No 120-51-4) No 86: Citronellol (CAS No 106-22-9) No 87: Hexyl cinnam-aldehyde (CAS No 101-86-0) No 88: Limonene (CAS No 5989-27-5) No 89: Methyl 2-octynoate (CAS No 111-12-6) No 90: alpha-Isomethyl ionone (CAS No 127-51-5) No 91: Evernia prunastri extract (CAS No 90028-68-5) No 92: Evernia furfuracea extract (CAS No 90028-67-4)</p> <p>Untill 23 August 2021 HICC (No.79) can be used according to Annex III RE 1223/2009. <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

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**Cosmetic products - Leave-on-Products**

Article No.:

req. no.	Statutory requirement	Law	Article
160119	<p>In leave-on products the following substances of Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 62: Trialkylamines, trialkanolamines and their salts (INCI: - , CAS No - )                      No 66: Polyacrylamides (INCI: - , CAS No - )                      No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS-No 93-15-2)                      No 134: 1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone (INCI: Acetyl hexamethyl indan, CAS No 15323-35-0)                      No 156: Cuminum cyminum oil and extract (INCI: Cuminum Cyminum Fruit Oil; Cuminum Cyminum Fruit Extract; Cuminum Cyminum Seed Oil; Cuminum Cyminum Seed Extract; Cuminum Cyminum Seed Powder, CAS No 84775-51-9)                      No 182: 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN) (INCI: Acetyl hexamethyl tetralin, CAS No 21145-77-7, CAS No 1506-02-1)                      No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)                      No 286 - C16-alkyltrimethylammonium chloride (INCI: Cetrimonium chloride, CAS No 112-02-7); C18-alkyltrimethyl- ammonium chloride (INCI: Steartrimonium chloride (CAS No 112-02-8)                      No 287: C22-alkyltrimethylammonium chloride (INCI: Behenrimonium chloride. CAS No 17301-53-0)  <b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160249	There should be a limit for kojic acid in leave-on-cosmetics of 1%.	Sitzungen BfR Kosmetik	18. Sitzung der BfR-Kommission für kosmetische Mittel



Category: Cosmetics

18-05

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**Cosmetic products - Products, which are rinsed out**

Article No.:

req. no.	Statutory requirement	Law	Article
160122	<p>In rinse-off products the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 15b: Lithium hydroxide (INCI: Lithium hydroxide, CAS No 1310-65-2)                      No 54: 1-Phenoxypropan-2- ol (INCI: Phenoxyisopropanol, CAS No 770-35-4)                      No 100: 1-(4-Chlorophenyl)- 3-(3,4-dichlorophenyl)urea (INCI: Triclocarban, CAS No 101-20-2)                      No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS-No 93-15-2)                      No 134: 1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone (INCI: Acetyl hexamethyl indan CAS No 15323-35-0)                      No 156: Cuminum cyminum oil and extract (INCI: Cuminum Cyminum Fruit Oil; Cuminum Cyminum Fruit Extract; Cuminum Cyminum Seed Oil; Cuminum Cyminum Seed Extract; Cuminum Cyminum Seed Powder, CAS No 84775-51-9)                      No 182: 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN) (INCI: Acetyl hexamethyl tetralin, CAS No 21145-77-7, CAS No 1506-02-1)                      No 297: 2-(2-Ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS-Nr. 111-90-0)</p> <p><b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

18-05

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**Cosmetic products - Products, which are rinsed out**

Article No.:

req. no.	Statutory requirement	Law	Article
160013	<p>Rinse-off products - means cosmetic substances which only for a short time come into contact with the skin - may contain the following dyes (including their salts and lakes) from Annex IV of RE (EC) No 1223/2009. Exceptions to these are hair dyeing and hair colouring substances.</p> <p>No 1: CI 10006            No 6: CI 11725            No 10: CI 12120            No 11: CI 12370            No 12: CI 12420            No 13: CI 12480            No 15: CI 12700            No 24: CI 15620            No 39: CI 18130            No 40: CI 18690            No 41: CI 18736            No 42: CI 18820            No 45: CI 20040            No 46: CI 20470            No 47: CI 21100            No 48: CI 21108            No 50: CI 24790            No 54: CI 40215            No 62: CI 42080            No 64: CI 42100            No 65: CI 42170            No 67: CI 42520            No 71: CI 45100            No 72: CI 45190            No 73: CI 45220            No 83: CI 50325            No 85: CI 51319            No 88: CI 60724            No 93: CI 61585            No 94: CI 62045            No 102: CI 73900            No 103: CI 73915            No 104: CI 74100            No 106: CI 74180            No 151: Bromothymol blue (INCI: Bromothymol blue, CAS No 76-59-5)            No 152: Bromocresol green (INCI: Bromocresol green, CAS No 76-60-8)</p> <p><b>Additional information:</b>            VO (EU) Nr.1223/2009 Anhang IV_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)



Category: Cosmetics

18-05

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**Cosmetic products - Products, which are rinsed out**

Article No.:

req. no.	Statutory requirement	Law	Article
160135	<p>In rinse-off products following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1: Benzoic acid (INCI: Benzoic acid, CAS No 65-85-0) and its sodium salt (INCI: Sodium Benzoate, CAS No 532-32-1)                      No 8: Pyrithione zinc (INCI: Zinc pyrithione, CAS No 13463-41-7)                      No 20: 5-Bromo-5-nitro-1,3-dioxane (INCI: 5-Bromo-5-nitro-1,3-di-oxane, CAS No 30007-47-7)                      No 35: 1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt (INCI: 1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl) 2-pyridon, Piroctone Olamine, CAS No 50650-76-5, 68890-66-4)                      No 43: 1-Phenoxypropan-2-ol (INCI: Phenoxyisopropanol, CAS No 770-35-4)                      No 53: Benzenemethanaminium, N,Ndimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy] ethyl]-, chloride (INCI: Benzethonium Chloride, CAS No 121-54-0)                      No 55: Methanol, (phenylmethoxy-) (INCI: Benzylhemiformal, CAS No 14548-60-8)                      No 56: 3-iodo-2-propynylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No 55406-53-6)                      No 57: 2-Methyl-2H-isothiazol-3-one (INCI: Methylisothiazolone, CAS 2682-20-4)</p> <p><b>Additional information:</b>                      VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

18-05

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**Cosmetic products - Products, which are rinsed out**

Article No.:

req. no.	Statutory requirement	Law	Article
160042	<p>If cosmetic products which are rinsed out (e.g. shampoos and shower gel) contain more than 0,01% of one of the following substances from Annex III No 1223/2009, then the name of the substances must be stated in the list of ingredients.</p> <p>No 45: Benzyl alcohol(CAS No 100-51-6) (if used as solvent no indication is needed) No 67: Amyl cinnamal (CAS No 122-40-7) No 69: Cinnamyl alcohol (CAS No 104-54-1) No 70: Citral (CAS No 5392-40-5) No 71: Eugenol (CAS No 97-53-0) No 72: Hydroxycitronellal CAS No 107-75-5 No 73: Isoeugenol CAS No 97-54-1 No 74: Amylcinnamyl alcohol (CAS No 101-85-9) No 75: Benzyl salicylate (CAS No 118-58-1) No 76: Cinnamal (CAS No 104-55-2) No 77: Coumarin (CAS No 91-64-5) No 78: Geraniol (CAS No 106-24-1) No 80: Anise alcohol (CAS No 105-13-5) No 81: Benzyl cinnamate (CAS No 103-41-3) No 82: Farnesol (CAS No 4602-84-0) No 83: 2-(4-tert-Butylbenzyl) propionaldehyde (CAS No 80-54-6) No 84: Linalool (CAS No 78-70-6) No 85: Benzyl benzoate (CAS No 120-51-4) No 86: Citronellol (CAS No 106-22-9) No 87: Hexyl cinnam-aldehyde (CAS No 101-86-0) No 88: Limonene (CAS No 5989-27-5) No 89: Methyl 2-octynoate (CAS No 111-12-6) No 90: alpha-Isomethyl ionone (CAS No 127-51-5) No 91: Evernia prunastri extract (CAS No 90028-68-5) No 92: Evernia furfuracea extract (CAS No 90028-67-4)</p> <p>Untill 23 August 2021 HICC (No.79) can be used according to Annex III RE 1223/2009. <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160250	<p>Rinse-off cosmetic products shall not contain the following substances listed in Annex XVII RE (EC) 1907/2006 in a concentration equal to or greater than 0,1 % by weight of either substance.</p> <p>No. 70 Octamethylcyclotetrasiloxan (D4) (CAS-Nr. 556-67-2; INCI: Cyclotetrasiloxane); Decamethylcyclopentasiloxan (D5) (CAS-Nr. 541-02-6; INCI Cyclopentasiloxane)</p> <p>Cyclomethicone contains D4 and D5 as a mixture.</p> <p>The limits apply from 31 January 2020. <b>Additional information:</b> VO (EG) Nr. 1907/2006 Anhang XVII_18-05</p>	VO (EG) Nr. 1907/2006	Artikel 67 Absatz 1 i.V.m. Anhang XVII



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

Hygienic towels/wipes

Article No.:

req. no.	Statutory requirement	Law	Article
50049	Diocetylzin combinations (DOT) are prohibited from 1. January 2012 in products if the substance concentration of DOT exceeds 0.1 per cent weight. The following products are affected: textiles with skin contact; - gloves; - parts of shoes that come into contact with skin; - wall and floor coverings; - baby articles; ladies hygiene products; - nappies/diapers; - packaging; - two-part room temperature vulcanisation form sets (RTV-2- form sets)	VO (EG) Nr. 1907/2006	Anhang XVII
50279	For all colourings (dyes) of sanitary products, the BfR recommendation IX is to be observed. <b>Additional information:</b> BfR IX Colorants Used in Commodities_11-02 BfR IX Farbmittel zum Einfärben von Bedarfsgegenständen_11-02	BfR-Empfehlung	BfR IX
50283	When using polypropylene the BfR recommendations are to be observed. <b>Additional information:</b> BfR VII. Polypropylen 2017-09-01_18-05 BfR VII. Polypropylene 2017-09-01_18-05	BfR-Empfehlung	BfR VII
50284	When using silicones the BfR recommendations XV are to be observed. <b>Additional information:</b> BfR XV. Silicone 2017-09-01_18-05 BfR XV. Silicones 2017-09-01_18-05	BfR-Empfehlung	BfR XV
50285	When using paper, cartons and cardboard the BfR recommendations are to be observed. <b>Additional information:</b> BfR XXXVI. Paper Board Food Contact 2017-09-01_18-05 BfR XXXVI. Papiere, Kartons und Pappen für den Lebensmittelkontakt 2017-09-01_18-05	BfR-Empfehlung	BfR XXXVI
50286	When using polyethelene the BfR recommendations are to be observed. <b>Additional information:</b> BfR III. Polyethylen 2017-09-01_18-05 BfR III. Polyethylene 2017-09-01_18-05	BfR-Empfehlung	BfR III

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

Hygienic towels/wipes

Article No.:

req. no.	Statutory requirement	Law	Article
716	<p>The goods stated below must not contain any azo dyes / pigments which may detach the prohibited amines. Textile and leather goods which may have prolonged direct contact with human skin or mouth, especially:</p> <ol style="list-style-type: none"> <li>1. Clothing, bed linen, towels, hair parts, toupees, hats, diapers and other sanitary articles, sleeping bags.</li> <li>2. Shoes, gloves, watch straps, bags, purses and wallets, folders, chair covers, breast bags.</li> <li>3. Textile and leather toys and toys with textile or leather garments</li> <li>4. Yarns and fabrics for end users.</li> </ol> <p>Prohibited amines :</p> <p>4-aminobiphenyl CAS-No. 92-67-1  Benzidine CAS-No.92-87-5  4-chloro-o-toluidine CAS-No. 95-69-2  2-naphthylamine CAS-No. 91-59-8  o-aminoazotoluene CAS-No. 97-56-3  5-nitro-o-toluidine CAS-No. 99-55-8  4-chloroaniline CAS-No.106-47-8  2,4-diaminoanisole CAS-No. 615-05-4  4,4'-diaminodiphenylmethane CAS-No. 01-77-9  3,3'-dichlorobenzidine CAS-No. 91-94-1  3,3'-dimethoxybenzidine CAS-No. 119-90-4  3,3'-dimethylbenzidine CAS-No. 119-93-7  3,3'-dimethyl-4,4'-diaminoiphenyl-methane CAS-No. 838-88-0  p-cresidine CAS-No.120-71-8  4,4'-methylene-bis-(2-chloraniline) CAS-No . 101-14-4  4,4'-oxydianiline CAS-No.101-80-4  4,4'-thiodianiline CAS-No.139-65-1  o-toluidine CAS-No. 95-53-4  2,4-toluylendiamine CAS-No. 95-80-7  2,4,5-trimethylaniline CAS-No. 137-17-7  o-anisidine (2-methoxyaniline) CAS-No. 90-04-0  4-amino azobenzene CAS-No. 60-09-3</p> <p>The use of prohibited azo dyes is deemed not to have been proven if the amounts contained of each amine component do not exceed 30 mg in one kilogram (0,003 Gew.-%) of specimen material.</p>	BedGgstV	§ 3 iVm Anl. 1 Nr. 7



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

Hygienic towels/wipes

Article No.:

req. no.	Statutory requirement	Law	Article
50835	<p>For fillers the BfR recommendations are observed.</p> <p>This Recommendation for fillers applies to the following materials:</p> <ol style="list-style-type: none"> <li>1. Plastics Dispersions according to Recommendation XIV</li> <li>2. Silicones according to Recommendation XV</li> <li>3. Commodities based on Natural and Synthetic Rubber according to Recommendation XXI</li> <li>4. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials according to Recommendation XXVIII</li> <li>5. Linear Polyurethanes for Paper Coatings according to Recommendation XLI</li> <li>6. Artificial Sausage Casings according to Recommendation XLIV</li> <li>7. Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking Utensils according to Recommendation LI</li> </ol> <p><b>Additional information:</b>                      BfR LII. Fillers 2017-09-01_18-05                      BfR LII. Füllstoffe 2017-09-01_18-05</p>	BfR-Empfehlung	BfR LII



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Ethereal oil**

Article No.:

req. no.	Statutory requirement	Law	Article
160235	Essential oils are only to be regarded as a cosmetic product, when a vast cosmetic purpose (oral care concentrate, bath additive) is present.	ALS	2014/43

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - eye-make-up and eye-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160215	In blemish concealer the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS No 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160218	Products for making-up and removing make-up from the eyes and all other cosmetic products which will come in contact with the mucosa of the eye should not contain following preservatives listed in Annex IV RE (EC) No 1223/2009:  No 59: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, silver(1+)salt, monohydrate (INCI: Citric acid (and) Silver citrate, CAS No -) (EG-Nr. 460-890-5)	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160011	Products for making-up and removing make-up from the eyes and all other cosmetic product which will come in contact with the mucosa of the eye should not contain the dyes (including their salts and lakes) listed in Annex IV RE (EC) No 1223/2009.  No 3: CI 10316 (yellow) No 21: CI 15510 (orange) No 78: CI 45405 (red) No 107: CI 74260 (green)	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160012	Cosmetic substances which come into contact with mucous membranes may not contain dyes (including their salts and lakes) from Annex IV RE (EC) No 1223/2009. Cosmetic substances which come into contact with the mucous membranes are e.g. mouth care substances and lotions for washing private parts.  No 2: CI 10020 No 4: CI 11680 No 5: CI 11710 No 8: CI 12010 No 26: CI 15800 No 34: CI 16230 No 38: CI 18050 No 49: CI 21230 No 51: CI 26100 No 59: CI 42045 No 66: CI 42510 No 68: CI 42735 No 69: CI 44045 No 81: CI 47000 No 84: CI 50420 No 87: CI 59040 No 90: CI 60730 No 97: CI 71105 No 153: Acid Red 195	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - eye-make-up and eye-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160140	<p>In the products intended to come into contact with mucous membranes the following conservation materials listed in Annex V RE (EC) No 1223/2009 are prohibited:</p> <p>No 24: Chlorocresol (INCI: p-Chloro-m-Cresol, CAS No 59-50-7)</p> <p>No 49: 5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane (INCI: 7-Ethylbicyclooxazolidine, CAS No 7747-35-5)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160138	<p>In eye make-up and eye make-up remover the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 16: Thiomersal (INCI: Thiomersal, CAS-Nr. 54-64-8)</p> <p>No 17: Phenylmercuric salts (including borate) (INCI: Phenyl Mercuric Acetate, Phenyl Mercuric Benzoate, CAS-Nr. 62-38-4, 94-43-9)</p> <p><b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160116	<p>In Talc the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1a: Boric acid, borates and tetraborates (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1 with the exception of substance No 1184 in Annex II: N-Dimethylanilinium-tetrakis(pentafluorphenyl)borat (CAS 118612-00-3)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05 VO (EU) Nr.1223/2009 Anhang II_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160180	<p>For decorative cosmetic products marketed in several shades, all colorants other than colorants intended to colour hair used in the range may be listed, provided that the words "kann...enthalten" ("may contain" or with the symbol "+/-" . The CI nomenclature shall be used. This must be stated on the packaging and on the container.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - depilation, depigmentation, self-tanning**

Article No.:

req. no.	Statutory requirement	Law	Article
160101	<p>In depilatories the following substances listed in Annex III RE (EC) No 1223/2009 are allowed if the stated limitations and additional labelling requirements are observed:</p> <p>No 2a: Thioglycollic acid and its salts (INCI: Thioglycolic acid, CAS No 68-11-1)            No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2)            No 15b: Lithium hydroxide (INCI: Lithium hydroxide, CAS No 1310-65-2)            No 15c: Calcium hydroxide (INCI: Calcium hydroxide, CAS No 1305-62-0)            No 23a: Alkali sulphides (INCI: -, CAS No -)            No 23b: Alkaline earth sulphides (INCI: -, CAS No -)            No 63: Strontium hydroxide (INCI: Strontium hydroxide, CAS No 18480-07-4)</p> <p><b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160188	<p>For depilatories with thioglycol acid a notice must be contained in the accompanying leaflet (instructions for use) that this substance is not suitable for use on large surfaces.</p> <p>It is also recommended to give clear recommendations of avoidance of sunlight after applying depilatory to accommodate the increased sensitivity of the skin after chemical depilation .</p> <p><b>Additional information:</b>            BfR Thioglykolsäure_11-11            NEU_7-sitzung-der-bfr-kommission-fuer-kosmetische-mittel_14-11.pdf</p>	BfR Thioglykolsäure	
160120	<p>In products for tanning without sun the followings substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 99: Inorganic sulfites and bisulfites (INCI: -, CAS No -)</p> <p><b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - deodorants and anti-perspirants**

Article No.:

req. no.	Statutory requirement	Law	Article
160219	In deodorants (non spray) the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No. 25: 5-Chloro-2-(2,4- dichlorophenoxy) phenol (INCI: Triclosan; CAS No 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160117	In deodorants, antiperspirants and astringent lotions the following substances listed in Annex III RE (EC) No 1223/2009 are allowed if they adhere to the limitations and requirements in the Annex for labelling:  deodorants, antiperspirants and astringent lotions: No 25: Zinc 4-hydroxybenzene sulphonate (INCI: Zinc phenolsulfonate, CAS No 127-82-2)  only for antiperspirants: No 50: Aluminium zirconium chloride hydroxyde Complexes Al <sub>x</sub> Zr(OH) <sub>y</sub> Cl <sub>z</sub> and the aluminium zirconium chloride sydroxide glycine complexes (INCI: - , CAS No - )  for non-sprayable deodorant substances: No 197 - Ethyl-N-alpha- dodecanoyl-L- arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)  sprayable deodorants and antiperspirants 2-(2-Ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS No 111-90-0) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160116	In Talc the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:  No 1a: Boric acid, borates and tetraborates (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1 with the exception of substance No 1184 in Annex II: N-Dimethylanilinium-tetrakis(pentafluorphenyl)borat (CAS 118612-00-3) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05 VO (EU) Nr.1223/2009 Anhang II_17-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160139	In deodorants/antiperspirants the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:  No 56 - 3-Iod-2-propinylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No 55406-53-6) <b>Additional information:</b> VO (EU) Nr.1223/2009 Anhang V_17-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - facial make-up, facial care and shaving**

Article No.:

req. no.	Statutory requirement	Law	Article
160214	In face powders the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS-No. 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160253	The intake of Vitamin A via cosmetic products should be limited.  The BfR recommends limiting the concentration of vitamin A in cosmetic products for facial care and hand care. In contrast, vitamin A should not be used in lip and body care products. <b>Additional information:</b> BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160215	In blemish concealer the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS No 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160231	PE -containing micro-plastic particles:  Based on the current state of knowledge, PE -containing micro-plastic particles having a size of 1 micron, such as those used in shower gels, peelings or toothpastes, pose no health risk to consumers. <b>Additional information:</b> NEU_ BfR polyethylene-containing-microplastic-particles_14-11.pdf	BfR PE-haltige Mikrokunststoff artikel	Polyethylenhaltige Mikrokunststoff artikel Stellungnahme Nr. 032/2014 des BfR vom 3. Januar 2014
160118	In skin-care mixtures the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:  No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS-No 7722-84-1) No 57: Strontium chloride hexahydrate (INCI: Strontium chloride, CAS-No 10476-85-4) (face care products only) No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0) No 286: C16-alkyltrimethylammonium chloride (INCI: Cetrimonium chloride, CAS No 112-02-7); C18-alkyltrimethylammonium chloride (INCI: Steartrimonium chloride (CAS No 112-02-8) (leave-on face care products only) No 287: C22-alkyltrimethylammonium chloride (INCI: Behentrimonium chloride. CAS No 17301-53-0) (leave-on face care products only) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - facial make-up, facial care and shaving**

Article No.:

req. no.	Statutory requirement	Law	Article
160116	<p>In Talc the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1a: Boric acid, borates and tetraborates (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1 with the exception of substance No 1184 in Annex II: N-Dimethylanilinium-tetrakis(pentafluorophenyl)borat (CAS 118612-00-3)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05 VO (EU) Nr.1223/2009 Anhang II_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160125	<p>In soap the following substances of Annex III RE (EC) No 1223/2009 is allowed adhere the limitations and requirements for labelling:</p> <p>No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and ist salts) (INCI: Etidronic acid, CAS No 2809-21-4) No 197: Ethyl-N-alpha-dodecanoyl-L-arginin-hydrochlorid (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160180	<p>For decorative cosmetic products marketed in several shades, all colorants other than colorants intended to colour hair used in the range may be listed, provided that the words "kann...enthalten" ("may contain" or with the symbol "+/-" . The CI nomenclature shall be used. This must be stated on the packaging and on the container.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - haircoloration, straightening & perms**

Article No.:

req. no.	Statutory requirement	Law	Article
160106	<p>In hair care products for cleaning, cleansing, waving, straightening, dyeing and setting the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1b: Tetraborates (INCI: -, CAS No -)            No 3: Oxalic acid, its esters and alkaline salts (INCI: Oxalic acid, CAS No 144-62-7)            No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS No 7722-84-1)            No 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)            No 51: Quinolin-8-ol and bis (8-hydroxy-quinolium)sulphate (INCI: Oxyquinoline and oxyquinoline sulfate, CAS No 148-24-3/ 134-31-6)            No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts) (INCI: Etidronic acid, CAS No 2809-21-4)            No 93: 2,4-Diamino-pyrimidine-3-oxide ((INCI: Diaminopyrimidine oxide CAS No 74638-76-9)            No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)</p> <p><b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160137	<p>In rinse-off hair products (for waving, straightening, fixing, cleansing, conditioning, setting and hairdressing) the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 8 - Pyrithione zinc (INCI: Zinc pyrithione, CAS No. 13463-41-7)</p> <p><b>Additional information:</b>            VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160103	<p>Hair dye substances are not regulated by Annex IV (allowed colorants) of RE (EC) No 1223/2009 but by Annex III (restricted substances). The stated limitations and additional labelling requirements of Annex III (see Annex) must be observed.</p> <p><b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160242	Herbal hair dyes which claim in their designation the ingredient "Henna" must contain significant quantities „Lawsonia inermis“.	ALS	2015/50
160194	<p>The warning notice for certain hair dyeing substances that these are not suitable for young persons under the age of 16 years is a compulsory notice regarding usage but not a prohibition regarding release/sale.</p> <p><b>Additional information:</b>            IKW - Hinweis Haarfärbemittel</p>	IKW - Hinweis Haarfärbemittel	



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - haircoloration, straightening & perms**

Article No.:

req. no.	Statutory requirement	Law	Article
160100	<p>In haircare products for waving or straightening the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1b: Tetraborates (INCI: -, CAS No -)                      No 2a: Thioglycolic acid and ist salts (INCI: Thioglycolic acid, CAS No 68-11-1)                      No 2b: Thioglycolic acid esters (INCI: -, CAS No -) (in hair waving or straightening products)                      No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2) (only in hair straighteners)                      No 15b: Lithium hydroxide (INCI: Lithium hydroxide, CAS No 1310-65-2) (only in hair straighteners)                      No 15c: Calcium hydroxide (INCI: Calcium hydroxide, CAS No 1305-62-0 (only in hair straighteners containing two components: calcium hydroxide and guanidine salt)                      No 99: Inorganic sulfites and bisulfites (INCI: -, CAS-No -) (only in hair straighteners)</p> <p>In hair care products for waving the substance No 1a of Annex III - Boric acid, borates and tetraborates (INCI: Boric acid, CAS No 10043-35-3 / 11113-50-1) is prohibited.</p> <p><b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160150	<p>The Federal Institute for Risk Analysis (BfR) evaluates the substance formaldehyde in a concentration of 1.7-1.8 % in hair straightener as sufficient to damage health.</p> <p><b>Additional information:</b>                      BfR Haarglättungsmittel_11-04</p>	BfR Haarglättungsmittel	

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - haircoloration, straightening & perms**

Article No.:

req. no.	Statutory requirement	Law	Article
160121	<p>In products intended for colouring eyelashes and eyebrows the followings substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 48: Silver nitrate (INCI: Silver nitrate, CAS No 7761-88-8) (colouring eyelashes and eyebrows)</p> <p>In products intended for colouring eyelashes followings substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 8b: p-Phenylenediamine and its salts (INCI: p-Phenylenediamine; p-Phenylenediamine HCl; p-Phenylenediamine Sulphate, CAS No 106-50-3 / 624-18-0 / 16245-77-5)</p> <p>No 9a: 1,4-Benzenediamine, 2-methyl- 2,5-Diaminotoluene sulphate (INCI: Toluene-2,5- Diamine, CAS No 95-70-5); (INCI: Toluene-2,5- Diamine Sulfate, CAS No 615-50-9)</p> <p>No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS-No 7722-84-1)</p> <p>No 22: 1,3-Benzoldiol (INCI: Resorcinol, CAS No 108-46-3)</p> <p>No 20: 2,4,5,6-Tetraaminopyrimidine sulphate (INCI: Tetraaminopyrimidine Sulfate, CAS No 5392-28-9)</p> <p>No 203: 6-Methoxy-N2-methyl-2,3-pyridinediamine hydrochloride and dihydrochloride salt (INCI: 6-Methoxy-2-methylamino-3-aminopyridine HCl, CAS No 90817-34-8 (HCl), CAS No 83732-72-3 (2HCl))</p> <p>No 206: 3-(2-Hydroxyethyl)- p-phenylenediammonium sulphate (INCI: Hydroxyethyl- p- Phenylenediamine Sulfate, CAS No 93841-25-9)</p> <p>No 211: 2-Aminopyridin-3-ol (INCI: 2-Amino-3- Hydroxypyridine, CAS No 16867-03-1)</p> <p>No 217: m-Aminophenol and its salts (INCI: m-Aminophenol, m-Aminophenol HCl, m-Aminophenol sulfate, CAS No 591-27-5 / 51-81-0 / 68239-81-6 / 38171-54-9)</p> <p>No 229 - 5-[(2-Hydroxyethyl)amino]-o-cresol (INCI: 2-Methyl-5-hydroxyethylaminophenol, CAS-No 55302-96-0)</p> <p>No 241: 5-Amino-o-cresol (INCI: 4-Amino-2- Hydroxytoluene, CAS-No 83-56-7)</p> <p>No 242: 2,4-Diaminophenoxyethanol, its hydrochloride and its sulphate (INCI: 2,4-Diaminophenoxyethanol; 2,4-Diaminophenoxyethanol HCl, CAS No 70643-19-5 / 66422-95-5 / 70643-20-8)</p> <p>No 243: 1,3-Benzenediol, 2- methyl (INCI: 2-Methylresorcinol, CAS No 608-25-3)</p> <p>No 244 : 4-Amino-m-cresol (INCI: 4-Amino-m-cresol, CAS-No 2835-99-6)</p> <p>No 245: 2-[(3-amino-4-methoxyphenyl) amino]ethanol and its sulphate (INCI: 2-Amino-4-hydroxyethylaminoanisole; 2-Amino-4-ydroxyethylaminoanisole, CAS-No 83763-47-7 / 83763-48-6)</p> <p>No 272: 4-Aminophenol (INCI: p-Aminophenol, CAS No 123-30-8)</p> <p>No 285: Pyridine-2,6- diyldiamine (INCI: 2,6-Diaminopyridine, CAS No 141-86-6)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
S. 51			



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - hair-cleansing & hair-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160106	<p>In hair care products for cleaning, cleansing, waving, straightening, dyeing and setting the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1b: Tetraborates (INCI: -, CAS No -)            No 3: Oxalic acid, its esters and alkaline salts (INCI: Oxalic acid, CAS No 144-62-7)            No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS No 7722-84-1)            No 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)            No 51: Quinolin-8-ol and bis (8-hydroxy-quinolium)sulphate (INCI: Oxyquinoline and oxyquinoline sulfate, CAS No 148-24-3/134-31-6)            No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts) (INCI: Etidronic acid, CAS No 2809-21-4)            No 93: 2,4-Diamino-pyrimidine-3-oxide ((INCI: Diaminopyrimidine oxide CAS No 74638-76-9)            No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160137	<p>In rinse-off hair products (for waving, straightening, fixing, cleansing, conditioning, setting and hairdressing) the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 8 - Pyrithione zinc (INCI: Zinc pyrithione, CAS No. 13463-41-7)  <b>Additional information:</b>            VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - hair-cleansing & hair-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160104	<p>In rinse-off hair care products the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 2a: Thioglycollic acid and its salts (INCI: Thioglycolic acid, CAS No 68-11-1)            No 21: Cinchonan-9-ol, 6'-methoxy-, (8.alpha.,9R)- and its salts (INCI: Quinine, CAS No 130-95-0)            No 54: 1-Phenoxypropan-2- ol (INCI: Phenoxyisopropanol, CAS No 770-35-4)            No 64: Strontium peroxide (INCI: Strontium peroxide, CAS No 1314-18-7)            No 65: Benzalkonium chloride, bromide and saccharinate (INCI: Benzalkonium bromide, CAS No 91080-29-4; INCI: Benzalkonium chloride, CAS No 63449-41-2/ 68391-01-5/ 68424-85-1/ 85409-22-9; INCI: Benzalkonium saccharinate, CAS No 68989-01-5)            No 98: Salicylic acid (INCI: Salicylic acid, CAS No 69-72-7)            No 286 - C16-alkyltrimethylammonium chloride (INCI: Cetrimonium chloride, CAS No 112-02-7); C18-alkyltrimethylammonium chloride (INCI: Steartrimonium chloride, CAS No 112-02-8)            No 287: C22-alkyltrimethylammonium chloride (INCI: Behentrimonium chloride, CAS No 17301-53-0)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160105	<p>In leave-on hair care products the following substance listed in Annex III RE (EC) No 1223/2009 is allowed adhere the limitations and requirements for labelling:</p> <p>No 21: Cinchonan-9-ol, 6'-methoxy-, (8.alpha.,9R)- and its salts (INCI: Quinine, CAS No 130-95-0)            No 101: Pyrithione zinc (INCI: Zinc pyrithione, CAS No 13463-41-7)            No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS No 93-15-2)            No 134 - 1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone (INCI: Acetyl Hexamethyl indan, CAS No 15323-35-0)            No 156 - Cuminum cyminum oil and extract (INCI: Cuminum Cyminum Fruit Oil; Cuminum Cyminum Fruit Extract; Cuminum Cyminum Seed Oil; Cuminum Cyminum Seed Extract; Cuminum Cyminum Seed Powder, CAS No 84775-51-9)            No 286 - C16-alkyltrimethylammonium chloride (INCI: Cetrimonium chloride, CAS No 112-02-7); C18-alkyltrimethylammonium chloride (INCI: Steartrimonium chloride, CAS No 112-02-8)            No 287 - C22-alkyltrimethylammonium chloride (INCI: Behentrimonium chloride, CAS No 17301-53-0)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - hair-cleansing & hair-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160113	<p>In shampoos the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 22: Resorcinol (INCI: Resorcinol, CAS No 108-46-3)                      No 57: Strontium chloride hexahydrate (INCI: Strontium chloride, CAS No 10476-85-4)</p> <p><b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160115	<p>In anti-dandruff shampoos the following substances listed in Annex III RE (EC) No 1223/2009 are allowed if they adhere to the limitations and requirements in the Annex for labelling:</p> <p>No 49: Selenium disulphide (INCI: Selenium disulphide, CAS No 7488-56-4)                      No 197 - Ethyl-N-alpha-dodecanoyl-L-arginate hydrochlorid (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p><b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160114	<p>In hair lotions the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 22: Resorcinol (INCI: Resorcinol, CAS No 108-46-3)</p> <p><b>Additional information:</b>                      VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - skin-cleansing & skin-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160200	The Federal Institute for Risk Analysis (BfR) evaluates the substance $\beta$ -Arbutin in Skin-lightening products as harmful to human health. <b>Additional information:</b> BfR - beta-Arbutin in Hautaufhellungsmitteln_13-04	BfR beta-Arbutin Hautaufhellung	
160253	The intake of Vitamin A via cosmetic products should be limited.  The BfR recommends limiting the concentration of vitamin A in cosmetic products for facial care and hand care. In contrast, vitamin A should not be used in lip and body care products. <b>Additional information:</b> BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160212	In hand soaps the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS-No. 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160213	In body soap/ shower gels the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS-No. 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160223	If the intended use of a soap given by the manufacturer is only for decoration purposes, the product still has to be classified as a cosmetic product.	ALS	2013/27
160231	PE -containing micro-plastic particles:  Based on the current state of knowledge, PE -containing micro-plastic particles having a size of 1 micron, such as those used in shower gels, peelings or toothpastes, pose no health risk to consumers. <b>Additional information:</b> NEU_ BfR polyethylene-containing-microplastic-particles_14-11.pdf	BfR PE-haltige Mikrokunststoffp artikel	Polyethylenhaltig e Mikrokunststoffp artikel Stellungnahme Nr. 032/2014 des BfR vom 3. Januar 2014
160233	Ingredients (substances) of soaps, that react with each other in the production, are not to be labeled on the final product.	ALS	2014/35

Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - skin-cleansing & skin-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160012	<p>Cosmetic substances which come into contact with mucous membranes may not contain dyes (including their salts and lakes) from Annex IV RE (EC) No 1223/2009. Cosmetic substances which come into contact with the mucous membranes are e.g. mouth care substances and lotions for washing private parts.</p> <p>No 2: CI 10020            No 4: CI 11680            No 5: CI 11710            No 8: CI 12010            No 26: CI 15800            No 34: CI 16230            No 38: CI 18050            No 49: CI 21230            No 51: CI 26100            No 59: CI 42045            No 66: CI 42510            No 68: CI 42735            No 69: CI 44045            No 81: CI 47000            No 84: CI 50420            No 87: CI 59040            No 90: CI 60730            No 97: CI 71105            No 153: Acid Red 195</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160140	<p>In the products intended to come into contact with mucous membranes the following conservation materials listed in Annex V RE (EC) No 1223/2009 are prohibited:</p> <p>No 24: Chlorocresol (INCI: p-Chloro-m-Cresol, CAS No 59-50-7)</p> <p>No 49: 5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane (INCI: 7-Ethylbicyclooxazolidine, CAS No 7747-35-5)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160118	<p>In skin-care mixtures the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS-No 7722-84-1)</p> <p>No 57: Strontium chloride hexahydrate (INCI: Strontium chloride, CAS-No 10476-85-4)            (face care products only)</p> <p>No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)</p> <p>No 286: C16-alkyltrimethylammonium chloride (INCI: Cetrimonium chloride, CAS No 112-02-7); C18-alkyltrimethylammonium chloride (INCI: Steartrimonium chloride (CAS No 112-02-8)            (leave-on face care products only)</p> <p>No 287: C22-alkyltrimethylammonium chloride (INCI: Behentrimonium chloride. CAS No 17301-53-0) (leave-on face care products only)</p> <p><b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - skin-cleansing & skin-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160125	<p>In soap the following substances of Annex III RE (EC) No 1223/2009 is allowed adhere the limitations and requirements for labelling:</p> <p>No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and ist salts) (INCI: Etidronic acid, CAS No 2809-21-4)            No 197: Ethyl-N-alpha-dodecanoyl-L-arginin-hydrochlorid (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160112	<p>In bath products the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1b: Tetraborates (INCI: -, Cas No -)</p> <p>The following substance listed in Annex III is definitely prohibited for bath products:            No 1a: Boric acid, borates and tetraborates (INCI: Boric acid, CAS-No 10043-35-3 / 11113-50-1)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160116	<p>In Talc the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1a: Boric acid, borates and tetraborates (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1 with the exception of substance No 1184 in Annex II:            N-Dimethylanilinium-tetrakis(pentafluorphenyl)borat (CAS 118612-00-3)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05            VO (EU) Nr.1223/2009 Anhang II_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160240	<p>In callosity softener/remover the following substance listed in Annex III RE (EC) No 1223/2009 is allowed adhere the limitations and requirements for labelling:</p> <p>No 15d - potassium hydroxide (INCI: potassium hydroxide; CAS No 1310-58-3)  <b>Additional information:</b>            VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160243	Products for bleaching facial hair or body hair are skin products.	ALS	2015/51

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - lip make-up & lip-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160088	Boracic acid should not be used in lip care materials, according to a recommendation by the Federal Institute for Risk Calculation (BfR). <b>Additional information:</b> BfR Borsäure	BfR Borsäure	
160253	The intake of Vitamin A via cosmetic products should be limited.  The BfR recommends limiting the concentration of vitamin A in cosmetic products for facial care and hand care. In contrast, vitamin A should not be used in lip and body care products. <b>Additional information:</b> BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160180	For decorative cosmetic products marketed in several shades, all colorants other than colorants intended to colour hair used in the range may be listed, provided that the words "kann...enthalten" ("may contain" or with the symbol "+/-" . The CI nomenclature shall be used. This must be stated on the packaging and on the container.	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g)
160141	In products intended for application on the lips the following preservatives listed in Annex V RE (EC) No 1223/2009 are prohibited:  No 52: Silver chloride deposited on titanium dioxide (INCI: Silver chloride, CAS-Nr. 7783-90-6) No 56: 3-Iodo-2-propynylbutylcarbamate (IPBC) (INCI: Iodopropynyl butylcarbamate, CAS-Nr. 55406-53-6) No 58: Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160254	BfR is the opinion that If cosmetic products comply with the recommendation of Cosmetics Europe, no health effects from the oral intake of highly refined mineral oils (MOSH / MOAH) are to be expected.  Cosmetics Europe recommends to use only those mineral hydrocarbons in oral and lip care products, for which an Acceptable Daily Intake (ADI) has been identified. <b>Additional information:</b> BfR hochraffinierte Mineralöle_18-05 Cosmetics Europe Recommendation No 14 Mineral hydrocarbons in oral and lip care_18-05	BfR Mineralöle	BfR Stellungnahme Nr. 008/2018

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Nail cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160216	In nail products for cleaning the fingernails and toenails before the application of artificial nail systems the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:  No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS-No. 3380-34-5) maximum 0,3% in ready for use preparation	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160225	hydroquinone monomethyl ether (MEHQ)  The processing aid hydroquinone monomethyl ether (MEHQ) can be present in modelling gel for artificial nails through carry over from raw materials. If the substance is detectable, it must be mentioned as an ingredient. The product manager must reconstruct if the product may contain MEHQ.	ALS	2013/24
160244	Color gels which are used for decoration (e.g. recoaters) are still cosmetic products.	ALS	2015/54
160109	In cosmetic products for nail care the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:  No 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)  No 185: Toluene (INCI: Toluene, CAS No 108-88-3) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160197	Products with very high methyl-methacrylate content (80-90%) should not be sold to the end user, because they were considered unsafe. <b>Additional information:</b> BfR Methylmethacrylat Nagelmodellage_12-11	BfR Methylmethacrylat at Nagelmodellage	
160108	In nail hardening the following substances listed in Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:  No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS No 7722-84-1)  No 13: Formaldehyde (INCI: Formaldehyde, CAS No 50-00-0) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - Nail cosmetics**

Article No.:

req. no.	Statutory requirement	Law	Article
160110	<p>In nail cuticle solvent the following substance listed in Annex III RE (EC) No 1223/2009 is allowed adhere the limitations and requirements for labelling:</p> <p>No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160111	<p>In products for artificial nail systems the following substances listed Annex III RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 14: Hydroquinone (INCI: Hydroquinone, CAS123-31-9) No 94: Dibenzoyl peroxide (INCI: Benzoyl peroxide, CAS No 94-36-0) No 95: Hydroquinone methylether / Mequinol (INCI: p-Hydroxyanisol, CAS No 150-76-5)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160180	<p>For decorative cosmetic products marketed in several shades, all colorants other than colorants intended to colour hair used in the range may be listed, provided that the words "kann...enthalten" ("may contain" or with the symbol "+/-" . The CI nomenclature shall be used. This must be stated on the packaging and on the container.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g)



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - perfume & toilet water**

Article No.:

req. no.	Statutory requirement	Law	Article
160148	For perfume and toilet water there are currently no requirements which exclusively affect this product group.	Zusatzinfo	



Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - sun protection**

Article No.:

req. no.	Statutory requirement	Law	Article
160018	For the protection of human skin from the sun's rays only the UV-filters listed in Annex VI of RE (EC) No 1223/2009 may be used if they adhere to the restrictions and requirements for declaration mentioned in the Annex. The use of other materials than UV-filters is prohibited. <b>Additional information:</b> VO (EG) Nr. 1223/2009 Anhang VI_17-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe e)
160060	Sun protection substances must have the minimum effectiveness stated in the Commission Recommendation 2006/647/EC.	Kom Empf 2006/647/EG	L265/39 (7)
160062	Sun protection substances should show, in line with the Commission Recommendation 2006/647/EC, one of the following sun protection factors: 6, 10, 15, 20, 25, 30, 50 und 50+ Further sun protection factors should be dispensed with. In addition the statements regarding the effectiveness of the sun protection substance should be categorized: - category "Low protection level" - sun protection factors 6 and 10 - category "medium protection level" - sun protection factor 15, 20 and 25 - category "high protection level" - sun protection factor 30 and 50 - category "very high protection level" sun protection factor 50+ Sun protection and category must be clearly visible on the label. <b>Additional information:</b> Kom Empf 2006/647/EG	Kom Empf 2006/647/EG	Abschn4
160061	For the designation of sun protection substances the following points in accordance with the Commission Recommendation 2006/647/EC must be adhered to: - Renunciation of statements which suggest a 100% protection from UV-rays (e.g. "Sunblocker"). - Renunciation of statements which suggest that the product must under no circumstances be applied again. - Attachment of warning notices from which can be understood that sun protection substances cannot offer 100% protection. (e.g. despite use of sun protection substances , do not stay too long in the sun). - Statement of conditions of use such that the correct use by the consumer may be ensured (e.g. Use sun protection substances before staying in the sun.) - Statement of the requisite amount which must be applied for sufficient sun protection.	Kom Empf 2006/647/EG	Abschn2
160241	Karanja oil is not permitted as an UV-filter in cosmetics. The use of this substance as an UV-Filter does not meet the requirements of EU-KosmetikVO.	Sitzungen BfR Kosmetik	16. Sitzung der BfR-Kommission für kosmetische Mittel

Category: Cosmetics

18-05

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Product: Kosmetik/cosmetics

**Cosmetic products - dental & mouth-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160226	Tooth care chewing gums are usually classified as cosmetic products.	ALS	2013/23
160231	PE -containing micro-plastic particles:  Based on the current state of knowledge, PE -containing micro-plastic particles having a size of 1 micron, such as those used in shower gels, peelings or toothpastes, pose no health risk to consumers. <b>Additional information:</b> NEU_ BfR polyethylene-containing-microplastic-particles_14-11.pdf	BfR PE-haltige Mikrokunststoff artikel	Polyethylenhaltige Mikrokunststoff artikel Stellungnahme Nr. 032/2014 des BfR vom 3. Januar 2014
160232	Zinc salts in oral products and toothpaste: Whether the legal limit for zinc should be adjusted from 1% to 0.1% is discussed controversially. Currently a benchmark of 0.1% free zinc in mouthwashes is respected by the manufacturers. From the perspective of risk assessment 1% free zinc in toothpaste is considered safe for consumers. Products for oral hygiene for children should be free from zinc.	Sitzungen BfR Kosmetik	13. Sitzung der BfR-Kommission für kosmetische Mittel
160234	If coated dental floss advertised as a cosmetic agent, this leads to the classification of the formulation used as a cosmetic product and it has to be considered the EU Cosmetics Regulation.	ALS	2014/36
160097	The following substances listed in Annex III RE (EC) No 1223/2009 are prohibited in oral products:  No 54: 1-Phenoxypropan-2- ol (INCI: Phenoxyisopropanol, CAS No 770-35-4) No 96: 5-tert-Butyl-2,4,6-trinitro-m-xylene (INCI: Musk xylene, CAS No 81-15-2) No 97: 4'-tert-Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone (INCI: Musk ketone, CAS No 81-14-1) No 182: 1-(5,6,7,8-Tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one (AHTN (INCI: Acetyl hexamethyl tetralin, CAS No 21145-77-7 / 1506-02-1) No 297: 2-(2-Ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS-Nr. 111-90-0) <b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)



Category: Cosmetics

18-05

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**Cosmetic products - dental & mouth-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160132	<p>In products for oral hygiene following preservatives of Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 1: Benzoic acid (INCI: Benzoic acid, CAS-Nr. 65-85-0) and its sodiumsalt (INCI: Sodium Benzoate, CAS No 532-32-1)                      No 5: Formaldehyde and paraformaldehyde (INCI: Formaldehyde Paraformaldehyde, CAS No 50-00-0, 30525-89-4)</p> <p>only for mouthwash and toothpaste:                      No. 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS No 3380-34-5)</p> <p>only for mouthwash:                      No. 58: Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p><b>Additional information:</b>                      VO (EU) Nr.1223/2009 Anhang V_17-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

18-05

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**Cosmetic products - dental & mouth-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160096	<p>In oral products (e.g. mouthwash, toothpaste...) the following substances listed in Annex III RE (EC) No 1223/2009 are allowed within all limitations and requirements. Adhere the warnings which must be printed on the label.</p> <p>No 1a: Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex 1 (INCI: Boric acid, CAS No 10043-35-3/ 11113-50-1)</p> <p>No 12: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide (INCI: Hydrogen peroxide, CAS No 7722-84-1)</p> <p>No 26: Ammonium monofluorophosphate (INCI: Ammonium Monofluorophosphate, CAS No 20859-38-5/ 66115-19-3)</p> <p>No 27: Disodium fluorophosphate (INCI: Sodium Monofluorophosphate, CAS No 10163-15-2/ 7631-97-2)</p> <p>No 28: Dipotassium fluorophosphate (INCI: Potassium Monofluorophosphate, CAS No 14104-28-0)</p> <p>No 29: Calcium fluorophosphate (INCI: Calcium Monofluorophosphate, CAS No 7789-74-4)</p> <p>No 30: Calcium fluoride (INCI: Calcium Fluoride, CAS No 7789-75-5)</p> <p>No 31: Sodium fluoride (INCI: Sodium Fluoride, CAS No 7681-49-4)</p> <p>No 32: Potassium fluoride (INCI: Potassium Fluoride, CAS No 7789-23-3)</p> <p>No 33: Ammonium fluoride (INCI: Ammonium Fluoride, CAS No 12125-01-8)</p> <p>No 34: Aluminium fluoride (INCI: Aluminum Fluoride, CAS No 7784-18-1)</p> <p>No 35: Tin difluoride (INCI: Stannous Fluoride, CAS No 7783-47-3)</p> <p>No 36: Hexadecyl ammonium fluoride (INCI: Cetylamine Hydrofluoride, CAS No 3151-59-5)</p> <p>No 37: 3-(N-Hexadecyl-N-2-hydroxyethylammonio) Propylbis (2-hydroxyethyl) ammonium difluoride (INCI: -, CAS No -)</p> <p>No 38: NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride (INCI: -, CAS No -)</p> <p>No 39: 9-Octadecen-1-amine hydrofluoride (INCI: Octadecenyl-Ammonium Fluoride, CAS No 36505-83-6)</p> <p>No 40: Disodium hexafluorosilicate (INCI: Sodium Fluorosilicate, CAS No 16893-85-9)</p> <p>No 41: Dipotassium Hexafluorosilicate (INCI: Potassium Fluorosilicate, CAS No 16871-90-2)</p> <p>No 42: Ammonium Hexafluorosilicate (INCI: Ammonium Fluorosilicate, CAS No 16919-19-0)</p> <p>No 43: Magnesium Hexafluorosilicate (INCI: Magnesium Fluorosilicate, CAS No 16949-65-8)</p> <p>No 46: 6-methylcoumarin (INCI: 6-Methylcoumarin, CAS No 92-48-8)</p> <p>No 47: 3-Pyridinemethanol hydrofluoride (INCI: Nicomethanol Hydrofluoride, CAS No 62756-44-9)</p> <p>No 56: Magnesium fluoride (INCI: Magnesium Fluoride, CAS No 7783-40-6)</p> <p>No 57: Strontium chloride hexahydrate (INCI: Strontium chloride, CAS No 10476-85-4)</p> <p>No 58: Strontium acetate hemihydrate (INCI: Strontium acetate, CAS No 543-94-2)</p> <p>No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS No 93-15-2)</p> <p>No 157: cis-Rose ketone1; (Z)-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (cis-alphaDamascone) (INCI: Alpha-Damascone, CAS No 23726-94-5 / 43052-87-5)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
S. 66			

Category: Cosmetics

18-05

Author: Lichey, Stefan

Product: Kosmetik/cosmetics

**Cosmetic products - dental & mouth-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160012	<p>Cosmetic substances which come into contact with mucous membranes may not contain dyes (including their salts and lakes) from Annex IV RE (EC) No 1223/2009. Cosmetic substances which come into contact with the mucous membranes are e.g. mouth care substances and lotions for washing private parts.</p> <p>No 2: CI 10020            No 4: CI 11680            No 5: CI 11710            No 8: CI 12010            No 26: CI 15800            No 34: CI 16230            No 38: CI 18050            No 49: CI 21230            No 51: CI 26100            No 59: CI 42045            No 66: CI 42510            No 68: CI 42735            No 69: CI 44045            No 81: CI 47000            No 84: CI 50420            No 87: CI 59040            No 90: CI 60730            No 97: CI 71105            No 153: Acid Red 195</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160140	<p>In the products intended to come into contact with mucous membranes the following conservation materials listed in Annex V RE (EC) No 1223/2009 are prohibited:</p> <p>No 24: Chlorocresol (INCI: p-Chloro-m-Cresol, CAS No 59-50-7)</p> <p>No 49: 5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane (INCI: 7-Ethylbicyclooxazolidine, CAS No 7747-35-5)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160131	<p>In products for oral hygiene the following preservatives listed in Annex V RE (EC) No 1223/2009 are prohibited:</p> <p>No 8: Pyrithione zinc (INCI: Zinc pyrithione, CAS No 13463-41-7)</p> <p>No 49: 5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane (INCI: 7-Ethylbicyclooxazolidine, CAS No 7747-35-5)</p> <p>No 52: Silver chloride deposited on titanium dioxide (INCI: Silver chloride, CAS No 7783-90-6)</p> <p>No 53: Benzenemethanaminium, N,Ndimethyl-N-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy] ethyl]-, chloride (INCI: Benzethonium Chloride, CAS No 121-54-0)</p> <p>No 56: 3-iodo-2-propynylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No 55406-53-6)</p> <p>No 58: Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2) (other than mouthwashes)</p> <p>No 59: 1,2,3-Propanetricarboxylic acid, 2- hydroxy-, monohydrate and 1,2,3-Propanetricarboxylic acid, 2- hydroxy-, silver(1+) salt, monohydrate (INCI: Citric acid (and) Silver citrate, CAS No -)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

18-05

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**Cosmetic products - dental & mouth-care**

Article No.:

req. no.	Statutory requirement	Law	Article
160098	<p>The following substances listed in Annex III RE (EC) No 1223/2009 are allowed in toothpaste adhere the limitations and requirements for labelling.</p> <p>No 6: Chlorates of alkali metals (INCI: Sodium chlorate, CAS-Nr. 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9)</p> <p><b>Additional information:</b> VO (EG) Nr.1223/2009 Anhang III_18-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160254	<p>BfR is the opinion that If cosmetic products comply with the recommendation of Cosmetics Europe, no health effects from the oral intake of highly refined mineral oils (MOSH / MOAH) are to be expected.</p> <p>Cosmetics Europe recommends to use only those mineral hydrocarbons in oral and lip care products, for which an Acceptable Daily Intake (ADI) has been identified.</p> <p><b>Additional information:</b> BfR hochraffinierte Mineralöle_18-05 Cosmetics Europe Recommendation No 14 Mineral hydrocarbons in oral and lip care_18-05</p>	BfR Mineralöle	BfR Stellungnahme Nr. 008/2018



Category: Cosmetics

18-05

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**tattooing**

Article No.:

permanent change of appearance through substances and mixtures which are applied under the skin.

req. no.	Statutory requirement	Law	Article
160222	<p>With regard to the manufacture of for tattoo products following substances are prohibited:</p> <ul style="list-style-type: none"> <li>-substances listed in Annex II RE (EC) 1223/2209</li> <li>- colorants listed in Annex IV RE (EC) 1223/2209 which are allowed for rinse-off products. Permitted are colorants used in products applied on mucous membranes and eye products.</li> <li>- azo dyes which have the capacity to release by reductive cleavage one or more amines listed in Annex I Tätov</li> <li>-colorants listed in annex II Tätov</li> <li>- para-phenyldiamine and its hydrochloride or sulfate (CI 76060)</li> </ul> <p><b>Additional information:</b>                      NEU_Tätov_14-11.pdf                      VO (EU) Nr.1223/2009 Anhang II_17-11                      VO (EU) Nr.1223/2009 Anhang IV_17-11</p>	Tätov	§ 1 + VO (EG) 1223/2009 Anhang II + IV
160246	<p>Chemical tattoo removers that require the injection of a substance or mixture under the epidermis with a device/pen are not cosmetic products.</p> <p>In general, the final decision on the classification of these products should be made on a case-by-case basis by the national competent authorities taking into account all the characteristics of the product including its presentation, composition, mode of action.</p> <p><b>Additional information:</b>                      LL Borderline products_18-05</p>	LL Borderline-products	
160255	<p>When assessing the safety of tattooing agents, the general criteria from the BfR statement should be observed.</p> <p>The opinion includes the following points:</p> <ol style="list-style-type: none"> <li>1 Introduction</li> <li>2 Necessary information on tattooing ingredients</li> <li>3 Necessary toxicological endpoints for the safety assessment of tattooing agents</li> <li>4 Exposure estimation on the basis of the current state of knowledge and based on the previously published data</li> <li>5 Health risks with tattoos</li> <li>6 Removal of tattoos and related health risks</li> <li>7 Frameworks / recommendations for action</li> </ol> <p><b>Additional information:</b>                      BfR Anforderungen an Tätowiermittel_18-05</p>	BfR Anforderungen an Tätowiermittel	BfR Stellungnahme Nr. 013/2013