

Category: Cosmetics

21-11

Author: Träger

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"> - Aerosol products - Dyes and paints - Cosmetics - Lubricants - Cleaning materials - Pressurised gas containers - Fire extinguishers - Insulation materials - Refrigerators - Air conditioning units - Mattresses - Foam material - Adhesives 	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>Additional information: VO (EG) Nr. 1223/2009 Anhang IV 21-11</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>	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>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

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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 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 32: 1-(4-Chlorophenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl (INCI: Climbazole, CAS No 38083-17-9) (see Annex III No 310)</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>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160064	<p>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.</p>	Zusatzinfo	

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substances

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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) No 5: Tosylchloramide sodium (INCI: Chloramine-T, CAS No 127-65-1) No 6: Chlorates of alkali metals (INCI: Sodium chlorate, CAS No 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9) No 11: Dichlorophene (INCI: Dichlorophene, CAS No 97-23-4) No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2) No 15c: Calcium hydroxide (INCI: Calcium hydroxide; CAS No 1305-62-0) No 17: Sodium nitrite (INCI: Sodium nitrite, CAS Nr. 7632-00-0) No 18: Nitromethane (INCI: Nitromethane, CAS No 75-52-5) No 24: Water-soluble zinc salts with the exception of zinc 4-hydroxy-benzenesulphonate and zinc pyrrithione (INCI: Zinc acetate, zinc chloride, zinc gluconate, zinc glutamate, CAS No -) No 45: Benzyl alcohol (INCI: Benzyl Alcohol, CAS No 100-51-6) No 52: Methanol (INCI: Methyl alcohol, CAS No 67-56-1) No 60: Fatty acid dialkylamides and dialkanolamides (INCI: -, CAS No -) No 61: Monoalkylamines, monoalkanolamines and their salts (INCI: -, CAS No -) No 66: Polyacrylamides (INCI: -, CAS No -) No 152: Allyl heptene carbonate (allyl oct-2-ynoate) (INCI: Allyl heptene carbonate, CAS No 73157-43-4) No 153: Amylcyclopentenone; 2-Pentylcyclopent-2-en-1-one (INCI: Amylcyclopentenone, CAS No 25564-22-1) No 154: Myroxylon balsamum var. pereirae; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru) (INCI: -, CAS No 8007-00-9) No 155: 4-tert.-Butylidihydrocinnamaldehyde; 3-(4-tert-Butylphenyl)propionaldehyde (INCI: 4-tert.-Butylidihydrocinnamaldehyde, CAS No 18127-01-0) 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) No 167: l-Limonene; (S)-p-Mentha-1,8-dien (INCI: Limonene, CAS No 5989-54-8) No 168: dl-Limonene (racemic); 1,8-p-Menthadiene; p-Mentha-1,8-diene (Dipentene) (INCI: Limonene, CAS No 138-86-3) No 170: Isobergamate; Menthadiene-7- methyl formate (INCI: Isobergamate, CAS No 68683-20-5) No 171: Methoxy dicyclopentadiene carboxaldehyde; Octahydro-5- methoxy-4,7- Methano-1H-indene-2-carboxaldehyde (INCI: Scentenal, CAS No 86803-90-9) No 172: 3-Methylnon-2- enenitrile (INCI: 3-methylnon-2-enenitrile, CAS No 53153-66-5) No 176: Isocyclogeraniol; 2,4,6-Trimethyl-3- cyclohexene-1- methanol (INCI: Isocyclogeraniol, CAS No 68527-77-5) No 179: p-methylhydrocinnamic aldehyde; Cresylpropionaldehyde; p-Methylidihydrocinnamaldehyde (INCI: p-methylhydrocinnamic aldehyde, CAS No 5406-12-2) No 180: Liquidambar orientalis oil and extract (styrax) (INCI: Liquidambar Orientalis Resin Extract; Liquidambar Orientalis Balsam Extract; Liquidambar Orientalis Balsam Oil, CAS No 94891-27-7) No 181: Liquidambar styraciflua oil and extract (styrax) (INCI: Liquidambar Styraciflua Oil; Liquidambar Styraciflua Balsam Extract; Liquidambar Styraciflua Balsam Oil, CAS No 8046-19-3) No 183: Commiphora erythra Engler var. glabrescens Engler gum extract and oil (INCI: Opoponax oil, CAS No 93686-00-1) No 184: Opopanax chironium resin (INCI: -, CAS No 93384-32-8) No 186: 2,2'-oxydiethanol Diethylene glycol (DEG) (INCI: Diethylene glycol, CAS No 111-46-6) No 194: Glyoxal (INCI: Glyoxal, CAS No 107-22-2) No 196- Verbena absolute (Lippia citriodora Kunth.) (INCI: -, CAS No 8024-12-2) No 306: Peanut oil, extracts and derivatives (INCI: Arachis Hypogaea Oil CAS No 8002-03-7; INCI: Arachis Hypogaea Seedcoat Extract, CAS No 8002-03-7; INCI: Arachis Hypogaea Flour, CAS No 8002-03-7, INCI: Arachis Hypogaea Fruit Extract CAS No 8002-03-7, INCI: Arachis Hypogaea Sprout Extract Hydrogenated Peanut Oil, CAS No 68425-36-5, INCI: Peanut Acid, CAS No 91051-35-3; INCI: Peanut Glycerides, CAS No 91744-77-3; INCI: Peanut Oil PEG-6 Esters, CAS No -; INCI: Peanutamide MEA, CAS No 93572-05-5; INCI: Peantamide MIPA Potassium Peantuate, CAS No 61789-56-8; INCI: Sodium Peantumphoacetate Sodium Peantuate, CAS No 61789-57-9; INCI: Sulfated Peanut Oil, CAS No 73138-79-1) No 307: Hydrolyzed Wheat Protein (INCI: Hydrolyzed Wheat Protein, CAS No 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5) No 312: 2-Furaldehyde (INCI: Furfural, CAS-Nr. 98-01-1) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

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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 6: Chlorates of alkali metals (INCI: Sodium chlorate, CAS No 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9) No 15a: Potassium or sodium hydroxide (INCI: Potassium hydroxide, CAS No 1310-58-3; INCI: sodium hydroxide, CAS No 1310-73-2) No 15c: Calcium hydroxide (INCI: Calcium hydroxide, CAS No 1305-62-0) No 59: Talc: Hydrated magnesium silicat (INCI: Talc, CAS No 14807-96-6) No 62: Trialkylamines, trialkanolamines and their salts (INCI: -, CAS No -) 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 66: Polyacrylamides (INCI: -, CAS No -) No 72: 7-Hydroxycitronellal (INCI: Hydroxycitronellal, CAS No 107-75-5) No 73: Phenol, 2-methoxy4-(1-propenyl) (INCI: Ioeugenol, CAS No 97-54-1) No 89: Methyl Oct-2-ynoate; Methyl heptene carbonate (INCI: Methyl 2-octynoate, CAS No 111-12-6) 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 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7) No 102: 1,2-Dimethoxy-4-(2-propenyl)-benzene (INCI: Methyl eugenol, CAS- No 93-15-2) 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) 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) 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) 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) 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) 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) No 165: trans-Rose ketone-3; 1-(2,6,6- Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (trans-delta-Damascone) (INCI: trans-Rose ketone-3, CAS No 71048-82-3) No 166: trans-2-hexenal (INCI: trans-2-hexenal, CAS No 6728-26-3) No 169: p-Mentha-1,8-dien-7-al (INCI: Perillaldehyde, CAS No 2111-75-3) No 173: 3-Methylnon-2-enenitrile (INCI: Methyl octine carbonate, CAS No 111-80-8) No 174: Amylvinylcarbonyl acetate; 1-Octen-3-yl acetate (INCI: Amylvinylcarbonyl acetate, CAS No 2442-10-6) No 175: Propylidenephthalide; 3-Propylidenephthalide (INCI: Propylidenephthalide, CAS No 17369-59-4) No 177: 2-Hexylidene cyclopentanone (INCI: 2-Hexylidene cyclopentanone, CAS No 17373-89-6) No 178: Methyl heptadienone; 6-Methyl3,5-heptadien-2-one (INCI: Methyl heptadienone, CAS No 1604-28-0) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

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160147	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 different products (see Annex). Additional information: LL Borderline Products 20-11	LL Borderline-products	
160153	In order to distinguish a cosmetic product 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 requisite action. Additional information: LL Borderline Products_20-05	LL Borderline Kosm-MedPr	
160245	Cosmetic products equally used as toys must bear the CE marking.	ALS	2019/15
160154	The Federal Institute for Risk Analysis (BfR) recommends for tea tree oil (Oil from Melaleuca alternifolia) 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. Additional information: 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. Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160159	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. Additional information: VO (EG) Nr. 1223/2009 Anhang II 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe a)

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160239	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. Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
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
160185	The responsible person provides on demand access for the public regarding certain information. This is : - the composition (qualitative and quantitative for substances considered dangerous according to RE (EEU) Nr. 1272/2008), - in case of perfume and aromatics the name and code number of the composition as well as the identity of the supplier - Data on undesirable effects and serious undesirable effects.	VO (EG) Nr. 1223/2009	Art. 21
160186	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: https://www.bvl.bund.de/DE/03_Verbraucherprodukte/03_AntragstellerUnternehmen/02_Kosmetik/02_SUE/bgs_fuerAntragsteller_kosmetik_SUE_node.html	VO (EG) Nr. 1223/2009	Art. 23
160187	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.	VO (EG) Nr. 1223/2009	Art. 24
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. Additional information: EuGH Urteil C-308/11 - Definition pharmakologische Wirkung	EuGH	C-308/11
160201	Information and clarifications about undesirable effects and serious undesirable effects might be provided by the guidelines from Cosmetics Europe. Additional information: 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

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160224	Fluorescent dyes are not classified as dyes in accordance to RE (EC) 1223/2009. If fluorescent dyes are used in cosmetic products, the harmless ness 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
160263	If declarable ingredients (e.g. allergenic fragrances or preservatives) are formed during manufacturing or storage they need to be taken into account during the security assessment. In this case a change of the recipe or a warning on the packaging is necessary.	ALS	2019/10
160264	To sell alcohol swabs with a cosmetic purpose (e.g. for skin cleaning) as a cosmetic product, the soaking solution must comply with the regulations for cosmetic products	ALS	2019/11

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Cosmetics – prepackage and filling quantity

Article No.:

req. no.	Statutory requirement	Law	Article
11332	For prepackages - the nominal filling quantity must be specified, - the filling quantity must meet the specified requirements - The required information, labels and symbols must be available. FPackV regulates the details of these requirements.	MessEG	§ 43 Abs. 1
11333	Sham packs which simulate a larger quantity than they contain are prohibited.	MessEG	§ 43 Abs. 2
11334	The requirements of the FPackV do not apply to: 1. prepackages with a nominal filling quantity according to area or piece, which are sold to commercial end users, 2. Free samples, 3. prepackages intended for export or for seagoing vessels 4. Conformity-assessed or calibrated measuring standards 5. prepackages with wine products and spirits (FPackV Annex 1) in duty-free shops, which intended for consumption outside the European Union. Additional information: FPackV Anlage 1_21-05	FPackV	§ 1 Abs. 2 + FPackV Anlage 1
11335	On prepackages of the same and different nominal filling quantity and on other sales units for which a nominal filling quantity is specified, the net filling quantity must be specified according to the size of weight or volume. If other regulations specify the number of pieces, length or area, than the size should be used. If there are no regulations for a specific size for specifying the nominal filling quantity, a size which corresponds to the general public opinion must be used.	FPackV	§ 3 Abs. 1, 2, § 31
11336	It is forbidden to specify - indefinite nominal filling quantities, - the additional specification of the product weight, unless this is permitted in other regulations.	FPackV	§ 3 Abs. 3, § 31
11338	Requirements for the filling quantity: - in the case of prepackaged cosmetic products with the same nominal filling quantity, specifying the volume or weight: - for cosmetic products that are not prepackaged: - -Indication in digits, followed by the name of the unit or the unit symbol - - possible units and symbols: milliliter (ml), centiliter (cl), (l, L), gram (g), kilogram (kg). Additional information: EinhV Anlage 1_21-05 EinhV Anlage 2_21-05	FPackV	§ 4 Abs. 4, § 13 Abs. 3, § 14 Abs. 4, + EinHV Anlage 1, EinHV Anlage 2
11340	Requirements for the filling quantity for aerosol packs with the same nominal filling quantity: - indication of the filling quantity according to volume, even if other regulations also specify labeling by weight - indication of the volume of the liquid phase - Additional information on the total capacity of the pack – it shall be designed in such a way that it clearly differs from the information on the filling quantity.	FPackV	§ 6 Abs. 1, § 13 Abs. 3, § 16 Abs. 1

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11347	<p>In the case of prepackages with the same nominal filling quantity, which are marked by weight or volume, at the time of manufacture</p> <p>-- the mean value of the filling quantity must not fall below the nominal filling quantity (FPackV Appendix 3 No. 6)</p> <p>-- the specified value for the minus deviation from the nominal filling quantity must not exceed = TU1 (FPackV § 9 Paragraph 3)</p> <p>-- The minus deviation from the nominal filling quantity must not exceed certain marketability values = TU2 (FPackV § 9 Paragraph 4).</p> <p>A different production time is defined for some products in Appendix 2 of the FPackV.</p> <p>Additional information: FPackV § 9_21-05 FPackV Anlage 2_21-05 FPackV Anlage 3_21-05</p>	FPackV	§ 9, § 12 Abs. 2, § 13 Abs.2, § 14 Abs. 1,2,3, § 16 Abs. 1, § 19 Abs. 2 + FPackV Anlage 3, FPackV Anlage 2
11353	<p>For cosmetic products which are not prepackaged or for cosmetic products that are packaged at the point of sale at the buyer's request or are prepackaged for immediate sale, § 5 of the KosmetikV must be observed with regard to the fill quantity information</p>	FPackV	§ 14 + KosmetikV § 5
11385	<p>If products are filled in measuring containers, these must meet the requirements of § 35, § 36, § 37 FPackV.</p> <p>Additional information: FPackV § 35, § 36, § 37_21-05</p>	FPackV	§ 35, § 36, § 37
11394	<p>The manufacturer of prepackages with the same nominal filling quantity according to weight or volume must fulfill certain control and documentation obligations, which are specified in § 41 FPackV.</p> <p>This requirement also applies to sales units without wrapping</p>	FPackV	§ 41, § 16 Abs. 2, § 12 Abs. 2, § 13 Abs. 2., § 14 Abs. 3, § 17 Abs. 4, § 18 Abs. 5, § 19 Abs. 3, § 30 Abs. 5
11395	<p>The requirements for the nominal filling quantity by volume relate to a temperature of 20 ° C, except refrigerated and frozen products.</p>	FPackV	§ 42, § 12 Abs. 3, § 13 Abs. 3, § 14 Abs. 4, § 16 Abs. 2, § 17 Abs. 4, § 19 Abs. 3

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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. Additional information: 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
50928	The mercury bans and mercury limit values of Regulation (EU) 2017/852 must be observed. Additional information: RE (EU) 2017/852_20-11 VO (EU) 2017/852_20-11	VO (EU) 2017/852	
160273	In the opinion of the BfR, cosmetic products that can be used externally should in principle be free from <i>P. gergoviae</i> in order to avoid a health risk for humans. The extent to which there is a health impairment when using such cosmetic products cannot currently be determined due to the inadequate data situation. Additional information: BfR Stellungnahme 038/2020_20-11	BfR Pluralibacter gergoviae	Stellungnahme 038/2020
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. Additional information: LL PID Kosmetik_13-11	LL PID	
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. Additional information: VO (EG) Nr. 1223/2009 Anhang VI 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe e)
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

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Cosmetic products - Materials used in the manufacture of cosmetics

Article No.:

req. no.	Statutory requirement	Law	Article
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
160167	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. A notification is not necessary for products which have already been placed on the market by the same responsible person before 11 January 2013.	VO (EG) Nr. 1223/2009	Art. 16
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
160189	An overview of the responsibilities and the labelling of cosmetic substances is provided by the Colipa- Guideline "Responsibilities". Additional information: LL Verantwortlichkeiten_11-11	LL Verantwortlichkeiten	
160162	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. Additional information: VO (EG) Nr. 1223/2009_Anhang I_20-05	VO (EG) Nr. 1223/2009	Art. 10 in Verb. mit Anhang I
160207	In order to assist of the creation of a safety report, the guidelines of the European Commission can be used. Additional information: Beschl 2013/674/EU_13-11	Beschl 2013/674/EU	Artikel 1

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Article No.:

req. no.	Statutory requirement	Law	Article
160159	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. Additional information: VO (EG) Nr. 1223/2009 Anhang II 21-11	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
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



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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 fulfill 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 -) No 61: Monoalkylamines, monoalkanolamines and their salts (INCI: -, CAS No -) No 88: d-Limonene(4R)-1-Methyl-4-(1-methylethenyl) cyclohexene (INCI: Limonene CAS No 5989-27-5) 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) 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) 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) 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) 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) 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) 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) 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) 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) 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) 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) No 115: Pinus species leaf and twig oil and extract (INCI: Pinus Strobus Bark Extract; Pinus Strobus Cone Extract; Pinus Strobus Twig Oil; Pinus Species Twig Leaf Extract; Pinus Species Twig Leaf Oil, CAS No 94266-48-5) 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) No 117: Pinus cembra leaf and twig extract acetylated CAS No 94334-26-6 (INCI: Pinus Cembra Twig Leaf Extract Acetylated, CAS No 94334-26-6) No 118: Picea Mariana Leaf Oil and Extract CAS No 91722-19-9 (INCI: Picea Mariana Leaf Extract; Picea Mariana Leaf Oil, CAS No 91722-19-9) No 119: Thuja Occidentalis: Bark Extract/ Leaf/Leaf Extract/Leaf Oil/Stem Extract/Stem Oil/Root Extract (INCI: Thuja Occidentalis Bark Extract; Thuja Occidentalis Leaf; Thuja Occidentalis Leaf Extract; Thuja Occidentalis Leaf Oil; Thuja Occidentalis Stem Extract; Thuja Occidentalis Stem Oil; Thuja Occidentalis Root Extract, CAS No 90131-58-1) No 121: 3-Carene CAS No 13466-78-9, 3,7,7-Trimethylbicyclo [4.1.0]hept-3-ene (isodiprene) (INCI: -, CAS No 13466-78-9) No 122: Cedrus atlantica wood oil and extract (INCI: Cedrus Atlantica Bark Extract; Cedrus Atlantica Bark Oil; Cedrus Atlantica Bark Water; Cedrus Atlantica Leaf Extract; Cedrus Atlantica Wood Extract; Cedrus Atlantica Wood Oil, CAS No 92201-55-3) No 123: Cupressus sempervirens leaf oil and extract (INCI: Cupressus Sempervirens Leaf Oil; Cupressus Sempervirens Bark Extract; Cupressus Sempervirens Cone Extract; Cupressus Sempervirens Fruit Extract; Cupressus Sempervirens Leaf Extract; Cupressus Sempervirens Leaf/Nut/Stem Oil; Cupressus Sempervirens Leaf/Stem Extract; Cupressus Sempervirens Leaf Water; Cupressus Sempervirens Seed Extract; Cupressus Sempervirens Oil, CAS No 84696-07-1) No 124: Turpentine gum (Pinus spp.) (INCI: Turpentine, CAS No 9005-90-7) No 125: Turpentine oil and rectified oil (INCI: Turpentine, CAS No 8006-64-2) No 126: Turpentine, steam distilled (Pinus spp.) (INCI: Turpentine, CAS No 8006-64-2) No 127: Terpene alcohols acetates (INCI: Terpene alcohols acetates, CAS No 69103-01-1) No 128: Terpene hydrocarbons (INCI: Terpene hydrocarbons, CAS No 68956-56-9) No 129: Terpenes and terpenoids with the exception of limonene (d-, l-, and d-isomers) listed under reference numbers 167, 168 and 88 of this Annex III (INCI: Terpenes and terpenoids, CAS No 65996-98-7) No 130: Terpene terpenoids (INCI: -, CAS No 68917-63-5) No 131: alpha-Terpinene; p-Mentha-1,3-diene (INCI: alpha-Terpinene, CAS No 99-86-5) No 132: gamma-Terpinene; p-Mentha-1,4-diene (INCI: gamma-Terpinene, CAS No 99-85-4) No 133: Terpinolene; p-Mentha-1,4(8)-diene (INCI: Terpinolene, CAS No 586-62-9) No 135: Allyl butyrate; 2-Propenyl Butanoate (INCI: Allyl butyrate, CAS No 2051-78-7) No 136: Allyl cinnamate; 2-Propenyl 3-Phenyl-2-Propenoate (INCI: Allyl cinnamate, CAS No 1866-31-5) No 137: Allyl cyclohexylacetate; 2-Propenyl Cyclohexanecarboxylate (INCI: Allyl cyclohexylacetate, CAS No 4728-82-9) No 138: Allyl cyclohexylpropionate; 2-Propenyl 3-Cyclohexanepropanoate (INCI: Allyl cyclohexylpropionate, CAS No 2705-87-5) No 139: Allyl heptanoate; 2-Propenyl heptanoate (INCI: Allyl heptanoate, CAS No 142-19-8) No 140: Allyl hexanoate (INCI: Allyl Caproate, CAS No 123-68-2) No 141: Allyl isovalerate; 2-Propenyl 3-Methylbutanoate (INCI: Allyl isovalerate, CAS No 2835-39-4) No 142: Allyl octanoate; 2-Allyl caprylate (INCI: Allyl octanoate, CAS No 4230-97-1) No 143: Allyl phenylacetate; 2-Propenyl Phenoxyacetate (INCI: Allyl phenoxyacetate, CAS No 7493-74-5) No 144: Allyl phenylacetate; 2-Propenyl Benzeneacetate (INCI: Allyl phenylacetate, CAS No 1797-74-6) No 145: Allyl 3,5,5-trimethylhexanoate (INCI: Allyl 3,5,5-trimethylhexanoate, CAS No 71500-37-3) No 146: Allyl cyclohexyloxyacetate (INCI: Allyl cyclohexyloxyacetate, CAS No 68901-15-5) No 147: Allyl isoamylxyloxyacetate (INCI: Isoamyl Allyl glycolate, CAS No 67634-00-8) No 148: Allyl 2-methylbutoxyacetate (INCI: Allyl 2-methylbutoxyacetate, CAS No 67634-01-9) No 149: Allyl nonanoate (INCI: Allyl nonanoate, CAS No 7493-72-3) No 150: Allyl propionate (INCI: Allyl propionate, CAS No 2408-20-0) No 151: Allyl trimethylhexanoate (INCI: Allyl trimethylhexanoate, CAS No 68132-80-9) No 151a: Allyl phenethyl ether (INCI: Allyl phenethyl ether, CAS No 14289-65-7) No 152: Allyl heptine carbonate (allyl oct-2-ynoate) (INCI: Allyl heptine carbonate, CAS No 73157-43-4) No 167: l-Limonene; (S)-p-Mentha-1,8-diene (INCI: Limonene, CAS No 5989-54-8) No 168: dl-Limonene (racemic); 1,8-p-Menthadiene; p-Mentha-1,8-diene (Dipentene) (INCI: Limonene, CAS No 138-86-3) No 297: 2-(2-Ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS No 111-90-0) No 306: Peanut oil, extracts and derivatives (INCI: Arachis Hypogaea Oil CAS No 8002-03-7; INCI: Arachis Hypogaea Seedcoat Extract, CAS No 8002-03-7; INCI: Arachis Hypogaea Flour, CAS No 8002-03-7; INCI: Arachis Hypogaea Fruit Extract CAS No 8002-03-7; INCI: Arachis Hypogaea Sprout Extract Hydrogenated Peanut Oil, CAS No 68425-36-5; INCI: Peanut Acid, CAS No 91051-35-3; INCI: Peanut Glycerides, CAS No 91744-77-3; INCI: Peanut Oil PEG-6 Esters, CAS No -; INCI: Peanutamide MEA, CAS No 93572-05-5; INCI: Peanutamide MIPA Potassium Peanutate, CAS No 61789-56-8; INCI: Sodium Peanutamphoacetate Sodium Peanutate, CAS No 61789-57-9; INCI: Sulfated Peanut Oil, CAS No 73138-79-1) No 307: Hydrolyzed Wheat Protein (INCI: Hydrolyzed Wheat Protein, CAS No 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5) No 308: Tagetes minuta flower extract (INCI: Tagetes minuta flower extract, CAS No 91770-75-1); Tagetes minuta flower oil (INCI: Tagetes minuta flower oil, CAS No 91770-75-1 / 8016-84-0) No 309 - Tagetes patula flower extract (Tagetes patula flower extract, CAS No 91722-29-1) Tagetes patula flower oil (Tagetes patula flower oil, CAS No 91722-29-1 / 8016-84-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

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Article No.:

req. no.	Statutory requirement	Law	Article
160142	<p>The following preservative have to fulfill the purity criteria listed in Annex V RE (EC) No 1223/2009:</p> <p>No 23: 1-(4-Chlorophenyl)-3-(3,4-dichlorophenyl)urea (INCI: Triclocarban, CAS No 101-20-2)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	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

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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. Additional information: HWG 21-11	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". Additional information: 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)

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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"> - Name or registered name and Address of the responsible person - nominal contents at the time of packaging - the date of minimum durability / use-by date - precaution to be observed in use - the batch number - the function unless it is clear from its presentation - list of ingredients <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>Additional information: 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> <p>The usage of formaldehyde in cosmetic products is prohibited. Preservatives (Annex V) used in cosmetic products may release formaldehyde.</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</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"> - in case of nominal content is less than 5g respectively 5 ml - free samples - single-application packs - 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. <p>These information must be stated on container and packaging.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 b)

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req. no.	Statutory requirement	Law	Article
160175	<p>The date of minimum durability must be stated as follows:</p> <ul style="list-style-type: none"> - 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 - followed by date or notice where the date is to be found - the date is stated with month and year or day month and year in this order - If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability - for cosmetic products with a minimum durability of more than 30 months this does not have to be stated . <p>Must be stated on containers and packaging. Additional information: VO (EG) Nr. 1223/2009_Anhang VII_20-05</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 c)
160178	<p>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.</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 f)
160176	<p>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:</p> <ul style="list-style-type: none"> - with the symbol Nr. 2 in Annex VII RE (EU) Nr. 1223/2009 followed by the time period (Months and 7 or years). <p>The statement may be dropped, if the concept of durability after opening is not relevant. Additional information: VO (EG) Nr. 1223/2009_Anhang VII_20-05</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 c)
160181	<p>Where it is impossible for practical reasons to label the particular precautions and the list of ingredients, then the information can be</p> <ul style="list-style-type: none"> - 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. <p>Additional information: VO (EG) Nr. 1223/2009_Anhang VII_20-05</p>	VO (EG) Nr. 1223/2009	Art. 19 Abs. 2

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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".</p> <p>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 - Cumarin (CAS-Nr. 91-64-5) Nr. 78 - Geraniol (CAS-Nr. 106-24-1) 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 - Methylheptincarbonat (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.</p> <p>The responsible person shall ensure, that the wording of the claim is in compliance.</p> <p>Additional information: VO (EU) Nr. 655/2013_13-11</p>	VO (EU) Nr. 655/2013	Artikel 1 und 2
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>Additional information: Technisches Dokument Werbeaussagen Kosmetik_18-05</p>	Technisches Dokument Werbeaussagen Kosmetik	

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Article No.:

req. no.	Statutory requirement	Law	Article
160179	<p>The indication of the list of ingredients must appear as follows:</p> <ul style="list-style-type: none"> - the term "Ingredients" be preceded - all intentionally used substances or mixtures must be listed except for impurities or additives which are no longer present in the finished product, - the ingredients are listed in descending order of the weight at the time they were added - ingredients in concentrations less than 1% may be listed in no order - colorants other than colorants intended to colour the hair, can be listed in any order - for the statement of colorants CI (Colour Index) nomenclature shall be used - for the designation of the ingredients the INCI nomenclature, or if none available, a designation out of a generally recognised nomenclature must be used. - all ingredients, which are contained in the form of nanomaterials, the name of such ingredients shall be followed by the word "nano" in brackets. <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
160258	<p>The ingredients are to be expressed using common ingredient name set out in a glossary.</p> <p>The glossary of common ingredient names is set out in the Annex of Decision (EU) 2019/701.</p> <p>The glossary shall be applied for the purpose of labelling cosmetic products placed on the market.</p> <p>Additional information: Beschluss (EU) 2019/701_19-11</p>	VO (EG) Nr. 1223/2009	VO (EG) Nr. 1223/2009 Art. 19 Abs. 6 und Art. 33 + Beschluss 2019/701
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"> 1. Impurities of used ingredients 2. technical Additives 	VO (EG) Nr. 1223/2009	Art. 19 Abs. 1 g) Buchstaben
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

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Author: Träger

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. Additional information: 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

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Author: Träger

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° or a steam pressure of 50° 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"> 1. Aerosol packages with metal containers, the total capacity of which exceeds 1000 millilitres; 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. 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. <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>Additional information: CD 75-324-EEC_15-04 RL 75-324-EWG_15-04</p>	13. ProdSV	§ 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
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"> - Aerosol products - Dyes and paints - Cosmetics - Lubricants - Cleaning materials - Pressurised gas containers - Fire extinguishers - Insulation materials - Refrigerators - Air conditioning units - Mattresses - Foam material - Adhesives 	ChemOzonSchi chtV	Art.4

Category: Cosmetics

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Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - aerosols

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 AlxZr(OH)yClz 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>in Hairspray: No 321: Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ (IINCI: titanium dioxide, CAS No. 13463-67-7/ 1317-70-0/ 1317-80-2)</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>Additional information: VO (EG) Nr. 1223/2009_Anhang III_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160267	<p>Cosmetic applications that could be easily inhaled should not contain folowing substances listed in Annex III RE (EC) No 1223/2009:</p> <p>No 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7) No 321: Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ (IINCI: titanium dioxide, CAS No. 13463-67-7/ 1317-70-0/ 1317-80-2)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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 11: Chlorobutanol (INCI: Chlorobutanol, CAS No 57-15-8) No 13: 3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydracetic 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-Largininhydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

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Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - aerosols

Article No.:

req. no.	Statutory requirement	Law	Article
160259	<p>Cosmetic products that may lead to exposure of the end-user's lungs bei inhalation shall not contain the following preservative (Annex V, VO (EC) No 1223/2009):</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)</p> <p>No 28 Polyhexamethylenbiguanidhydrochlorid (INCI: Polyaminopropylbiguanide, CAS No 32289-58-0, 27083-27-8, 28757-47-3, 133029-32-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</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)</p> <p>No. 144: Zinc oxide (INCI: 77947; CAS No 1314-13-2)</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)

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Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - for children and babies

Article No.:

req. no.	Statutory requirement	Law	Article
160102	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: No 59: Talc: Hydrated magnesium silicate (INCI: Talc, CAS No 14807-96-6) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160268	Following substances listed in Annex III RE (EC) No 1223/2009 are not allowed in cosmetic products for children under three years of age: No 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7)	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160134	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: 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 salts in shampoos within the limit for maximum amount) No 52: Silver chloride deposited on titanium dioxide (INCI: Silver chloride, CAS No 7783-90-6) 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) Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160093	Cosmetics for children should not contain any allergy-inducing peanut-oil (INCI-Name "ARACHIS HYPOGAEA OIL") Additional information: BfR Erdnussöl_10-05	BfR Erdnussöl	

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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"> -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; - residues of heavy metals and pesticides only in extremely minimal trace concentrations which are toxicologically unobjectionable/harmless - use of particularly mild tenside combinations - taking into account various assessments of the SCCFNP (see the applicable documentation "Babykosmetik") - At the safety evaluation stage, particularly close scrutiny of predictable application/use and possible misuse <p>Additional information: Babykosmetik_10-05</p>	Babykosmetik	

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Author: Träger

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 7: Biphenyl-2-ol (INCI: o-Phenylphenol, CAS-Nr. 90-43-7) 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)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</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.</p> <p>Additional information: BfR Vitamin A_18-05</p>	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014

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Author: Träger

Product: Kosmetik/ cosmetics

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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

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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 308: Tagetes minuta flower extract (INCI: Tagetes minuta flower extract, CAS No 91770-75-1); Tagetes minuta flower oil (INCI: Tagetes minuta flower oil, CAS No 91770-75-1/ 8016-84-0) No 309: Tagetes patula flower extract (Tagetes patula flower extract, CAS No 91722-29-1); Tagetes patula flower oil (Tagetes patula flower oil, CAS No 91722-29-1/ 8016-84-0) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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

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Author: Träger

Product: Kosmetik/ cosmetics

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) No 308: Tagetes minuta flower extract (INCI: Tagetes minuta flower extract, CAS No 91770-75-1); Tagetes minuta flower oil (INCI: Tagetes minuta flower oil, CAS No 91770-75-1/ 8016-84-0) No 309: Tagetes patula flower extract (Tagetes patula flower extract, CAS No 91722-29-1); Tagetes patula flower oil (Tagetes patula flower oil, CAS No 91722-29-1/ 8016-84-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

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Author: Träger

Product: Kosmetik/ cosmetics

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>Additional information: VO (EG) Nr. 1223/2009 Anhang IV 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)

Category: Cosmetics

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Author: Träger

Product: Kosmetik/ cosmetics

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 7: Biphenyl-2-ol (INCI: o-Phenylphenol, CAS-Nr. 90-43-7) 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 butylcar-bamate, CAS No 55406-53-6) No 57: 2-Methyl-2H-isothiazol-3-one (INCI: Methylisothiazolino-ne, CAS 2682-20-4)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

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Author: Träger

Product: Kosmetik/ cosmetics

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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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>	VO (EG) Nr. 1907/2006	Artikel 67 Absatz 1 i.V.m. Anhang XVII

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products -other sprays

Article No.:

req. no.	Statutory requirement	Law	Article
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>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe c)
160267	<p>Cosmetic applications that could be easily inhaled should not contain following substances listed in Annex III RE (EC) No 1223/2009:</p> <p>No 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7) No 321: Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ (INCI: titanium dioxide, CAS No. 13463-67-7/ 1317-70-0/ 1317-80-2) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160259	<p>Cosmetic products that may lead to exposure of the end-user's lungs bei inhalation shall not contain the following preservative (Annex V, VO (EC) No 1223/2009):</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) No 28 Polyhexamethylenbiguanidhydrochlorid (INCI: Polyaminopropylbiguanide, CAS No 32289-58-0, 27083-27-8, 28757-47-3, 133029-32-0) Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Hygienic towels/wipes

Article No.:

req. no.	Statutory requirement	Law	Article
50049	<p>Diocetylzin combinations (DOT) are prohibited 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; -walll and floor coverings; - baby articles; ladies hygiene products; -nappies/diapers; -packaging;-two-part room temperature vulcanisation form sets (RTV-2- form sets)</p>	VO (EG) Nr. 1907/2006	Anhang XVII
50945	<p>The following single-use plastic articles must be marked on the packaging and the outer packaging with the harmonized marking requirement of the Implementing Regulation (EU) 2020/2151:</p> <ul style="list-style-type: none"> - Sanitary towels (pads), tampons and tampon applicators; - Wet wipes, i.e. pre-wetted personal care and domestic wipes; - Tobacco products with filters and filters marketed for use in combination with tobacco products; <p>On the other hand, on cups for beverages made of disposable plastic, the harmonized marking requirement from the Implementing Regulation (EU) 2020/2151 is placed directly on the product.</p> <p>Manufacturers and importers who place the above-mentioned products on the market for the first time in the respective EU member state are obliged to do so.</p> <p>As a transitional measure, the markings can also be affixed as stickers up to 03.07.2022. From 04.07.2022, the markings must be applied as print.</p> <p>The position, size and design of the marking must be taken from the Implementing Regulation (EU) 2020/2151</p> <p>Additional information: DVO (EU) 2020/2151_21-11</p>	EWKKennzV	§ 4 i.V.m. DVO (EU) 2020/2151
50947	<p>Extended producer responsibility applies to the following single-use plastic articles:</p> <ul style="list-style-type: none"> - Wet wipes, i.e. pre-wetted personal care and domestic wipes; - Balloons, except balloons for industrial or other professional uses and applications that are not distributed to consumers <p>For these products, the following costs must be covered from 31.12.2024 at the latest:</p> <ul style="list-style-type: none"> - Awareness-raising measures - cleaning up litter resulting - data gathering and reporting in accordance with Directive 2008/98/EC. <p>The above-mentioned costs must already be borne from 05.01.2023 if the extended producer responsibility regime for the single-use plastic products concerned was introduced before 04.07.2018.</p>	Richtlinie (EU) 2019/904	Art. 8 i.V.m. Teil E

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Author: Träger

Product: Kosmetik/ cosmetics

Hygienic towels/wipes

Article No.:

req. no.	Statutory requirement	Law	Article
50279	For all colourings (dyes) of sanitary products, the BfR recommendation IX is to be observed. Additional information: BfR IX Colorants 2019-06-01_20-05 BfR IX Farbmittel 2019-06-01_20-05	BfR-Empfehlung	BfR IX
50283	When using polypropylene the BfR recommendations are to be observed. Additional information: BfR VII. Polypropylen 2019-06-01_20-05 BfR VII. Polypropylene 2019-06-01_20-05	BfR-Empfehlung	BfR VII
50284	When using silicones the BfR recommendations XV are to be observed. Additional information: BfR XV. Silicone 2019-06-01_20-05 BfR XV. Silicones 2019-06-01_20-05	BfR-Empfehlung	BfR XV
50285	When using paper, cartons and cardboard the BfR recommendations are to be observed. Additional information: BfR XXXVI. Paper and Board for Food Contact 2019-06-01_20_05 BfR XXXVI. Papiere, kartons, Pappen für Lebensmittelkontakt 2019-06-01_20_05	BfR-Empfehlung	BfR XXXVI
50286	When using polyethylene the BfR recommendations are to be observed. Additional information: BfR III. Polyethylen 2019-06-01_20-05 BfR III. Polyethylene 2019-06-01_20-05	BfR-Empfehlung	BfR III

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21-11

Author: Träger

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"> 1. Clothing, bed linen, towels, hair parts, toupees, hats, diapers and other sanitary articles, sleeping bags. 2. Shoes, gloves, watch straps, bags, purses and wallets, folders, chair covers, breast bags. 3. Textile and leather toys and toys with textile or leather garments 4. Yarns and fabrics for end users. <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

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21-11

Author: Träger

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"> 1. Plastics Dispersions according to Recommendation XIV 2. Silicones according to Recommendation XV 3. Commodities based on Natural and Synthetic Rubber according to Recommendation XXI 4. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials according to Recommendation XXVIII 5. Linear Polyurethanes for Paper Coatings according to Recommendation XLI 6. Artificial Sausage Casings according to Recommendation XLIV 7. Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking Utensils according to Recommendation LI <p>Additional information: BfR LII. Fillers 2019-06-01_20-05 BfR LII. Füllstoffe 2019-06-01_20-05</p>	BfR-Empfehlung	BfR LII



Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - Ethereal oil

Article No.:

req. no.	Statutory requirement	Law	Article
160235	Pure essential oil sold to private costumers can be seen as a cosmetic product if the essential oils are dedicated to a cosmetic purpose, such as a bath additive	ALS	2019/89

Category: Cosmetics

21-11

Author: Träger

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 Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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) Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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)
160279	The following substance from Annex III of the EU Cosmetics Regulation is restricted in eyeliners and eye shadow: No 98: 2-hydroxy benzoic acid (salicylic acid, CAS No 69-72-7) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - eye-make-up and eye-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> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</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) No 17: Phenylmercuric salts (including borate) (INCI: Phenyl Mercuric Acetate, Phenyl Mercuric Benzoate, CAS-Nr. 62-38-4, 94-43-9)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
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

21-11

Author: Träger

Product: Kosmetik/ cosmetics

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

Article No.:

req. no.	Statutory requirement	Law	Article
160239	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. Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160266	Products for eyelash coloring, that contain silver nitrate should not be sold to private consumers	Sitzungen BfR Kosmetik	23. Sitzung der BfR-Kommission für kosmetische Mittel

Category: Cosmetics

21-11

Author: Träger

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: Thioglycolic 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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160188	<p>For depilatories with thioglycolic 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>Additional information: 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 following 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 -) Nr. 321 - Dihydroxyacetone (CAS No 96-26-4)</p> <p>Self-tanning agents that contain more than 10% dihydroxyacetone may still be placed on the market until January 26, 2022 and sold until April 22, 2022.</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - deodorants and anti-perspirants

Article No.:

req. no.	Statutory requirement	Law	Article
160219	<p>In deodorants (non spray) the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:</p> <p>No. 25: 5-Chloro-2-(2,4- dichlorophenoxy) phenol (INCI: Triclosan; CAS No 3380-34-5) maximum 0,3% in ready for use preparation</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160117	<p>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:</p> <p>deodorants, antiperspirants and astringent lotions: No 25: Zinc 4-hydroxybenzene sulphonate (INCI: Zinc phenolsulfonate, CAS No 127-82-2)</p> <p>only for antiperspirants: No 50: Aluminium zirconium chloride hydroxyde Complexes AlxZr(OH)yClz and the aluminium zirconium chloride sydroxide glycine complexes (INCI: - , CAS No -)</p> <p>for non-sprayable deodorant substances: No 197 - Ethyl-N-alpha- dodecanoyl-L- arginate hydrochloride (INCI: Ethyl Lauroyl Arginate HCl, CAS No 60372-77-2)</p> <p>for roll stick deodorants: Nr. 98 - 2-Hydroxy-benzoic acid (INCI: salicylic acid, CAS-No 69-72-7)</p> <p>sprayable deodorants and antiperspirants 2-(2-Ethoxyethoxy)ethanol Diethylene Glycol Monoethyl Ether (DEGEE) (INCI: Ethoxydiglycol, CAS No 111-90-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160139	<p>In deodorants/antiperspirants the following preservatives listed in Annex V RE (EC) No 1223/2009 are allowed adhere the limitations and requirements for labelling:</p> <p>No 56 - 3-Iod-2-propinylbutylcarbamate (INCI: Iodopropynyl butylcarbamate, CAS No 55406-53-6)</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - Foot care products

Article No.:

req. no.	Statutory requirement	Law	Article
160261	<p>In foot care products the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:</p> <p>No 32 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9): Maximum concentration in ready for use preparatoin 0,2%</p> <p>Current transitional period: 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl (INCI: Climbazole, CAS No 38083-17-9) - prohibition of sales from 27 February 2020.</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d

Category: Cosmetics

21-11

Author: Träger

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 Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
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 Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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. Additional information: BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160281	The following substance from Annex III of the EU Cosmetics Regulation is restricted in facial products in loose powder form: No 321: Titanium dioxide in powder form containing 1 % or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$ (INCI: titanium dioxide, CAS No. 13463-67-7/ 1317-70-0/ 1317-80-2) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160260	In face creams the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations: No 32 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9): Maximum concentration in ready for use preparatoin 0,2% Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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. Additional information: 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

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

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

Article No.:

req. no.	Statutory requirement	Law	Article
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) 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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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

21-11

Author: Träger

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 3: Oxalic acid, its esters and alkaline salts (INCI: Oxalic acid, CAS No 144-62-7)</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 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)</p> <p>No 51: Bis(8-hydro-xyquinolini-um) sulphate (INCI: Oxyquinoline sulphate, CAS-Nr. 134-31-6)</p> <p>No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts) (INCI: Etidronic acid, CAS No 2809-21-4)</p> <p>No 93: 2,4-Diamino-pyrimidine-3-oxide ((INCI: Diaminopyrimidine oxide CAS No 74638-76-9)</p> <p>No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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>No 32 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9)</p> <p>Current transitional period: 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl (INCI: Climbazole, CAS No 38083-17-9) - prohibition of sales from 27 February 2020.</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang V_20-05</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>From January 26, 2022: Hair dyes that contain more than 6.25% dehydroxyacetone may no longer be placed on the market. They can be sold until April 22, 2022.</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - haircoloration, straightening & perms

Article No.:

req. no.	Statutory requirement	Law	Article
160194	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. Additional information: IKW - Hinweis Haarfärbemittel	IKW - Hinweis Haarfärbemittel	
160100	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: No 2a: Thioglycollic acid and its salts (INCI: Thioglycollic acid, CAS No 68-11-1) No 2b: Thioglycollic 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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

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) 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) 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 22: 1,3-Benzoldiol (INCI: Resorcinol, CAS No 108-46-3) No 200: 2,4,5,6-Tetraaminopyrimidine sulphate (INCI: Tetraaminopyrimidine Sulfate, CAS No 5392-28-9) 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)) No 206: 3-(2-Hydroxyethyl)- p-phenylenediammonium sulphate (INCI: Hydroxyethyl- p- Phenylenediamine Sulfate, CAS No 93841-25-9) No 211: 2-Aminopyridin-3-ol (INCI: 2-Amino-3- Hydroxypyridine, CAS No 16867-03-1) 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) No 229 - 5-[(2-Hydroxyethyl)amino]-o-cresol (INCI: 2-Methyl-5-hydroxyethylaminophenol, CAS-No 55302-96-0) No 241: 5-Amino-o-cresol (INCI: 4-Amino-2- Hydroxytoluene, CAS-No 83-56-7) 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) No 243: 1,3-Benzenediol, 2- methyl (INCI: 2-Methylresorcinol, CAS No 608-25-3) No 244 : 4-Amino-m-cresol (INCI: 4-Amino-m-cresol, CAS-No 2835-99-6) No 245: 2-[(3-amino-4-methoxyphenyl) amino]ethanol and its sulphate (INCI: 2-Amino-4-hydroxyethylaminoanisole; 2-Amino-4-hydroxyethylaminoanisole, CAS-No 83763-47-7 / 83763-48-6) No 272: 4-Aminophenol (INCI: p-Aminophenol, CAS No 123-30-8) No 285: Pyridine-2,6- diyldiamine (INCI: 2,6-Diaminopyridine, CAS No 141-86-6)</p> <p>The following substances are restricted in mascara: No 98 - 2-Hydroxy benzoic acid (Salicylic acid, CAS-Nr. 69-72-7)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - haircoloration, straightening & perms

Article No.:

req. no.	Statutory requirement	Law	Article
160150	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. Additional information: BfR Haarglättungsmittel_11-04	BfR Haarglättungsmittel	
160265	Temporary hair colors (e.g. hair crayons or coloring hair sprays) are considered as hair colorants and should not contain any prohibited color pigments according to the EU Cosmetics Regulation	ALS	2019/90

Category: Cosmetics

21-11

Author: Träger

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 3: Oxalic acid, its esters and alkaline salts (INCI: Oxalic acid, CAS No 144-62-7)</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 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)</p> <p>No 51: Bis(8-hydro-xyquinolini-um) sulphate (INCI: Oxyquinoline sulphate, CAS-Nr. 134-31-6)</p> <p>No 53: Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts) (INCI: Etidronic acid, CAS No 2809-21-4)</p> <p>No 93: 2,4-Diamino-pyrimidine-3-oxide ((INCI: Diaminopyrimidine oxide CAS No 74638-76-9)</p> <p>No 257: Polidocanol (INCI: Laureth-9, CAS No 3055-99-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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>No 32 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9)</p> <p>Current transitional period: 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl (INCI: Climbazole, CAS No 38083-17-9) - prohibition of sales from 27 February 2020.</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

21-11

Author: Träger

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)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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) No 310 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160262	<p>In hair lotion the following preservative listed in Annex V RE (EC) No 1223/2009 is allowed adhere the limitations:</p> <p>No 32 - 1-(4-Chlorphenoxy)-1-(1-imidazol-1-yl)-3,3-dimethyl-2-butanone (INCI: Climbazole, CAS No 38083-17-9): Maximum concentration in ready for use preparatoin 0,2%</p> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - skin-cleansing & skin-care

Article No.:

req. no.	Statutory requirement	Law	Article
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 Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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. Additional information: BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160275	Castor oil should not be used on its own when formulating cosmetics. Additional information: 24-sitzung-der-bfr-kommission-fuer-kosmetische-mittel_21-05	Sitzungen BfR Kosmetik	24. Sitzung der BfR-Kommission für kosmetische Mittel
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 Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	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
160280	The following substance from Annex III of the EU Cosmetics Regulation is restricted in body lotions: No 98: 2-hydroxy benzoic acid (salicylic acid, CAS No 69-72-7) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b
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. Additional information: 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
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

21-11

Author: Träger

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> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - skin-cleansing & skin-care

Article No.:

req. no.	Statutory requirement	Law	Article
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) 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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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
160200	<p>The Federal Institute for Risk Analysis (BfR) evaluates the substance β-Arbutin in Skin-lightening products as harmful to human health. Additional information: BfR - beta-Arbutin in Hautaufhellungsmitteln_13-04</p>	BfR beta-Arbutin Hautaufhellung	

Category: Cosmetics

21-11

Author: Träger

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). Additional information: BfR Borsäure	BfR Borsäure	
160275	Castor oil should not be used on its own when formulating cosmetics. Additional information: 24-sitzung-der-bfr-kommission-fuer-kosmetische-mittel_21-05	Sitzungen BfR Kosmetik	24. Sitzung der BfR-Kommission für kosmetische Mittel
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)
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. Additional information: BfR Vitamin A_18-05	BfR Vitamin A	BfR Stellungnahme Nr. 005/2014
160278	The following substance from Annex III of the EU Cosmetics Regulation is restricted in lipsticks: Nr. 98 - 2-hydroxy benzoic acid (salicylic acid, CAS No 69-72-7) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
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) Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)



Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - lip make-up & lip-care

Article No.:

req. no.	Statutory requirement	Law	Article
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>Additional information: 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

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - Nail cosmetics

Article No.:

req. no.	Statutory requirement	Law	Article
160216	<p>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:</p> <p>No 25: 5-Chloro-2- (2,4-dichlorophenoxy)phenol (INCI: Triclosan, CAS-No. 3380-34-5) maximum 0,3% in ready for use preparation Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
160225	<p>hydroquinone monomethyl ether (MEHQ)</p> <p>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.</p>	ALS	2013/24
160109	<p>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:</p> <p>No 44: 1,3-Bis (hydroxymethyl)imidazolidine-2-thione (INCI: Dimethylol ethylene thiourea, CAS No 15534-95-9)</p> <p>No 185: Toluene (INCI: Toluene, CAS No 108-88-3)</p> <p>No 313 2-Hydroxyethylmethylacrylat (INCI: HEMA, CAS-No 868-77-9)</p> <p>No 314 11,14-Dioxa-2,9- diazaheptadec-16- ensäure, 4,4,6,16-Tetramethyl- 10,15-dioxo, 2- [(2-methyl-1-oxo- 2-propenyl)oxy] ethylester (INCI: DI-HEMA-TRIMETHYLHEXYLDICARBAMATE, CAS-No 41137-60-4 and 72869-86-4) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160197	<p>Products with very high methyl-methacrylate content (80-90%) should not be sold to the end user, because they were considered unsafe. Additional information: BfR Methylmethacrylat Nagelmodellage_12-11</p>	BfR Methylmethacrylat at Nagelmodellage	
160108	<p>In nail hardening 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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

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>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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) No 311 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (INCI: Trimethylbenzoyldiphenylphosphineoxide, CAS No 75980-60-8)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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

21-11

Author: Träger

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

21-11

Author: Träger

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. Additional information: VO (EG) Nr. 1223/2009 Anhang VI 21-11	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. Additional information: 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

21-11

Author: Träger

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. Additional information: 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 98: Benzoic acid, 2-hydroxy- (INCI: Salicylic acid, CAS No 69-72-7) 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) Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)
160239	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. Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

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>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

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 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> <p>No 158: trans-Rose ketone2; (E)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one (trans-betaDamascone) (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 (DeltaDamascone) (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 (cisbeta-Damascone) (INCI: cis-Rose ketone-2, CAS No 23726-92-3)</p> <p>No 163: trans-Rose ketone1; (E)-1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one (trans-alphaDamascone) (INCI: trans-Rose ketone-1, CAS No 24720-09-0)</p> <p>No 165: trans-Rose ketone3; 1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one (trans-deltaDamascone) (INCI: trans-Rose ketone-3, CAS No 71048-82-3)</p> <p>No 166: trans-2-hexenal (INCI: trans-2-hexenal, CAS No 6728-26-3)</p> <p>No 169: p-Mentha-1,8-dien-7-al (INCI: Perillaldehyde, CAS No 2111-75-3)</p> <p>No 173: Methyl octine carbonate; Methyl non-2-ynoate (INCI: Methyl octine carbonate, CAS No 111-80-8)</p> <p>No 174: Amylvinylcarbonyl acetate; 1-Octen-3-ylacetate (INCI: Amylvinylcarbonyl acetate, CAS No. 2442-10-6)</p> <p>No 175: Propylidenephthalide; 3-Propylidenephthalide (INCI: Propylidenephthalide, CAS No 17369-59-4)</p> <p>No 177: 2-Hexylidene cyclopentanone (INCI: 2-Hexylidene cyclopentanone, CAS No 17373-89-6)</p> <p>No 178: Methyl heptadienone; 6-Methyl-3,5-heptadien-2-one (INCI: Methyl heptadienone, CAS No 1604-28-0)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe b)

Category: Cosmetics

21-11

Author: Träger

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> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)

Category: Cosmetics

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - dental & mouth-care

Article No.:

req. no.	Statutory requirement	Law	Article
160131	<p>In products for oral hygiene the following preservatives listed in Annex V RE (EC) No 1223/2009 are prohibited:</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)</p> <p>No 8: Pyrithione zinc (INCI: Zinc pyrithione, CAS No 13463-41-7)</p> <p>No 49: 5-Ethyl-3,7-dioxo-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-[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> <p>Additional information: VO (EG) Nr. 1223/2009_Anhang V_20-05</p>	VO (EG) Nr. 1223/2009	Art. 14 Abs. 1 Buchstabe d)
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 No 7775-09-9; INCI: Potassium chlorate, CAS No 3811-04-9)</p> <p>No 12 - Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide, with the exception of the following substances in Annex II: No 1397, 1398, 1399 (INCI: Hydrogen peroxide, CAS No 7722-84-1)</p> <p>Additional information: VO (EG) Nr. 1223/2009 Anhang III 21-11</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>Additional information: 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

21-11

Author: Träger

Product: Kosmetik/ cosmetics

Cosmetic products - dental & mouth-care

Article No.:

req. no.	Statutory requirement	Law	Article
160256	<p>The BfR points out that there is no clear evidence that a toothpaste containing 500 ppm fluoride (0.05% fluoride) is less effective than one containing 1000 ppm (0.1% fluoride). The Exposure to fluoride from supplements, toothpaste (and possibly table salt) increases the risk of tooth fluorosis. The BfR is of the opinion that in infants no toothpaste with fluoride concentrations ≥ 1000 ppm should be used.</p> <p>Additional information: BfR Fluoridprophylaxe Kleinkinder_18-11</p>	BfR Fluoridprophylaxe Kleinkinder	BfR Stellungnahme Nr. 015/2018