

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Requirements for all products**

Article No.:

The topic safety of products concerns the complete range of "hardware", since products generally have to be designed to be safe.

req. no.	Statutory requirement	Law	Article
3063	<p>Bis(pentabromphenyl)ether (Decabromdiphenylether, DecaBDE; CAS-Nr.: 1163-19-5; EG-Nr.: 214-604-9)</p> <p>1.) shall not be manufactured or placed on the market as a substance on its own</p> <p>2.) shall not be used in the production of, or placed on the market in:</p> <p>(a) another substance, as a constituent;</p> <p>(b) a mixture;</p> <p>(c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight</p>	VO (EG) Nr. 1907/2006	Anhang XVII
50671	<p>Prohibitions and restrictions for persistent organic pollutants are to be observed (POP-Regulation).</p> <p>Additional information: RE (EU) 2019/1021_21-05 VO (EU) 2019/1021_21-05</p>	VO (EU) 2019/1021	
50795	<p>Consumer Goods or part thereof under 5 cm (not toys) that could be used by children under normal or reasonably foreseeable conditions of use in the mouth may not be placed on the market if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight.</p> <p>This does not apply to products which were first placed on the market before 01 June 2016.</p> <p>Exceptions (see Additional information) to be observed.</p> <p>Additional information: RE (EU) No. 2015-628 REACH Lead_15-04 VO (EU) 2015-628 Änderung REACH Blei_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII i.V.m. VERORDNUNG (EU) 2015/628
50538	<p>Following mercury compounds may no longer be manufactured or placed on the market as substances. In mixtures, articles or any parts thereof, they may no longer be placed on the market, if the concentration of mercury is equal to or greater than 0.01 percent weight:</p> <ul style="list-style-type: none"> - Phenylmercury acetate (EC-No 200-532-5, CAS-No 62-38-4) - Phenylmercury propionate (EC-No 203-094-3, CAS-No 103-27-5) - Phenylmercury 2-ethylhexanoate (EC-No 236-326-7, CAS-No 13302-00-6) - Phenylmercury octanoate (CAS-No 13864-38-5) - Phenylmercury neodecanoate (EC-No 247-783-7, CAS-No 26545-49-3) 	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 62
50525	<p>If a product marked with a CE mark and complies with it by the CE- requirements, the GS- mark should not to be used. Equivalent requirements of CE criteria and GS criteria rules out a GS-mark.</p>	ProdSG	§ 20 (2)
50527	<p>The GS-mark must be designed in accordance with the provisions of ProdSG.</p> <p>Additional information: GS-Zeichen_21-11</p>	ProdSG	§ 24 (3)



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req. no.	Statutory requirement	Law	Article
50518	<p>The product safety of a product is completely to examined. All components of a product, as:</p> <ul style="list-style-type: none"> - the product as self, - identification, - correct instructions, - adequate warnings, - Information about foreseeable misuse, - disposal instructions, - Information for specific user groups, <p>must be checked.</p>	ProdSG	§ 3
50519	<p>Manufacturers and importers have provisions for appropriate measures (market monitoring, complaint analysis, etc.) shall be taken to avoid risks associated with the product. This applies to organizational measures to alert consumers and any necessary withdrawal or the recall. Product complaints must be registered. This should include the reason for the complaint and measures initiated.</p> <p>Manufacturers and importers have the competent market surveillance authority immediately informed about health and safety risks associated with the product that they put on the market. The actions taken to represent.</p>	ProdSG	§ 6
50522	<p>The CE marking must be visible, legible and permanently be directly attached to the product or its data plate. This also applies to the address of the manufacturer, importer or the trademark owner. If the type of product that is not possible or not warranted, the CE marking is affixed on the packaging, as well as on the accompanying documents, provided they are prescribed.</p> <p>Attention! Information from public authorities are exceptions to the direct labeling of the product if they are only economic.</p>	ProdSG	§7 (3)
50523	<p>If the production (production control) of the product by a notified conformity assessment body has been audited, according to the CE mark, the number have to apply on the product.</p>	ProdSG	§ 7 (4)
50524	<p>Behind the CE mark and the number can be apply an icon indicating a special risk or special use.</p>	ProdSG	§ 7 (5)
160071	<p>It is prohibited to place consumer goods on the market under misleading designation, information or presentation.</p>	LFGB	§33 Abs. 1
103003	<p>Consumer articles and toys with liquids, for example in double-walled articles, are subject to a purchase ban.</p>	QS	
160070	<p>Articles for daily use must not be placed on the market if they do not conform to stipulated requirements from the regulation (EG) Nr 1935/2004 regarding their manufacture</p>	LFGB	§31 Abs.1
5046	<p>Products may be introduced onto the market only if they do not endanger the safety and health of consumers or damage other objects (products). In addition, for products which are subject to other legal provisions the higher requirements specified must also be fulfilled.</p>	ProdSG	§ 3

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req. no.	Statutory requirement	Law	Article
160069	Articles or substances must not be placed on the market as consumer goods if their intended or predictable use is likely to impair health by virtue of their material composition, e.g. through toxic substances or impurities.	LFGB	§30
5047	All products must be clearly marked on the product as follows: 1. with the full address of the manufacturer. 2. with the full address of the importer, if the headquarters of the manufacturer or person authorised by him is not in Germany. 3. with the full address of the dealer, if he has imported the product himself. If a direct product marking is not possible (technically), it can also be attached to the packaging (Exceptions are to be observed). Furthermore, applies to products in the harmonized area (ProdSV and more) supplemental label elements.	ProdSG	§ 6 (1)
5048	Harmonized standards, non-harmonized standards and technical specifications can be used to ensure conformity.	ProdSG	§ 4 und § 5
5351	Products that are not food, but which are due to - their shape, - her smell, - their color, - her appearance, - her presentation, - their marking, - their volume or - her size it is foreseeable that they will be confused with food by consumers, especially children, and therefore be taken to the mouth, sucked or swallowed, which may give rise, in particular, to the risk of suffocation, poisoning, perforation or obstruction of the digestive tract, are forbidden.	LFGB	§ 5, in V. m. § 3 Abs. 1 Nr. 5
5049	Instructions for use / safety instructions in German must be enclosed with all products if certain rules are to be observed to protect the health of people. The use, addition and maintenance of the product must be considered.	ProdSG	§ 3 (4)
5050	The DIN EN IEC / IEEE 82079 standard can be used to create instructions for use. Following information is recommended: 1. Type of use 2. Assembly 3. Installation 4. Maintenance instructions 5. Warnings, particularly when used for a purpose other than that intended 6. Prevention of maloperation 7. Special instructions for user groups which are exposed to greater danger (children, pregnant women, older people) 8. Complete address of the manufacturer or importer 9. Note on how to keep the instructions for use 10. Note on the legally prescribed disposal	DIN EN IEC/IEEE 82079	



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req. no.	Statutory requirement	Law	Article
5052	The GS mark may be used only if a notified GS testing institute has carried out a test and confirmed this. The GS mark can only be applied for by manufacturers or authorized representatives based in the EU or the European free trade area.	ProdSG	§ 20 (1)
5051	The CE marking may be used only if this is subject to the relevant directives and these requirements have also been observed.	ProdSG	§ 7 (2)

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by REACH**

Article No.:

Manufactured item means a product which intentionally releases a substance and acquires at the manufacturing stage a specific form, surface or configuration, which, to a greater extent than its chemical composition, determines its function. As such are accounted e.g. scented candles, textiles releasing scent, perfumed handkerchiefs, Manufactured items are articles, which at the manufacturing stage acquire a specific form, surface or configuration, which to a greater extent than the chemical composition determines their function.

req. no.	Statutory requirement	Law	Article
50395	The requirements of the safety data sheets are to be fulfilled according to RE (EC) 1907/2006 Annex II. Additional information: RE (EG) Nr. 1907/2006 Annex II 21-11 VO (EG) Nr. 1907/2006 Anhang II 21-11	VO (EG) Nr. 1907/2006	Anhang II
50177	For articles you can find the REACH requirements for producers, importers and distributors in the Guideline of the REACH CLP Helpdesk: http://www.reach-clp-biozid-helpdesk.de/en/Homepage.html?jsessionid=2AC4AEBE23776D9211A35669BF9C6791.s2t2	VO (EG) Nr. 1907/2006	
5220	For all ready-made articles (products), which intentionally release more than 1 ton of chemical substance the REACH requirements apply and must be adhered to from 1 June 2007 or 1 June 2008 respectively. Additional information: RE (EC) No 1907/2006_21-05 VO (EG) Nr. 1907/2006_21-05	VO (EG) Nr. 1907/2006	Art.141
50046	The material limits and prohibitions of Annex XVII, current form in each case are to be observed. https://echa.europa.eu/substances-restricted-under-reach	VO (EG) Nr. 1907/2006	Anhang XVII
5221	The manufacturers are responsible for the adherence to the obligations arising from REACH for all ready-made articles (products) produced in the EU. This also applies to own brands.	VO (EG) Nr. 1907/2006	Art.3 Abs.3,4,7,9,11
5222	Manufacturers within the EU, who come under the REACH obligations will, after registration, make their registration numbers known without being asked. This also applies to private labels.	QS	



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Articles of natural latex

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

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Product:Hygieneprodukte_Wellness_Gesundheit/
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Article No.:

All types of timber such as solid timber, wood veneer, wooden material boards (e.g. chipboard) and pulp and paper with the exception of bamboo-based and recovered products.

req. no.	Statutory requirement	Law	Article
711	Coated and uncoated wood materials such as chipboard, carpentry, veneer or fiber boards must comply with the test requirements for formaldehyde of the ChemVerbotsVO.	ChemVerbotsV	§ 1 Abs. 1 iVm Anh. Abschn. 3
706	Wood products must not contain more than 5 mg / kg of PCP or PCP salts or compounds.	ChemVerbotsV	§ 3 Anlage 1
3061	It is prohibited to treat wooden goods with arsenic compounds.	VO (EG) Nr. 1907/2006	Anhang XVII
50801	Untreated lumbers and twigs, heather and coniferous timber seeds for the production of smoke used for smoking foodstuffs (smoked chips, strands, boards and woods) are consumer goods and may not exceed the threshold values for pentachlorophenol and its salts, expressed as pentachlorophenol of 0.05 mg/kg wood .	BedGgstV	§ 6 Nr.3 + Anlage 5
50799	Follow chemicals shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market: (a) Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5 (b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8 (c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8 (d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8EC No 292-605-3 (e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1 (f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7 (g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3 (h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1 (i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5	VO (EG) Nr. 1907/2006	Anhang XVII
50778	Cellulose and paper with a content of about 0.1 percent by weight of nonylphenol is prohibited.	VO (EG) Nr. 1907/2006	Anhang XVII



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Wood, animal fibre, animals and plants

Article No.:

req. no.	Statutory requirement	Law	Article
50801	Untreated lumbers and twigs, heather and coniferous timber seeds for the production of smoke used for smoking foodstuffs (smoked chips, strands, boards and woods) are consumer goods and may not exceed the threshold values for pentachlorophenol and its salts, expressed as pentachlorophenol of 0.05 mg/kg wood .	BedGgstV	§ 6 Nr.3 + Anlage 5
706	Wood products must not contain more than 5 mg / kg of PCP or PCP salts or compounds.	ChemVerbotsV	§ 3 Anlage 1
711	Coated and uncoated wood materials such as chipboard, carpentry, veneer or fiber boards must comply with the test requirements for formaldehyde of the ChemVerbotsVO.	ChemVerbotsV	§ 1 Abs. 1 iVm Anh. Abschn. 3
3061	It is prohibited to treat wooden goods with arsenic compounds.	VO (EG) Nr. 1907/2006	Anhang XVII
50799	Follow chemicals shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market: (a) Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5 (b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8 (c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8 (d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8EC No 292-605-3 (e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1 (f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7 (g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3 (h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1 (i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5	VO (EG) Nr. 1907/2006	Anhang XVII



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Plastics

Article No.:

Plastics also include fully or partly synthetically manufactured rubbers. Plastic fibres were handled under "Textile Fibres"!

Foamed plastics are for example mattresses, cushions, cold boxes, bicycle saddles, insulating materials.

req. no.	Statutory requirement	Law	Article
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req. no.	Statutory requirement	Law	Article
713	<p>It must be ascertained that the limits for dioxins and furans are not exceeded.</p> <p>Limits must be adhered to for the following groups of dioxins and furans:</p> <p>Group 1</p> <p>a) 2,3,7,8-Tetrachlorodibenzo-p-dioxin b) 1,2,3,7,8-Pentachlorodibenzo-p-dioxin c) 2,3,7,8-Tetrachlorodibenzofuran d) 2,3,4,7,8-Pentachlorodibenzofuran</p> <p>Group 2</p> <p>a) 1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin b) 1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin c) 1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin d) 1,2,3,7,8-Pentachlorodibenzofuran e) 1,2,3,4,7,8-Hexachlorodibenzofuran f) 1,2,3,7,8,9-Hexachlorodibenzofuran g) 1,2,3,6,7,8-Hexachlorodibenzofuran h) 2,3,4,6,7,8-Hexachlorodibenzofuran</p> <p>Group 3</p> <p>a) 1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin b) 1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin c) 1,2,3,4,6,7,8-Heptachlorodibenzofuran d) 1,2,3,4,7,8,9-Heptachlorodibenzofuran e) 1,2,3,4,6,7,8,9-Octachlorodibenzofuran</p> <p>Group 4</p> <p>a) 2,3,7,8-Tetrabromodibenzo-p-dioxin b) 1,2,3,7,8-Pentabromodibenzo-p-dioxin c) 2,3,7,8-Tetrabromodibenzofuran d) 2,3,4,7,8-Pentabromodibenzofuran</p> <p>Group 5</p> <p>a) 1,2,3,4,7,8-Hexabromodibenzo-p-dioxin b) 1,2,3,7,8,9-Hexabromodibenzo-p-dioxin c) 1,2,3,6,7,8-Hexabromodibenzo-p-dioxin d) 1,2,3,7,8-Pentabromodibenzofuran</p> <p>The following limits must be met:</p> <ol style="list-style-type: none"> 1 µg/kg for the total amounts contained of chemical compounds stated in Group 1 5 µg/kg for the total amounts contained of chemical compounds stated in Group 1 and 2 100 µg/kg for the total amounts contained of chemical compounds stated in Group 1, 2 and 3 1 µg/kg for the total amounts contained of chemical compounds stated in Group 4 5 µg/kg for the total amounts contained of chemical compounds stated in Group 4 and 5 <p>The limits in Items 2, 3 and 5 are deemed to have been met only provided the limits applicable to the groups listed there are met.</p> <p>Routes of entry for dioxins and furans may be:</p> <ul style="list-style-type: none"> - Direct Blue 106 + 108, Violet 23 dyestuffs - Anthraquinonoid vat dyes and anthraquinonoid pigments - Dyestuffs produced using chloranil as the basis - Fiber materials or leather treated with pentachlorophenol (PCP). 	ChemVerbotsV	§ 3 Anlage 1

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Plastics also include fully or partly synthetically manufactured rubbers. Plastic fibres were handled under "Textile Fibres"!

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req. no.	Statutory requirement	Law	Article
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
50940	<p>Certain single-use plastic articles and products made of oxo-degradable plastic are banned.</p> <p>These include in particular</p> <ul style="list-style-type: none"> - cotton buds sticks, - cutlery (forks, knives, spoons, chopsticks), - plates, - straws; - beverage stirrers - sticks to be attached to and to support balloons, including the mechanisms of such sticks - food containers made of styrofoam - beverage containers made of styrofoam, including their caps and lids; and - cups for beverage made of styrofoam, including their covers and lids. 	EWKVerbotsV	§ 3

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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
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; - wall 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
671	<p>Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material.</p> <p>By way of derogation, above restriction shall not apply to articles coloured with mixtures containing cadmium for safety reasons.</p>	VO (EG) Nr. 1907/2006	Anhang XVII



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req. no.	Statutory requirement	Law	Article
50737	<p>Products of rubber or plastic components (e.g. sport equipment, household utensils, tools, clothing, footwear, wrist-bands), that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 1.0 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAhA)</p> <p>This shall not apply to articles placed on the market for the first time before 27 December 2015. For these articles the values of BfR and ZEK apply.</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: RE (EC) No 1907/2006_20-05 VO (EG) Nr. 1907/2006_20-05</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50
50738	<p>Toys, including activity toys, and childcare articles of rubber or plastic components, that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 0.5 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAhA)</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: CR (EC) 2015-326_test method_15-04 VO(EU) Nr. 2015-326_Prüfverfahren_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50

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Foamed plastics are for example mattresses, cushions, cold boxes, bicycle saddles, insulating materials.

req. no.	Statutory requirement	Law	Article
721	<p>Products made of vinyl chloride polymers (e.g. PVC) which are intended to</p> <ul style="list-style-type: none"> - come into contact with food during manufacture, treatment, distribution, or use - come into contact with cosmetics or tobacco products - come into contact with the skin, not just temporarily - come into contact with the mouth - as well as all - toys and joke articles - cleaning and care agents - products for personal hygiene <p>may not contain more than 1 mg monomer vinyl chloride per kg</p>	BedGgstV	§ 6 Abs. 3 iVm Anl.5 Nr. 1
723	<p>Analysis of the Consumer Goods must be done according to the methods laid down in Annex 10 of the regulation concerning consumer goods (BedGgstV).</p> <p>Additional information: Bedarfsgegenständeverordnung_17-05.pdf</p>	BedGgstV	§ 11 + Anlage 10
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
50050	<p>Trisubstituted zinc compounds (e.g. TBT, TPT) with a concentration of more than 0.1 per cent weight in products, not mixtures such as:</p> <ul style="list-style-type: none"> - carpets; - clothing; - wood preservation substances; - leather goods; - PVC-products; - paints and varnishes <p>are prohibited.</p>	VO (EG) Nr. 1907/2006	Anhang XVII

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Plastics**

Article No.:

Plastics also include fully or partly synthetically manufactured rubbers. Plastic fibres were handled under "Textile Fibres"!

Foamed plastics are for example mattresses, cushions, cold boxes, bicycle saddles, insulating materials.

req. no.	Statutory requirement	Law	Article
50051	<p>Dibutyl zinc compounds (DBT) with a concentration of more than 0.1 per cent weight are prohibited if these are intended for end-users in such products and mixtures as:</p> <ul style="list-style-type: none"> - impregnating sprays; - mattresses; - PVC articles; - polyurethane foam; - textiles, - where applicable other articles and mixtures. <p>The above date does not apply to the following products and mixtures:</p> <ul style="list-style-type: none"> one- and two part room temperature vulcanisation sealing substances and glues (RTV-1 and RTV-2 sealing substances); - paints and coatings containing DBT-compounds as catalysts if these are painted on products; - soft polyvinylchloride (PVC) profiles whether these are extruded with hard PVC or not; material covered with a layer of PVC which contains DBT-compounds as stabilisers, if intended for outdoor use; - outside rainwater piping, guttering and joints as well as roof and exterior wall cladding. 	VO (EG) Nr. 1907/2006	Anhang XVII
50349	<p>For the dyes of plastic household use articles, the recommendations of the BfR "IX. Colourings for dyeing plastics and other polymers for articles for household use" are to be adhered to.</p> <p>Additional information: BfR IX Colorants 2019-06-01_20-05 BfR IX Farbmittel 2019-06-01_20-05</p>	BfR-Empfehlung	BfR IX



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Metallic surfaces

Article No.:

Concerns metallic surfaces of household appliances, furniture, sanitary systems, air-conditioning systems, devices for freezing and deep-freezing and so on.

req. no.	Statutory requirement	Law	Article
100669	Avoidance of lead-containing metals for bearings and cadmium containing colours and screws.	QS	
675	For household items, furniture, sanitary systems, airconditions and devices for freezing and deep-freezin and others metallic surfaces must not be treated with cadmium.	VO (EG) Nr. 1907/2006	Anhang XVII
103075	All steel and steelproducts from India must provide freedom of radioactive contamination (Cobalt 60). Limit: 500 mikrobecquerel per gram. Analytical method: nuclide specific CO-60 measurement (Gamma-spectroscopy)	ProdSG	
103071	With the application of Chrome III it is essential to ensure that the treatment of the product is absolutely flawless, no corrosion occurs, so that no chrome VI forms	QS	
50795	Consumer Goods or part thereof under 5 cm (not toys) that could be used by children under normal or reasonably foreseeable conditions of use in the mouth may not be placed on the market if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight. This does not apply to products which were first placed on the market before 01 June 2016. Exceptions (see Additional information) to be observed. Additional information: RE (EU) No. 2015-628 REACH Lead_15-04 VO (EU) 2015-628 Änderung REACH Blei_15-04	VO (EG) Nr. 1907/2006	Anhang XVII i.V.m. VERORDNUNG (EU) 2015/628
50772	For all consumer goods made of metal (jewelry, writing instruments, mobile phones) which are intended to come into direct and prolonged in contact with the skin, the corresponding material restrictions of Annex XVII to Regulation (EC) no. 1907/2006 must be observed. https://www.echa.europa.eu/substances-restricted-under-reach	VO (EG) Nr. 1907/2006	Anhang XVII



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Textile fibre materials / leather and imitation leather

Article No.:

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

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> <ul style="list-style-type: none"> 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>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
50696	<p>For toys and childcare articles which can be placed in the mouth, the limit of 0.1% is observed for following phthalate:</p> <ul style="list-style-type: none"> - DPHP (Di-2-propylheptylphthalat) <p>Additional information: BfR Opinion No. 004-2012_13-11.pdf BfR Stellungnahme DPHP Nr. 004-2012_13-11.pdf</p>	BfR DPHP	

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
50687	<p>The limit values below apply to the following textiles:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers following limits:</p> <ul style="list-style-type: none"> - Cadmium and its compounds: 1 mg/kg nach Extraktion - Chromium VI compounds: 1 mg/kg nach Extraktion - Arsenic compounds: 1 mg/kg nach Extraktion - Lead and its compounds: 1 mg/kg nach Extraktion - Benzene: 5 mg/kg - Benz[a]anthracen: 1 mg/kg - Benz[e]acephenanthrylene: 1 mg/kg - Benzo[a]pyrene; Benzo[def]chrysene: 1 mg/kg - Benzo[e]pyrene: 1 mg/kg - Benzo[j]fluoranthene: 1 mg/kg - Benzo[k]fluoranthene: 1 mg/kg - Chrysene: 1 mg/kg - Dibenz[a,h]anthracene: 1 mg/kg - α, α, α, 4-tetrachlorotoluene; p-chlorobenzotrchloride: 1 mg/kg - α, α, α-trichlorotoluene; benzotrchloride: 1 mg/kg - α-chlorotoluene; benzyl chloride: 1 mg/kg - Formaldehyde: 75 mg/kg - 1,2-benzenedicarboxylic acid; di-C 6-8-branched alkylesters, C 7-rich: 1000 mg/kg - Bis(2-methoxyethyl)phthalate: 1000 mg/kg - Diisopentylphthalate: 1000 mg/kg - Di-n-pentylphthalate (DPP): 1000 mg/kg - Di-n-hexylphthalate (DnHP): 1000 mg/kg - N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone (NMP): 3000 mg/kg - N,N-Dimethylacetamide (DMAC): 3000 mg/kg - N,N-Dimethylformamide; Dimethylformamide (DMF): 3000 mg/kg - 1,4,5,8-Tetraamino-anthrachinon; C.I. Disperse Blue 1: 50 mg/kg - Benzolamin, 4,4'-(4-Iminocyclohexa-2,5- dienyldenmethylene)dianilinhydrochlorid; C.I. Basic Red 9: 50 mg/kg - 4-[4,4'-Bis(dimethylamino)benzhydriiden]cyclohexa-2,5-dien-1-yliden]dimethylammoniumchlorid; C.I. Basic Violet 3 mit $\geq 0,1$ % Michlers Keton (EG-Nr. 202- 027-5): 50 mg/kg - 4-Chlor-o-toluidiniumchloride: 30 mg/kg - 2-Naphthylammoniumacetate: 30 mg/kg - 4-Methoxy-m-phenylendiammoniumsulfate; 2,4-Diaminoanisolsulfate: 30 mg/kg - 2,4,5-Trimethylanilin-Hydrochloride: 30 mg/kg - Quinoline: 50 mg/kg <p>By way of derogation, in relation to the placing on the market of formaldehyde in jackets, coats or upholstery, the relevant concentration for the purposes shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. Thereafter, the above concentration applies.</p> <p>The requirements do not apply to:</p> <p>(a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;</p> <p>(b) non-textile fasteners and non-textile decorative attachments;</p> <p>(c) second-hand clothing, related accessories, textiles other than clothing or footwear</p> <p>(d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.</p> <p>e) disposable textiles,</p> <p>f) personal protective equipment</p> <p>g) medical devices</p>	VO (EG) Nr. 1907/2006	Anhang XVII



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
50051	<p>Dibutyl zinc compounds (DBT) with a concentration of more than 0.1 per cent weight are prohibited if these are intended for end-users in such products and mixtures as:</p> <ul style="list-style-type: none"> - impregnating sprays; - mattresses; - PVC articles; - polyurethane foam; - textiles, - where applicable other articles and mixtures. <p>The above date does not apply to the following products and mixtures:</p> <ul style="list-style-type: none"> one- and two part room temperature vulcanisation sealing substances and glues (RTV-1 and RTV-2 sealing substances); - paints and coatings containing DBT-compounds as catalysts if these are painted on products; - soft polyvinylchloride (PVC) profiles whether these are extruded with hard PVC or not; material covered with a layer of PVC which contains DBT-compounds as stabilisers, if intended for outdoor use; - outside rainwater piping, guttering and joints as well as roof and exterior wall cladding. 	VO (EG) Nr. 1907/2006	Anhang XVII
50737	<p>Products of rubber or plastic components (e.g. sport equipment, household utensils, tools, clothing, footwear, wrist-bands), that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 1.0 mg / kg of one of the listed PAHs:</p> <ul style="list-style-type: none"> a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAha) <p>This shall not apply to articles placed on the market for the first time before 27 December 2015. For these articles the values of BfR and ZEK apply.</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: RE (EC) No 1907/2006_20-05 VO (EG) Nr. 1907/2006_20-05</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
50738	<p>Toys, including activity toys, and childcare articles of rubber or plastic components, that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 0.5 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBA_hA)</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: CR (EC) 2015-326_test method_15-04 VO(EU) Nr. 2015-326_Prüfverfahren_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50
50050	<p>Trisubstituted zinc compounds (e.g. TBT, TPT) with a concentration of more than 0.1 per cent weight in products, not mixtures such as:</p> <ul style="list-style-type: none"> - carpets; - clothing; - wood preservation substances; - leather goods; - PVC-products; - paints and varnishes <p>are prohibited.</p>	VO (EG) Nr. 1907/2006	Anhang XVII
50245	<p>For products made of leather, which are not only temporarily with skin contact, e.g.:</p> <ul style="list-style-type: none"> - Watch Bands, - Bags, - Backpacks, - Chair covers, - Money bag, - Shoes, - Gloves, - Toys made of leather, <p>must chromium VI not be detected. (Method B 82.02-11, 2008-10 - § 64-1 LFGB, according to DIN EN ISO 17075)</p> <p>This requirement applies from May 1st 2014 in all EU-Countries (CR (EU) No. 301/2014 amending annex XVII of REACH-CR)</p>	BedGgstV	Anl. 4 Nr. 2 und Anl. 10, Nr. 8

Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
50438	<p>Textile products are:</p> <p>a) products with a weight share of textile fibres of at least 80 %;</p> <p>b) Material covers for furniture, umbrella and parasols with a weight share of textile components of at least 80 %;</p> <p>c)the textile components of</p> <p>i) the uppermost layer of multi-layered floorcoverings,</p> <p>ii)mattress covers,</p> <p>iii) the covers of camping articles,</p> <p>in so far as these textile components a weight share which comprises at least 80 % of these upper layers or covers;</p> <p>d) Textiles which are worked into other goods and become integral parts of these as far as their composition is stated.</p> <p>The requirements of the Textile Labelling Regulation (EU) Nr. 1007/2011 must be observed.</p> <p>Additional information: FAQ Regulation EU No. 1007-2011_14-11 FAQ zur Textilkennzeichnungsverordnung EU Nr. 1007-2011_14-11</p>	VO (EU) Nr. 1007/2011	Artikel 2 i.V.m.TextilKennzG
5289	<p>Textiles containing Nonylphenol or Nonylphenol ethoxylates equal to or greater than 0,1 % by weight are prohibited.</p> <p>Nonylphenol ethoxylates (NPE) shall not be placed on the market in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.</p>	VO (EG) Nr. 1907/2006	Anhang XVII
5162	<p>When marking leather articles, the following regulations regarding identification must be observed:</p> <p>1.Only those products made of animal skin or fur may be marked with the designation 'leather' or 'real leather';</p> <p>2.The types of artificial product which make up artificial leather must be named;</p> <p>3.Leaner products having a coating of more than 0.15 mm must be marked with following: 'leather with coating';</p> <p>4.Leaner products in combination with other materials may only bear the mark 'leather' if 80% of the product is of leather. Otherwise all the materials must be named.</p>	RAL 060 A2	
705	<p>Textiles and leather must not contain more than 5 mg/kg PCP or its salts or compounds.</p> <p>The conscious use of pentachlorophenol (PCP), its salts or compounds must be omitted in order to adhere to this limit.</p>	ChemVerbotsV	§ 3 Anlage 1
3031	<p>Imitation leather made of vinyl chloride polymers (e.g. PVC) which are intended to come into contact with the skin, not just temporarily, must not contain more than 1 mg monomer vinyl chloride per kg.</p>	BedGgstV	§ 6 Abs. 3 iVm Anl.5 Nr. 1

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
713	<p>It must be ascertained that the limits for dioxins and furans are not exceeded.</p> <p>Limits must be adhered to for the following groups of dioxins and furans:</p> <p>Group 1</p> <p>a) 2,3,7,8-Tetrachlorodibenzo-p-dioxin b) 1,2,3,7,8-Pentachlorodibenzo-p-dioxin c) 2,3,7,8-Tetrachlorodibenzofuran d) 2,3,4,7,8-Pentachlorodibenzofuran</p> <p>Group 2</p> <p>a) 1,2,3,4,7,8-Hexachlorodibenzo-p-dioxin b) 1,2,3,7,8,9-Hexachlorodibenzo-p-dioxin c) 1,2,3,6,7,8-Hexachlorodibenzo-p-dioxin d) 1,2,3,7,8-Pentachlorodibenzofuran e) 1,2,3,4,7,8-Hexachlorodibenzofuran f) 1,2,3,7,8,9-Hexachlorodibenzofuran g) 1,2,3,6,7,8-Hexachlorodibenzofuran h) 2,3,4,6,7,8-Hexachlorodibenzofuran</p> <p>Group 3</p> <p>a) 1,2,3,4,6,7,8-Heptachlorodibenzo-p-dioxin b) 1,2,3,4,6,7,8,9-Octachlorodibenzo-p-dioxin c) 1,2,3,4,6,7,8-Heptachlorodibenzofuran d) 1,2,3,4,7,8,9-Heptachlorodibenzofuran e) 1,2,3,4,6,7,8,9-Octachlorodibenzofuran</p> <p>Group 4</p> <p>a) 2,3,7,8-Tetrabromodibenzo-p-dioxin b) 1,2,3,7,8-Pentabromodibenzo-p-dioxin c) 2,3,7,8-Tetrabromodibenzofuran d) 2,3,4,7,8-Pentabromodibenzofuran</p> <p>Group 5</p> <p>a) 1,2,3,4,7,8-Hexabromodibenzo-p-dioxin b) 1,2,3,7,8,9-Hexabromodibenzo-p-dioxin c) 1,2,3,6,7,8-Hexabromodibenzo-p-dioxin d) 1,2,3,7,8-Pentabromodibenzofuran</p> <p>The following limits must be met:</p> <ol style="list-style-type: none"> 1 µg/kg for the total amounts contained of chemical compounds stated in Group 1 5 µg/kg for the total amounts contained of chemical compounds stated in Group 1 and 2 100 µg/kg for the total amounts contained of chemical compounds stated in Group 1, 2 and 3 1 µg/kg for the total amounts contained of chemical compounds stated in Group 4 5 µg/kg for the total amounts contained of chemical compounds stated in Group 4 and 5 <p>The limits in Items 2, 3 and 5 are deemed to have been met only provided the limits applicable to the groups listed there are met.</p> <p>Routes of entry for dioxins and furans may be:</p> <ul style="list-style-type: none"> - Direct Blue 106 + 108, Violet 23 dyestuffs - Anthraquinonoid vat dyes and anthraquinonoid pigments - Dyestuffs produced using chloranil as the basis - Fiber materials or leather treated with pentachlorophenol (PCP). 	ChemVerbotsV	§ 3 Anlage 1

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textile fibre materials / leather and imitation**

Article No.:

leather

Include textile fibre materials and leather for the manufacture of textiles, home textiles and products/articles with textile components or leather components such as, for example dolls, wigs, seat covers.

req. no.	Statutory requirement	Law	Article
3034	Trichlorobenzene may not be used as a carrier in dyeing of synthetic materials bydisperse dyes. (further notes can be found in the publications of the BfR	LFGB	§ 30
721	Products made of vinyl chloride polymers (e.g. PVC) which are intended to - come into contact with food during manufacture, treatment, distribution, or use - come into contact with cosmetics or tobacco products - come into contact with the skin, not just temporarily - come into contact with the mouth - as well as all - toys and joke articles - cleaning and care agents - products for personal hygiene may not contain more than 1 mg monomer vinyl chloride per kg	BedGgstV	§ 6 Abs. 3 iVm Anl.5 Nr. 1
671	Mixtures and articles produced from plastic material as listed above shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight of the plastic material. By way of derogation, above restriction shall not apply to articles coloured with mixtures containing cadmium for safety reasons.	VO (EG) Nr. 1907/2006	Anhang XVII
5169	Toys and childcare articles which can be placed in the mouth must not contain more than 0,1% (by weight) of the following phthalates in the plasticised material: - Di-isononylphthalat (DINP) CAS-Nrn. 28553-12-0 und 68515-48-0 EINECS-Nrn. 249-079-5 und 271-090-9 - Di-isodecylphthalat (DIDP) CAS-Nrn. 26761-40-0 und 68515-49-1 EINECS-Nrn. 247-977-1 und 271-091-4 -Di-n-octylphthalat (DNOP) CAS-Nr. 117-84-0 EINECS-Nr. 204-214-7 In this context, childcare articles comprise any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of the children.	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 52



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Packaging (also wooden packing)

Article No.:

Products produced out of any material to contain, protect, operate, deliver or offer merchandise.
Packagings include sales-, re-, and transport packagings (acc. VerpackV).

req. no.	Statutory requirement	Law	Article
50939	Plastic carrier bags with a wall thickness of less than 50 micrometres will be banned in Germany from 2022 without any further sales opportunities. Not affected by the ban are very light plastic carrier bags with a wall thickness of less than 15 micrometres.	VerpackG	§ 5
50925	Wood packaging material, whether or not actually in use in the transport of objects of all kinds, shall only be introduced into the Union territory if it fulfils all of the following requirements:(a) it has been subject to one or more of the approved treatments and complies with the applicable requirements set out in Annex 1 to the International Standard for Phytosanitary Measures No 15 Regulation of Wood Packaging Material in International Trade (ISPM15);(b) it is marked with the mark referred to in Annex 2 of ISPM15 attesting that it has been subject to the treatments referred to in point (a) This paragraph shall not apply to wood packaging material which is subject to the exemptions provided for in ISPM15.	VO (EU) 2016/2031	Art. 43 Abs. 1
50956	From 01.01.2022, distributors and manufacturers of system-incompatible sales and secondary packaging as well as sales packaging of pollutant-containing filling goods must comply with their obligation to provide evidence that they have fulfilled the take-back and recovery requirements. In addition, self-monitoring mechanisms must be introduced for transport packaging, sales and secondary packaging not subject to system participation, system-incompatible sales and secondary packaging and sales packaging of hazardous filling goods in order to be able to maintain the take-back and recovery requirements.	VerpackG	§ 15
50950	Beverage bottles with a capacity of up to three litres, including their caps and lids, which are mainly made of PET, shall be made of at least 25% recycled material on average from 2025 onwards. From 2030, a minimum average of 30% recycled content will apply to all single-use plastic beverage bottles. Not affected are: a) Glass or metal beverage bottles with plastic caps or lids; (b) beverage bottles intended for and used for liquid food for special medical purposes as referred to in Article 2(g) of Regulation (EU) No 609/2013.	VerpackG	§ 30 a VerpackG

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Packaging (also wooden packing)**

Article No.:

Products produced out of any material to contain, protect, operate, deliver or offer merchandise.
Packagings include sales-, re-, and transport packagings (acc. VerpackV).

req. no.	Statutory requirement	Law	Article
50957	<p>From 01.01.2022, single-use plastic beverage bottles must be subject to additional deposits if they are filled with the following contents:</p> <ul style="list-style-type: none"> a. Sparkling wine, mixed sparkling drinks with a sparkling wine content of at least 50% and sparkling drinks made from non-alcoholic or reduced-alcohol wine. b. Wine and mixed wine beverages with a wine content of at least 50 % and non-alcoholic or reduced-alcohol wine c. wine-like drinks and mixed drinks, including those in processed form, with a wine-like product content of at least 50%. d. alcohol products subject to alcohol tax (beverages with alcopops tax with mandatory deposit!) e. other mixed drinks containing alcohol with an alcohol content of at least 15%. f. Fruit juices and vegetable juices g. fruit nectars without carbonic acid and vegetable nectars without carbonic acid <p>In addition, the regulation applies to all beverage cans.</p> <p>Sales are permitted until 01.07.2022. After that, beverage containers subject to a deposit may no longer be sold to the end consumer without a deposit.</p> <p>From 01.01.2024, the deposit obligation will be extended again to one-way plastic beverage bottles with</p> <ul style="list-style-type: none"> a. Milk and mixed milk drinks with a milk content of at least 50%. b. other drinkable milk products. 	VerpackG	§ 31, 38 Abs. 7
50951	<p>From January 1, 2023, a reusable alternative for single-use plastic food packaging and single-use beverage cups must also be made available to the end customer if, in each case, the single-use solution is only filled with goods at the final distributor. The end consumer must be informed of the option.</p>	VerpackG	§ 33 VerpackG
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

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Packaging (also wooden packing)**

Article No.:

Products produced out of any material to contain, protect, operate, deliver or offer merchandise.
Packagings include sales-, re-, and transport packagings (acc. VerpackV).

req. no.	Statutory requirement	Law	Article
50952	<p>From 03.07.2024, beverage containers with a capacity of up to three litres, including their caps and lids, must be designed in such a way that the caps and lids are firmly attached to the container during the period of use.</p> <p>The following shall not be included</p> <p>(a) Glass or metal beverage containers with caps or lids made of plastic;</p> <p>(b) Metal beverage containers in which only the seals on the lid or caps are made of plastic;</p> <p>(c) beverage containers intended for and used for liquid foods for special medical purposes as defined in Article 2(g) of Regulation (EU) No 609/2013 of the European Parliament and of the Council.</p>	EWKKennzV	§ 3 EWKKennzV
50959	For 2025, at least 25% recyclates must be used in single-use plastic beverage bottles made predominantly of PET. Recyclate use must be 30% for all single-use plastic beverage bottles from 2030.	VerpackG	§ 30a
50958	Final distributors where the single-use plastic food packaging and single-use plastic beverage cups are filled with goods on site must provide a reusable alternative for this in addition to the single-use packaging from 01.01.2023 onwards. Relief applies to small businesses with no more than five employees and to vending machines. Here, containers brought by the end consumer can be used if information boards inform the end consumer of this at the point of sale.	VerpackG	§§ 33, 34
50491	<p>Whoever manufactures, treats and puts, with a label regarding the treatment, wood packaging according to the international standard for wooden packaging material into circulation, must be registered with the authority responsible and label the wood packaging.</p> <p>Appropriate records must be kept and retained for three years.</p>	PfIBeschauV 1989	§13p und 13q
160069	Articles or substances must not be placed on the market as consumer goods if their intended or predictable use is likely to impair health by virtue of their material composition, e.g. through toxic substances or impurities.	LFGB	§30
5321	<p>Manufacturers are required to register before placing the packaging on the market.</p> <p>https://www.verpackungsregister.org</p> <p>https://lucid.verpackungsregister.org</p>	VerpackG	§ 9
5320	All packaging which accumulates in private households must be licensed by a Dual System.	VerpackG	§ 7
3051	<p>Plastic bags with an aperture volume larger as 38 cm have to be marked with following bilingual warning label:</p> <p>"Plastiktüte ist kein Spielzeug. Von Kindern fernhalten. Erstickungsgefahr !"</p> <p>"Plastic bag is not a toy. Keep out of reach of children. Danger of suffocation !"</p>	QS	Unternehmensint ern



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Packaging (also wooden packing)**

Article No.:

Products produced out of any material to contain, protect, operate, deliver or offer merchandise.
Packagings include sales-, re-, and transport packagings (acc. VerpackV).

req. no.	Statutory requirement	Law	Article
2655	Packaging must not exceed the defined concentrations value of - Lead - Cadmium - Mercury - Chromium VI: 100 ppm This applies to transport, re-packaging and sales packaging.	VerpackG	§ 5

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Packaging for filling goods containing
dangerous materials**

Article No.:

Packaging for 1. products which are subject to self-service prohibition (products which are to be identified as being toxic, very toxic, corrosive, oxidizing or highly inflammable or products which are to be identified as being harmful, as long as they are to be identified by R 40 (possible risks of irreversible effects), R 62 (possible risk of impaired fertility) or R 63 (possible risk of harm to the unborn child).

req. no.	Statutory requirement	Law	Article
2654	Sales packaging of pollutant-containing filling goods must be taken back free of charge and must be disposed separate from the public waste disposal. Consumers are to be informed correspondingly.	VerpackG	§ 3, 15 i.V.m. Anlage 2
50939	Plastic carrier bags with a wall thickness of less than 50 micrometres will be banned in Germany from 2022 without any further sales opportunities. Not affected by the ban are very light plastic carrier bags with a wall thickness of less than 15 micrometres.	VerpackG	§ 5
5320	All packaging which accumulates in private households must be licensed by a Dual System.	VerpackG	§ 7
5321	Manufacturers are required to register before placing the packaging on the market. https://www.verpackungsregister.org https://lucid.verpackungsregister.org	VerpackG	§ 9
50956	From 01.01.2022, distributors and manufacturers of system-incompatible sales and secondary packaging as well as sales packaging of pollutant-containing filling goods must comply with their obligation to provide evidence that they have fulfilled the take-back and recovery requirements. In addition, self-monitoring mechanisms must be introduced for transport packaging, sales and secondary packaging not subject to system participation, system-incompatible sales and secondary packaging and sales packaging of hazardous filling goods in order to be able to maintain the take-back and recovery requirements.	VerpackG	§ 15
2655	Packaging must not exceed the defined concentrations value of - Lead - Cadmium - Mercury - Chromium VI: 100 ppm This applies to transport, re-packaging and sales packaging.	VerpackG	§ 5
11345	Requirements for the Information of the filling quantity for prepackages with photochemical products and with chemical and technical standard materials and reagent materials with the same nominal filling quantity: - Instead of the nominal filling quantity, the volume of the ready-to-use preparation or the number of applications or examinations may be stated.	FPackV	§ 6 Abs. 6



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

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. 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". 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: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Batteries/Accumulator

Article No.:

Sources of electrical energy consisting out of one or more non rechargeable primary cells or rechargeable secondary cells, which are produced through/by direct transformation of chemical energy.

req. no.	Statutory requirement	Law	Article
656	Producer and importers of batteries have to re-accept collected batteries free of charge and re-use them resp. have to dispose non-reusable batteries according to the regulations. For the fulfilment of these obligations, they can also use the services of third parties(contribution in pool).	BattG	§ 5
50044	Batteries with lithium metal or lithium alloy (maximal 2 g lithium, with lithium ions (maximal a stated energy in watthours of 100 watthours) must be labelled on the casing with the stated energy in watt-hours. The manufacturere/supplier must supply a safety data sheet or a technical data sheet. In particular it must be clear from the documantation that the tests according to UN-manual (III.38.3) were passed.	ADR	
3044	The sale and trading of batteries (including such installed in appliances) containing more than 0.0005 % mercury by weight is prohibited. Button cells: The marketing of button cells containing more than 0.0005 percent by weight of mercury, is prohibited.	BattG	§ 3
50112	It is prohibited to put batteries for equipment into circulation which contain more cadmium than 0.002 per cent by weight . This prohibition does not apply to nickel-cadmium batteries which are deployed in the following systems or equipment: emergency and alarm systems; emergency lighting; medical equipment (medical products);	BattG	§ 3 Abs. 2
658	All Batteries must be labelled according to Annex 1 (struck through waste bin). Batteries containing hazard substances (if exceptions are made) must labelled as well with the chemical symbols (Cd, Hg or Pb) if the shares of the heavy metals exceed the following values: 0.0005 mass per cent mercury; 0.0002 mass per cent cadmium; 0.004 mass per cent lead Additional information: Anlage BattG_21-05	BattG	§ 17
50269	rechargeable batteries and accumulators for devices (including automobile batteries) must be labelled with a charge label. This does not apply to such batteries and accumulators which are built into a device and which cannot or should not be removed, Additional information: VO (EU) 1103/2010 de_10-11 VO (EU) 1103/2010 en_10-11	VO (EU) Nr. 1103/2010	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Batteries/Accumulator**

Article No.:

Sources of electrical energy consisting out of one or more non rechargeable primary cells or rechargeable secondary cells, which are produced through/by direct transformation of chemical energy.

req. no.	Statutory requirement	Law	Article
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	

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Biocides and treated articles**

Article No.:

req. no.	Statutory requirement	Law	Article
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	
50802	For biocidal products and treated articles the requirements of Regulation (EU) No. 528/2012 shall apply. Exceptions are to be observed. (e.g. Pesticides, cosmetics, pharmaceuticals, toys,..) Additional information: RE (EU) No 528/2012 21-11 VO (EU) Nr. 528/2012 21-11	VO (EU) Nr. 528/2012	Art. 2
50549	For non-food products and textiles which have been treated with biocides, the safety data sheets or a list with the biocides used are to be delivered. Should a licence number be available (inside EU) then this is equally to be communicated.	VO (EU) Nr. 528/2012	Art. 58, Abs. 1
50774	Where biocidal products are from the EU, the respective registration of the country of origin shall apply. Where products are from third countries, the importer must apply for registration.	VO (EU) Nr. 528/2012	Art. 17
50776	Manufacturers, importers of biocidal products that contain existing active substances do not have to approve these products. Instead, the products must be reported to the Federal Institute for Occupational Safety and Health (BAuA). This applies as long as no decision on approval or non-approval has been made for existing active substances (Annex II of Regulation (EU) No. 1062/2014). The report can be made online via the following page: https://www.baua.de/DE/Biozid-Meldeverordnung/startseite.html Additional information: Liste Altwirkstoffe 21-11	ChemBiozidDV	§ 4
50806	Biocidal products may only be made available on the market if either the substance supplier or the product supplier is included in the list of active substance suppliers. This also applies for biocidal products that are marketed during the transitional period in Germany. Pls. see Link below for the list: https://www.reach-clp-biozid-helpdesk.de/de/Biozide/Wirkstoffe/Genehmigte-Wirkstoffe/Genehmigte-Wirkstoffe.html	VO (EU) Nr. 528/2012	Art. 95, Abs. 2



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Electric devices, battery or mains operated

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
605	For electrical appliances, the mechanical stability of the plastic housing must correspond to the requirements of DIN EN 60335-1.	DIN EN 60335-1	DIN EN 60335-1 i.V.m. § 3 GSG
150449	From 1.1.2022: Each producer shall provide electrical and electronic equipment containing a battery or accumulator with information informing the end-user about 1. the type and chemical system of the battery or accumulator; and 2. its safe removal. This does not apply to EEE in which an uninterrupted power supply is necessary for reasons of safety, performance, medical reasons or completeness of data and where a permanent connection between the equipment and the battery or accumulator is required.	ElektroG	§ 4 Abs. 3, 4
672	Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight. (brazing shall mean a joining technique using alloys and undertaken at temperatures above 450 °C.) By way of derogation, above restriction shall not apply to brazing fillers used for safety reasons.	VO (EG) Nr. 1907/2006	Anhang XVII



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
917	<p>Electrical equipment designed for use with a voltage rating of between 50 and 1.000 V for alternating current and between 75 and 1.500 V for direct current made available on the Union market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Union, it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made.</p> <p>The principal elements of the safety objectives are listed in Annex I of the DIRECTIVE 2014/35/EU.</p> <p>When placing their electrical equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the safety objectives referred to in Article 3 and set out in Annex I.</p> <p>Manufacturers shall draw up the technical documentation referred to in Annex III and carry out the conformity assessment procedure referred to in Annex III or have it carried out.</p> <p>Where compliance of electrical equipment with the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated by the conformity assessment procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.</p> <p>Manufacturers shall keep the technical documentation referred to in Annex III and the EU declaration of conformity for 10 years after the electrical equipment has been placed on the market.</p> <p>Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in product design or characteristics and changes in the harmonised standards referred to in Article 12, the international or national standards referred to in Articles 13 and 14, or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.</p> <p>When deemed appropriate with regard to the risks presented by electrical equipment, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of electrical equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming electrical equipment and electrical equipment recalls, and shall keep distributors informed of any such monitoring.</p> <p>Manufacturers shall ensure that electrical equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the electrical equipment does not allow it, that the required information is provided on its packaging or in a document accompanying the electrical equipment.</p> <p>Manufacturers shall indicate on the electrical equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.</p> <p>Manufacturers shall ensure that the electrical equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.</p> <p>Manufacturers who consider or have reason to believe that electrical equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.</p> <p>Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the electrical equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have placed on the market.</p> <p>Manufacturers shall, on request, identify the following to the market surveillance authorities:</p> <p>(a) any economic operator who has supplied them with electrical equipment;</p> <p>(b) any economic operator to whom they have supplied electrical equipment.</p> <p>Manufacturers shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the electrical equipment and for 10 years after they have supplied the electrical equipment.</p> <p>Note: The requirements of DIRECTIVE 2014/35/EU must be adhered to as of 20. April 2016.</p> <p>Additional information: DIR. 2014-35-EU_15-11 Draft Guidance LVD_16-05 Risk Assessment and Risk Reduction CENELECGuide32 RL 2014-35-EU_15-11</p>	1. ProdSV	§ 1, 3, 7, 8, 14, 21

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
3070	Surfaces of handles, knobs, grips and similar components, which are held permanently when used !properly! and are fitted to electrical appliances, must not exceed the following temperature increases: made of metal: 30 K made of porcelain or glass materials: 40 K made of plastic-, rubber-materials or wood: 50 K	DIN EN 60335-1	
3071	Surfaces of handles, knobs, grips and similar components, which are held only for a !short time! when used properly and are fitted to electrical appliances, must not exceed the following temperature increases: made of metal: 35 K made of porcelain or glass materials: 45 K made of plastic-, rubber-materials or wood: 60 K	DIN EN 60335-1	
5078	The relevant harmonized standards of the low-voltage directive must be observed. Probability of conformity = the manufacturer can assume that if these standards are correctly applied, the requirements of the directive will be fulfilled. The standards are given under: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en	Normenverz. 1. ProdSV	Abschnitt 1
5110	Every manufacturer (importer) or authorised representative must quote his registration number in written business dealings.	ElektroG	§ 6 Abs.3
5111	Every manufacturer (importer) or authorised representative is obliged to collect and recycle the WEEE handed in to the public waste management authorities. They may use third parties for this purpose.	ElektroG	§ 16 Abs. 1, § 43

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
5113	<p>It is forbidden to place on the market new electrical and electronic equipment (alternating current not exceeding 1000 V, direct current of not more than 1500 V) exceeding 0,1% by weight:</p> <p>a) lead, b) mercury, c) hexavalent chromium, d) polybrominated biphenyl (PBB), e) polybrominated diphenyl ethers (PBDE), f) di (2-ethylhexyl) phthalate (DEHP), g) butyl benzyl phthalate (BBP), h) dibutyl phthalate (DBP), i) diisobutyl phthalate (DIBP),</p> <p>per homogeneous material or more than 0.01% by weight of cadmium per homogeneous material.</p> <p>The above prohibited substances a) -e) apply to the following electrical and electronic</p> <p>The prohibition of substances (f) - (h) shall not apply to toys which are already subject to restrictions under Annex XVII.</p> <p>Exceptions to the prohibition of substances shall be observed in accordance with the current state of the annexes to Directive 2011/65 / EU and the Regulation.</p> <p>Additional information: Dir 2011/65/EU_20-11 RL 2011/65/EU_20-11</p>	ElektroStoffV	§ 3 Abs. 1, § 15
5137	Plugs and sockets for domestic use must fulfill the requirements of Norm DIN VDE 0620-1.	DIN VDE 0620-1	
5181	All electrical appliances for household and similar purposes must fulfill the requirements of DIN EN 60335-1 regarding appliance safety.	DIN EN 60335-1	
5337	Electrical devices, must be constructed according to the technical state of the art and may not interfere with other devices electromagnetically nor may they be susceptible to electromagnetic interference	EMVG	§ 4



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
5339	<p>Any equipment or finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance shall meet the essential requirements set out in Annex I of the Directive 2014/30EU.</p> <p>When placing their apparatus on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.</p> <p>Manufacturers shall draw up the technical documentation referred to in Annex II or Annex III and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out. Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.</p> <p>Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market.</p> <p>Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in apparatus design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.</p> <p>Manufacturers shall ensure that apparatus which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is provided on the packaging or in a document accompanying the apparatus.</p> <p>Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.</p> <p>Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18 in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.</p> <p>Manufacturers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate.</p> <p>Furthermore, where the apparatus presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.</p> <p>Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the apparatus with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.</p> <p>Manufacturers shall, on request, identify the following to the market surveillance authorities:</p> <p>(a) any economic operator who has supplied them with apparatus;</p> <p>(b) any economic operator to whom they have supplied apparatus.</p> <p>Manufacturers shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the electrical equipment and for 10 years after they have supplied the electrical equipment.</p> <p>Additional information: Dir 2014/30/EU_20-05 RL 2014/30/EU_20-05</p>	RL 2014/30/EU	Art. 6,7,12

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
5340	All electrical equipment must be permanently fitted with the CE mark.	EMVG	§ 18
5341	Every electrical device must be labelled with the type/model mark, the type series, the serial number or be marked with other information to enable the assignment of the device to an EC declaration of conformity and the batch.	EMVG	§ 9
5342	Every electrical device must be labelled with the name and address of the manufacturer. If the manufacturer is from a third country it must be labelled with the name and address of the importer.	EMVG	§ 9



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
50024	<p>For household appliances (eg white goods, kitchen appliances, appliances for personal care products), consumer electronics, electrical toys, leisure and sports equipment, binding power consumption limits apply.</p> <p>From 7th Jan. 2010:</p> <ul style="list-style-type: none"> - Power consumption in off-mode: max. 1.00 Watt - Power consumption in standby mode: Reactivation function max. 1.00 watts; Reactivation function with a progress bar and / or information max. 2.00 watts, - Availability of the standby or hibernation function: The network-connected devices across the Standby or off condition, or other condition can be moved without the applicable Consumption limits are exceeded. <p>From 7th Jan. 2013:</p> <ul style="list-style-type: none"> - Power consumption in off-mode: max. 0.50 Watt - Power consumption in standby mode: Reactivation function max. 0.50 watts; Reactivation function with a progress bar and / or information max. 1.00 watts, - Availability of the standby or hibernation function: The network-connected devices across the Standby or off condition, or other condition can be moved without the applicable Consumption limits are exceeded, - The network-connected devices must be automatically and in a very short time (according to the intended use) put in one of the following states: <ul style="list-style-type: none"> - readiness - off-state - in a different state, with the consumption values not be exceeded, - The power management function shall be enabled at the factory. <p>As of 1 January 2015:</p> <ul style="list-style-type: none"> - Ability to disable the wireless network connections - Power management function for networked devices - Power consumption in standby mode: HiNA devices max. 12.00 watts; Other connected devices max 6.00 W <p>This does not apply to: i) printer with a power supply, the rated power is 750 W; ii) large format printer; iii) telepresence systems; iv) desktop thin clients; v) workstations; vi) mobile workstations; vii) Small-Scale Server; viii) computer server.</p> <p>As of 1 January 2015 (only for Coffeemakers) :</p> <ul style="list-style-type: none"> - For filter - home coffee machines where the coffee in an insulated Container is kept , a waiting period of no more than five shall Minutes after the last brew cycle or 30 minutes after completion of descaling or self- cleaning process ; - Filter for home coffee machines where the coffee is not in a insulated container is kept , a waiting period of up to 40 applies Minutes after the last brew cycle or 30 minutes after completion of descaling or self- cleaning process ; - For domestic coffee machines , with the exception of filter coffee machines subject to a waiting period of no more than 30 minutes after the last Brewing cycle , a maximum of 30 minutes after the activation of the heating element ,maximum of 60 minutes after activation of the preheat cups function and a maximum of 30 minutes after a Descaling or self- cleaning process , except when an alarm is triggered was that requires user intervention to damage or to prevent an accident . <p>As of 1 January 2017:</p> <ul style="list-style-type: none"> - In networked devices that have one or more standby modes must meet the requirements of this standby / standby modes this be met if all wired network ports by Separated network and all wireless network ports are disabled. - Networked devices (except HiNA devices) must automatically and in a very short time (according to the intended use) put in one of the following states: <ul style="list-style-type: none"> - readiness - off-state - in a different state, with the consumption values not be exceeded, - The power management function shall be enabled at the factory. - Power consumption in standby mode: HiNA devices max. 8.00 watts; Other connected devices max 3:00 W <p>This does not apply to: i) large format printers; ii) desktop thin clients; iii) workstations; iv) mobile workstations; v) Small-Scale Server; vi) computer server.</p> <p>As of 1 January 2019:</p> <ul style="list-style-type: none"> - Power consumption in standby mode: Other connected devices (except HiNA devices) max 2.00 W <p>In addition, from 1 January 2015 :</p> <p>following information on free-access websites of manufacturers specify for networked devices :</p> <p>a) for each of the standby and / or the off-state and for the state of the networked standby mode , in which the device is set using the power management function or a similar function :</p> <ul style="list-style-type: none"> - The power consumption data in Watts rounded to one decimal place , - The time period after which the device using the power management function or a similar function is automatically ready and / or the off-state and / or a state of the standby mode set in the cross-linked ; b) the power consumption of the product in the networked standby mode , when all wired network ports connected to the network and all wireless network ports activated; c) information on the activation and deactivation of wireless network ports. <p>The power consumption of the product in the networked standby mode are also indicated in the User 's Guide.</p> <p>This Regulation shall not apply to devices that are placed on the market with a low voltage external power supply.</p> <p>Additional information: CE (EG) No. 1275/2008 codesign electrical and electronic household equipment Annex I-II_13-11.pdf VO (EG) Nr. 1275/2008 Ökodesign elektrische und elektronische Haushalts-Bürogeräte Anhang I-II_13-11</p>	VO (EG) Nr. 1275/2008	Artikel 3, 8 i.V.m.Anhang I, II

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
50025	For household equipment (e.g. White goods, kitchen machines, equipment for body care), electronic entertainment equipment, electrical toys, spare-time or sports equipment, the technical documentation regarding electricity consumption and features affecting or relevant to the environment are to be available for the declaration of conformity Additional information: CE (EG) No. 1275/2008 ecodesign electrical and electronic household equipment Annex I_13-11.pdf VO (EG) Nr.1275-2008 Ökodesign Haushalts- Bürogeräte Anhang II_13-11.pdf	VO (EG) Nr. 1275/2008	Artikel 4 i.V.mit Anhang II
50192	Electric household appliances are to be tested for safety analogue standards DIN EN 60335-ff, in particular also for possible wrong applications and the labelling.	Normenreihe DIN EN 60335-ff	
818	Manufacturers and importers who distribute household devices which are obliged to be labelled, have to provide the trade with labels and data sheets free of charge in German language. The following household items have to be marked with respect to energy consumption, in so far as they cannot also be operated by battery: -Electric household refrigerators and freezers and corresponding combination devices -Electric household washing machines apart from machines without a spin-drying facility and apart from machines with separate washing and spin-drying vessels -electric household washing driers -electric automatic combined household wash/driers -electric household dishwashers, - electric ovens, - household lamps, - room air conditioning units, - ventilators, - television sets - vacuum cleaner - space heaters - water heaters - computer Labels and data sheets must correspond to the regulations of the relevant EC directives	EnVKV	§ 3
824	For household devices with compulsory marking, the supplier must draw up technical documentation which is to be available for a period of five years after the end of production. The supplier is the manufacturer within the EC or the person who markets the appliance.	EnVKV	§ 6
825	Brands, symbols, wordings or other labels which can lead the end consumer to confusion with the label required may not be used.	EnVKV	§ 7

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
50639	<p>Cable with a rated voltage of less than 250 V, which serves as a connection or extension cable for the connection of an electrical or electronic device to a socket or for the connection of two or more electrical or electronic devices, must not exceed 0.1% by weight:</p> <p>a) lead, b) mercury, c) hexavalent chromium, d) polybrominated biphenyl (PBB), e) polybrominated diphenyl ethers (PBDE), f) di (2-ethylhexyl) phthalate (DEHP), g) butyl benzyl phthalate (BBP), h) dibutyl phthalate (DBP), i) diisobutyl phthalate (DIBP),</p> <p>per homogeneous material or more than 0.01% by weight of cadmium per homogeneous material.</p> <p>The prohibited substances a) - e) do not apply to cables from:</p> <ol style="list-style-type: none"> 1. Electrical and electronic equipment which has been placed on the market until 30 June 2006, 2. medical devices placed on the market until the end of 21 July 2014, 3. In vitro diagnostic medical devices placed on the market until the end of 21 July 2016, 4. Surveillance and control instruments placed on the market until the end of 21 July 2014, 5. industrial monitoring and control instruments placed on the market until the end of 21 July 2017, 6. Electrical and electronic equipment, in so far as it is an exception to Directive 2002/95 / EC (see also applicable dossier). <p>The substance prohibitions f) - i) do not apply to cables from:</p> <ol style="list-style-type: none"> 1. household appliances, household appliances, information and telecommunication equipment, consumer electronics, lighting equipment, electrical and electronic tools, toys and sports and recreation equipment and automatic dispensers marketed until 21 July 2019; 2. medical devices, including in vitro diagnostic medical devices and monitoring and control instruments, including industrial monitoring and control devices placed on the market until 21 July 2021. <p>Exceptions to the prohibition of substances shall be observed in accordance with the current state of the annexes to Directive 2011/65 / EU and the Regulation.</p> <p>Additional information: DIR 2002-95-EC RoHs_13-04 RL 2002-95-EG RoHs_13-04</p>	ElektroStoffV	§ 3 Abs. 1, § 15

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
50640	<p>Spare parts for electrical or electronic equipment may not contain more than 0.1% by weight</p> <p>a) lead, b) mercury, c) hexavalent chromium, d) polybrominated biphenyl (PBB), e) polybrominated diphenyl ethers (PBDE), f) di (2-ethylhexyl) phthalate (DEHP), g) butyl benzyl phthalate (BBP), h) dibutyl phthalate (DBP), i) diisobutyl phthalate (DIBP)</p> <p>per homogeneous material or more than 0.01% by weight of cadmium per homogeneous material.</p> <p>The prohibited substances a) -e) do not apply to spare parts of:</p> <ol style="list-style-type: none"> 1. Electrical and electronic equipment which has been placed on the market until 30 June 2006, 2. medical devices placed on the market until the end of 21 July 2014, 3. In vitro diagnostic medical devices placed on the market until the end of 21 July 2016, 4. Surveillance and control instruments placed on the market until the end of 21 July 2014, 5. industrial monitoring and control instruments placed on the market until the end of 21 July 2017, 6. Electrical and electronic equipment, in so far as it is an exception to Directive 2002/95 / EC (see also applicable dossier). <p>The substance prohibitions f) - i) do not apply to spare parts of:</p> <ol style="list-style-type: none"> 1. household appliances, household appliances, information and telecommunication equipment, consumer electronics, lighting equipment, electrical and electronic tools, toys and sports and recreation equipment and automatic dispensers marketed until 21 July 2019; 2. medical devices, including in vitro diagnostic medical devices and monitoring and control instruments, including industrial monitoring and control devices placed on the market until 21 July 2021. <p>Electrical and electronic equipment placed on the market until the end of 30 June 2006 and used in equipment placed on the market until 30 June 2016. In these parts, it must be made clear to the consumers that these parts have been recycled.</p> <p>Exceptions to the prohibition of substances shall be observed in accordance with the current state of the annexes to Directive 2011/65 / EU and the Regulation.</p> <p>Additional information: DIR 2002-95-EC RoHs_13-04 RL 2002-95-EG RoHs_13-04</p>	ElektroStoffV	§ 3 Abs. 1, § 15



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Electric devices, battery or mains operated**

Article No.:

All products that are mains-operated and/or are battery/accumulator driven. Included are also installation materials and e.g. dimmers, mains testing screwdrivers etc.

req. no.	Statutory requirement	Law	Article
50641	<p>The manufacturer shall provide the following documents available for electrical and electronic equipment with a rated voltage not exceeding 1000 V AC and 1500 V DC:</p> <p>a) Technical documentation b) demonstrate compliance with the appropriate procedures of conformity c) demonstrate internal production controls, d) a regularly updated Declaration of Conformity with the following information to create:</p> <ol style="list-style-type: none"> 1. Unique identification of electrical and electronic equipment; 2. Name and address of the manufacturer or his authorized representative; 3. The sole responsibility for issuing this declaration carries the manufacturer (or installer); 4. Identification of the electrical / electronic device for traceability, possibly with photo; 5. The object of the declaration described above is in conformity with the provisions of regulation restricting the use of certain hazardous substances in electrical and electronic equipment (electrical and electronic equipment Substances Ordinance); 6. If necessary. References to the relevant harmonized standards have been applied, or the technical specification. Specifications, to which conformity is declared, 7. Additional information; 8. Signature, place and date of issue. <p>The records are kept for 10 years from the placing of the last piece of an electrical or electronic device series.</p> <p>Above requirements apply to importers and distributors to own brands and with changes already placed on the market on the electrical or electronic device, if the requirements of the regulation are impaired.</p> <p>The documents must be written in German or English and if necessary to make available to the authorities.</p>	ElektroStoffV	§ 4, § 9, § 11

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Dangerous substances according to GHS (CLP)**

Article No.:

req. no.	Statutory requirement	Law	Article
50084	Producers of dangerous substances must fulfill the requirements of the Regulation (EC) No. 1272/2008. Included herein: - assessment of materials and mixtures ; - documentation which has led to the discovery of the assessment and labelling of the dangerous substances; - safety data sheet; - secure packaging; - labelling of the packaging. Additional information: RE (EG) No 1272/2008_21-05 VO (EG) Nr. 1272/2008_21-05	VO (EG) Nr.1272/2008	
50671	Prohibitions and restrictions for persistent organic pollutants are to be observed (POP-Regulation). Additional information: RE (EU) 2019/1021_21-05 VO (EU) 2019/1021_21-05	VO (EU) 2019/1021	
933	Packaging of dangerous materials or preparations is to be fitted with child-proof locks if they are classified: - classified for acute toxicity, categories 1 to 3, STOT - single exposure category 1, STOT - repeated exposure category 1, or skin corrosion category 1, and/or contain - more than 3% methanol, and/or - more than 1% dichloromethane, and/or - containing a substance or mixture with an aspiration hazard (with the exception of substances and mixtures placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment).	VO (EG) Nr.1272/2008	Artikel 35 i.V.m. Anh. II
50794	Packaging of dangerous materials or preparations is to be fitted with a tactile warning if they are classified: - for acute toxicity, skin corrosion, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory sensitisation, or Stot, categories 1 and 2, aspiration hazard, or flammable gases, liquids and solids in categories 1 and 2. This provision does not apply to aerosols which are only classified and labelled as 'flammable aerosols, Category 1' or 'flammable aerosols, Category 2'. It does not apply either to transportable gas receptacles.	VO (EG) Nr.1272/2008	Artikel 35 i.V.m. Anh. II

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Dangerous substances according to GHS (CLP)**

Article No.:

req. no.	Statutory requirement	Law	Article
50830	<p>Annex VIII of the CLP Regulation will provide harmonized information for emergency health and preventive measures:</p> <ul style="list-style-type: none"> - Notification requires mixtures that have been classified as dangerous due to their health or physical effects. - The notification obligation does not apply to mixtures for research and development as well as mixtures classified as gases under pressure or as explosive. - A unique formula identifier (UFI) must appear on the label. - Include information on the name of the mixture and on the identification of the transmitter, the hazard labeling and the components of the mixture, including non-classified components. Concerning the concentration of mixture components, exact percentages or concentration ranges can be given. - Communications must be made electronically in an XML format prepared by the European Chemicals Agency (ECHA) and made available free of charge. ECHA is also developing a pan-European product categorization system to be used in the communication. - Notifications that have been submitted before the date of application and do not comply with the new requirements remain valid until 01.01.2025, unless there are significant changes in the formulation, the product identifier or the toxicology of the mixture. <p>The application of the new information requirements is staggered for importers and downstream users:</p> <ul style="list-style-type: none"> - for mixtures for consumer use - for mixtures for professional use - 01.01.2024 for mixtures for industrial use <p>Additional information: RE (EG) No 1272/2008 Annex VIII_20-11 VO (EG) Nr. 1272/2008 Anhang VIII_20-11</p>	VO (EG) Nr.1272/2008	Anhang VIII

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Dangerous materials**

Article No.:

The dangerous materials include all products which are explosive, oxidizing, highly or extremely inflammable, inflammable, very toxic, toxic, harmful, corrosive, irritant, sensitising, cancerogenic, endangering to reproduction, heredity-altering or dangerous for the environment, possess other chronic damaging properties, are explosive or can transfer infectious germs.

req. no.	Statutory requirement	Law	Article
828	It has to be guaranteed, that dangerous substances are marked correctly	GefStoffV	§ 4
850	Suppliers must enclose safety data sheets for dangerous products. In so far as the products are passed on to commercial purchasers, the safety data sheets must be transmitted to the purchasers at the latest with the first delivery.	GefStoffV	§5 (1)
2602	Substances which are carcinogenic, mutagenic or toxic to reproduction must not be placed on the market.	ChemVerbotsV	
2643	Draw attention to dangerous features of materials in the product description.	GefStoffV	
5009	Biocidal products have to be labelled according to the Gefahrstoff-VO [Dangerous Chemicals Ordinance] where dangerous substances are contained.	BiozidGz	§ 15
50671	Prohibitions and restrictions for persistent organic pollutants are to be observed (POP-Regulation). Additional information: RE (EU) 2019/1021_21-05 VO (EU) 2019/1021_21-05	VO (EU) 2019/1021	
933	Packaging of dangerous materials or preparations is to be fitted with child-proof locks if they are classified: - classified for acute toxicity, categories 1 to 3, STOT - single exposure category 1, STOT - repeated exposure category 1, or skin corrosion category 1, and/or contain - more than 3% methanol, and/or - more than 1% dichloromethane, and/or - containing a substance or mixture with an aspiration hazard (with the exception of substances and mixtures placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment).	VO (EG) Nr.1272/2008	Artikel 35 i.V.m. Anh. II
50794	Packaging of dangerous materials or preparations is to be fitted with a tactile warning if they are classified: - for acute toxicity, skin corrosion, germ cell mutagenicity category 2, carcinogenicity category 2, reproductive toxicity category 2, respiratory sensitisation, or Stot, categories 1 and 2, aspiration hazard, or flammable gases, liquids and solids in categories 1 and 2. This provision does not apply to aerosols which are only classified and labelled as 'flammable aerosols, Category 1' or 'flammable aerosols, Category 2'. It does not apply either to transportable gas receptacles.	VO (EG) Nr.1272/2008	Artikel 35 i.V.m. Anh. II



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Personal hygiene products

Article No.:

req. no.	Statutory requirement	Law	Article
50049	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; -wall and floor coverings; - baby articles; ladies hygiene products;- nappies/diapers; -packaging;-two-part room temperature vulcanisation form sets (RTV-2- form sets)	VO (EG) Nr. 1907/2006	Anhang XVII
50273	For all hygiene articles the requirements and prohibitions of the household article regulations are to be taken into account.	BedGgstV	
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
50940	<p>Certain single-use plastic articles and products made of oxo-degradable plastic are banned.</p> <p>These include in particular</p> <ul style="list-style-type: none"> - cotton buds sticks, - cutlery (forks, knives, spoons, chopsticks), - plates, - straws; - beverage stirrers - sticks to be attached to and to support balloons, including the mechanisms of such sticks - food containers made of styrofoam - beverage containers made of styrofoam, including their caps and lids; and - cups for beverage made of styrofoam, including their covers and lids. 	EWKVerbotsV	§ 3

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Personal hygiene products**

Article No.:

req. no.	Statutory requirement	Law	Article
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
50279	<p>For all colourings (dyes) of sanitary products, the BfR recommendation IX is to be observed.</p> <p>Additional information: BfR IX Colorants 2019-06-01_20-05 BfR IX Farbmittel 2019-06-01_20-05</p>	BfR-Empfehlung	BfR IX
50283	<p>When using polypropylene the BfR recommendations are to be observed.</p> <p>Additional information: BfR VII. Polypropylen 2019-06-01_20-05 BfR VII. Polypropylene 2019-06-01_20-05</p>	BfR-Empfehlung	BfR VII
50284	<p>When using silicones the BfR recommendations XV are to be observed.</p> <p>Additional information: BfR XV. Silicone 2019-06-01_20-05 BfR XV. Silicones 2019-06-01_20-05</p>	BfR-Empfehlung	BfR XV
50285	<p>When using paper, cartons and cardboard the BfR recommendations are to be observed.</p> <p>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</p>	BfR-Empfehlung	BfR XXXVI
50286	<p>When using polyethelene the BfR recommendations are to be observed.</p> <p>Additional information: BfR III. Polyethylen 2019-06-01_20-05 BfR III. Polyethylene 2019-06-01_20-05</p>	BfR-Empfehlung	BfR III

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21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Personal hygiene products**

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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Hygiene Products_Wellness_Health**Personal hygiene products**

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



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Hygiene Products_Wellness_Health

Medical products

Article No.:

req. no.	Statutory requirement	Law	Article
11293	<p>Regulation (EU) 2017/745 applies for medical devices.</p> <p>The following medical devices may continue to be made available on the market until May 27th 2025:</p> <ul style="list-style-type: none"> - medical devices lawfully placed on the market pursuant to the former legislation prior to May 26th 2021 - devices placed on the market from May 26th 2021 by virtue of a certificate issued in accordance with former legislation - devices which are class I and which may be placed on the market from May 26th 2021 pursuant to the former legislation, because pursuant to the new legislation they require a certificate of a notified body. <p>After that, products that do not comply with Regulation (EU) 2017/745 must not be placed on the market.</p>	VO (EU) 2017/745	
90006	<p>Until May 26th 2021: Coloured contact lenses which serve decorative purposes only are consumer goods.</p> <p>From May 26th 2021: Coloured contact lenses which serve decorative purposes only are considered medical devices.</p>	ALS	2019/63 + § 2 Abs. 6 Nr. 6 LFGB + VO (EU) 2017/745 Art 1

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Hygiene Products_Wellness_Health**Medical products**

Article No.:

req. no.	Statutory requirement	Law	Article
5317	<p>Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article to be used for human beings for one or more of the following medical purposes:</p> <ul style="list-style-type: none"> - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations <p>Medical devices do not achieve their principal intended action by pharmacological, immunological or metabolic means, in or on the human body.</p> <p>The following products shall also be deemed to be medical devices:</p> <ul style="list-style-type: none"> - devices for the control or support of conception - products for the cleaning, disinfection or sterilisation of medical devices and accessories thereof. <p>The regulation on medical devices also applies to the following products without an intended medical purpose (listed in Annex XVI of Regulation (EU) 2017/745):</p> <ol style="list-style-type: none"> 1. Contact lenses or other items to be introduced into or onto the eye 2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings. 3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing. 4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty. 5. High intensity electromagnetic radiation (e. g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment. 6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify activity in the brain. <p>Additional information: VO (EU) 2017/745 Anhang XVI_18-11</p>	VO (EU) 2017/745	Artikel 2 Nr. 1 + Anhang XVI

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Hygiene Products_Wellness_Health**Medical products**

Article No.:

req. no.	Statutory requirement	Law	Article
11299	To differentiate between medical devices /in vitro diagnostic medical devices and other products (such as cosmetic products, medicinal products and biocidal products), the "MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES" can be consulted. Additional information: Borderline Medizinprodukte_19-11	Borderline Medizinprodukte	
50846	Medical devices shall comply with RE (EU) 2017/745 and meet the essential requirements set out in Annex I to RE (EU) 2017/745. Additional information: VO (EU) 2017/745 Anhang I_20-05	VO (EU) 2017/745	Artikel 5 Abs. 1, 2 + MPG § 7 Abs. 1
50847	Medical devices shall comply with the relevant following requirements: - the harmonized standards, or the relevant parts of those standards; - the monographs of th European Pharmacopoeia - the common specifications The standards are available under https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/	VO (EU) 2017/745	Artikel 8+9, Normenverz. MPG
50854	Medical devices require an EU declaration of conformity that - contains as a minimum the information set out in Annex IV RE (EU) 2017/745 - and is in German or English language. Where devices are subject to other Union legislation, which also requires an EU declaration of conformity, a single EU declaration of conformity, shall be drawn up in respect of all Union acts applicable to the device. Additional information: VO (EU) 2017/745 Anhang IV_19-11	VO (EU) 2017/745	Artikel 19, Art. 120 Abs. 2 + MPDG § 8 Abs. 1
1587	Medical devices must be identified by the CE symbol according to Annex V to RE (EU) 2017/745. The CE marking - shall be affixed visibly, legibly and indelibly to the device or its sterile packaging; where such affixing is not possible or not warranted, the CE marking shall be affixed to the packaging. - shall also appear in any instructions for use and on any sales packaging. - shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use. - shall be followed, where applicable, by the identification number of the notified body; the identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking. Additional information: VO (EU) 2017/745 Anhang V_19-11	VO (EU) 2017/745	Art. 20

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Hygiene Products_Wellness_Health**Medical products**

Article No.:

req. no.	Statutory requirement	Law	Article
50857	<p>Medical devices are divided into classes I, IIa, IIb and III according to Annex VIII RE (EU) 2017/745.</p> <p>The MDCG Classification Guide can be used as an aid to classification.</p> <p>Additional information: MDCG Leitfaden Klassifizierung 21-11 VO (EU) 2017/745 Anhang VIII_19-11</p>	VO (EU) 2017/745	Art. 51 Abs. 1
50855	<p>Medical devices requires an Unique Device Identification (UDI) and must be registered in the UDI database. UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging shall not be understood to include shipping containers. The UDI carriers are required</p> <ul style="list-style-type: none"> - for class III devices - from 26 May 2023 for class IIa and class IIb devices - from 26 May 2025 for class I devices <p>The UDI carriers are required for reusable devices that shall bear the UDI carrier on the device itself,</p> <ul style="list-style-type: none"> - from 26 May 2023 for class II devices - from 26 May 2025 for class IIa and class IIb devices - from 26 May 2027 for class I devices. 	VO (EU) 2017/745	Art. 27 Abs. 3,4, Art. 123 Abs. 3 f), g)



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 Hygiene Products_Wellness_Health
Measuring instruments (e.g.fever thermometers, manometers, barometers and thermometers for other purposes) Article No.:
 fever thermometers, manometers, barometers and thermometers for other purposes)

req. no.	Statutory requirement	Law	Article
5296	Measuring instruments (fever thermometers, manometers, barometers and thermometers for other purposes) are subject to a mercury prohibition.	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 18a
50484	Measuring instruments for commercial and official use must comply with the essential requirements of the device-specific requirements (EU and national). Additional information: Mess- und Eichgesetz MessEG_15-04 Mess- und Eichverordnung MessEV_15-04 PBT_Regelermittlung_Mess-und Eichgesetz_15-11 Übersicht über Anwendungsbereich und Ausnahmen von MessEG und MessEV_14-11	MessEG	§ 6, Abs. 2
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	
50781	Manufacturer must perform a conformity assessment for measuring instruments for commercial and official use, create technical documents and issue a declaration of conformity. These documents are kept for 10 years from placing on the market. The required mark (CE mark, possibly type approval and others) and inscriptions should appear on the product. The specific instructions for their use (Operating Instructions) be submitted in German language. Furthermore, if necessary, an EC type approval by an approved body, as well as an initial verification must be carried out. Additional information: Kennzeichnung Messgeräte_15-04 Mess- und Eichgesetz MessEG_15-04 Mess- und Eichverordnung MessEV_15-04	MessEG	§ 23, Abs. 1, 2, 3, 4
50782	Manufacturer of measuring instruments for commercial and official use must carry out sampling tests and instruct dealers for quality deficiencies. A register of complaints and recalls is to conduct.	MessEG	§ 23, Abs. 5
50783	If the manufacturer has reasonable grounds to believe that measuring instruments for commercial and official use or other measuring device does not meet the statutory requirements, corrective action must be performed. If this is not possible, the instruments must be recalled. The manufacturer must immediately inform the competent authority, if the product cause dangers.	MessEG	§ 23, Abs. 6

Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Products with food contact**

Article No.:

Includes all products/articles which, during manufacture, treatment, distribution or during consumption can come into contact with food.

Product examples: eating, drinking and cooking crockery, dough presses, packing and packaging paper, wooden sticks/metal pins for, e.g. shashlik, ice bowls for preparing ice, foil for cheese, measuring devices and scales for food, packaging, container for keeping food, wall shelves (mainly for loose food), grills, refrigerators, electric ovens, work boards.

req. no.	Statutory requirement	Law	Article
40974	<p>The migration into or onto food of Bisphenol A ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a specific migration limit of 0,05 mg of BPA per kg of food (mg/kg).</p> <p>By derogation from that, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children.</p> <p>The rules of RE (EU) 10/2011 should apply to compliance testing (see Annex).</p> <p>Additional information: VO (EU) Nr. 10/2011 Anhang III_19-05 VO (EU) Nr. 10/2011 Anhang V_20-11</p>	VO (EU) 2018/213	Art. 2, 3 + VO (EU) Nr. 10/2011
40975	<p>The written declaration shall contain the following information:</p> <ol style="list-style-type: none"> (1) the identity and address of the business operator issuing the declaration of compliance; (2) the identity and address of the business operator which manufactures or imports the coated material or article; (3) the identity of the varnished or coated material or article; (4) the date of the declaration; (5) confirmation that the varnish or coating applied to the material or article meets the restrictions laid down Regulation (EC) No 1935/2004 and Regulation (EU) 2018/213 (6) specifications on the use of the coated material or article, such as: the type or types of food with which it is intended to be put into contact; the time and temperature of treatment and storage in contact with food 	VO (EU) 2018/213	Art. 4
90000	<p>According to the opinion of the German Federal Institute for Risk Assessment (BfR), tableware made of melamine formaldehyde resin is not suitable for contact with hot food and beverages. This applies in particular to tableware to which bamboo fiber has been added as filler ("bambooware"). Moreover, fillers like bamboo and similar substances including corn are not authorised in plastic food contact materials according to the note of the Expert Working Group of the Standing Committee.</p> <p>Additional information: BfR Melamin Formaldehyde Resin 20-05 BfR Melamin-Formaldehyd-Harz 20-05 Mitteilung Bambus_20-11</p>	BfR Melamin- Formaldehyd- Harz	+ Mitteilung Bambus

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req. no.	Statutory requirement	Law	Article
50964	Food contact materials made of textile plastic fibers or parts thereof are subject to Regulation (EU) No. 10/2011. This means, for example, cheesecloths, tea bags and lye cloths made of polyamide and / or polyester fibers.	ALS	2021/16
50965	In the case of food contact materials made of plastic that are intended for multiple use, the migration from the first to the third migration must not increase, even if the specific migration limit value is still observed in the third migration. Otherwise, good manufacturing practice is not considered to have been met.	ALS	2021/17
677	Household items made of ceramics must only emit lead and cadmium up to the permitted tolerance: - Items which cannot be filled up, items which can be filled up with a depth of up to 25 mm: lead 0,8 mg/square decimeter; cadmium 0,07 mg/square decimetre; - Items which can be filled up with a depth of more than 25 mm: Lead 4,0 mg/l, cadmium 0,3/l - Cooking and baking utensils; packaging and storage containers with more than 3 l volume: lead 1,5 ml/l; cadmium 0,1 mg/l.	BedGgstV	§ 8 Abs. 3 iVm Anl. 6 Nr. 2
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
50843	When using Linear Polyurethanes for Paper Coatings the BfR recommendation is to be observed. Additional information: BfR XLI. Linear Polyurethanes for Paper Coatings 1975-01-01_18-05 BfR XLI. Lineare Polyurethane für Papierbeschichtungen 1975-01-01_18-05	BfR-Empfehlung	BfR XLI
50844	When using polyurethanes as extensive adhesive layers in the manufacture of packaging materials (composite materials, mainly laminated films) made of plastic and/or paper and/or aluminium foil the BfR recommendation is to be observed. Additional information: BfR XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials 2010-01-01_18-05 BfR XXVIII. Vernetzte_Polyurethane als Klebeschichten für Lebensmittelverpackungen 2010-01-01_18-05	BfR-Empfehlung	BfR XXVIII

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req. no.	Statutory requirement	Law	Article
50845	When using artificial sausage casings the BfR recommendation is to be observed. Additional information: BfR XLIV. Artificial Sausage Casings 2014-10-01_18-05 BfR XLIV. Kunstdärme 2014-10-01_18-05	BfR-Empfehlung	BfR XLIV
718	For household items, which come into contact with food, only plastic must be used which is permitted according to the Consumer Goods Regulation (enclosure 3). Explanation: In case for the plastic in enclosure SML (specific migration value) or QM (maximum remaining content) values are stated, these tolerances are valid for the permitted plastics. In case it is not very clearly indicated, whether the merchandise is used for food, a label with the symbol 'fork + glas' is necessary If it is not clearly recognisable that the goods are to be used for food, identification with the "fork + glass" symbol is necessary. Additional information: BedGgstV Anlage 3	BedGgstV	§ 7 (1) i.V.m. § 30 LMBG
50826	The declaration of compliance for toy dishes must fulfill requirements for toys as well as for food contact materials.	ALS	2020/18
50827	Statements like "An Lebensmittel abgegebene Aluminiumbestandteile sind jedoch nicht gesundheitsschädlich" on the packaging of aluminium foil are not allowed.	ALS	2015/13
723	Analysis of the Consumer Goods must be done according to the methods laid down in Annex 10 of the regulation concerning consumer goods (BedGgstV). Additional information: Bedarfsgegenständeverordnung_17-05.pdf	BedGgstV	§ 11 + Anlage 10
3032	Products made of vinyl chloride polymers (e.g. PVC) must not transferred more than 0,01 mg monomer vinyl chloride into 1 kg foodstuff.	BedGgstV	§ 8 Abs. 3 iVm Anl. 6 Nr. 1
3065	For food contact materials of plastic (plastic containers for holding foodstuffs, foil, bags for deep-freeze foods, cling film) only defined materials (monomers, additives, auxiliary materials / adjuvants) which are listed in Annex I of RE (EC) No 10/2011 may be deployed. Deviating from this, materials in Annex 13 may be deployed.	BedGgstV	Artikel 1, § 4 Abs. 2, Abs.3, Anlage 3
3066	Specified migration values for the requisites must not be exceeded.	BedGgstV	§ 6, Nr. 2, Anlage 3
3068	As from 1st January 2005 metal tins (oil sardines) and food requisites with a surface coating must not incorporate a coating with novolac glycidyl ether (NOGE), or find any use for this	BedGgstV	Anlage 3, Abschnitt 3

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req. no.	Statutory requirement	Law	Article
5163	For all plastic materials and articles intended to come into contact with food with direct or indirect contact to foodstuffs, as for example: - packaging - household cans - food-grade films - household appliances made of or with synthetic materials (plastics), the following basic principles apply: 1. No endangerment to human health; 2. No misguidance or misleading of the users.	VO (EG) Nr. 1935/2004	Art. 3
5164	For the following groups of materials and objects, which come into contact with foodstuffs, specific measures regarding authorised substances and for purity standards, special conditions of use for substances and migration values may be decreed: 1. Active and intelligent materials and articles 2. Adhesives 3. Ceramics 4. Cork 5. Rubbers 6. Glass 7. Ion-exchange resins 8. Metals and alloys 9. Paper and board 10. plastics 11. Printing inks 12. Regenerated cellulose 13. Silicons 14. Textiles 15. varnishes and coatings 16. Waxes 17. Wood	VO (EG) Nr. 1935/2004	Art. 5 + Anhang I
5165	Food contact materials which have not yet been in contact with foodstuffs must be marked as follows: - name and address of the manufacturer - appropriate marking or identification for traceability - articles which are not obviously suitable for contact with foodstuffs must be marked with the pictogram 'Glass and fork' alternatively with the designation 'For contact with foodstuffs' - if necessary, special instructions to be observed for safe and appropriate use (if understandable pictograms are possible) Additional information: Symbol Glas Gabel_14-04	VO (EG) Nr. 1935/2004	Art. 15 + ALS 2014/05
5166	If individual measures regulate food contact materials, these products may only be released with a written declaration of compliance.	VO (EG) Nr. 1935/2004	Art. 16
5167	The traceability of food contact materials must be ensured at all levels.	VO (EG) Nr. 1935/2004	Art. 17

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req. no.	Statutory requirement	Law	Article
5168	A certificate of conformity in the German language is to be supplied with all ceramic objects which are suitable for contact with foodstuffs. Contents: Name and address of the manufacturer, alternatively the importer (in cases of import into the EU); identity of the product; date of issue of the declaration; confirmation (analysis report) that the product adheres to the requirements (lead, cadmium). A general declaration of compliance (only refers to glaze) is not allowed.	BedGgstV	§ 10 Abs. 2 + ALS 2017/17
5208	The cobalt content of ceramics and/or stoneware may not exceed: - 0,1 mg/l for hollow objects - 0,02 mg/dm ² for flat objects	VO (EG) Nr. 1935/2004	Art. 3 + ALS 2017/15
50932	The BfR recommends that significantly lower release values should be taken into account than the applicable limit values for lead and cadmium in ceramic dishes. The amount released of cobalt should also be kept as low as possible. Additional information: BfR Keramikgeschirr_20-11	BfR Keramikgeschirr	
5213	In plastic food containers, the zinc group migration value may not exceed 25mg/kg.	BedGgstV	§ 8
5356	For materials and articles intended to come into contact with food a) materials and objects of plastic of any kind b) with materials and objects provided with surface coating, c) glues), in particular also tins with coating must adhere to limit values laid down for the use of BADGE . The limit values for BADGE are 9 mg/kg or 1 mg/kg depending on derivative (see annex). Additional information: VO (EG) Nr.1895/2005 Anhang I_16-11	VO (EG) Nr. 1895/2005	Art. 2
5357	BFDGE At the production of materials and articles intended to come into contact with food, BFDGE may not be used and/or present in a) materials and objects of plastic of any kind b) with materials and objects provided with surface coating, c) glues	VO (EG) Nr. 1895/2005	Art. 3
5358	NOGE At the production of materials and articles intended to come into contact with food, NOGE may not be used and/or present in a) materials and objects of plastic of any kind b) with materials and objects provided with surface coating, c) glues	VO (EG) Nr. 1895/2005	Art. 4
5359	BADGE in food contact materials: A Declaration of compliance is to be issued which must be with the goods at all levels of marketing. This does not apply for retail supply.	BedGgstV	§ 10 Abs. 2a



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req. no.	Statutory requirement	Law	Article
50162	For the substance "Triclosan" (2,4,4'-Trichlor-2'-hydroxydiphenylether) which is used mainly in coatings for material and articles intended to come in contact with food made of plastic there is a production prohibition valid from 29 of september 2009.	BedGgstV	§ 3
50194	Additives in material and articles intended to come in contact with food made of plastic may only be used , if these have been permitted.	BedGgstV	§4
50200	Aluminium devices for baking (e.g. baking trays) which predictably could be used for alkali-dipped bakery products must be labelled appropriately: a notice must be given that without special measures to avoid the aluminium migration, these are unsuitable for baking alkali-dipped products.	ALS	2008/48
50229	For utensils of aluminium coming into contact with foodstuffs the requirements of Norm DIN EN 601 are to be adhered to.	DIN EN 601	
50354	for materials and articles which are intended to come into contact with foodstuffs the following documentation must be kept ready: - specifications, manufacturing composition and production processes in so far as they are relevant to the conformity and safety of the finished material or finished article; -statements about the individual stages of production in so far as they are relevant to the conformity or safety of the finished material or finished articles as well as statements of the results of the quality control system. * Affected /relevant materials and articles are the following: 1. active and intelligent materials and articles 2. adhesives 3. ceramics 4. cork 5. rubber 6. glass 7. ion exchange resins 8. metals and alloys 9. paper and cardboard 10. plastics 11. print colours 12. regenerative cellulose 13. silicones 14. textiles 15. paints and varnishes 16. wax 17. wood For importer from third countries the importer must hold the documentation in readiness and supply this on demand to the authorities. Additional information: CR (EC) No. 2023/2006_11-04 VO (EG) Nr. 2023/2006_11-04	VO (EG) Nr. 282/2008	VO (EG) Nr. 2023/2006 Art. 7

Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
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req. no.	Statutory requirement	Law	Article
50359	<p>For household articles made of plastic intended for use for foodstuffs, only those materials listed in the Union list may be used.</p> <p>Exceptions apply to:</p> <ul style="list-style-type: none"> - materials which do not come into direct contact with foodstuffs, - substances which are nationally regulated, - dyes and solvents which are nationally regulated, - salts, mixes without chemical reactions, particular additives, monomers and other chemical precursor which are required for synthesis and are listed in the Union list, - non-intentionally added substances; - aids to polymerisation - additives which are nationally regulated. <p>Current transitional periods:</p> <p>Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until the exhaustion of stocks.</p> <p>Additional information: VO (EU) Nr. 10/2011 Anhang I_20-11</p>	VO (EU) Nr. 10/2011	Art. 5, Art. 6 + Anhang I
50360	<p>The general restrictions for plastic materials and articles are to be observed which are laid down in Annex II of RE (EU) 10/2011.</p> <p>Additional information: VO (EU) Nr. 10/2011 Anhang II_20-11</p>	VO (EU) Nr. 10/2011	Art. 10 + Anhang II
50361	<p>The specific migration limit (SML) in the Union list are to be adhered to.</p> <p>Food additive or flavouring substances which have been introduced into foodstuffs and are authorised may be introduced in plastic materials if these have no technical effect on the foodstuff exceed the restrictions provided in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I in Regulation (EU) No. 10/2011.</p> <p>If the migration of a substance is prohibited a detection limit of 0,01 mg/kg is valid.</p> <p>Additional information: VO (EU) Nr. 10/2011 Anhang I_20-11</p>	VO (EU) Nr. 10/2011	Art. 11 + Anhang I

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req. no.	Statutory requirement	Law	Article
50362	<p>The overall migration value for materials and articles of plastic comprises 10mg for the total amount of constituent parts released to foodstuffs per dm² of the surface coming into contact with foodstuffs.</p> <p>This value for materials and articles for small children and babies amounts to 60 mg per 1 kg food simulant.</p>	VO (EU) Nr. 10/2011	Art. 12
50363	<p>For multi-layered materials or articles the composition of each plastic layer must conform to the migration values and limitations laid down.</p> <p>Exceptions apply to layers which do not come into direct contact with foodstuffs. This does not apply to CMR-materials.</p> <p>For multi-layered composite materials the above limitations do not apply except for CMR-materials.</p> <p>Temperature-resistant coatings on pans (e.g. PTFE) are not multi-layered composite materials.</p>	VO (EU) Nr. 10/2011	Art. 13, 14 + ALS 2015/14
50364	<p>The declaration of compliance is to be made available until the retail trade (for details see the valid documentation)</p> <p>Furthermore, appropriate documentation is to be held in readiness, certifying that the materials and articles conform to the regulations. These are:</p> <ul style="list-style-type: none"> - test reports or calculations, - analyses, - evidence on the safety . <p>Additional information: Declaration of Compliance plastic materials for foodstuffs_20-11 Konformitätserklärung Kunststoffe mit Lebensmittelkontakt_20-11</p>	VO (EU) Nr. 10/2011	Art. 15, 16 + Anhang IV
50365	<p>For materials and articles which are already in contact (packaging) with foodstuffs, testing of the migration limit values will be implemented analogue Annex V, Chapter 1.</p> <p>Annex V Chapter 2 apply regarding the materials and articles which have not yet come into contact with foodstuffs.</p> <p>Annex III and Annex V Chapter 3 apply regarding the overall migration value for materials and articles which have not yet come into contact with foodstuffs.</p> <p>Additional information: VO (EU) Nr. 10/2011 Anhang III_19-05 VO (EU) Nr. 10/2011 Anhang V_20-11</p>	VO (EU) Nr. 10/2011	Art. 18 + Anhang III, Anhang V

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req. no.	Statutory requirement	Law	Article
50691	For paper, paperboard and board that comes into contact with foodstuffs the following BfR recommendation is applicable. 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
50692	For papers that come into contact with aqueous foods (Cooking Papers, Hot Filter Papers and Filter Layers), the following BfR Recommendation are applicable. Additional information: BfR XXXVI-1. Cooking Papers, Hot Filter Papers and Filter Layers 2019-06-01_20_05 BfR XXXVI-1. Koch- und Heißfilterpapier und Filterschichten 2019-06-01_20_05	BfR-Empfehlung	BfR XXXVI/1
50693	For paper and paperboard , that comes into contact with or affects foodstuffs during baking (also Microwave baking), the following BfR Recommendation are applicable. Additional information: BfR XXXVI-2 Paper and Paperboard for Baking Purposes 2019-06-01_20-05 BfR XXXVI-2 Papiere, Kartons und Pappen für Backzwecke 2019-06-01_20-05	BfR-Empfehlung	BfR XXXVI/2
50694	For absorber pads based on cellulosic fibres for food packaging, the following BfR recommendation is applicable. Additional information: BfR XXXVI-3 absorber pads cellulosis fibers for food packaging 2019-06-01_20-05 BfR XXXVI-3 Saugelagen Cellulosefasern für Lebensmittelverpackungen 2019-06-01_20-05	BfR-Empfehlung	BfR XXXVI/3
50697	For temperature-resistant coating systems of polymers for frying, cooking and baking equipment, the BfR recommendations are to be observed. Additional information: BfR LI Temperaturbeständige Beschichtungen 2019-06-01_20_05 BfR LI Temperature resistant coatings 2019-06-01_20_05	BfR-Empfehlung	BfR LI
50698	For plastic materials and articles intended for use with food and polyamides containing or treated with polyamides BfR recommendations should be observed: Additional information: BfR Empfehlung X Polyamide_13-11.pdf BfR Recommendation X Polyamides_13-11.pdf	BfR-Empfehlung	BfR X

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req. no.	Statutory requirement	Law	Article
50699	For coatings based on polymer dispersions for the articles for food contact (eg adhesives or paper coatings), BfR recommendations should be observed. Additional information: BfR XIV. Polymer Dispersionen 2019-06-01_20-05 BfR XIV. Polymer Dispersionen 2019-06-01_20-05.	BfR-Empfehlung	BfR XIV
50700	For plastic materials and articles intended to come into contact with food and contain Poly(terephthalic acid diol esters) or have been treated with Poly(terephthalic acid diol esters) the BfR recommendations should be observed. Additional information: BfR XVII. Poly(terephthalic acid diol esters) 2016-07-01_16-11 BfR XVII. Polyterephthalsäurediolester 2016-07-01_16-11	BfR-Empfehlung	BfR XVII
50701	For plastic materials and articles intended for use with foods and include copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their salts and esters or treated with these, the BfR recommendations should be observed. Additional information: BfR XXXV. Copolymers of Ethylene Propylene Butylene Vinyl Esters Unsaturated Aliphatic Acids 2017-09-01_18-05 BfR XXXV. Mischpolymerisate Ethylen Propylen Butylen Vinylestern ungesättigten aliphatischen Säuren 2017-09-01_18-05	BfR-Empfehlung	BfR XXXV
50702	One-way salt mills with plastic grinders which make particles do not fulfill the general requirements for food contact materials.	ALS	2015/11

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req. no.	Statutory requirement	Law	Article
50737	<p>Products of rubber or plastic components (e.g. sport equipment, household utensils, tools, clothing, footwear, wrist-bands), that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 1.0 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAhA)</p> <p>This shall not apply to articles placed on the market for the first time before 27 December 2015. For these articles the values of BfR and ZEK apply.</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: RE (EC) No 1907/2006_20-05 VO (EG) Nr. 1907/2006_20-05</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50

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req. no.	Statutory requirement	Law	Article
50738	<p>Toys, including activity toys, and childcare articles of rubber or plastic components, that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 0.5 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBA_hA)</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: CR (EC) 2015-326_test method_15-04 VO(EU) Nr. 2015-326_Prüfverfahren_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50
50762	<p>Guidelines on Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food are available at follow links:</p> <p>https://ec.europa.eu/food/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf https://ec.europa.eu/food/safety/docs/cs_fcm_plastic-guidance_201110_reg_en.pdf https://ec.europa.eu/food/safety/docs/cs_fcm_legis_pm-guidance_reg-10-2011_boxes_deut.pdf</p>	Guideline VO (EU) Nr. 10/2011	
721	<p>Products made of vinyl chloride polymers (e.g. PVC) which are intended to</p> <ul style="list-style-type: none"> - come into contact with food during manufacture, treatment, distribution, or use - come into contact with cosmetics or tobacco products - come into contact with the skin, not just temporarily - come into contact with the mouth - as well as all - toys and joke articles - cleaning and care agents - products for personal hygiene <p>may not contain more than 1 mg monomer vinyl chloride per kg</p>	BedGgstV	§ 6 Abs. 3 iVm Anl.5 Nr. 1

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req. no.	Statutory requirement	Law	Article
5377	For metal food contact materials (e.g. cooking utensils, sets of cutlery) the following limit values must be observed: Pb < 0.010mg/dm ² Cd < 0.005mg/dm ² Cr < 0.450mg/dm ² Ni < 0.100mg/dm ² Cu < 0.500mg/dm ² Co < 0.100mg/dm ² Fe < 5.000mg/dm ² Mn < 5.000mg/dm ² .	VO (EG) Nr. 1935/2004	Zusatzinfo
50412	Cooking crockery of ceramics, glass, glass ceramics or plastics for use in microwave units must fulfil the tests of the norm DIN EN 15284.	DIN EN 15284	
50419	You may see the "BfR Recommendations on Food Contact Materials" (formerly "Plastics Recommendations") under: https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp	BfR-Empfehlung	BfR Kunststoff
50421	Articles used in connection with foodstuffs must adhere to the MSL limit values of 0,05 mg/kg for cobalt.	BedGgstV	BedGgstV Abschnitt 2
50773	For printed food commodities such as napkins or baker bags the following BfR Recommendation are applicable: Additional information: BfR Opinion No. 021-2014 Primary aromatic amines from printed food contact materials_14-11 BFR Stellungnahme Nr. 021-2014 Primäre aromatische Amine aus bedruckten Lebensmittelbedarfsgegenständen_14-11	BfR bedruckte LM-BG	
20711	Materials releasing 3-hydroxy-2-naphthanilide (Naphthol AS), N-Acetoacetyl-m-xylidine (NAAX) or N-(2,4-Dimethylphenyl)acetamide (NDPA) or precursors of those substances should not be used as food contact materials. Additional information: BfR bedruckte LMBG2 19-11	BfR bedruckte LMBG2	BfR Stellungnahme Nr. 037/2019
50836	For Polystyrene produced exclusively from the polymerisation of styrene the BfR recommendations are observed. Additional information: BfR V. Polystyrene from Polymerisation of Styrene 2017-09-01_18-05 BfR V. Polystyrol aus Polymerisation von Styrol 2017-09-01_18-05	BfR-Empfehlung	BfR V

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req. no.	Statutory requirement	Law	Article
50837	For Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers the BfR recommendations are observed. Additional information: BfR VI. Styrene Copolymers Graft Polymers Mixtures of Polystyrene with other Polymers 2017-09-01_18-05 BfR VI. Styrol-Misch und Pfropfpolymerisate und Mischungen Polysterol mit Polymerisaten 2017-09-01_18-05	BfR-Empfehlung	BfR VI
50838	When using Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics the BfR recommendations are to be observed. Additional information: BfR XXV. Hard Paraffins, Microcrystalline Waxes, Mixtures 2019-06-01_20-05 BfR XXV. Hartparaffine, mikrokristalline Wachse, Mischungen 2019-06-01_20-05	BfR-Empfehlung	BfR XXV
50839	When using vinylidene chloride copolymers with a predominant content of polyvinylidene chloride the BfR recommendations are to be observed. Additional information: BfR XXXIV. Vinylidenchlorid Mischpolymerisate 2017-09-01_18-05 BfR XXXIV. Vinylidene Chloride Copolymers 2017-09-01_18-05	BfR-Empfehlung	BfR XXXIV
50835	For fillers the BfR recommendations are observed. This Recommendation for fillers applies to the following materials: 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 Additional information: BfR LII. Fillers 2019-06-01_20-05 BfR LII. Füllstoffe 2019-06-01_20-05	BfR-Empfehlung	BfR LII
50933	The ESG guidelines can be used to ensure compliance with paper packaging for food. Additional information: ESG Food Contact Guideline_21-05	ESG Guideline	

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req. no.	Statutory requirement	Law	Article
50935	Edible food contact materials and articles such as edible drinking straws must meet all the legal requirements for a foodstuff.	ALS	2020/07
50936	Food contact materials made of mixtures of plastics and natural fibres, the shape and structure of which are determined by the polymer content, fall within the scope of Regulation (EU) No 10/2011, irrespective of the polymer content. Claims such as "no plastic", "plastic-free" or similar claims are misleading for these products.	ALS	2020/13
50937	Indications on food packaging regarding the packaging materials used shall not be misleading.	ALS	2020/15



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Products, close to skin

Article No.:

Products that come into direct contact with the skin.

req. no.	Statutory requirement	Law	Article
723	Analysis of the Consumer Goods must be done according to the methods laid down in Annex 10 of the regulation concerning consumer goods (BedGgstV). Additional information: Bedarfsgegenständeverordnung_17-05.pdf	BedGgstV	§ 11 + Anlage 10
50049	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)	VO (EG) Nr. 1907/2006	Anhang XVII
50050	Trisubstituted zinc compounds (e.g. TBT, TPT) with a concentration of more than 0.1 per cent weight inproducts, not mixtures such as: - carpets; - clothing; - wood preservation substances; - leather goods; - PVC-products; - paints and varnishes are prohibited.	VO (EG) Nr. 1907/2006	Anhang XVII
50051	Dibutyl zinc compounds (DBT) with a concentration of more than 0.1 per cent weight are prohibited if these are intended for end-users in such products and mixtures as: - impregnating sprays; - mattresses; - PVC articles; - polyurethane foam; - textiles, - where applicable other articles and mixtures. The above date does not apply to the following products and mixtures: one- and two part room temperature vulcanisation sealing substances and glues (RTV-1 and RTV-2 sealing substances); - paints and coatings containing DBT-compounds as catalysts if these are painted on products; - soft polyvinylchloride (PVC) profiles whether these are extruded with hard PVC or not; material covered with a layer of PVC which contains DBT-compounds as stabilisers, if intended for outdoor use; - outside rainwater piping, guttering and joints as well as roof and exterior wall cladding.	VO (EG) Nr. 1907/2006	Anhang XVII

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Hygiene Products_Wellness_Health**Products, close to skin**

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req. no.	Statutory requirement	Law	Article
50245	<p>For products made of leather, which are not only temporarily with skin contact, e.g.:</p> <ul style="list-style-type: none"> - Watch Bands, - Bags, - Backpacks, - Chair covers, - Money bag, - Shoes, - Gloves, - Toys made of leather, <p>must chromium VI not be detected. (Method B 82.02-11, 2008-10 - § 64-1 LFGB, according to DIN EN ISO 17075)</p> <p>This requirement applies from May 1st 2014 in all EU-Countries (CR (EU) No. 301/2014 amending annex XVII of REACH-CR)</p>	BedGgstV	Anl. 4 Nr. 2 und Anl. 10, Nr. 8

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Products that come into direct contact with the skin.

req. no.	Statutory requirement	Law	Article
50687	<p>The limit values below apply to the following textiles:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers following limits:</p> <ul style="list-style-type: none"> - Cadmium and its compounds: 1 mg/kg nach Extraktion - Chromium VI compounds: 1 mg/kg nach Extraktion - Arsenic compounds: 1 mg/kg nach Extraktion - Lead and its compounds: 1 mg/kg nach Extraktion - Benzene: 5 mg/kg - Benz[a]anthracen: 1 mg/kg - Benz[e]acephenanthrylene: 1 mg/kg - Benzo[a]pyrene; Benzo[def]chrysene: 1 mg/kg - Benzo[e]pyrene: 1 mg/kg - Benzo[j]fluoranthene: 1 mg/kg - Benzo[k]fluoranthene: 1 mg/kg - Chrysene: 1 mg/kg - Dibenz[a,h]anthracene: 1 mg/kg - α, α, α, 4-tetrachlorotoluene; p-chlorobenzotrchloride: 1 mg/kg - α, α, α-trichlorotoluene; benzotrchloride: 1 mg/kg - α-chlorotoluene; benzyl chloride: 1 mg/kg - Formaldehyde: 75 mg/kg - 1,2-benzenedicarboxylic acid; di-C 6-8-branched alkylesters, C 7-rich: 1000 mg/kg - Bis(2-methoxyethyl)phthalate: 1000 mg/kg - Diisopentylphthalate: 1000 mg/kg - Di-n-pentylphthalate (DPP): 1000 mg/kg - Di-n-hexylphthalate (DnHP): 1000 mg/kg - N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone (NMP): 3000 mg/kg - N,N-Dimethylacetamide (DMAC): 3000 mg/kg - N,N-Dimethylformamide; Dimethylformamide (DMF): 3000 mg/kg - 1,4,5,8-Tetraamino-anthrachinon; C.I. Disperse Blue 1: 50 mg/kg - Benzolamin, 4,4'-(4-Iminocyclohexa-2,5- dienyldenmethylen)dianilinhydrochlorid; C.I. Basic Red 9: 50 mg/kg - 4-[4,4'-Bis(dimethylamino)benzhydryliden]cyclohexa-2,5-dien-1-yliden]dimethylammoniumchlorid; C.I. Basic Violet 3 mit $\geq 0,1$ % Michlers Keton (EG-Nr. 202- 027-5): 50 mg/kg - 4-Chlor-o-toluidiniumchloride: 30 mg/kg - 2-Naphthylammoniumacetate: 30 mg/kg - 4-Methoxy-m-phenylendiammoniumsulfate; 2,4-Diaminoanisolsulfate: 30 mg/kg - 2,4,5-Trimethylanilin-Hydrochloride: 30 mg/kg - Quinoline: 50 mg/kg <p>By way of derogation, in relation to the placing on the market of formaldehyde in jackets, coats or upholstery, the relevant concentration for the purposes shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. Thereafter, the above concentration applies.</p> <p>The requirements do not apply to:</p> <ul style="list-style-type: none"> (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. e) disposable textiles, f) personal protective equipment g) medical devices 	VO (EG) Nr. 1907/2006	Anhang XVII



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Products, close to skin**

Article No.:

Products that come into direct contact with the skin.

req. no.	Statutory requirement	Law	Article
50737	<p>Products of rubber or plastic components (e.g. sport equipment, household utensils, tools, clothing, footwear, wrist-bands), that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 1.0 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAha)</p> <p>This shall not apply to articles placed on the market for the first time before 27 December 2015. For these articles the values of BfR and ZEK apply.</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: RE (EC) No 1907/2006_20-05 VO (EG) Nr. 1907/2006_20-05</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50
50738	<p>Toys, including activity toys, and childcare articles of rubber or plastic components, that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 0.5 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAha)</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: CR (EC) 2015-326_test method_15-04 VO(EU) Nr. 2015-326_Prüfverfahren_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Products, close to skin**

Article No.:

Products that come into direct contact with the skin.

req. no.	Statutory requirement	Law	Article
689	In textiles and home textiles which are intended to come not only temporarily into contact with the human body, and in textile toy animals and dolls, the following flame proofing agents may not be used: 1. tri-(2,3-dibromopropyl)-phosphate (TRIS) 2. Tris-(aziridinyl)-phosphine oxide (TEPA) 3. Polybrominated biphenyls (PBB)	BedGgstV	§ 3 iVm Anl. 1 Nr. 4
721	Products made of vinyl chloride polymers (e.g. PVC) which are intended to - come into contact with food during manufacture, treatment, distribution, or use - come into contact with cosmetics or tobacco products - come into contact with the skin, not just temporarily - come into contact with the mouth - as well as all - toys and joke articles - cleaning and care agents - products for personal hygiene may not contain more than 1 mg monomer vinyl chloride per kg	BedGgstV	§ 6 Abs. 3 iVm Anl.5 Nr. 1
826	Textiles, which contain more than 1500 ppm formaldehyde and are intended to come into contact with the human body, have to be marked as follows: "Enthält Formaldehyd. Es wird empfohlen, das Kleidungsstück zur besseren Hautverträglichkeit vor dem ersten Tragen zu waschen." ("Contains formaldehyde. It is recommended that the article is washed before wearing for the first time for better skin tolerance"). The text is to be altered correspondingly for home textiles.	BedGgstV	§ 10 Abs. 3 + Anlage 9
2662	The use of nickel and its compounds is prohibited for products in which the nickel-containing parts (e.g. buttons, zips, jewellery, watches, rivet heads, hair slides) come, not just temporarily, into contact with the body and give off more than 0.5 µg/cm ² /week Nickel. For nickel-containing products with a nickel-free coating, a limit value of 0,5 µg/cm ² /week Nickel, over a period of at least 2 years with normal use, is to be observed. The Norm DIN EN 1811:2015-10 is to be used for the assessment of nickel continence.	BedGgstV	§ 6 Nr. 4 i.V.m. Anlage 5a u Norm DIN EN 1811:2015
2916	The allergenic dispersion dyes Dispersion blue 1, 35, 106 and 124 Dispersion yellow 3 Dispersion orange 3, 37/76 and Dispersion red 1 must not be contained in products worn close to the skin. (further information can be found in the publicatins of the BfR)	LFGB	§30

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Products, close to skin**

Article No.:

Products that come into direct contact with the skin.

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
80202	stationery like pens and it`s top are intended to come into direct and prolonged contact with the skin	ALS	Stellungnahme Nr. 2019/48
80199	The rate of nickel release from articles intended to come into direct and prolongt contact with the skin must not exceed 0,5µg/cm ² /week.	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 27



Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Textiles

Article No.:

req. no.	Statutory requirement	Law	Article
5138	All textiles must be fitted with the care instructions of DIN EN ISO 3758 (2013).	DIN EN ISO 3758	
50050	Trisubstituted zinc compounds (e.g. TBT, TPT) with a concentration of more than 0.1 per cent weight in products, not mixtures such as: - carpets; - clothing; - wood preservation substances; - leather goods; - PVC-products; - paints and varnishes are prohibited.	VO (EG) Nr. 1907/2006	Anhang XVII
5289	Textiles containing Nonylphenol or Nonylphenol ethoxylates equal to or greater than 0,1 % by weight are prohibited. Nonylphenol ethoxylates (NPE) shall not be placed on the market in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.	VO (EG) Nr. 1907/2006	Anhang XVII

Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Textiles

Article No.:

req. no.	Statutory requirement	Law	Article
50687	<p>The limit values below apply to the following textiles:</p> <p>(a) clothing or related accessories;</p> <p>(b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;</p> <p>(c) footwear;</p> <p>if the clothing, related accessory, textile other than clothing or footwear is for use by consumers following limits:</p> <ul style="list-style-type: none"> - Cadmium and its compounds: 1 mg/kg nach Extraktion - Chromium VI compounds: 1 mg/kg nach Extraktion - Arsenic compounds: 1 mg/kg nach Extraktion - Lead and its compounds: 1 mg/kg nach Extraktion - Benzene: 5 mg/kg - Benz[a]anthracen: 1 mg/kg - Benz[e]acephenanthrylene: 1 mg/kg - Benzo[a]pyrene; Benzo[def]chrysene: 1 mg/kg - Benzo[e]pyrene: 1 mg/kg - Benzo[j]fluoranthene: 1 mg/kg - Benzo[k]fluoranthene: 1 mg/kg - Chrysene: 1 mg/kg - Dibenz[a,h]anthracene: 1 mg/kg - α, α, α, 4-tetrachlorotoluene; p-chlorobenzotrchloride: 1 mg/kg - α, α, α-trichlorotoluene; benzotrchloride: 1 mg/kg - α-chlorotoluene; benzyl chloride: 1 mg/kg - Formaldehyde: 75 mg/kg - 1,2-benzenedicarboxylic acid; di-C 6-8-branched alkylesters, C 7-rich: 1000 mg/kg - Bis(2-methoxyethyl)phthalate: 1000 mg/kg - Diisopentylphthalate: 1000 mg/kg - Di-n-pentylphthalate (DPP): 1000 mg/kg - Di-n-hexylphthalate (DnHP): 1000 mg/kg - N-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone (NMP): 3000 mg/kg - N,N-Dimethylacetamide (DMAC): 3000 mg/kg - N,N-Dimethylformamide; Dimethylformamide (DMF): 3000 mg/kg - 1,4,5,8-Tetraamino-anthrachinon; C.I. Disperse Blue 1: 50 mg/kg - Benzolamin, 4,4'-(4-Iminocyclohexa-2,5- dienylidenmethyl)endianilinhydrochlorid; C.I. Basic Red 9: 50 mg/kg - 4-[4,4'-Bis(dimethylamino)benzhydryliden]cyclohexa-2,5-dien-1-yliden]dimethylammoniumchlorid; C.I. Basic Violet 3 mit $\geq 0,1$ % Michlers Keton (EG-Nr. 202- 027-5): 50 mg/kg - 4-Chlor-o-toluidiniumchloride: 30 mg/kg - 2-Naphthylammoniumacetate: 30 mg/kg - 4-Methoxy-m-phenylendiammoniumsulfate; 2,4-Diaminoanisolsulfate: 30 mg/kg - 2,4,5-Trimethylanilin-Hydrochloride: 30 mg/kg - Quinoline: 50 mg/kg <p>By way of derogation, in relation to the placing on the market of formaldehyde in jackets, coats or upholstery, the relevant concentration for the purposes shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. Thereafter, the above concentration applies.</p> <p>The requirements do not apply to:</p> <ul style="list-style-type: none"> (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide; (b) non-textile fasteners and non-textile decorative attachments; (c) second-hand clothing, related accessories, textiles other than clothing or footwear (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners. e) disposable textiles, f) personal protective equipment g) medical devices 	VO (EG) Nr. 1907/2006	Anhang XVII

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Textiles**

Article No.:

req. no.	Statutory requirement	Law	Article
50051	<p>Dibutyl zinc compounds (DBT) with a concentration of more than 0.1 per cent weight are prohibited if these are intended for end-users in such products and mixtures as:</p> <ul style="list-style-type: none"> - impregnating sprays; - mattresses; - PVC articles; - polyurethane foam; - textiles, - where applicable other articles and mixtures. <p>The above date does not apply to the following products and mixtures:</p> <ul style="list-style-type: none"> one- and two part room temperature vulcanisation sealing substances and glues (RTV-1 and RTV-2 sealing substances); - paints and coatings containing DBT-compounds as catalysts if these are painted on products; - soft polyvinylchloride (PVC) profiles whether these are extruded with hard PVC or not; material covered with a layer of PVC which contains DBT-compounds as stabilisers, if intended for outdoor use; - outside rainwater piping, guttering and joints as well as roof and exterior wall cladding. 	VO (EG) Nr. 1907/2006	Anhang XVII
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
50438	<p>Textile products are:</p> <ul style="list-style-type: none"> a) products with a weight share of textile fibres of at least 80 %; b) Material covers for furniture, umbrella and parasols with a weight share of textile components of at least 80 %; c)the textile components of <ul style="list-style-type: none"> i) the uppermost layer of multi-layered floorcoverings, ii)mattress covers, iii) the covers of camping articles, <p>in so far as these textile components a weight share which comprises at least 80 % of these upper layers or covers;</p> <ul style="list-style-type: none"> d) Textiles which are worked into other goods and become integral parts of these as far as their composition is stated. <p>The requirements of the Textile Labelling Regulation (EU) Nr. 1007/2011 must be observed.</p> <p>Additional information: FAQ Regulation EU No. 1007-2011_14-11 FAQ zur Textilkennzeichnungsverordnung EU Nr. 1007-2011_14-11</p>	VO (EU) Nr. 1007/2011	Artikel 2 i.V.m.TextilKenn zG

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Preparations**

Article No.:

Preparations are e.g.: dyes/paints/lacquers and all products listed under the dangerous substances regulations. These are subject to additional requirements, which arise out of REACH. Not affected by this are:

plant protection products, biocides and medicinal products

req. no.	Statutory requirement	Law	Article
5229	Manufacturers of compounds within the EU, who come under the REACH obligations will, after registration, make their registration numbers known without being asked. This also applies to private labels.	QS	
50046	The material limits and prohibitions of Annex XVII, current form in each case are to be observed. https://echa.europa.eu/substances-restricted-under-reach	VO (EG) Nr. 1907/2006	Anhang XVII
5227	For all mixes the REACH requirements apply and must be adhered to from 1 June 2007 or 1 June 2008 respectively, if more than 1 ton of one constituent substance is imported.	VO (EG) Nr. 1907/2006	Art. 141
5228	The manufacturers are responsible for the adherence to the obligations arising from REACH for all mixes produced in the EU. This also applies to own brands.	VO (EG) Nr. 1907/2006	Art. 3 Abs. 2, 9
5230	Manufacturers of mixes will make available, of their own accord, a safety data sheet and where appropriate further documentation (evaluation of reliability). The requirements for safety data sheets are changed. Safety data sheets that do not yet meet the new requirements may be made available until December 31, 2022. Additional information: RE (EU) 2020/878 New SDS_20-11 VO (EU) 2020/878_Änderung SDB_20-11	VO (EG) Nr. 1907/2006	Art. 31, 32
50927	From February 24, 2022, diisocyanates may only be placed on the market individually or in combination in substances and mixtures for industrial and commercial use if they contain less than 0.1% by weight or if the customer is aware of the restriction . Substances and mixtures that contain more than 0.1% by weight of diisocyanates and are sold to informed customers must be clearly marked with the sentence: "From August 24, 2023, appropriate training must take place before industrial or commercial use" . From August 24, 2023, labor law requirements will also apply. From this date, employers and the self-employed ensure that the user has completed training on the safe use of diisocyanates. The content, documentation and repetition of the training are explained in detail in the entry on diisocyanates in Annex XVII of the REACH regulation.	VO (EG) Nr. 1907/2006	Anh. XVII Nr. 74
50395	The requirements of the safety data sheets are to be fulfilled according to RE (EC) 1907/2006 Annex II. Additional information: RE (EG) Nr. 1907/2006 Annex II 21-11 VO (EG) Nr. 1907/2006 Anhang II 21-11	VO (EG) Nr. 1907/2006	Anhang II



Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Articles for infants and small children (dummy holders)

Article No.:

e.g. Dummy (pacifier) holders

req. no.	Statutory requirement	Law	Article
50009	<p>For dummy (pacifier) holders, an article with which the dummy(pacifier) can be attached to clothing or other objects, the following fundamental requirements must be adhered to:</p> <ul style="list-style-type: none"> -no parts of the dummy-holder can become unattached unintentionally, points, edges and corners must be avoided, safety pins are prohibited, all openings may be maximally from 5mm to 12mm if the baby's fingers could be trapped or pinched (degree of hardness), where applicable:if ventilation holes are supplied, this always applies, if a surface area which forms a circle with a diameter of 25mm then a ventilation hole is to be provided, - stick-on pictures and stickers are not permitted, -the length of the dummy-holder may not exceed 22mm, the band width must be at least 6mm, the cord hanging free may be 1.5mm thick and 15mm long, other fasteners such as press studs, Klett or others must not be wider than the band, at least one fastener must be permanently attached to the band, detachable fasteners must adhere to certain sizes which can not go through a determined shape, supplementary parts may not lead to a lengthening of the dummy holder of 22cms, the elasticity of all parts is to be tested, all materials used must be tested (migration, nickel, colour fastness, formaldehyde, phthalat concentration,amino, monomers, and wood preservation materials). <p>Tests according to the norms must be demonstrable.</p>	DIN EN 12586, 2011-04	
5169	<p>Toys and childcare articles which can be placed in the mouth must not contain more than 0,1% (by weight) of the following phthalates in the plasticised material:</p> <ul style="list-style-type: none"> - Di-isononylphthalat (DINP) CAS-Nrn. 28553-12-0 und 68515-48-0 EINECS-Nrn. 249-079-5 und 271-090-9 - Di-isodecylphthalat (DIDP) CAS-Nrn. 26761-40-0 und 68515-49-1 EINECS-Nrn. 247-977-1 und 271-091-4 -Di-n-octylphthalat (DNOP) CAS-Nr. 117-84-0 EINECS-Nr. 204-214-7 <p>In this context, childcare articles comprise any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of the children.</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 52

Category: Hygiene Products, Wellness, Health

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Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Articles for infants and small children (dummy holders)**

Article No.:

e.g. Dummy (pacifier) holders

req. no.	Statutory requirement	Law	Article
50696	<p>For toys and childcare articles which can be placed in the mouth, the limit of 0.1% is observed for following phthalate:</p> <p>- DPHP (Di-2-propylheptylphthalat)</p> <p>Additional information: BfR Opinion No. 004-2012_13-11.pdf BfR Stellungnahme DPHP Nr. 004-2012_13-11.pdf</p>	BfR DPHP	
50738	<p>Toys, including activity toys, and childcare articles of rubber or plastic components, that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, should not contain more than 0.5 mg / kg of one of the listed PAHs:</p> <p>a) Benzo(a)pyren (BaP) b) Benzo(e)pyren (BeP) c) Benzo(a)anthracen (BaA) d) Chrysen (CHR) e) Benzo(b)fluoranthen (BbFA) f) Benzo(j)fluoranthen (BjFA) g) Benzo(k)fluoranthen (BkFA) h) Dibenzo(a,h)anthracen (DBAhA)</p> <p>(The standard EN 16143:2013 (Petroleum products- Determination of content of Benzo (a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils- Procedure using double LC cleaning and GC/MS analysis) shall be used as the test method for demonstrating conformity with the limits.)</p> <p>Additional information: CR (EC) 2015-326_test method_15-04 VO(EU) Nr. 2015-326_Prüfverfahren_15-04</p>	VO (EG) Nr. 1907/2006	Anhang XVII Nr. 50



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Blood-pressure apparatus

Article No.:

req. no.	Statutory requirement	Law	Article
5256	Blood-pressure meters must fulfil the requirements of the following standards: - DIN EN ISO 81060-1 (non-automated measurement type)	DIN EN ISO 81060-1	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Gloves for single use

Article No.:

req. no.	Statutory requirement	Law	Article
50858	Medical gloves for single use must fulfil the requirements of the following standards: - DIN EN 455-1 (freedom from holes) - DIN EN 455-2 (physical propertie) - DIN EN 455-3 (biological evaluation) - DIN EN 455-4 (shelf life determination)	DIN EN 455-1 bis 4	



Category: Hygiene Products, Wellness, Health

21-11

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Hygiene Products_Wellness_Health

Fever thermometers

Article No.:

req. no.	Statutory requirement	Law	Article
50860	Clinical thermometers must fulfil the requirements of the following standards: - DIN EN 12470-1 (Metallic liquid-in-glass thermometers with maximum device) - DIN EN 12470-2 (Phase change type (dot matrix) thermometers) - DIN EN ISO 80601-2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	DIN EN 12470-1, 2, DIN EN ISO 80601-2-56	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Personal hygiene products

Article No.:

req. no.	Statutory requirement	Law	Article
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
50049	<p>Diocylzin 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

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Personal hygiene products**

Article No.:

req. no.	Statutory requirement	Law	Article
50280	<p>For personal sanitary products such as sanitary towels and panty liners (absorbent pads) tampons, nappies and nappy liners (diapers, diaper liners) the BfR-information is to be observed along with the legal requirements.</p> <p>Additional information: BfR Guidelines for the Evaluation of Personal Sanitary Products_11-02 BfR Intimhygieneerzeugnisse_11-02</p>	BfR Empfehlung Intimhygiene	
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'-diaminophenyl-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-toluyldiamine CAS-No. 95-80-7 2,4,5-trimethylaniline CAS-No. 137-17-7 o-anisidine (2-methoxyaniline) CAS-No. 90-04-0 4-amino azobenzene CAS-No. 60-09-3</p> <p>The use of prohibited azo dyes is deemed not to have been proven if the amounts contained of each amine component do not exceed 30 mg in one kilogram (0,003 Gew.-%) of specimen material.</p>	BedGgstV	§ 3 iVm Anl. 1 Nr. 7



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

condoms

Article No.:

req. no.	Statutory requirement	Law	Article
50859	Natural rubber latex condoms must fulfil the requirements of the following standard: - DIN EN ISO 4074	DIN EN ISO 4074	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Tissues

Article No.:

(e.g. handkerchief and so one)

req. no.	Statutory requirement	Law	Article
50778	Cellulose and paper with a content of about 0.1 percent by weight of nonylphenol is prohibited.	VO (EG) Nr. 1907/2006	Anhang XVII
50271	For paper handkerchiefs, cosmetic handkerchiefs toilet paper and intimate hygiene products the BfR criteria for the individual products are to be observed. Additional information: BfR_Hygienepapiere_10_11	BfR Empfehlung Hygienepapiere	
50945	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: - 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; 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. 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. 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. The position, size and design of the marking must be taken from the Implementing Regulation (EU) 2020/2151 Additional information: DVO (EU) 2020/2151_21-11	EWKKennzV	§ 4 i.V.m. DVO (EU) 2020/2151

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Tissues**

Article No.:

(e.g. handkerchief and so one)

req. no.	Statutory requirement	Law	Article
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

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Tampons**

Article No.:

Hygiene products for ladies

req. no.	Statutory requirement	Law	Article
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
50272	<p>For Tampons the code "Tampon Code of Practice" of EDANA is to be observed.</p> <p>Additional information: EDANA COP Tampons_21-05</p>	EDANA	

Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health**Tampons**

Article No.:

Hygiene products for ladies

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



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Bandaging materials, plasters

Article No.:

req. no.	Statutory requirement	Law	Article
50861	Wound dressings must fulfil the requirements of the following standards: - DIN EN 13726-1 - DIN EN 13726-2	DIN EN 13726-1 und 2	
50862	Absorbent cotton gauze and absorbent cotton and viscose gauze must fulfil the requirements of the following standard: - DIN EN 14079	DIN EN 14079	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Microwavable personal warmers

Article No.:

req. no.	Statutory requirement	Law	Article
50539	Microwavable personal warmers are to be tested according to the norm: BS 8433:2004.	Norm BS 8433:2004	



Category: Hygiene Products, Wellness, Health

21-11

Author: Träger

Product:Hygieneprodukte_Wellness_Gesundheit/
Hygiene Products_Wellness_Health

Hot-water bottles (USA bags)

Article No.:

req. no.	Statutory requirement	Law	Article
5315	Hot-water bottles (USA bags) made of polyolefinplast must be leakproof and fulfil the BS 1970 Norm for thermoplast hot-water bottles - conditions of supply for poleolefinplast hotwaterbottles.	QS	