

German Environment Agency

As at: 23<sup>rd</sup> August 2024 having regard to 4<sup>th</sup> amendment

## **EVALUATION CRITERIA DOCUMENT**

**Annexes to evaluation criteria document for plastics  
and other organic materials in contact with drinking  
water (KTW-BWGL)**

**Polymer-specific part**

English translation – only the German document version is legally binding

# **Annex A           Plastics**

## **A.1           Scope of application**

### **A.1.1           Plastics**

Materials whose main components consist of macromolecular organic compounds that are produced synthetically or by modifying natural products are designated as plastics (as per DIN EN 472:2013-06). In many cases, under specific conditions (heat and pressure), they can be melted and moulded. Plastics are organic materials consisting mainly of polymers with a high molecular weight. These polymers are macromolecular substances manufactured from monomers and other starting substances using a polymerisation process such as polyaddition, polycondensation or similar. Organic coatings, elastomers, lubricants and silicones do not come under this scope of application. Adhesives whose base polymer corresponds to plastics (see Example 2 in Section 5.7) and filter membranes fall within the scope of Annex A.

In addition to polymers made up of monomers as the main structural component, additives may also be contained in plastics, which give specific properties during the manufacturing process or in the end product.

Aids to polymerisation (AtP) may also be contained in the plastic. They initiate polymerisation and/or control the formation of the macromolecular structure (e.g. catalysts, accelerators) and are used in very low quantities. They may be present in the end product but are not intended to be there.

Polymer production aids (PPA) are used in the manufacture of plastics. They only have a function in the manufacturing process and are not intended to have any effects in the end-product. However, they may be present in the end-product.

In food law, the requirements for manufacturing plastic materials and articles are regulated in Commission Regulation (EU) No 10/2011 on plastic materials and articles that are intended to come into contact with food. The starting materials listed therein may also be used for the manufacture of plastics intended to come into contact with drinking water.

### **A.1.2           Crosslinked plastics**

Crosslinked plastics have polymer chains linked with covalent bonds. Crosslinked polyethylene (PE-X) is mainly significant for products in contact with drinking water. Crosslinking can be carried out using various processes: Crosslinked polyethylene can be manufactured using peroxides (PE-X<sub>a</sub>), using silanes (PE-X<sub>b</sub>) or by high-energy radiation (PE-X<sub>c</sub>). Crosslinking agents currently used are only partly listed in Commission Regulation (EU) No 10/2011. Therefore, additional crosslinking agents are listed in the supplementary positive list in this evaluation criteria document.

### **A.1.3           Recycled plastics**

The use of recycled plastics is restricted to the use of offcuts and scraps generated by the producer that are uncontaminated and not yet placed on the market. It must be ensured that the formulation of the recycled materials is known and can be indicated and tested.

### **A.1.4           Glass Reinforced Plastics (GRP)**

GRP are composite materials in which glass fibres are placed in a plastic matrix.

The glass materials used for fibre reinforcement (see glass fibres) are present in the GRP as fibres, yarns, rovings (glass silk strands), fleece, woven fabrics or mats. The polymeric matrices can be both duroplasts (e.g. unsaturated polyester resins, melamine resins, epoxy laminates, phenolic and furan resins) and thermoplastics (e.g. polyamides, polycarbonates, polyacetals, polyethylene terephthalate, polyphenylene oxides and sulfides, polypropylene and styrene copolymers).

## A.2 Positive list of starting substances for the manufacture of plastics

Only the starting substances approved in Commission Regulation (EU) No 10/2011 (EU list), substances of the 4MSI Positive Lists accepted for plastics and those listed in Table A-1 may be used to manufacture plastics in contact with drinking water.

Aids to polymerisation, solvents and colourants are not regulated in Commission Regulation (EU) No 10/2011 and can be regulated under national food law. Where these starting substances are not included in Table A-1, the requirements for unlisted starting substances apply, including their contaminants and degradation and reaction products (see Chapter 5.2.2 of the general part of the evaluation criteria for organic materials). The requirements according to Chapters 5.4.2 and 5.4.3 of the general part of the evaluation criteria for organic materials apply to fillers and colourants.

For the production of GRP, the requirements for fillers in point 5.4.2 apply to the glass fibres used, including glass fibre sizing. The starting substances used to produce the polymer matrices shall correspond to the positive lists for plastics. For other reinforcement fillers, the requirements of point 5.4.2 shall also apply.

**Table A-1: Supplementary positive list for plastics in contact with drinking water**

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
<b>Monomers</b>				
<b>Additives and polymer production aids</b>				
-	7637-07-2	Boron trifluoride**	100 as B 150 als fluoride	
40430	109-63-7	Boron trifluoride etherate**	100 as B 150 as fluoride	
4120	7789-75-5	Calcium fluoride**	150 as fluoride	
-	21679-31-2	Chromium (III) acetylacetonate**	5 as Cr	
-	25182-44-9	Chromium methacrylate**	5 as Cr 300 as methacrylic acid	
53600	60-00-4	Ethylendiaminetetraacetic acid (EDTA)**	60	
56320	1323-83-7	Glyceryl distearate**		
-	12136-45-7	Potassium oxide**		
-	7681-65-4	Copper (II) iodide**	50 for iodide, 200 for copper	
-	7681-49-4	Sodium fluoride**	150 for fluoride	
-	1313-59-3	Sodium oxide**		
-	27619-97-2	1H,1H,2H,2H-Perfluorooctane sulfonic acid (FTS)**	0.1	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	7782-99-2	Sulfurous acid*	500 as SO <sub>2</sub>	
95870	-	Wheat protein**		
	1503-48-6	Quino[2,3-b]acridine-6,7,13,14(5H,12H)-tetron with a purity of at least 90 %*	2.0	Specific nano-material, however, only in a particle dimension of the platelets 1-100 nm
	25086-89-9	Polyvinylpyrrolidone-vinyl acetate copolymer (PVP/VA)*		Specification in accordance with Annex II to Regulation (EC) No 1333/2008; in addition, hydrazine in copolymer < 0,5 mg/kg, oligomeric components in the copolymer below 1000 Da < 2%, aldehyde < 500 mg/kg as acetaldehyde
<b>Aids to Polymerisation</b>				
-	10025-73-7	Chromium (III) chloride**	5 as Cr	
-	11118-57-3	Chromium oxide**	5 as Cr	
47080	110-05-4	Di- <i>tert.</i> -butyl peroxide*	0.1 15 for methyl- <i>tert.</i> -butyl ether (MtBE) 500 for <i>tert.</i> -butanol	
49160	127-19-5	N,N-Dimethyl - acetamide (DMAC)*	2.5	
59330	110-54-3 EC-Nr. 925-292-5	n-Hexane* incl. structural isomers up to 40 % (cyclohexane < 3 %)	250	MTC <sub>tap</sub> for n-hexane need not be tested if the process temperature is above 100 °C
-	93685-81-5 (13475-82-6)	Isododecane (main isomer: 2,2',4,6,6'-pentamethyl-heptane)**	2.5	
23680 81280	9002-89-5	Polyvinyl alcohol**		manufactured by sintering
-	7782-44-7	Oxygen**		
	111-92-2	Dibutylamine*	1.0	
	3437-84-1	2-methylpropanoyl-2-methylpropane peroxoate*	0.1 µg/l for isopropylisobutyrate 2.5 µg/l for 2,3-dimethyl-butane	Maximum application quantity 0.2%, only for PVC and PVC-C

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
<b>Solvents</b>				
	78-93-3	Butan-2-one*	250	Note: MTC <sub>tap</sub> is above the odour threshold
	1330-20-7	Xylene isomers*	50	
	108-88-3	Toluene	60	
	108-10-1	Methyl isobutyl	250	
	75-65-0	tert-Butanol	500	
	75-09-2	Dichloromethane	2.5	

\* Substances that are assessed nationally

\*\* Substances that are assessed by another EU Member State as part of the 4MS initiative and adopted by the other states (listed in the 4MSI Core List)

### A.3 Additional requirements for plastics

The additional requirements for plastics laid down in Table A-2 apply. The general part of the evaluation criteria for organic materials must be observed.

**Table A-2: Additional requirements for plastics**

Substances/substance groups	MTC <sub>tap</sub> in µg/l	Test method (Other equivalent test methods may be used)
Sum of Primary Aromatic Amines (PAA) <sup>1</sup> for plastics containing PAA or whose manufacture may result in the presence of PAA (e. g. polyamide, polyurethane)	0.1	specific detection by GC-ECD/GC-MS with derivatisation <sup>2</sup>
Where substances from the following group are used:		
unlisted catalysts	Requirements according to 5.2.2l)	DEV <sup>3</sup>
Fillers	requirements according to 5.4.2 of the general part of the Evaluation Criteria Document	
Colourants	requirements according to 5.4.3 of the general part of the Evaluation Criteria Document	

<sup>1</sup> Except PAAs allowed in Commission Regulation (EU) No 10/2011.

<sup>2</sup> Test method: Pietsch et al. (1996) Fresenius J. Anal. Chem. 355:164-173 or Pietsch et al. (1997) Vom Wasser 88: 119-135

<sup>3</sup> German standard methods for the examination of water, waste water and sludge (Deutsche Einheitsverfahren (DEV) zur Wasser-, Abwasser- und Schlammuntersuchung)

## Annex B      Organic coatings

### B.1      Scope of application

This annex applies to materials described below:

Coatings as envisaged in this evaluation criteria document are products made from substances — or mixtures of predominantly organic substances — which in their final state do not themselves form a load-bearing layer, but which in case of application on a substrate (metals, cementitious materials) form a solid layer with a particular technological effect.

Coatings are produced from coating substances by means of application (DIN 55945: 2016-08). Coating substances are usually processed by means of procedures such as spreading, immersing, filling, spraying etc.

Coating systems used in contact with drinking water may have a multi-layer structure (base, intermediate and finish coat). The assessment can be conducted as a complete system or each layer can be assessed separately in accordance with Chapter 5.7.

Organic coatings contain resins and curing agents as binding agents. These can be epoxy resins, polyurethane or polyester for example.

This annex also applies to the following reactive systems:

- ▶ **Resins** used for example as paint resins for coatings, as impregnating resins, injection resins or for chemically curing adhesives
- ▶ **Aqueous plastic dispersions**

### B.2      Information on organic coatings

#### B.2.1      Various products

**Resins** are solid to liquid organic polymers and oligomers with an amorphous structure when dry. These include:

- ▶ **Impregnating resins** are liquid or liquefiable resins that serve for soaking and impregnating porous materials such as casting materials. The pores set when the resin hardens. Epoxy resins, unsaturated polyester resins, polyurethane resins and acrylic resins are used as a basis for impregnating resins.
- ▶ **Injection resins** are liquid or liquefiable resins used to pressure fill cracks in the basic material and that set after hardening. Epoxy resins, polyurethane resins or polyester resins are commonly used as a basis for injection resins.
- ▶ **Casting resins** are synthetic resins that are liquid or liquefiable after moderate warming, that are poured into open moulds and that can be cured therein without any application of pressure. Casting resins include reaction resins such as epoxy resins, formaldehyde resins, isocyanate resins, methacrylic resins and unsaturated polyester resins. **Sealing compounds** made from plastic, e.g. polyamides, are casting resins in which other components are moulded. Among other things, this protects parts against the penetration of moisture, dust, foreign particles, water, etc. **Adhesives** (as per DIN EN 923: 2016-03) are non-metallic materials that bond two surfaces by surface adherence (adhesion) and internal strength (cohesion). They are assessed on the basis of

the chemical structure of their base polymer (see Section 5.7 Example 2) and can either fall within the scope of Annex A or Annex B.

#### Single-component reaction adhesives:

Single-component reaction adhesives cure on the basis of external influences. These can be systems that react to moisture, that use water in substrates or ambient air, or radiation curing adhesives where polymerisation is started in UV light. Adhesives based on acrylates are examples of radiation curing adhesives. The advantage of this type of polymerisation is that the adhesive only solidifies as and when needed because the reaction only begins when sufficient light of a specific wavelength is available. The curing times required for these adhesives are generally short, typically in the range of 0.5-60 seconds.

#### Multi-component reaction adhesives:

Most multi-component reaction adhesives are mixed from two components (two-component adhesives). The raw material is combined with a curing agent or activator. Reaction adhesives can cure (set) through various mechanisms. Reaction adhesives made of epoxy resins and anhydrides or polyamines (epoxy resin adhesives) react after polyaddition mechanisms, cyanoacrylate (cyanoacrylate adhesives) or methacrylate (methacrylic ester) after polymerisation mechanisms, and systems based on aminoplasts or phenoplasts (see phenolic resins) after polycondensation mechanisms.

**Aqueous plastic dispersions** contain thermoplastics finely distributed in water and are stable colloidal systems. Acrylic resins are used inter alia as binding agent systems for plastic dispersions. Aqueous plastic dispersions can be used as surface protection systems or dispersion adhesives for example. <sup>4</sup>

**Anaerobic adhesives** are reactive sealants that only harden in the presence of metals and in the absence of oxygen. They are used for the adhesive bonding of threaded connections, for example angle valves or for the adhesive bonding of connections in the tap.

For anaerobic adhesives only the provisions set out in Chapter B.5 apply.

#### **Coatings with cementitious fillers** (polymer content > 25% (w/w) related to cement)

Cementitious materials can be assessed for suitability in contact with drinking water according to DVGW standard W 347<sup>5</sup>. Conventional cementitious materials contain only small quantities of organic additives such as concrete admixtures. Where large quantities of polymers are added to the cementitious materials (> 25% (w/w) with regard to the dry matter cement content) the migration behaviour of the materials is comparable to organic coatings. Cementitious fillers are listed in the positive list for organic coatings in Table B-1.

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<sup>4</sup> Roland Benedix, Bauchemie - Einführung in die Bauchemie für Ingenieure, 3. Auflage, Teubner, 2006, S. 457 ff.

<sup>5</sup> Definition of this evaluation criteria document will have regard of the revised European Drinking Water Directive (Directive (EU) 2020/2184).

### B.2.2 Composition information

Coating substances and other products under this evaluation criteria document generally consist of the following main components:

- ▶ Binding agents (resins and curing agents if any),
- ▶ Fillers and colourants,
- ▶ Organic modifying agents,
- ▶ Solvents and thinners,
- ▶ Additives and polymer production aids,
- ▶ Aids to polymerisation.

The **binding agent** of a coating substance is considered to be the non-volatile component of the binding agent solution or dispersion, which forms the coating (DIN EN ISO 4618: 2015-1).

Binding agents are polymer components of coatings and determine the type of coating (see information on crosslinking conditions). The starting substances for binding agents are to be understood as monomers as defined in Commission Regulation (EU) No 10/2011.

**Fillers and colourants** provide mechanical stabilisation and coloration. Fillers enhance the protective function. They enhance the applicability of the coating substance by giving it a viscous consistency.

**Organic modifying agents** serve among other things to enhance usability and/or drying properties.

**Solvents** are used to lower viscosity in order to enhance applicability. They should not remain present after the curing process. In aqueous or water-dilutable coatings, water is used as a solvent or thinner.

**Additives and polymerisation production aids are used to increase:**

- the shelf life of starting substances and preparations,
- performance characteristics (e.g. rheological additives to enhance flow properties such as runoff behaviour and smoothness),
- film quality (e.g. anti-foam additives to prevent formation of bubbles, pores and craters,
- wetting of the substrate surface,
- the surface structure.

Due to the multiple functions of the listed starting substances, no distinction is made between additives and polymerisation production aids (PPA)

**Aids to polymerisation** may also be contained in the material.

**Binding agent systems:**

Resins based on Bisphenol A diglycidyl ether; Bisphenol F diglycidyl ether and other glycidyl ethers with various molecular weights are used in the case of **epoxy resins**. Curing agents



may be amines, amido-amines and amine adducts, whose amine hydrogens react with the epoxy groups. Isocyanates can be other curing agents. Other compounds, such as acids or other H-active compounds, can also be used as curing agents.

In **polyurethane coatings**, isocyanates and compounds containing hydroxyl groups (polyols) may be used as binding agents. The combination of isocyanates with amino-functional compounds produces polycarbamide coatings.

**Polyesters** contain polyester compounds as their binding agents, which are produced through esterification of polyvalent alcohols and polycarbonic acids, and may be crosslinked with isocyanates for example.

**Acrylic resins** are crosslinked synthetic resins obtained by the polymerisation of acrylic acid esters and methacrylic acid esters. They comprise functional groups (hydroxyl-, N-hydroxymethyl, carboxyl and epoxy groups), used for crosslinking. Acrylic resins can be crosslinked internally or externally (e.g. after adding polyisocyanates, epoxy resins or polycarbonic acids).

### **B.2.3 Information on crosslinking conditions**

Cold curing binding agents must cure at ambient temperature and are generally not heated after application (where necessary, they can be force dried with moderately heated air). Hot-curing binding agents are heated or annealed until cured. The curing time for cold curing systems depends on their composition and on ambient temperature during curing. In some cases, it can take more than 2 weeks before it is usable. Hot-curing systems are ready for use after the annealing time, typically less than an hour.

A further distinction is made between solvent-based and solvent-free binding agent systems. Solvent-free binding agents may be used to produce thicknesses of up to 2 000 µm in a single application. Solvent-based binding agents may only be only applied in thin layers, since the solvent contained in them needs to evaporate to the surface before this is prevented by the physical drying process and/or the ongoing reaction of the reactive components.

## **B.3 Composition requirements**

### **B.3.1 Positive list of starting substances for the manufacture of organic coatings**

Only the starting substances listed in Table B-1 and substances of the 4MSI Positive Lists accepted for coatings may be used to manufacture organic coatings in contact with drinking water.

For unlisted starting substances, the requirements for unlisted starting substances apply, including their contaminants and degradation and reaction products (see Chapter 5.2.2 of the general part of the evaluation criteria document for organic materials). The requirements according to Chapters 5.4.2 and 5.4.3 of the general part of the evaluation criteria document for organic materials apply to fillers and colourants.

**Table B-1 Starting substances for coatings assessed by the UBA or recognised as part of the 4MSI cooperation**

**B.3.1.1 Starting substances for resins and curing agents**

**B.3.1.1.1 Phenolic compounds**

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
13480 13607	80-05-7	2,2-Bis(4-hydroxyphenyl)-propane (Bisphenol A)	2.5	
14020	98-54-4	p-tert-Butylphenol	2.5	
14710	108-39-4	m-Cresol		
14740	95-48-7	o-Cresol		
14770	106-44-5	p-Cresol		
15880 24051	120-80-9	1,2-Dihydroxybenzene	300	
15910 24072	108-46-3	1,3-Dihydroxybenzene	120	
15940 18867	123-31-9	1,4-Dihydroxybenzene	30	
16000	92-88-6	4,4'-Dihydroxybiphenyl	300	
16360	576-26-1	2,6-Dimethylphenol	2.5	
22960	108-95-2	Phenol	150	
25927	27955-94-8	1,1,1-Tris(4-hydroxyphenyl)- ethane	0.25	
-	8007-24-7	Cashew nut shell oil, distilled (> 90% Cardanol)*	2.5	not as reactive diluent

**B.3.1.1.2 Aldehydes**

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10060	75-07-0	Acetaldehyde	300	
14110	123-72-8	Butyraldehyde		
17260	50-00-0	Formaldehyde	750	
23860	123-38-6	Propionaldehyde		

**B.3.1.1.3 Oxirane and glycidyl compounds**

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
13160 22552	28064-14-4	Novolac glycidyl ether (NOGE)*	2.5	for powder coatings only
13460 12976	54208-63-8 57469-07-5 39817-09-9 2095-03-6 9003-36-5	Bisphenol-F-diglycidyl ether*	2.5	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
13510	1675-54-3	Bisphenol-A-diglycidyl ether*	450	
13610				
13780	2425-79-8	1,4-Butanediol diglycidyl ether	0.1	QM = 1 mg/kg
16750	106-89-8	Epichlorohydrin	0.1	
14570				
17020	75-21-8	Ethylene oxide	0.1	QM = 1 mg/kg
21823	598-09-4	2-Methyl epichlorohydrin*	0.1	
24010	75-56-9	Propylene oxide	0.1	QM = 1 mg/kg
25360		Trialkyl(C5-C15)acetic acid, 2,3-epoxypropyl ester	0.1	QM = 1 mg/kg
88640	8013-07-8	epoxidised soybean oil	TOC	

#### B.3.1.1.4 Amines

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
12670	2855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethyl cyclohexane	300	
12761	693-57-2	12-Aminododecanoic acid	2.5	
12763	141-43-5	2-Aminoethanol	2.5	
35170				
12788	2432-99-7	11-Aminoundecanoic acid	250	
12789	7664-41-7	Ammonia	50 as NH <sub>4</sub> <sup>+</sup>	
35320				
13000	1477-55-0	1,3-Benzene-dimethanamine	2.5	
13075	91-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	250	
15310				
13210	1761-71-3	Bis(4-aminocyclohexyl) methane	2.5	
13250	101-77-9	Bis(4-aminophenyl) methane**	0.1	
15250	110-60-1	1,4-Diaminobutane		
15695	461-58-5	Dicyanodiamide	TOC	
15790	111-40-0	Diethylenetriamine	250	
16145	124-40-3	Dimethylamine*	3	
16150	108-01-0	Dimethylamino ethanol	900	
16960	107-15-3	Ethylenediamine	600	
15272				
17005	151-56-4	Ethyleneimine	0.1	
18460	124-09-4	Hexamethylenediamine	120	
15274				
18670	100-97-0	Hexamethylenetetramine	750 as form-aldehyde	
21754	15520-10-2	2-Methyl-1,5-diaminopentane*	5	
21765	106246-33-7	4,4'-Methylene-bis(3-chloro-2,6-diethylaniline)	2.5	
22331	25513-64-8	mixture of (35-40 %) 1,6-Diamino-2,2,4-trimethylhexane and (55-65 %) 1,6-Diamino-2,4,4-trimethylhexane	2.5	
23050	108-45-2	1,3-Phenylenediamine	0.1	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
25180	102-60-3	N,N,N',N'-Tetrakis(2-hydroxypropyl)ethylene diamine		
25420 19975	108-78-1	2,4,6-Triamino-1,3,5-triazine	125	
25960	57-13-6	Urea		
45760	108-91-8	Cyclohexylamine		
94560	122-20-3	Triisopropanolamine	250	
-	936-49-2	2-Phenylimidazoline*	2.5	
	9046-10-0	Polyoxypropylene diamine*	2.5	specification of minimum content of 80% polyoxy- propylene- diamine and an average molecular mass ≥ 230 Da
	618-36-0, 3886-69- 9, 2627- 86-3	1-Phenylethylamine*	0.1	
	694-83-7	Cyclohexane-1,2-diamine	2.5	
	80-08-0	4,4'-Diaminodiphenylsulfone	250	

#### B.3.1.1.5 Isocyanates

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
14877	2556-36-7	1,4-Cyclohexylene diisocyanate**	0.1	QM(T) = 1 mg/kg as NCO
14950	3173-53-3	Cyclohexyl isocyanate	0.1	
15700	5124-30-1	Dicyclohexylmethane-4,4'- diisocyanate	0.1	
16240	91-97-4	3,3'-Dimethyl-4,4'- diisocyanatobiphenyl	0.1	
16570	4128-73-8	Diphenylether-4,4'-diisocyanate	0.1	
16600	5873-54-1	Diphenylmethane-2,4'- diisocyanate	0.1	
16630	101-68-8	Diphenylmethane-4,4'- diisocyanate	0.1	
16920	87057-87-2	2-Ethylbutane-1,4-diisocyanate**	0.1	
18640	822-06-0	Hexamethylene diisocyanate	0.1	
19110 19147	4098-71-9	1-Isocyanato-3-isocyanatomethyl- 3,5,5- trimethylcyclohexane	0.1	
22065	34813-62-2	2-Methylpentane-1,5- diisocyanate**	0.1	
22420	3173-72-6	1,5-Naphthalene diisocyanate	0.1	
22570	112-96-9	Octadecyl isocyanate	0.1	
23060	104-49-4	1,4-Phenylene diisocyanate**	0.1	
23125	103-71-9	Phenyl isocyanate**	0.1	
25208	26471-62-5	Toluene diisocyanate	0.1	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
25210	584-84-9	2,4-Toluene diisocyanate	0.1	QM(T) = 1 mg/kg as NCO
25240	91-08-7	2,6-Toluene diisocyanate	0.1	
25270	26747-90-0	2,4-Toluene diisocyanate dimer	0.1	
25445	28807-72-9	Tricyclodecane diisocyanate**	0.1	
25573	16938-22-0	2,2,4-Trimethylhexane-1,6-diisocyanate**	0.1	
25574	15646-96-5	2,4,4-Trimethylhexane-1,6-diisocyanate**	0.1	

#### B.3.1.1.6 Diols/Polyols

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions	
13390	105-08-8	1,4-Bis(hydroxymethyl)-cyclohexane			
14880					
13690	107-88-0	1,3-Butanediol	250		
13720	110-63-4	1,4-Butanediol			
40580					
14500	9004-34-6	Cellulose			
43280					
15760	111-46-6	Diethylene glycol	TOC		
13326					
47680					
16390	126-30-7	2,2-Dimethyl-1,3-propanediol,	2.5		
22437		Neopentyl glycol			
16480	126-58-9	Dipentaerythritol			
16660	110-98-5	Dipropylene glycol			
13550					
16925	9004-57-3	Ethylcellulose			
53280					
16990	107-21-1	Ethylene glycol (1,2-Ethanediol)	TOC		
53650					
17530	50-99-7	Glucose			
18100	56-81-5	Glycerol			
18700	629-11-8	1,6-Hexanediol			
19972	87-78-5	Mannitol	2.5		
65520					
22190	2163-42-0	2-Methyl-1,3-propanediol**	250		
22840	115-77-5	Pentaerythritol			
23590	25322-68-3	Polyethylene glycol			
23651	25322-69-4	Polypropylene glycol			
23740	57-55-6	1,2-Propanediol			
81840					
23770	504-63-2	1,3-Propanediol			2.5
24490	50-70-4	Sorbitol			
24880	57-50-1	Sucrose			
25090	112-60-7	Tetraethylene glycol			
25510	112-27-6	Triethylene glycol			
25600	77-99-6	1,1,1-Trimethylolpropane			
13380			300		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
25910	24800-44-0	Tripropylene glycol		

#### B.3.1.1.7 Monoalcohols

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
12375 33120	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C <sub>4</sub> -C <sub>22</sub> )		
13150	100-51-6	Benzyl alcohol		
13840	71-36-3	1-Butanol		
13845	75-65-0	tert-Butanol*	500	
15100	112-30-1	1-Decanol		
16701	112-53-8	1-Dodecanol**		
16780	64-17-5	Ethanol		
17050	104-76-7	2-Ethyl-1-hexanol	TOC	
17160	97-53-0	Eugenol	0.1	
18150	111-70-6	1-Heptanol**		
18310	36653-82-4	1-Hexadecanol		
18780	111-27-3	1-Hexanol**		
21550	67-56-1	Methanol		
22480	143-08-8	1-Nonanol		
22555	112-92-5	1-Octadecanol**		
22600	111-87-5	1-Octanol		
22766 69760	143-28-2	Oleyl alcohol		
22870	71-41-0	1-Pentanol		
23800	71-23-8	1-Propanol		
23830	67-63-0	2-Propanol		
25070	112-72-1	1-Tetradecanol**		

#### B.3.1.1.8 Oils and acids

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10030	514-10-3	Abietic acid		
10090 30000	64-19-7	Acetic acid		
10150	108-24-7	Acetic anhydride		
10599/90A 10599/91	61788-89-4	Dimers of unsaturated fatty acids (C <sub>18</sub> ), non-hydrogenated, distilled and non-distilled	2.5	
10599/92A 10599/93	68783-41-5	Dimers of unsaturated fatty acids (C <sub>18</sub> ), hydrogenated, distilled and non-distilled		
10690	79-10-7	Acrylic acid	300	
12130	124-04-9	Adipic acid		
12280	2035-75-8	Adipic anhydride		
12810	506-30-9	Arachidic acid**		
12813	7771-44-0	Arachidonic acid**		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
12820	123-99-9	Azelaic acid		
12970	4196-95-6	Azelaic anhydride		
12980	8015-74-5	Beechnut oil**		
12990	112-85-6	Behenic acid**		
13090	65-85-0	Benzoic acid		
13620	10043-35-3	Boric acid	100 for B	
14140	107-92-6	Butyric acid		
14320	124-07-2	Caprylic acid		
14411	8001-79-4	Castor oil		
42880				
14440	64147-40-6	Castor oil, dehydrogenated		
42960				
14445	61789-44-4	Castor oil fatty acids**		
14450/1	-	Castor oil fatty acids, dehydrogenated**		
14453	61790-39-4	Castor oil fatty acids, hydrogenated**		
14470	8001-78-3	Castor oil, hydrogenated**		
42960				
14505	9004-35-7	Cellulose acetate**		
14512	9004-39-1	Cellulose acetate propionate**		
14680	77-92-9	Citric acid		
14685	8001-31-8	Coconut oil**		
14693	8001-30-7	Corn oil**		
14695/1	-	Corn oil fatty acids**		
14698	8001-29-4	Cotton seed oil**		
14700/1	68308-51-0	Cotton seed oil fatty acids**		
15095	334-48-5	n-Decanoic acid		
16697	693-23-2	Dodecanedioic acid		
16775	112-86-7	Erucic acid		
52730				
17170	61788-47-4	Coconut fatty acids		
17175	68938-15-8	Coconut fatty acids, hydrogenated**		
24440	9000-59-3	Shellac**		
17200	68308-53-2	Soya fatty acids		
17215	84625-38-7	Sunflower oil fatty acids**		
17230	61790-12-3	Tall oil fatty acids		
17236	61790-37-2	Tallow oil fatty acids**		
17245	8016-13-5	Fish oil**		
17247/1	-	Fish oil fatty acids**		
17275	64-18-6	Formic acid		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
55040				
17290	110-17-8	Fumaric acid		
17510	29204-02-2	Gadoleic acid		
55190				
18010	110-94-1	Glutaric acid		
18070	108-55-4	Glutaric anhydride		
18124	8016-24-8	Hempseed oil**		
18126/1	-	Hempseed oil fatty acids		
18250	115-28-6	Hexachloroendomethylene-tetrahydrophthalic acid	0.1	
14527		Hexachloroendomethylene-tetrahydrophthalic anhydride		
18280	115-27-5	n-Hexanoic acid		
18770	142-62-1			
59360				
18880	99-96-7	4-Hydroxybenzoic acid		
18900	106-14-9	12-Hydroxystearic acid		
61840				
19150	121-91-5	Isophthalic acid	250	
19270	97-65-4	Itaconic acid		
19460	50-21-5	Lactic acid		
19470	143-07-7	Lauric acid		
19515	557-59-5	Lignoceric acid**		
19518	60-33-3	Linoleic acid		
64015				
19526	28290-79-1	Linolenic acid		
64150				
19532	8001-26-1	Linseed oil**		
64160				
19534/1	68424-45-3	Linseed oil fatty acids**		
19540	110-16-7	Maleic acid	TOC	
64800				
19960	108-31-6	Maleic anhydride	TOC	
64900				
19965	6915-15-7	Malic acid		
65020				
19968	141-82-2	Malonic acid		
65040				
22350	544-63-8	Myristic acid		
67891				
22763	112-80-1	Oleic acid		
69040				
22769/1	92044-96-7	Olive oil fatty acids**		
22775	144-62-7	Oxalic acid	300	
69920				
22780	57-10-3	Palmitic acid		
70400				
22785	373-49-9	Palmitoleic acid**		
71020				



Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
22790/1	-	Palmkernel oil fatty acids**		
22795/1	-	Palm oil fatty acids**		
22867	109-52-4	n-Pentanoic acid (valeric acid)**		
22945	68132-21-8	Perilla oil**		
22950/1	-	Perilla oil fatty acids**		
23170	7664-38-2	Phosphoric acid		
72640				
23173	1314-56-3	Phosphoric anhydride**		
23200	88-99-3	o-Phthalic acid		
74480				
23380	85-44-9	Phthalic anhydride		
76320				
23730	8002-11-7	Poppy-seed oil**		
23733/1	-	Poppy-seed oil fatty acids**		
23890	79-09-4	Propionic acid		
23950	123-62-6	Propionic anhydride		
24045	8016-49-7	Pumpkin seed oil**		
24047/1	-	Pumpkin seed oil fatty acids**		
24055	89-05-4	Pyromellitic acid**	2.5	
13040				
24057	89-32-7	Pyromellitic dianhydride		
24065/1	93165-31-2	Rapeseed oil fatty acids**		
24070	73138-82-6	Resin acids and Rosin acids		
83610				
24075	141-22-0	Rizinoleic acid	TOC	
83700				
24078	-	Rizinoleic acid, dehydrogenated**		
24100	8050-09-7	Rosin		
24130				
24190				
24160	8052-10-6	Tall oil rosin		
24260	8001-23-8	Safflower oil**		
24262/1	-	Safflower oil fatty acids**		
24270	69-72-7	Salicylic acid		
24280	111-20-6	Sebacic acid		
24430	2561-88-8	Sebacic anhydride		
24435	8008-74-0	Sesame oil**		
24437/1	-	Sesame oil fatty acids**		
24520	8001-22-7	Soybean oil		
24550	57-11-4	Stearic acid		
24820	110-15-6	Succinic acid		
24850	108-30-5	Succinic anhydride		
24895	8001-21-6	Sunflower oil**		
24900/1	84625-38-7	Sunflower oil fatty acids**		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
24905	8002-26-4	Tall oil**		
24910	100-21-0	Terephthalic acid	375	
24940	100-20-9	Terephthalic acid dichloride		
25540	528-44-9	Trimellitic acid	250	
13050				
25550	552-30-7	Trimellitic acid anhydride		
26340	8024-09-7	Walnut oil**		
26345/1	-	Walnut oil fatty acids**		
36000	50-81-7	Ascorbic acid		
52000	27176-87-0	Dodecylbenzenesulphonic acid	TOC	
80720	8017-16-1	Polyphosphoric acids		
83440	2466-09-3	Pyrophosphoric acid		
92160	87-69-4	Tartaric acid		

#### B.3.1.1.9 Other monomers

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10120	108-05-4	Vinyl acetate	600	
10690	79-10-7	Acrylic acid	300 as acrylic acid	
10780	141-32-2	n-Butyl acrylate		
11470	140-88-5	Ethyl acrylate		
11510	818-61-1	Ethylene glycol monoacrylate		
11830				
11710	96-33-3	Methyl acrylate	2.5	
11530	999-61-1	2-Hydroxypropyl acrylate		
13870	106-98-9	Butene	0.1	
10630	79-06-1	Acrylamide		
10660	15214-89-8	2-Acrylamido-2-methylpropane sulphonic acid	2.5	
11500	103-11-7	2-Ethylhexyl acrylate	2.5	
12100	107-13-1	Acrylonitrile	0.1	
13395	4767-03-7	2,2-Bis(hydroxymethyl) propionic acid	2.5	only as monomer for polymeric additive
13630	106-99-0	1,3-Butadiene	0.1	QM = 1 mg/kg
14260	502-44-3	Caprolactone	2.5 as the sum of caprolactone and 6-hydroxyhexanoic acid	
14380/ 23155	75-44-5	Carbonyl chloride	0.1	QM = 1 mg/kg
16950	74-85-1	Ethylene		
19490	947-04-6	Lauro lactam	250	
20020	79-41-4	Methacrylic acid	300 as	
20110	97-88-1	Butyl methacrylate	methacrylic acid	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
21130	80-62-6	Methyl methacrylate		
21190	868-77-9	Ethylene glycol monomethacrylate		
20440	97-90-5	Ethylenglycol dimethacrylate	2.5	
20530	2867-47-2	2-(Dimethylamino)ethyl methacrylate	0.1	
20590	106-91-2	2,3-Epoxypropyl methacrylate	1	QMA = 0.02 mg/6 dm <sup>2</sup>
25120	116-14-3	Tetrafluoro ethylene	2.5	only as monomers for polymer additives
25150	109-99-9	Tetrahydrofuran	30	
26050	75-01-4	Vinyl chloride	0.1	QM = 1 mg/kg
26110	75-35-4	Vinyliden chloride	0.1	
22660	111-66-0	1-Octene	TOC	
23980	115-07-1	Propylene		
24610	100-42-5	Styrene		
	22208-25-9	2-Ethyl-2-(hydroxymethyl)-1,3-propanedioltriaceo acetate*	2.5 µg/l for a sum of 2-Ethyl-2-(hydroxy-methyl)-1,3-propanediol-(mono-, di-, tri-) triaceoacetate 300 µg/l for 1,1,1-trimethylolpropane	

#### B.3.1.1.10 Blocking agents

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	96-29-7	2-Butanoxime*		for hot-cured coatings only
14200 41840	105-60-2	Caprolactam	750	for hot-cured coatings only

#### B.3.1.2 Fillers/Colourants

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
34480		Aluminium fibres, -flakes and -powder		
34560	21645-51-2	Aluminium hydroxide	20 for Al	
34690	11097-59-9	Aluminium-magnesium hydroxy-carbonate		
34720	1344-28-1	Aluminium oxide		
92000	7727-43-7	Barium sulfate	70 for Ba	
41520	1305-78-8	Calcium oxide		
42080	1333-86-4	Carbon black	PAH and benzo(a)-pyrene 10% of	Purity requirements in Table 1 of

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
			the threshold of TrinkwV	Regulation (EU) No 10/2011
42500		Carbonic acid, salts		
55520		Glass fibres (without glass fibre sizing)		
55600		Glass microballs		
62240	1332-37-2	Iron oxide	20 for Fe	
62720	1332-58-7	Kaolin		
62800	92704-41-1	Kaolin, calcinated		
64720	1309-48-4	Magnesium oxide		
65360	11129-60-5	Manganese oxide	5 for Mn	
67120	12001-26-2	Mica		
83470	14808-60-7	Quartz		
85601		Silicates, natural (except asbestos)		
85610		Silicates, natural, silylated (except asbestos)		
85680	1343-98-2	Silicic acid		
86000	1343-98-2	Silicic acid, silylated		
86240	7631-86-9 69012-64-2	Silicon dioxide		requirements as per Table 1 of Commission Regulation (EU) No 10/2011
86285		Silicon dioxide, silylated		requirements as per Table 1 of Commission Regulation (EU) No 10/2011
85950	37296-97-2	Silicic acid, magnesium-sodium- fluoride salt	150 for fluoride	
86160	409-21-2	Silicon carbide		
92080	14807-96-6	Talc		
93440	13463-67-7	Titanium dioxide		
96180	-	Zinc dust*		
96240	1314-13-2	Zinc oxide	250 for Zn	
96200	55799-16-1	Zinc hydroxy phosphite**		

### B.3.1.3 Cementitious fillers

Substance	Restrictions
Cements as per the list of accepted generic constituents <sup>6</sup> in the 4MSI common approach 'Assessment of cementitious products in contact with drinking water'	Requirements according to DVGW standard W 347 <sup>7</sup>
Aggregates as per the list of accepted generic constituents in the 4MSI common approach	Requirements according to DVGW standard W 347

<sup>6</sup> [https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/cementitious\\_products\\_-\\_4ms\\_common\\_approach\\_jmc\\_final\\_draft\\_sep\\_2018\\_2\\_0.pdf](https://www.umweltbundesamt.de/sites/default/files/medien/374/dokumente/cementitious_products_-_4ms_common_approach_jmc_final_draft_sep_2018_2_0.pdf)

<sup>7</sup> DVGW standard W 347 (May 2006): Hygiene requirements for cement-bound materials intended for use in drinking water supply systems - Testing and evaluation

Substance	Restrictions
'Assessment of cementitious products in contact with drinking water'	
Inorganic additives as per the list of accepted generic constituents in the 4MSI common approach 'Assessment of cementitious products in contact with drinking water'	Requirements according to DVGW standard W 347
Organic additives as per the positive list for organic coatings – Table B-1	Requirements as per B.4 and positive list restrictions
Mixing water as per the list of accepted generic constituents in the 4MSI common approach 'Assessment of cementitious products in contact with drinking water'	Requirements according to DVGW standard W 347

#### B.3.1.4 Modifying agents, organic

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
13150	100-51-6	Benzyl alcohol		
47520	-	Dicyclopentadiene-indene-styrene-alpha-methylstyrene-vinyltoluene-isobutylene-copolymer, hydrogenated**	250	
74560	85-68-7	Benzyl butyl phthalate	1500	see CR (EU) No 2018/2005
74640	117-81-7	Bis(2-ethylhexyl)phthalate	75	
74880	84-74-2	Dibutyl phthalate	15	
75105	68515-49-1 26761-40-0	Phthalic acid, diester with primary saturated (C <sub>9</sub> -C <sub>11</sub> ) alcohols, > 90 % C <sub>10</sub>	450	
92200	6422-86-2	Bis(2-ethylhexyl)terephthalate	TOC	

#### B.3.1.5 Solvents

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
13840	71-36-3	1-Butanol		
25150	109-99-9	Tetrahydrofuran	30	
30045	123-86-4	Butyl acetate		
30140	141-78-6	Ethyl acetate		
30295	67-64-1	Acetone		
40594	75-65-0	tert-Butanol**	500	
48030	112-34-5	Diethylene glycol monobutyl ether***		
48050	111-90-0	Diethylene glycol monoethyl ether***		
53765	111-76-2	Ethylene glycol monobutyl ether (Butyl glycol)**	150	
53820	110-80-5	Ethylene glycol monoethyl ether**		
16999	112-25-4	Ethylene glycol monoethyl ether**		
53860	109-86-4	Ethylene glycol monomethyl ether**		
49540	67-68-5	Dimethyl sulphoxide		
52800	64-17-5	Ethanol		
53255	100-41-4	Ethylbenzene**	30	
66620	75-09-2	Dichloromethane**	2.5	
66655	78-93-3	Methyl ethyl ketone**	250	
66725	108-10-1	Methyl isobutyl ketone**	250	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
81882	67-63-0	2-Propanol, Isopropanol		
93540	108-88-3	Toluene**	60	
95855	7732-18-5	Water	as per TrinkwV	
26945 95945	1330-20-7	Xylene isomers**	50	

### B.3.1.6 Propellant

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	115-10-6	Dimethyl ether*	< 1	

### B.3.1.7 Additives and polymer production aids

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
	-	Polymeric additives made of monomers under B.3.1.1.9		
12786	919-30-2	3-Aminopropyltriethoxysilane	2.5	
	119345-04-9	Benzene, 1,1'-oxybis-, tetrapropylene derivatised, sulphonated, sodium salts	450	
-	119-53-9	Benzoin*	2.5	
21498	2530-85-0	[3-(Methacryloxy)propyl]tri-methoxysilane	2.5	
26305	78-08-0	Vinyltriethoxysilane	2.5	
26320	2768-02-7	Vinyltrimethoxysilane	2.5	
43120	8001-78-3	Castor oil, hydrogenated		
53600	60-00-4	Ethylendiaminetetraacetic acid (EDTA)**	60	
-	91744-27-3	Glycerides, mono-, di- and tri-castor oil *		
57520	31566-31-1	Glycerol monostearate**		
19960	108-31-6	Maleic anhydride	TOC	
66930	68554-70-1	Methylsilsesquioxane		< 1 mg methyl-trimethoxy-silane /kg methyl-silsesquioxane
	1313-59-3	Sodium oxide**		
68960	301-02-0	Oleamide*		
69760	143-28-2	Oleyl alcohol		
76960	25322-68-3	Polyethylene glycol		
81840	57-55-6	1,2-Propandiol		
30280	108-24-7	Acetic anhydride		
34230	-	Alkyl(C <sub>8</sub> -C <sub>22</sub> )sulphonic acid	300	
33801	-	n-Alkyl(C <sub>10</sub> -C <sub>13</sub> )benzene-sulphonic acid	1500	
34240	91082-17-6	n-Alkyl(C <sub>10</sub> -C <sub>21</sub> )sulphonic acid phenylester	2.5	
35600	1336-21-6	Ammonium hydroxide	50 as NH <sub>4</sub> <sup>+</sup>	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
37280	1302-78-9	Bentonite		
37520	2634-33-5	1,2-Benzothiazolin-3-one**	25	for in-can preservation only
38560	7128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	30	
39090	-	N,N-Bis(2-hydroxyethyl)alkyl- (C <sub>8</sub> -C <sub>18</sub> )amine	60 as tertiary amine	
42500	-	Carbonates		
42720	8015-86-9	Carnauba wax		
43730	55965-84-9	Mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one 3:1**	7.5	for in-can preservation only, QMA = 25 µg/dm <sup>2</sup>
43760	26172-55-4	5-Chloro-2-methyl-2H-isothiazol-3-one**	0.5	for in-can preservation only
45640	5232-99-5	2-Cyano-3,3-diphenyl ethyl acrylate	2.5	
45705	166412-78-8	1,2-Cyclohexyl dicarbonic acid diisononyl ester	TOC	
46640	128-37-0	2,6-Di-tert-butyl-p-cresole	150	
50640	3648-18-8	Di-n-octyltin dilaurate	0.3 as Sn	
53520	110-30-5	N,N'-Ethylene-bis-stearamide		
58960	57-09-0	Hexadecyltrimethylammonium bromide	300	
59120	23128-74-7	1,6-Hexamethylenebis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide]	TOC	
60480	3896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	TOC	
60560	9004-62-0	Hydroxyethyl cellulose		
61600	1843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	300	
62140	6303-21-5	Hypophosphorous acid		
63760	8002-43-5	Lecithin		
64270	7447-41-8	Lithium chloride**	30 for Li	
66715	693-98-1	2-Methylimidazole*	2.5	
66755	2682-20-4	2-Methyl-4-isothiazolin-3-one	25	for in-can preservation only
67850	8002-53-7	Montan wax		
-	1313-59-3	Sodium oxide**		
68320	2082-79-3	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	300	
71680	6683-19-8	Pentaerythritoltetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]		
74240	31570-04-4	Tris(2,4-di-tert-butylphenyl)-phosphite		
76721	63148-62-9	Polydimethylsiloxane MW > 6800 Da		specification as per Commission Regulation (EU) No 10/2011
77360	9005-07-6	Polyethylene glycol dioleate**	TOC	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
77520	61791-12-6	Polyethylene glycol ester with castor oil	TOC	
77600	61788-85-0	Polyethylene glycol ester with hydrogenated castor oil		
77702	-	Polyethylene glycol esters of aliphatic monocarbonic acids (C <sub>6</sub> -C <sub>22</sub> ) and their ammonium and sodium sulphates		
77895	68439-49-6	Polyethylene glycol (EO=2-6) monoalkyl(C <sub>16</sub> -C <sub>18</sub> )ether	2.5	
	69011-36-5	Isotridecanol, ethoxylated	90	specification for polymer: maximum residue of 0.2 mg ethylene oxide/kg
78160	9004-96-0	Poly (ethylene glycol) monooleate**	TOC	
79550	9014-85-1	2,4,7,9-tetramethyl-5-decyn-4,7-diol ether, ethoxylated (polyethylene glycol-2,4,7,9-tetramethyl-5-decyn-4,7-diol ether)**		for sintered PTFE coating only
80000	9002-88-4	Polyethylene wax		
80077	68441-17-8	Polyethylene wax, oxidised	TOC	
80160	37349-34-1	Polyglycerol-5-stearate**		
80480	82451-48-7	Poly(6-morpholino-1, 3, 5-triazin-2,4-diyl)-[(2, 2, 6, 6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2, 2, 6, 6-tetramethyl-4-piperidyl)-imino]	250	
80640	-	Silicone polyether, polyoxyalkyl(C <sub>2</sub> -C <sub>4</sub> )dimethyl-polysiloxane		
81200	71878-19-8	Poly[6-[(1,1,3,3-tetramethyl-butyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)imino-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]	150	
81870	35674-65-8	N,N"-Propane-1,3-diylbis[N'-octadecyl urea]	2.5	
85360	109-43-3	Dibutyl sebacate	TOC	
contained in 86000	67762-90-7	Silicon dioxide, reaction product with polydimethylsiloxane		
86240/85580	7631-86-9, 69012-64-2	Silicon dioxide		requirements as per Table 1 of Commission Regulation (EU) No 10/2011
87680	1338-43-8	Sorbitan monooleate		
80720	8017-16-1	Polyphosphoric acids		
87760	26266-57-9	Sorbitan monopalmitate		



Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
91530	-	Sulphosuccinic acid, alkyl (C <sub>4</sub> -C <sub>20</sub> ) or cyclohexyl diester, salts	250	
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol-diisobutyrate	250	
95859	-	Waxes, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks, high viscosity		specification as per Commission Regulation (EU) No 10/2011
95883	-	White mineral oil, paraffinic, derived from petroleum-based hydrocarbon feedstocks		specification as per Commission Regulation (EU) No 10/2011
95870	-	Wheat protein**		
95935	11138-66-2	Xanthan gum		

### B.3.1.8 Photoinitiators for adhesives

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
38240	119-61-9	Benzophenone	30	
48640	131-56-6	2,4-Dihydroxybenzophenone		
48720	611-99-4	4,4'-Dihydroxybenzophenone	300	
92470	106990-43-6	N,N',N'',N'''-Tetrakis(4,6-bis(butyl(N-methyl-2,2,6,6-tetramethyl-piperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecan-1,10-diamine	2.5	
94000	102-71-6	Triethanolamine	2.5	
94560	122-20-3	Triisopropanolamine	250	

Additionally, all substances listed under Solvents, Organic modifying agents, Binding agents or Fillers/Colourants.

### B.3.1.9 Aids to Polymerisation

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	9005-82-7	Amylose**		
-	7727-54-0	Ammonium persulphate*	50 as NH <sub>4</sub> <sup>+</sup>	
-	7727-21-1	Potassium persulphate*		
	7775-27-1	Sodium persulphate*		
-	7681-65-4	Copper(II)iodide**	50 for iodide, 200 for copper	
63240	8006-54-0	Lanolin**		specification according to EAB <sup>8</sup>
-	219756-63-5	Sodium-α-C11-alcohol-heptaglycol ether-ω-sulphate*	250	
-	7775-27-1	Sodium persulphate		
-	27619-97-2	1H,1H,2H,2H perfluorooctane sulfonic acid (FTS)**	0.1	
94000	102-71-6	Triethanolamine	2.5	
67680	27107-89-7	Mono-n-octyltin-tris(2- ethylhexylthioglycolate)	60 as Sn	
50320	15571-58-1	Di-n-octyltin-bis(2- ethylhexylthioglycolate)	0.3 as Sn	
51040	15535-79-2	Di-n-octyltin thioglycolate		
93420	7646-78-8	Tin(IV)chloride**		

Explanation:

\* Substances which have been assessed nationally in the context of this evaluation criteria document.

\*\* Substances that are assessed by another EU Member State as part of the 4MS initiative and adopted by the other states (listed in the 4MSI Core List).

### B.3.2 Intermediate products

The list of intermediate products is informative. It illustrates the reaction paths taken into account when determining the positive list. Due to the diversity of possible reaction paths, the list of possible intermediate products is not exhaustive. The starting substances for manufacturing intermediate products must appear in Table B-1.

Some examples are given below:

**Tabelle B-2 Intermediate products**

German designation	English designation	Components
Intermediate products with epoxy groups		
BPA-Harze	Bisphenol A resins	Epichlorhydrin, Bisphenol A
BPF-Harze	Bisphenol F resins	Epichlorhydrin, Bisphenol F
Phenol-Novolac-Harze (nur für Pulverlacke)	Phenol novolac resins (for powder coatings only)	Bisphenol F diglycidyl ether

<sup>8</sup> Lanolin is mentioned as *Wollwachs* („wool wax or -fat“) in the European pharmacopoeia ([BfArM - Homepage - Gesamtregister des Europäischen Arzneibuch](#), 10. Ausgabe, 2. Nachtrag, Amtliche deutsche Ausgabe), in German

German designation	English designation	Components
Epoxyesterharze	Epoxyester resins	Epoxy resins, fatty acids
<b>Intermediate products with amines</b>		
Kondensationsprodukt von Aldehyd und Polyamin	Condensation product of aldehyde and polyamine	Aldehydes, Amines
Mannich Basen und Salze hiervon	Mannich base and salts thereof	Phenols, formaldehyde, amines
Michael-Additionsprodukte	Michael addition products	unsaturated compounds like e.g. unsaturated acids, amines
Polyaminoamide	Polyaminoamides	Monomeric fatty acids, dimeric fatty acids, amines
<b>Intermediate products with isocyanates</b>		
Urethanpolyamine	Urethane polyamines	Isocyanates, amines
Poly-/Oligomere von Isocyanaten (Uretidion, Isocyanurat, Biuret)	Polymers or Oligomers of Isocyanates	Isocyanates
Blockierte Isocyanate (nur für heißhärtende Beschichtungen)	blocked Isocyanates	Isocyanates, caprolactam, butanonoxime
Prepolymere	Prepolymers	Isocyanates, alcohols, amines
<b>Various polymer types</b>		
Polyacrylate	Polyacrylates	
Copolymer aus Ethylacrylat und Ethylhexylacrylat	Ethylacrylate-Ethylhexylacrylate-copolymer	Ethyl acrylate, ethylhexyl acrylate
Polybutylacrylate	Polybutylacrylates	Butyl acrylat
Polymethacrylate	Polymethacrylates	
Poly(meth)acrylatpolyole	Poly(meth)acrylate polyols	Acrylic acid, methacrylic acid, alcohols
Polyethylenglycoldiacrylat	Polyethyleneglycoldiacrylate	Polyethylene glycol, acrylic acid
Polyacrylnitrilpolyole	Polyacrylonitrile Polyols	Acrylic acid, methacrylic acid, acrylonitrile, alcohols
Polyetherpolyole	Polyether Polyols	Oxirane compounds, alcohols, tetrahydrofuran, amines
Polyesterpolyole	Polyester Polyols	Carboxylic acids, alcohols
Polyamid	Polyamide	Lactams
Phenol-Formaldehydharze	Phenol formaldehyde resins	Phenols, formaldehyde
Harnstoff-Formaldehydharze	Urea formaldehyde resins	Formaldehyde, urea
Copolymer aus Vinylidenchlorid	Vinylidene chloride copolymer	Vinylidene chloride, other monomers

## B.4 Additional requirements

The additional requirements laid down in Table B-3 apply to the various binding agent systems of organic coatings. The general part of the evaluation criteria document for organic materials must be observed.

In case of combinations of different types of binding agents, the additional requirements shall be met for all types of binding agents included.

**Table B-3 List of additional requirements for the different binding agent systems**

Substances/substance groups	Restriction MTC <sub>tap</sub> in µg/l	Test method (Other equivalent test methods may be used)
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a) Coatings containing epoxy resins

Substances/substance groups	Restriction MTC <sub>tap</sub> in µg/l	Test method (Other equivalent test methods may be used)
Bisphenol A	2.5	DIN EN 13130-13: 2005-05
Bisphenol F	2.5	DIN EN 13130-13: 2005-05
BADGE including their hydrolysis products	450	Official method <sup>9</sup> L 00.00-51
BFDGE including their hydrolysis products	2.5	Official method <sup>10</sup> L 00.00-51
NOGE isomers with M < 1000 Da including hydrolysis products	2.5	DIN EN 15137: 2006-06
Epichlorhydrin and 3-Monochloro-1,2-propandiol (hydrolysis product)	0.1 6	DIN EN 14207: 2003-09 official method <sup>11</sup> B80.56-2
Formaldehyde	750	Notification 50 (Federal Health Gazette 30 (1987)368)
Primary aromatic amines	0.1	specific detection by GC-ECD/GC-MS with derivatisation <sup>12</sup>
b) Coatings containing polyurethanes		
Total of all isocyanates Alternatively, hydrolysing amines may be determined in migration waters	QM = 1mg/kg	DIN EN 13130-8: 2004-08
Primary aromatic amines	0.1	specific detection by GC-ECD/GC-MS with derivatisation
c) Coatings containing polyesters		
d) Coatings containing polyacrylates		
Acrylates	300 as acrylic acid	
e) Polyamides		
Primary aromatic amines	0.1	specific detection by GC-ECD/GC-MS with derivatisation
f) Reaction products of photoinitiators for adhesives		

## B.5 Regulation on the hygienic evaluation of anaerobic adhesives in contact with drinking water

Generally, anaerobic adhesives cross-link to polyacrylates and polymethacrylates with the help of catalysts. The following starting substances are typically used:

Mono-/multifunctional acrylates and/or mono-/multifunctional methacrylates (e.g. (meth-)acrylate terminated compounds in the form acrylate-R-acrylate and/or acrylate-r, where r = organic residue such as H, urethane, epoxy, acrylate, aliphatic and aromatic

<sup>9</sup> Official methods for analysing food: Official collection of analysis procedures under § 64 LFGB [German Food and Feed Code] (formerly § 35 LMBG): <https://www.methodensammlung-bvl.de/de/dokumente> (in German)

<sup>10</sup> Official methods for analysing food: Official collection of analysis procedures under § 64 LFGB [German Food and Feed Code] (formerly § 35 LMBG): <https://www.methodensammlung-bvl.de/de/dokumente> (in German)

<sup>11</sup> Official methods for analysing food: Official collection of analysis procedures under § 64 LFGB [German Food and Feed Code] (formerly § 35 LMBG): <https://www.methodensammlung-bvl.de/de/dokumente> (in German)

<sup>12</sup> Test method: Pietsch et al (1996) Fresenius J. Anal. Chem. 355:164-173 or Pietsch et al. (1997) Vom Wasser 88: 119-135

residue, polyol) with content of > 60% in relation to the end-product, which cross-link to polyacrylates/polymethacrylates with the help of catalysts (e.g. peroxide and amine).

Other starting substances include plasticizers, fillers, thickeners, aids to polymerisation, additives such as stabilisers and colourants.

The positive list of Annex B, Table B-1 of this evaluation criteria document, which also includes air-curing adhesives such as epoxy resin adhesives, does not cover the typical formulations for anaerobic adhesives. In addition, there is no possibility of testing these products according to the migration testing as per DIN EN 12873-1 or -2.

The contact areas of the cured anaerobic adhesive with drinking water are smaller than for seals in drinking water distribution. Therefore, potential migration of starting substances from the cured adhesive can be estimated as (very) low.

As regards the factory application of anaerobic adhesives, it can be assumed that the curing takes place exhaustively under the (optimal) conditions specified and no measurable amount of migration into the water distribution system occurs. When used on-site, too much adhesive could be wrongly applied to the thread. If these amounts are not left to react, the drinking water may become contaminated. For this reason, proper application is important. The industry federation *Klebstoffe e.V.* has issued guidance<sup>13</sup> (in German) on proper application.

If applied properly, anaerobic adhesives as described above should not have any adverse impact on drinking water quality.

Anaerobic adhesives do not require a certificate of conformity.

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<sup>13</sup> [https://www.klebstoffe.com/wp-content/uploads/2020/04/Empfehlung\\_Einsatz\\_anaerob\\_haertender\\_Gewindedichtmittel\\_im\\_Trinkwasserbereich.pdf](https://www.klebstoffe.com/wp-content/uploads/2020/04/Empfehlung_Einsatz_anaerob_haertender_Gewindedichtmittel_im_Trinkwasserbereich.pdf) (in German)

## **Annex C Lubricants**

### **C.1 Scope of application**

This annex applies to lubricants.

Lubricants reduce friction and wear in a tribological system in which the surfaces of two components are in moving contact with one another. Lubricants within the meaning of this evaluation criteria document can come into direct contact with drinking water. Lubricants are broken down into liquid, plastic rigid and solid types. These lubricants must be classed as a building element/component in a drinking water or sanitary installation.

Food technology lubricants, which demonstrate compliance with DIN EN ISO 21469 or other international regulations, are not exempt from a hygienic assessment before use in drinking water in accordance with this evaluation criteria document.

Sliding or fitting lubricants, metal machining lubricants and other lubricants are not covered by the scope of application.

### **C.2 Information on lubricants**

Lubricants for use with fittings/ancillaries are generally composed of the base oil, the thickener and if necessary a low dose of additives or adjuvants. Base oils are the principal component and account for more than 50% of the lubricant. Thickeners account for approximately 20% of the lubricant. Additives and polymerisation production aids are used to create specific properties such as corrosion protection and are added to lubricants in amounts of approximately 2%.

The content information mentioned is used solely to classify technological function, they are not relevant for compliance with the positive list.

### **C.3 Composition requirements**

#### **C.3.1 Positive list for lubricants**

Only the starting substances listed in Table C-1 and substances of the 4MSI Positive Lists accepted for lubricants may be used to manufacture lubricants in contact with drinking water.

For unlisted starting substances, the requirements for unlisted starting substances apply, including their contaminants and degradation and reaction products (see Chapter 5.2.2 of the general part of the evaluation criteria document for organic materials). The requirements according to Chapter 5.4.3 of the general part of the evaluation criteria document for organic materials apply to colourants.

**Table C-1 Positive list for lubricants****C.3.1.1 Base oils**

Ref. No	CAS No	Substance	Restriction MTCtap in µg/l	Other restrictions
-	-	Cyclic Organopolysiloxanes with methyl groups only or n-alkyl groups (C <sub>2</sub> -C <sub>32</sub> ) *		composition in accordance with BfR Recommendation XV <sup>14</sup>
-	70131-67-8	Polydimethylsiloxane, hydroxy terminated*		composition in accordance with BfR Recommendation XV <sup>14</sup>
14411 42880	8001-79-4	Castor oil		
14440 42960	64147-40-6	Castor oil, dehydrogenated		
-	68083-14-7, 73138-88-2, 68440-81-3	Silicone oils with methyl and phenyl groups, linear and branched*		composition in accordance with BfR Recommendation XV <sup>14</sup>
17200	68308-53-2	Soya fatty acids		
17236	61790-37-2	Tallow oil fatty acids		
	163149-29-9	Polyalphaolefin from 1-Dodecene and 1-Octene		average molecular weight at least 440 Da, viscosity at 100°C at least 3.8 cSt ( $3,8 \times 10^{-6}$ m <sup>2</sup> /s); polymerisation production aids and additives less than 0.02 % (w/w) in polymer
66930	68554-70-1	Methylsilsesquioxane		< 1 mg Methyltrimethoxy-silane /kg Methylsilsesquioxane
76520	9003-29-6	Polybutene*		composition as per Annex A
76530	68937-10-0	Polybutene, hydrogenated*		composition as per Annex A
76685	68037-01-4	Poly 1-decene, hydrogenated		residual hydrocarbon contamination with carbon number less than 30: not exceeding 1.5%, free of naphthenes, aromatic compounds, PAHs
76721	63148-62-9	Polydimethylsiloxane MW > 6800 Da		specification as per Commission Regulation (EU) No 10/2011
76721	9016-00-6, 63148-62-9, 68037-74-1	Methyl silicone oil: linear and branched*		composition in accordance with BfR Recommendation XV <sup>14</sup>

<sup>14</sup> [https://bfr.ble.de/kse/faces/DBEmpfehlung\\_en.jsp](https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp)

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
76950 80000 80360	9002-88-4	Polyethylene*		composition as per Annex A
95858	9003-27-4	Polyisobutylene*		composition as per Annex A
95883	-	Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks, low viscosity	2.5	specification as per Commission Regulation (EU) No 10/2011
-	-	White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstocks		specification as per Commission Regulation (EU) No 10/2011
-	68604-46-6	Lithium salt of castor oil fatty acids, hydrogenated*	30 for Li	

### C.3.1.2 Thickener

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10090 30000 10599/5 6	64-19-7	Acetic acid		
13090 37600	-	Calcium salts of linear, aliphatic, saturated monovalent carboxylic acids C <sub>10</sub> -C <sub>20</sub> *		
18900 61840	65-85-0	Benzoic acid		
24550 89040	106-14-9	12-Hydroxystearic acid		
34720 41280	57-11-4	Stearic acid		
54450	1344-28-1	Aluminium oxide	20 for Al	
54480	1305-62-0	Calcium hydroxide		
66240 69885	-	Fats and oils, from animal or vegetable food sources		
81160	-	Fats and oils, hydrogenated, from animal or vegetable food sources		
83560	9004-67-5	Methyl cellulose (gelling agent)		
85680	68988-56-7	Silicon dioxide, reaction product with trimethylchlorosilane and isopropylalcohol*		composition in accordance with BfR recommendation XV <sup>14</sup>
	9002-84-0	Polytetrafluorethylene*	2.5 for tetrafluoro-ethylene	
	68953-58-2	Dialkyldimethylammonium-aluminium silicate*		
	1343-98-2	Silicic acid		purity requirements for fillers according to Chapter 5.4.2 (general part)



Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
86240	7631-86-9 69012-64-2	Silicon dioxide		requirements as per Table 1 of Commission Regulation (EU) No 10/2011
included in 86285	68611-44-9	Silicon dioxide, reaction product with dimethyldichlorosilane*		
included in 86285	68909-20-6	Silicon dioxide, reaction product with hexamethyldisilazane*		
included in 86285	67762-90-7	Silicon dioxide, reaction product with polydimethylsiloxane*		
-	54326-11-3	Aluminium stearoyl benzoyl-hydroxide*		
-	71011-24-0	Quarternary ammonium compounds, benzyl(hydrogenated tallow-alkyl)dimethyl, salts with bentonite*		
-	-	reaction product of sebacic acid with stearylamine, neutralised with calcium hydroxide*		
-	7620-77-1	Lithium salt of 12-Hydroxystearic acid*	30 for Li	
-	25038-74-8	Polylauro lactam (Polyamide-12)*	250 for lauro lactam	composition as per Annex A, oligomers with MW > 1000 Da max. 2 %

### C.3.1.3 Additives

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	637-12-7	Aluminium tristearate*		
40320	10043-35-3	Boric acid	100 for B	
40400	10043-11-5	Boron nitride		
40720	25013-16-5	tert-Butyl-4-hydroxyanisole (BHA)	TOC	
45940 15095	334-48-5	n-Decanoic acid		
46640	128-37-0	2,6-Di-tert-butyl-4-cresol (BHT)	150	
52800 16780	64-17-5	Ethanol		
53600	60-00-4	Ethylenediaminetetraacetic acid (EDTA)	60	
59200	35074-77-2	1,6-Hexamethylene-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	300	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
66655 21827	78-93-3	Methyl ethyl ketone*	250	
	1313-59-3	Sodium oxide**		
68320	2082-79-3	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	300	
71680	6683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]		
74240	31570-04-4	Tris(2,4-di-tert-butylphenyl)-phosphite		
85030 24280	111-20-6	Sebacic acid		
86160	409-21-2	Silicon carbide		purity requirements for fillers according to Chapter 5.4.2
92880 92900	41484-35-9	Thiodiethylene-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	120	
95858	-	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	2.5	specification as per Commission Regulation (EU) No 10/2011
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity		specification as per Commission Regulation (EU) No 10/2011
95870	-	Wheat protein**		
96240	1314-13-2	Zinc oxide	250 for Zn	purity requirements for fillers according to Chapter 5.4.2

#### C.3.1.4 Polymer production aids

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	108-32-7	Propylene carbonate*		
16960 15272	107-15-3	Ethylendiamine	600	
42500	-	Carbonates		purity requirements for fillers according to Chapter 5.4.2 (general part)
52720	112-84-5	Erucic acid amide		
53520	110-30-5	N,N'-Ethylene-bis-stearamide		
72640 23170	7664-38-2	Phosphoric acid		
76960	25322-68-3	Polyethyleneglycol*		
81840 23740	57-55-6	1,2-Propanediol		
83440	2466-09-3	Pyrophosphoric acid		
83470	14808-60-7	Quartz		

92080	14807-96-6	Magnesium silicate (talcum)	250 for Zn	purity requirements for fillers according to Chapter 5.4.2 (general part)
93440	13463-67-7	Titanium dioxide		
96320	1314-98-3	Zinc sulfide		

Explanation:

\* Substances which have been assessed nationally in the context of this evaluation criteria document.

\*\* Substances that are assessed by another EU Member State as part of the 4MS initiative and adopted by the other states (listed in the 4MSI Core List).

## C.4 Specification of testing for lubricants

### C.4.1 Test samples

Lubricant testing involves the lubricant to be tested being applied to a glass plate measuring 200 mm × 200 mm at a thickness of 1 mm.

### C.4.2 Surface/volume ratio

For testing as per DIN EN 12731-1: 2014-09 a surface to volume ratio of 5 dm<sup>-1</sup> is used.

For testing as per DIN EN 1420-1: 2016-05 a surface to volume ratio of 0.2 dm<sup>-1</sup> is used.

### C.4.3 Conversion factor

The conversion requirements laid down in Table 8 of the general part of this evaluation criteria document shall apply. For lubricants used in kitchen or sanitary fittings, the conversion factor ( $F_c$ ) of 0.2 d/dm is used to calculate  $C_{\text{tap}}$ .

## Annex D      Elastomers

### D.1      Scope of application

This annex applies to elastomers.

Elastomers (hard and soft rubbers) are highly polymeric, organic networks which are able to resist and reverse large deformations.

Junction sites of the network are chemical bonds formed by cross-linking in rubbers (natural or synthetic rubbers) or in thermoplastic elastomers (e.g. TPE-V).

Silicon rubbers and thermoplastic elastomers based on silicones do not fall within the scope of Annex D.

### D.2      Information on composition

Elastomers are multi-compound systems and consist of the main constituents explained below:

- ▶ Rubbers
- ▶ Fillers
- ▶ Plasticisers
- ▶ Anti-ageing agents
- ▶ Processing aids
- ▶ Cross-linking agents

**Rubber** is the designation for non-crosslinked polymers, which can be crosslinked (vulcanised), with rubber elastic properties at 20 °C. Rubbers are systematically broken down into natural and synthetic rubbers. **Natural rubber** consists almost exclusively of saps (latex). **Synthetic rubbers** are artificially manufactured polymers, which are obtained by polymerising monomers. According to the many different areas of application and the requirements for thermal and chemical stability, there is a variety of synthetic rubber types. The material properties can be varied widely in terms of their limits through the copolymerisation of various monomers.

**Fillers**, e. g. soot or finely dispersed silicic acid, have a strengthening effect on the polymer matrix and are used to increase the tensile strength and abrasion resistance of the product, for example.

**Plasticisers** are added to the rubber compound, for example, to adjust the hardness of the vulcanisate or to improve flexibility at low temperatures.

**Anti-ageing agents** protect the elastomers against external effects. For example, they counteract the harmful effects of oxidation, heat, light or even ozone on the elastomer.

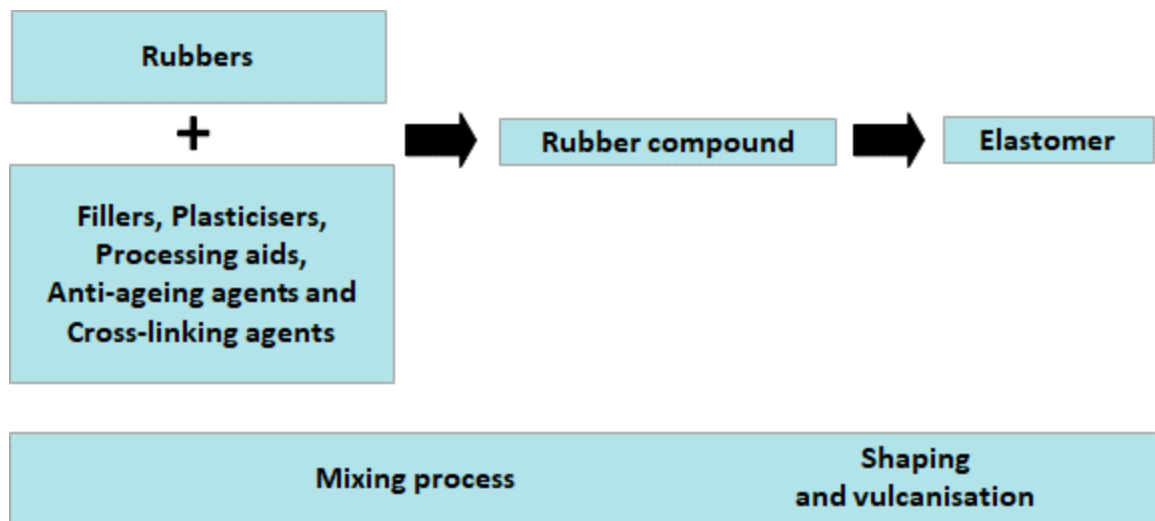
**Processing aids** have a wide range of uses in a rubber compound. These include, inter alia, improving the deformation resistance of rubber blanks, increasing processability during the mixing process and/or during forming, and many more.

**Cross-linking agents** such as sulphur, sulphur donors or peroxides are required to finally fabricate the elastomer from the rubber compound in the vulcanization process. Accelerating and retarding agents are also used for vulcanisation with sulphur.

### D.3 Information on the manufacture of elastomers

The composition and manufacturing process determine the final properties of elastomers. The construction of the compound and the manufacturing process are important processes that require a wide range of machines and a large amount of energy. In most cases manufacturing is carried out in three stages. This is shown in figure 1:

**Figure D-1: manufacture of elastomers**



The individual components listed in D.2 (Information on composition) are combined on a rolling mill or in an internal mixer with the addition of energy to produce the non-crosslinked **rubber compound**.

The rubber compound can be formed into **rubber blanks** in a variety of ways. One of the simplest methods is extrusion. This involves pressing the rubber compound through shaped nozzles to form flat strips, round cords, profiles or hoses depending on the shape of the nozzle. Calenders are used to manufacture films, plates or rubberised fabrics. Calenders consist of more than two temperature-controlled mills.

By **vulcanisation**, the rubber compound or the rubber blank is cross-linked three-dimensionally by applying cross-linking agents and heat. This generally creates highly elastic materials, also known as elastomers.

The most widespread vulcanisation process is press heating. In the traditional type of pressing, a roughly preformed compound blank is placed into a preheated metal mould, which is then sealed and placed between the plates of a heated press. This softens the rubber compound, which adopts the shape of the cavity under pressure and becomes fully vulcanised.

A more recent development, which is specifically designed for the mass production of moulded parts, is injection moulding. This involves automatised pressing of the hot rubber compound into the cavities in the mould.

For other articles (e.g. products that are coated with elastomers) vulcanisation is carried out in vulcanisation autoclaves which function on the principle of a pressure cooker.

For elastomers that are manufactured in continuous form, e.g. profiles, hoses, conveyor belts, cables etc., special equipment is used to allow continuous vulcanisation. This can be carried out for example in a liquid bath or in processing lines involving hot-air or steam chambers.

## D.4 Composition requirements

Only the starting substances listed in Tables D-1, D-2 and starting substances of the Core List of the 4MSI Positive Lists may be used to manufacture elastomers in contact with drinking water.

For unlisted starting substances, the requirements for unlisted starting substances apply, including their contaminants and degradation and reaction products (see Chapter 5.2.2 of the general part of the evaluation criteria document for organic materials). The requirements according to Chapters 5.4.2 and 5.4.3 of the general part of the evaluation criteria document for organic materials apply to fillers and colourants.

### D.4.1 Assessed starting substances

**Table D-1: Starting substances for elastomers that have been assessed by UBA or within the 4MSI collaboration**

#### D.4.1.1 Monomers

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10120	108-05-4	Vinylacetate	600	
10690	79-10-7	Acrylic acid	300	
12100	107-13-1	Acrylonitrile	0.1	
13630	106-99-0	Butadiene	0.1	QM = 1 mg/kg
13870	106-98-9	1-Butene		
13900	107-01-7	2-Butene		
14530	7782-50-5	Chlorine		
15030	931-88-4	Cyclooctene	2.5	
16950	74-85-1	Ethylene		
17110	16219-75-3	5-Ethylidene-bicyclo-[2,2,1]hept-2-ene (ENB)	2.5	QMA = 0.05 mg/6 dm <sup>2</sup>
18430	116-15-4	Hexafluoropropylene	0.1	
19000	115-11-7	Isobutene		
20020	79-41-4	Methacrylic acid	300	
20410	2082-81-7	1,4-Butandiol-dimethacrylate	2.5	
21640	78-79-5	2-Methyl-1,3-butadiene (Isoprene)	0.1	QM = 1 mg/kg
22660	111-66-0	1-Octene	750	
-	1187-93-5	Perfluoromethyl-perfluorovinylether*	0.1	
23980	115-07-1	Propene		
24610	100-42-5	Styrene		
25120	116-14-3	Tetrafluoroethylene	2.5	
26140	75-38-7	Vinylidene fluoride	250	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	3048-64-4	5-Vinyl-bicyclo[2,2,1] hept-2-ene (VNB)*	2.5	
24250	9006-04-6	Natural rubber		at recovery and coagulation of the natural rubber, ammonia, formic acid, acetic acid and sodium bisulfite may be used. Other additives of the natural rubber must be listed in the positive list.

#### D.4.1.2 Fillers, pigments and colourants

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
34480	-	Aluminium fibres, -flakes, -powder	20 for Al	
34560	21645-51-2	Aluminium hydroxide		
34690	11097-59-9	Aluminium-magnesium-hydroxycarbonate		
34720	1344-28-1	Aluminium oxide		
41600	12004-14-7	Calciumsulfoaluminate		
	37293-22-4			
41280	1305-62-0	Calcium hydroxide		
41520	1305-78-8	Calcium oxide		
42080	1333-86-4	Carbon black	PAH and benzo(a)-pyrene 10% of the threshold of TrinkwV	Purity requirements in Table 1 of Regulation (EU) No 10/2011
42240	-	Carbon fibres		according to enamel/ceramics evaluation criteria document
42500	-	Carbonates		
43280	9004-34-6	Cellulose		
45280	-	Cotton fibres		
55520	-	Glass fibres including mineral wool with a diameter greater than 1 µm (mean diameter: 5-30 µm)		
55600	-	Micro glass beads with a mean diameter of 5-100 µm		
58320	7782-42-5	Graphite		according to enamel/ceramics evaluation criteria document
62800	92704-41-1	Kaoline, calcinated		
64640	1309-42-8	Magnesium hydroxide		
64720	1309-48-4	Magnesium oxide		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
83470	14808-60-7	Quartz		
85601	-	Silicates, natural (except asbestos)		
85610	-	Silicates, natural, silanated (except asbestos)		
85680	1343-98-2	Silicic acid		
85950	37296-97-2	Magnesium-sodium-fluoride silicate	150 for Fluoride	
86000	-	Silicic acid, silanated		
86240	7631-86-9 69012-64-2	Silicium dioxide		requirements of Table 1 of Commission Regul. (EU) No 10/2011
92000	7727-43-7	Barium sulphate	70 for Barium	
92080	14807-96-6	Talcum		
93440	13463-67-7	Titanium dioxide		
96240	1314-13-2	Zinc oxide		additional requirement
-	7778-18-9	Calcium sulfate (Anhydrite)		
-	10101-41-9	Calcium sulfate (Dihydrate)		

#### D.4.1.3 Plasticisers

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
31920	103-23-1	Di(2-ethylhexyl) adipate	900	
34240	91082-17-6	Alkylsulfonic acid esters of phenol (C <sub>10</sub> - C <sub>21</sub> )	2.5	
45705	166412-78-8	1,2-Cyclohexanedicarboxylic acid diisononylester		
-	9003-29-6	Polybutene		composition according to Annex A (plastics), molar mass > 1000 Da
-	9003-17-2	Polybutadiene		composition according to Annex A (plastics), molar mass > 1000 Da
72081/ 10	-	Petroleum hydrocarbon resins (hydrogenated)		requirements of Table 1 of Commission Regul. (EU) No 10/2011
74560	85-68-7	Benzylbutylphthalate*	1500	see Regulation (EU) No 2018/2005
75105	68515-49-1 26761-40-0	Phthalic acid diesters with primary, saturated alcohols (C <sub>9</sub> -C <sub>11</sub> ), (> 90 % C <sub>10</sub> )	450	
-	9003-27-4	Polyisobutylene		composition according to Annex A (plastics), molar mass > 1000 Da
-	9003-31-0	Polyisoprene		composition according to Annex A (plastics), molar mass > 1000 Da



Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbons, high viscosity		requirements of Table 1 of Commission Regul. (EU) No 10/2011
95883	-	White mineral oils, paraffinic, which can be extracted from petroleum based hydrocarbons		requirements of Table 1 of Commission Regul. (EU) No 10/2011
-	-	Silicones according to Silicon transitional recommendation*		requirements according to silicon transitional recommendation

#### D.4.1.4 Anti-ageing agents

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
38800	32687-78-8	N,N'-Bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl]-hydrazide	750	
40000	991-84-4	2,4-Bis-n-octylmercapto-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	1500	
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	250	
45450	68610-51-5	p-Kresol-Dicyclopentadiene-isobutylene, Copolymer	250	
46640	128-37-0	2,6-Di-tert-butyl-p-kresol (BHT)	150	
66400	88-24-4	2,2'-Methylene-bis(4-ethyl-6-tert-butylphenol)	75	
66480	119-47-1	2,2'-Methylene-bis(4-methyl-6-tert-butylphenol)		
66560	4066-02-8	2,2'-Methylene-bis(4-methyl-6-cyclohexylphenol)		
66580	77-62-3	2,2'-Methylene-bis[4-methyl-6-(1-methylcyclohexyl)phenol]		
67850	8002-53-7	Montan wax	300	
68320	2082-79-3	Octadecyl-3(3,5-di-tert-butyl-4-hydroxyphenyl)propionate		
71680	6683-19-8	Pentaerythritoltetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]		
74240	31570-04-4	Tris(2,4-di-tert-butylphenyl)-phosphite		
74400	-	Tris(nonyl- und/oder Dinonyl-phenyl)phosphite	1500	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
92800	96-69-5	4,4'-Thio-bis(6-tert-butyl-3-methylphenol)	24	
95200	1709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-benzene		
95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbons, high viscosity		requirements of Table 1 of Commission Regul. (EU) No 10/2011
-	7782-99-2	Sulfurous acid*	500 as SO <sub>2</sub>	

#### D.4.1.5 Processing aids, adhesive agents and additives for fillers

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
10599/90 A	61788-89-4	Fatty acids, unsaturated (C <sub>18</sub> ), dimers, distilled	2.5	
10599/91	61788-89-4	Fatty acids, unsaturated (C <sub>18</sub> ), dimers, non-distilled		
10599/92 A	68783-41-5	Fatty acids, unsaturated (C <sub>18</sub> ), hydrogenated, dimers, distilled		
10599/93	68783-41-5	Fatty acids, unsaturated (C <sub>18</sub> ), hydrogenated, dimers, non-distilled		
14450/1	-	Castor oil fatty acids, dehydrogenated	120	
15910	108-46-3	1,3-Dihydroxybenzene		
16697	693-23-2	Dodecanedioic acid		
17170	61788-47-4	Fatty acids from coconut oil		
18070	108-55-4	Glutaric anhydride	0.1	
18250	115-28-6	Hexachlorendomethylene tetrahydrophthalic acid		
18280	115-27-5	Hexachlorendomethylene tetrahydrophthalic anhydride		
18880	99-96-7	p-Hydroxybenzoic acid		
19150	121-91-5	Isophthalic acid	250	
19270	97-65-4	Itaconic acid		
24160	8052-10-6	Tall oil rosin		
24280	111-20-6	Sebacic acid		
24430	2561-88-8	Sebacic anhydride		
24520	8001-22-7	Soybean oil		
25960	57-13-6	Urea		
26305	78-08-0	Vinyltriethoxysilane	2.5	
26320	2768-02-7	Vinyltrimethoxysilane	2.5	
30000	64-19-7	Essigsäure*		
30610	-	Monocarboxylic acids (C <sub>2</sub> -C <sub>24</sub> ), aliphatic, linear, from		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
		natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)		
30612	-	Monocarboxylic acids (C <sub>2</sub> -C <sub>24</sub> ), aliphatic, linear, synthetic and their mono-, di-, triglycerol esters		
31348	85116-93-4	Fatty acids (C <sub>16</sub> -C <sub>18</sub> ), esters with pentaerythritol*		not converted fatty acids < 5 %
34230	-	Alkyl(C <sub>8</sub> -C <sub>22</sub> )sulfonic acids	300	
34240	91082-17-6	Alkyl(C <sub>10</sub> -C <sub>21</sub> )sulfonic acid, esters with phenol	2.5	
35320	7664-41-7	Ammonia*	50 for NH <sub>4</sub> <sup>+</sup>	
37520	2634-33-5	1,2-Benzothiazolin-3-one**	25	for in-can preservation only
42720	8015-86-9	Carnauba wax		
44160	77-92-9	Citric acid		
45940	334-48-5	n-Decanoic acid		
46720	4130-42-1	2,6-Di-tert-butyl-4-ethyl-phenol	240	
47060	171090-93-0	3-(3,5-Di-tert-butyl-4-hydroxyphenyl)propionic acid esters with linear or branched alcohols (C <sub>13</sub> - C <sub>15</sub> )	2.5	
52720	112-84-5	Erucic acid amide		
52730	112-86-7	Erucic acid		
54450	-	Fats and oils (animal and plant origin)		
55040	64-18-6	Formic acid		
55120	110-17-8	Fumaric acid		
55190	29204-02-2	Gadoleic acid		
55680	110-94-1	Glutaric acid		
55920	56-81-5	Glycerol		
56540	-	Glycerol, esters with oleic acid		
61840	106-14-9	12-Hydroxystearic acid		
62960	50-21-5	Hydroxypropionic acid (lactic acid)		
63280	143-07-7	Lauric acid		
63760	8002-43-5	Lecithin		
64560	7786-30-3	Magnesium chloride		
	7791-18-6			
64800	110-16-7	Maleic acid	1500	
64900	108-31-6	Maleic anhydride		
65020	6915-15-7	Malic acid		
65040	141-82-2	Malonic acid		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
67840	-	Montanic acids and/or their esters with ethyleneglycol and/or 1,3-butanediol and/or glycerol		
67891	544-63-8	Myristic acid		
68960	301-02-0	Oleamide		
69040	112-80-1	Oleic acid		
69920	144-62-7	Oxalic acid	300	
70400	57-10-3	Palmitic acid		
76721	63148-62-9	Polydimethylsiloxane (molar mass > 6800 Da)		requirements of Table 1 of Commission Regulation (EU) No 10/2011
76960	25322-68-3	Polyethyleneglycol		
77520	61791-12-6	Polyethyleneglycol esters of castor oil	TOC	
77600	61788-85-0	Polyethyleneglycol esters of hydrogenated castor oil		
77702	-	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C <sub>6</sub> -C <sub>22</sub> ) and their ammonium and sodium sulphates		
77708	-	Polyethyleneglycol ethers (EO=1-50) of linear and branched primary alcohols (C <sub>8</sub> - C <sub>22</sub> )	90	requirements of Table 1 of Commission Regulation (EU) No 10/2011
77895	68439-49-6	Polyethyleneglycol (EO=2-6) monoalkyl ethers (C <sub>16</sub> -C <sub>18</sub> )	2.5	
79040	9005-64-5	Polyethyleneglycolsorbitan-monolaurate		
79120	9005-65-6	Polyethyleneglycolsorbitan-monooleate		
79280	9005-67-8	Polyethyleneglycolsorbitan-monostearate*		
79920	9003-11-6 106392-12-5	Poly(ethylenepropylene)glycol		
80000	9002-88-4	Polyethylene wax		
83610	73138-82-6	Rosin acids		
83840	8050-09-7	Rosin		
84000	8050-31-5	Rosin esters with glycerol		
84640	69-72-7	Salicylic acid		
88640	8013-07-8	Soybean oil, epoxidised (oxirane < 8%, iodine number < 6%)	TOC	
88960	124-26-5	Stearamide		
89040	57-11-4	Stearic acid		
90960	110-15-6	Succinic acid		
92160	87-69-4 133-37-9	Tartaric acid		

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
93520	59-02-9 10191-41-0	α-Tocopherol		
94320	112-27-6	Triethyleneglycol*		
95858	-	Waxes, paraffinic, refined, extracted from mineral oil-based or synthetic hydrocarbons, low viscosity	2.5	requirements of Table 1 of Commission Regulation (EU) No 10/2011
95870	-	Wheat protein**		
-	1313-59-3	Sodium oxide**		
-	9002-88-4	Polyethylene		composition according to Annex A (plastics), molar mass > 1000 Da
-	9003-07-0	Polypropylene		composition according to Annex A (plastics), molar mass > 1000 Da
-	63148-62-9	Silicon oil according to silicon transitional recommendation*		requirements according to silicon transitional recommendation
-	2098907-70-9	Siloxane and silicone, dimethyl, hydroxy terminated (molar mass > 7400 Da), ethers with C <sub>16</sub> -C <sub>18</sub> - fatty acid esters with pentaerythritol*		polymer contains siloxane and silicone, dimethyl, hydroxy terminated, C <sub>16</sub> -C <sub>18</sub> -fatty acid esters with pentaerythritol and fatty acids
-	9006-24-0	Xylolformaldehyde resins*		composition according to Annex B (organic coatings), molar mass > 1000 Da
-	-	Zinc salts of fatty acids (animal and plant origin) of chain length C <sub>14</sub> - C <sub>20</sub>		additional requirement
-	557-05-1	Zinc stearate		additional requirement

#### D.4.1.6 Cross-linking agents

##### D.4.1.6.1 Peroxides and coagents for peroxidic cross-linking

###### Peroxides

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
47080	110-05-4	Di-tert-butylperoxide**	0.1 15 for methyl-tert-butylether (MtBE) 500 for tert. butanol	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
47080	110-05-4	Di-tert-butylperoxide**	0.1 15 for methyl-tert- butylether (MtBE) 500 for tert. butanol	
38600	78-63-7	2,5-Bis(tert-butylperoxy)-2,5- dimethylhexane	0.1 500 for tert- butanol 0.1 for tert- amylalcohol 0.1 for 2,5- dimethyl- 2,5- hexanediol 0.1 for 2,2,5,5- tetramethyl- tetra- hydrofuran e	if applied above 0.4 % (w/w) in formulation: 0.1 µg/l for 3,3,6,6- tetramethyl-1,2- dioxane 0.1 µg/l for di-tert- butylperoxide
-	80-43-3	Dicumylperoxide	0.1 2.5 for cumyl- alcohol 0.1 for methyl- cumyl-ether 2.5 for α- methyl- styrene 0.7 for aceto- phenone	

#### Coagents for peroxidic cross-linking

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
25840	3290-92-4	1,1,1-Trimethylolpropane- trimethacrylate	2.5	
25390	101-37-1	Triallylcyanurate*	2.5	

#### D.4.1.6.2 Mercapto accelerators

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions

#### D.4.1.6.3 Other accelerators

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
37600	65-85-0	Benzoic acid		
41280	1305-62-0	Calcium hydroxide		
41520	1305-78-8	Calcium oxide		
42500	3486-35-9	Zinc carbonate		additional requirement
45760	108-91-8	Cyclohexylamine		
47680	111-46-6	Diethyleneglycol	1500	
59280	100-97-0	Hexamethylenetetramine	750 as form- aldehyde	
64720	1309-48-4	Magnesium oxide		
76320	85-44-9	Phthalic anhydride		
76960	25322-68-3	Polyethyleneglycol		
80800	25322-69-4	Polypropyleneglycol		
84640	69-72-7	Salicylic acid		
89040	57-11-4	Stearic acid		
91840	7704-34-9	Sulphur		
94560	122-20-3	Triisopropanolamine	250	
96240	1314-13-2	Zinc oxide		additional requirement

#### D.4.1.6.4 Other cross-linking agents

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	9003-35-4	Phenolformaldehyde resins		composition according to Annex B (organic coatings), molar mass > 1000 Da
-	25085-50-1	4-tert-Butylphenol- formaldehyde resin*	2.5 µg/l for 4- tert-butyl- phenol, 750 µg/l for form- aldehyde, 50 µg/l for xylene	including specification of maximum content of oligomeric components with molar mass below 1000 Da of 25 % and of maximum content of methylol group of 16 %

#### D.4.1.7 Aids to polymerisation

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
23680/8 1280	9002-89-5	Polyvinyl alcohol**		preparation by sintering
59330	110-54-3	n-Hexane* incl. structural isomers up to 40 % (cyclohexane <3%) EC No: 925-292-5	250	MTC <sub>tap</sub> does not need to be determined if process temperature is > 100 °C
93540	108-88-3	Toluene*	60	MTC <sub>tap</sub> is above threshold odour number
53600	60-00-4	Ethylenediamine tetraacetic acid (EDTA)*	60	
66620	75-09-2	Dichloromethane**	2.5	
91920	7664-93-9	Sulphuric acid*		
-	7637-07-2	Boron trifluoride**	100 as boron 150 as fluoride	
-	7681-65-4	Copper iodide**	50 as iodide 200 as copper	
18115/5 7520	31566-31-1	Glycerol monostearate**		
-	1333-74-0	Hydrogen**		

Explanation:

\* Substances which have been assessed nationally in the context of this evaluation criteria document.

\*\* Substances that are assessed by another EU Member State as part of the 4MS initiative and adopted by the other states (listed in the 4MSI Core List).

#### D.4.2 Provisionally assessed starting substances

The following substances are listed provisionally, because their assessment has not yet been finalised.

**Table D-2 Starting substances for elastomers that have been assessed provisionally by UBA**

##### D.4.2.1 Fillers, pigments and colourants

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	26125-61-1	p-Aramid fibres	0.1 for p-phenylene diamine,	molar mass > 1000 Da



Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
			375 for terephthalic acid	

#### D.4.2.2 Processing aids, adhesive agents and additives for fillers

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	68071-15-8	Butanediol oleate, ethoxylated	2.5	

#### D.4.2.3 Cross-linking agents

##### D.4.2.3.1 Peroxides

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions

##### D.4.2.3.2 Mercapto accelerators

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
65768	149-30-4	2-Mercaptobenzothiazole (2-MBT)	100	
-	155-04-4	Zinc-2-mercaptobenzothiazole	100 for 2-MBT	additional requirement
	95-33-0	N-Cyclohexylbenzothiazene-2- sulfenamide (CBS)*	0.1 100 for 2- Mercapto- benzothia- zole (2-MBT) 2.5 for 2,2'- Dithio-bis- benzothia- zole (Di(benzo- thiazol-2-yl)- disulphide, MTBS) 2.5 for cyclohexyl- amine, 0,1 for benzothia- zole and 0.1 for 2-Benzo- thiazolone	

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
			(until 31.12.2026 MTC <sub>tap</sub> = 2.5 µg/l applies as the sum of benzothia- zole and benzo- thiazolone)	

#### D.4.2.3.3 Other accelerators

Ref. No	CAS No	Substance	Restriction MTC <sub>tap</sub> in µg/l	Other restrictions
-	1318-02-1	Zeolites, natural and synthetic, sodium form	20 µg/l for Al	requirements according to 5.4.2

### D.4.3 Rubbers

In Table D-1, typical rubbers are compiled which have been considered for the definition of the positive list. Due to the wealth of possible reaction pathways this compilation is not exhaustive. Starting substances for the manufacture of rubbers must be listed in Table D-1.

**Table D-1 Informative List of rubbers for the manufacture of elastomers**

Name	Abbreviation according to DIN ISO 1629
Acrylnitrile-buta-1,3-diene rubber	NBR
Chlorinated polyethylene	CM
Chloro-isobutene-isoprene rubber (chlorobutyl rubber)	CIIR
Copolymer of ethene and propene	EPM
Copolymers of hexafluoropropene and vinylidene fluoride	FPM
Ethylene-vinylacetate mixed polymerisates	EVM or EVA, both names allowed, EVM for VA contents > 40%, EVA for VA contents < 40%
Isobutene-isoprene rubber (butyl rubber)	IIR
Isoprene rubbers, synthetic	IR
Natural rubber	NR
Polybutadiene	BR
Polybutylene	

Name	Abbreviation according to DIN ISO 1629
Polycyclooctene	
Polyisobutene	IM or PIB both names allowed
Quatropolymer of ethene, propene, vinylnorbornene and ethylidene-norbornene	EPDM
Styrene-butadiene rubber	SBR
Terpolymer of ethene, propene and ethylidene-norbornene	EPDM
Terpolymer of ethene, propene and vinylnorbornene	EPDM
Terpolymers of hexafluoropropylene, vinylidene fluoride and tetrafluoroethylene	FPM
Blends of rubber polymers and polymers according to Annex A (plastics)	

## D.5 Additional requirements

Additional requirements as defined in Table D-2 apply for elastomers. The general part of the evaluation criteria document for organic materials must be observed.

If elastomers are blended with polymers which fall within the scope of Annex A, additional requirements of Annex A must also be tested for.

**Table D-2 Additional requirements for elastomers**

Substances/ substance groups	MTC <sub>tap</sub> in µg/l	Analytical method
Zinc	250	DEV <sup>15</sup>

<sup>15</sup> Deutsche Einheitsverfahren zur Wasser-, Abwasser- und Schlammuntersuchung (DEV)

## **Annex E            Thermoplastic elastomers (TPE)**

### **E.1            Scope of application**

TPE occupy a special position between plastics and elastomers. They exhibit elastic properties similar to those of vulcanised rubber and can be processed like thermoplastics.

TPE may be composed of different polymers with soft and hard segments appearing in separate phases. A characteristic feature of TPE are physical (thermolabile, reversibly cleavable) or chemical sites of cross-linking. DIN EN ISO 18064: 2015-03 distinguishes between different TPE types and classifies them in a nomenclature system.

### **E.2            Information on TPE**

Physically cross-linked TPE in contact with food are deemed to be covered by Commission Regulation (EU) No 10/2011, in accordance with the European Commission's position (Union Guidance on Regulation (EU) No 10/2011)<sup>16</sup>. In keeping with this position, the suitability of physically cross-linked TPE with a plastics-like formulation for drinking water hygiene has to be proven according to Annex A (plastics).

Chemically cross-linked TPE more resemble elastomers in terms of composition. Therefore, the suitability of these types of TPE for drinking water hygiene must be evaluated according to Annex D (elastomers) of this evaluation criteria document.

### **E.3            Anforderung an die Zusammensetzung**

Depending on composition of the polymers, formulation assessment is made according to Annexes A and/or D and/or F.

## **Annex F Silicones (informative)**

Silicones do not currently fall under the scope of this evaluation criteria document. To demonstrate drinking water hygienic suitability, the transitional regulation for preliminary evaluation of hygiene suitability of silicones in contact with drinking water<sup>17</sup> can be used.

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<sup>16</sup> [https://ec.europa.eu/food/system/files/2016-10/cs\\_fcm\\_plastic-guidance\\_201110\\_en.pdf](https://ec.europa.eu/food/system/files/2016-10/cs_fcm_plastic-guidance_201110_en.pdf)

<sup>17</sup> <https://www.umweltbundesamt.de/en/document/transitional-recommendation-for-preliminary>