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Federal Environment Agency

Fourth amendment to the notice of evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL)^{1, 2}

Of 23 August 2024

The Notice — Evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL) of 11 March 2019 (BAnz AT 21.3.2019 B5), as last amended by the Third Amendment to the Notice — Evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL) of 7 March 2022 (BAnz AT 16.3.2022 B11), is amended.

I. Amendments

1. The following abbreviations are added alphabetically in the list of abbreviations: List of abbreviations

4MSI	4 Member State Initiative				
ATP	Adenosine triphosphate				
M1/M2 M3	Microbiological requirements according to point 5.6.3				
In the list of abbreviations, the following abbreviation is amended: List of abbreviations					
Ctap	maximum concentration to be expected on the tap in µg/l				
	(calculated with the help of conversion factor F_{c} and $c_{measured}$)				

3. In the definitions and text of the evaluation criteria, the term 'drinking water installation' is replaced by 'drinking water installation'.

4. Point 1 Introduction is recast:

2.

'Substances and materials used for the construction or maintenance of plants for the production, treatment or distribution of drinking water, which have contact with drinking water may not, in accordance with § 14 of the Drinking Water Ordinance (TrinkwV)

- 1. reduce, directly or indirectly, the intended protection of human health;
- 2. impair the colour, smell or taste of the water;
- 3. promote the propagation of microorganisms; or
- 4. release substances into the water in larger quantities than is unavoidable if they comply with the generally accepted rules of technology.

The present evaluation criteria pursuant to § 15(1) TrinkwV specifies the aforementioned general hygiene requirements for the organic materials listed in the scope of application.

Organic materials within the scope of this evaluation criteria correspond to § 14 TrinkwV if they meet the requirements listed here. Pursuant to § 15(2) TrinkwV, the evaluation criteria is binding two years after being notified in the Federal Gazette (i.e. since 12 March 2021). Since that date, water supply operators have to ensure that only organic materials that meet the requirements of this evaluation criteria are used for the construction and maintenance of water supply facilities in accordance with § 13(2) TrinkwV.

Proof of compliance of a product with the requirements of this assessment guideline may be given e.g. in the form of a certificate from a certifying body accredited for drinking water.

If, in the course of maintenance of existing installations, only a few components of a product need to be replaced and the required components are made from a material that does not meet the requirements of this basis for assessment but nonetheless demonstrably has no adverse effect on drinking water quality, then a replacement of the entire installation is not necessary. The replacement of the entire plant would be an unreasonable hardship for the operator of the old plant and would be disproportionate. Possible evidence that no impairment of drinking water quality is caused can be provided with the help of the UBA recommendation 'Assessment of material-handling contaminants of

Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

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drinking water'3.

The EU Member States Germany, France, the Netherlands, Denmark and the United Kingdom of Great Britain (4MSI) work together to align their national requirements. This basis for assessment implements the jointly prepared regulation proposal for organic materials in contact with drinking water⁴. The Federal Environment Agency is also working with the competent authorities of the Member States on preparing and updating the basis for assessment.

Under the revised Drinking Water Directive (Directive (EU) 2020/2184), requirements that are uniform across Europe for materials in contact with drinking water will be imposed in the future. These rules will replace the present evaluation criteria.'

- 5. In other passages of the evaluation criteria, '4MS' is renamed to '4MSI'.
- 6. In point 2 of the scope of application, in paragraph 4, '§ 17(3)' is amended to '§ 15(1)'.
- 7. In point 3(4), the term 'microbial growth' is replaced by 'microbial propagation'.
- 8. In point 4.1, footnote 8 is updated 'https://www.efsa.europa.eu/en/efsajournal/pub/6768'
- 9. In point 4.2 letter (e), 'antimicriobial' is replaced by 'antimicrobial'.
- 10. In point 4.3(1), '§ 17(4) TrinkwV' is replaced by '§ 15(5) and (6) TrinkwV'.
- 11. In point 4.3(2), 'polymerisation agent' is replaced by 'polymerisation agents'.
- 12. In point 5.1, in paragraph 2, 'Table 7' is replaced by '(Table 8)'.
- 13. In point 5.2.1, the following paragraph is added as the third paragraph:

The use of perfluorinated starting substances is limited to the substances listed in the corresponding positive lists. The exceptions specified in point 5.2.2 letters (a) and (b) and point 5.7 do not apply to perfluorinated starting substances (regardless of technological function).

- 14. In point 5.2.2 letter (b), 'on the tap maximum concentration to be expected' is replaced by 'maximum concentration to be expected on the tap'.
- 15. In point 5.2.2 letter (b) and at all of the following points in the KTW evaluation criteria, DIN EN 12873-2: 2020-07 is replaced by DIN EN 12873-2: 2022-02.
- 16. In point 5.2.2 letter (b) and (k) 'CLP Regulation (EC) No 1272/2008' is replaced by 'Regulation (EC) No 1272/2008 (CLP Regulation)'.
- 17. Point 5.2.2 letter (c) is recast:
 - (c) Salts of listed acids, phenols or alcohols

Aluminium salts, ammonium salts, barium salts, calcium salts, iron salts, europium salts, gadolinium salts lithium salts, magnesium salts, manganese salts, potassium salts, cobalt salts, copper salts, sodium salts, lanthanum salts, terbium salts and zinc salts of acids, phenols or alcohols listed on the material-specific positive lists may additionally be used as starting substances. The migration restrictions MTC_{tap} of Table 9 of Annex 1 apply to these cations.

18. In point 5.2.2 letter (e), the following shall be added after the third sentence:

The low-molecular fractions with a molecular mass below 1,000 Da of all polymeric additives must not exceed 1 % (m/m) relative to the final product.

19. In point 5.2.2. letter (I) Glass fibre sizing shall be deleted. In point 5.2.2, letter (I) is recast:

l) Catalysts

Catalysts are needed for the production of polymers and are often constructed as a metal-ligand complex. If derogations point 5.2.2 letter (a) and (b) do not apply, these catalysts still need not be listed if the migration restrictions MTC_{tap} for the central metal ions in Table 9 of Annex 1 are complied with and the associated ligands do not pass into drinking water (detection limit 0.1 $\mu g/l$).

- 20. In point 5.3.5 in the second indent of the note 'in migratory water' is deleted.
- 21. In point 5.4.2, the following paragraph is added:
 - Glass fibres

Glass fibres used as reinforcing fillers shall comply with the positive list set out in Regulation (EU) No 10/2011. Coupling agents used in glass fibre sizing must be listed on one of the positive lists of Appendices A and/or B, the 4MSI Core List or Combined List. Where further starting substances for the production of glass fibre sizing are not listed, it shall be ensured that the requirements for the starting substances, including their monomers, their oligomers and reaction and degradation products in accordance with the derogations in point 5.2.2 letter (a) to (f) are complied with.

Carbon fibres

Carbon fibres shall be assessed according to the enamel/ceramic evaluation criteria.

³ https://www.umweltbundesamt.de/dokument/beurteilung-materialbuertiger-kontaminationen-des

⁴ https://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/anerkennung-harmonisierung-4ms-initiative



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Metal fibres

Metal fibres must comply with the requirements of the metal evaluation criteria, unless they are listed individually in the corresponding positive list of the KTW evaluation criteria (Appendices A to D).

Synthetic fibres

Synthetic fibres are spun from polymers. The starting substances for the production of the polymers shall be listed in the positive list of Appendix A. The additives, excipients and polymerisation agents used for the production and processing of the fibres must be assessed according to point 5.2.

– Woven fabric

Woven fabric is made from synthetic, metal, carbon or glass fibre threads crossed at right angles (chain and weft). For the fibres, the above requirements shall be complied with. In addition, if the individual fibres are used in the form of a reinforcing layer (e.g. woven fabrics in fabric-reinforced products), the requirements for multi-layered products according to point 5.7 apply.

- 22. In point 5.4.2 Fillers, in the second sentence, the reference to parts 2, 3, 4, 5 and 6 of DIN 53770 is deleted without replacement. Footnote 14 contains only DIN 53770 Part 1, Part 13 and Part 16.
- 23. In point 5.4.2 Fillers in paragraph 3 of the first sentence, the reference to DIN 53770-4: 2007-09 is deleted.
- 24. Point 5.4.3 Colourants is recast:

'Colourants are not listed in the material-specific positive lists unless they have a nanostructure (cf. point 4.2 letter (f)).

Note 1: The colourants are divided into pigments and dyestuffs. Pigments are insoluble colourants made of solid particles (according to DIN EN ISO 18451-1: 2019-09, 3.96). These can be inorganic or organic compounds. Dyestuffs are colourants soluble in the application medium (according to 3.30 of DIN EN ISO 18451-1: 2019-09).

As a rule, only pigments are used in the production of organic materials in contact with drinking water.

Note 2: It is assumed that potential colourant transfer can be detected with the basic requirement parameters (colouring and turbidity). For this reason, no further requirements are placed on the material transition of the colourants. This exception does not apply to excipients, additives, impurities and possible degradation products.

The colourant products (compounds according to point 3.23.1 and point 3.23.2 and pigment preparations according to point 3.97 of DIN EN ISO 18451-1: 2019-09) may contain additional additives and excipients. These must be listed in the respective material-specific positive list and the corresponding requirements apply.

The following purity requirements apply to the colourants:

The soluble fractions in 0.07 N hydrochloric acid (in relation to the colourant) for

Lead 0.01 % Arsenic 0.01 % Mercury 0.005 % Selenium 0.01 % Barium 0.01 % Chromium 0.1 % Cadmium 0.01 % Antimony 0.05 % must not be exceeded.

'The soluble fractions are determined in accordance with DIN 53 770: Testing of pigments, determination of the hydrochloric acid soluble fractions, parts 1, 13 or 16 or a comparable method.

Where primary aromatic amines can be released from the colourants used as impurities or as a reaction and degradation product, $MTC_{tap} = 0.1 \,\mu g/l$ shall apply for the relevant primary aromatic amines. This migration limitation must be checked on the product that comes into contact with drinking water.

Azo dyes which may decompose into primary aromatic amines classified as mutagenic, carcinogenic or reprotoxic substances of categories 1A and 1B under Regulation (EC) No 1272/2008 (CLP Regulation) shall not be used.'

- 25. In point 5.5.2, 'expected concentration' is replaced by 'maximum expected concentration'.
- 26. Table 3a in point 5.6.3 Requirements for volumetric testing (Procedure 2) is renamed to Table 3 and Table 3b to Table 4 and the related references in the text are adjusted.
- 27. The following Tables 4, 5, 6 and 7 in point 6.3 Migration test shall be numbered accordingly as Tables 5, 6, 7 and 8. The references in the text of the assessment base shall be adjusted in points 5.1, 5.3.1, 6.3.1 and Annex 2.
- 28. In point 5.6.3 letter (c), the following paragraph is added:

'For elastomers and components of equipment with a content in contact with water of < 10 % in the equipment used outside the drinking water installation, the test value M2 shall apply, even if the diameter of the associated pipes has a diameter of less than 80 mm.'

29. In point 5.7, in Example 1, the sentence 'The outer layer shall be assessed according to the elastomer guideline' is replaced by 'The rubberisation of the outer layer of the hose shall be assessed in accordance with Appendix D Elastomers and the woven fabric reinforcement shall be assessed in accordance with point 5.4.2 and

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Appendix A'.

30. In point 5.7, the following paragraph is added after Example 3:

'The review of the migration restrictions of the layer directly in contact with drinking water shall be carried out in accordance with point 6.3.1.'

- In point 5.7, the following sentence is added in the last paragraph:
 In addition, substances with nanostructure can be used, as it can be assumed that they do not diffuse through the polymer layers.
- 32. In point 6.1, first sentence, the third indent is amended to:

'Presentation of all starting substances for the production of the product (monomers, additives, excipients and other starting substances) with the compilation of the chemical names, trade names, CAS No, technological functions, quantities of inputs and suppliers.'

33. In point 6.1, paragraph 2, the following is added:

In order to assess the purity of the starting substances, the following impurities shall be known:

- Impurities exceeding 0.1 % in the starting substance classified as carcinogenic, mutagenic or toxic for reproduction of category 1A or 1B in accordance with Regulation (EC) No 1272/2008 (CLP Regulation), or, and
- Impurities exceeding 1 % in the starting substance that are not classified as carcinogenic, mutagenic or reprotoxic substances in accordance with Regulation (EC) No 1272/2008 (CLP Regulation) of category 1A or 1B.'
- 34. In point 6.1, paragraph 3 is recast:

'Where there is no information on purity or possible impurities for certain starting substances, such as a declaration of purity by the manufacturer, a separate determination of the purity of the substance with the relevant impurities is necessary.

If polymeric starting substances are used in accordance with point 5.2.2 letter (e), in addition to the impurities to be reported, information on molecular weight distribution and the proportions of oligomers with molecular masses below 1 000 Da is also required.'

35. In point 6.3.1, paragraph 2 is amended:

'The testing of filter membranes is carried out in accordance with DIN EN 12873-1: 2014-09. In the test, only the outer surface of the filter membrane is taken into account as a contact surface with the drinking water.'

- 36. In point 6.3.1, in 'Table 5: O/V ratio for the tests', the entry 'Equipment items' is extended to 'Equipment items and their components'.
- 37. In point 6.3.3, 'expected concentration' is replaced by 'maximum expected concentration'.
- 38. In point 6.4, the term 'microbial growth' is replaced by 'microbial propagation'.
- 39. Annex 1 is renamed to Annex 2. In Table 10 (new numbering) in the entry 'Containers', the term 'in the drinking water supply system' is replaced by 'in the water supply'. The references to the table are adjusted in the text of the evaluation criteria in points 5.1 and 6.3.3.
- 40. Annex 1 is recast:

Annex 1: Migration restrictions on metals

The following table lists the accepted metals (in ion form) with their migration restrictions. Where the derogation in accordance with point 5.2.2 letter (c) is applied for listed substances, the corresponding migration restrictions set out in Table 9 for metal ions and ammonium shall be complied with.

Where non-listed catalysts consisting of metal-ligand complexes are used, the relevant migration restrictions for the ions set out in Table 9 shall be complied with. The corresponding ligands are subject to the derogation in point 5.2.2 letter (b).

Elements or ions		References	MTCtap [µg/I]
Aluminium	AI	10 % of the threshold of the TrinkwV	20
Ammonium	NH4*	10 % of the threshold of the TrinkwV	50
Antimony	Sb	10 % of the threshold of the TrinkwV	0,5
Barium Ba		1/20 SML of Regulation (EU) No 10/2011	50
Bismuth	Bi	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	0,1

Table 9: Migration restrictions for metals and ammonium



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ns	References	
В	10 % of the WHO guideline	150
Ca	No requirement required	
Ce	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	4,0
Cr	10 % of the threshold of the TrinkwV	5,0
Со	1/20 SML of Regulation (EU) No 10/2011	2,5
Cu	10 % of the threshold of the TrinkwV	200
Eu	1/20 SML of Regulation (EU) No 10/2011	2,5
Ga	1/20 SML of Regulation (EU) No 10/2011	2,5
Hf	UBA (<u>https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte-bewertungsgrundlage-fuer)</u>	0,1
Fe	10 % of the threshold of the TrinkwV	20
La	1/20 SML of Regulation (EU) No 10/2011	2,5
Li	1/20 SML of Regulation (EU) No 10/2011	30
Mg	No requirement required	
Mn	10 % of the threshold of the TrinkwV	
Мо	10 % of the WHO guideline	7,0
К	No requirement required	
Pr	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	
Na	No requirement required	
Ni	10 % of the threshold of the TrinkwV	2,0
Sr	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	210
Tb	1/20 SML of Regulation (EU) No 10/2011	2,5
Sn	1/20 SML of Regulation (EU) No 10/2011	0,3
Ti	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	
W	1/20 SML of Regulation (EU) No 10/2011	
V	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	
Y	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	
Zn	1/20 SML of Regulation (EU) No 10/2011	250
	ns B Ca Ce Cr Co Cu Eu Ga Hf Ga Hf Ca Na Ni Sr Tb Sn Ti W V Y Zn	nsReferencesB10 % of the WHO guidelineCaNo requirement requiredCaUBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)Cr10 % of the threshold of the TrinkwVCo1/20 SML of Regulation (EU) No 10/2011Cu10 % of the threshold of the TrinkwVEu1/20 SML of Regulation (EU) No 10/2011Ga1/20 SML of Regulation (EU) No 10/2011Ga1/20 SML of Regulation (EU) No 10/2011Ga1/20 SML of Regulation (EU) No 10/2011Fe10 % of the threshold of the TrinkwVLa1/20 SML of Regulation (EU) No 10/2011File10 % of the threshold of the TrinkwVLa1/20 SML of Regulation (EU) No 10/2011Li1/20 SML of Regulation (EU) No 10/2011Mitps://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)MaNo requirement requiredMaNo requirement requiredNi10 % of the threshold of the TrinkwVMaNo requirement requiredNi10 % of the threshold of the TrinkwVSrUBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)Ni10 % of the threshold of the TrinkwVSrUBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)Th1/20 SML of Regulation (EU) No 10/2011SrUBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)Wi1/20 SML of Regulation (



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Elements or ions		References	
Zirconium	Zr	UBA (https://www.umweltbundesamt.de/dokument/begruendung-pruefwerte- bewertungsgrundlage-fuer)	1,0

Appendices to the basis for assessment for plastics and other organic materials in contact with drinking water (KTW-BWGL)

Polymer-specific part

Appendix A Plastics

41. In point A.1, the following paragraph is added:

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 duroplastics (e.g. unsaturated polyester resins, melamine resins, epoxy laminates, phenolic and furan resins) and thermoplastics (e.g. polyamides, polycarbonates, polyacetals, polyethylene terephthalates, polyphenylene oxides and sulfides, polypropylene and styrene copolymers).

42. In point A.2, the following third paragraph, the following is added:

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.

- 43. In Table A-1, the substance 'Fluorine' is deleted without replacement.
- 44. In Table A-1, the entry 'Xylene*' with CAS No 1330-20-7 is amended to 'Xylene isomer mixture*'.
- 45. The following substances are added to Table A-1:

Ref. no.	CAS no.	Substance	Restriction MTC_{tap} in $\mu g/l$	Other restrictions
Additiv	es and polymeri			
	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 nanomaterial, 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 1 000 Da
				< 2 %, aldehyde < 500 mg/kg as acetaldehyde

Aids to polymerisation

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- dimethylbutane	Maximum application quantity 0.2 %, only for PVC and PVC-C

Solvents

	in contoita
100-41-4 Ethylbenzene 30	
108-10-1 Methyl isobutyl ketone 250	
75-65-0 tert- Butanol 500	



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Ref. no.	CAS no.	Substance	Restriction MTC _{tap} in μg/l	Other restrictions
	75-09-2	Dichloromethane	2.5	

46. In point A.3, Table A-2 is amended to:

Substances/substance groups	Restriction MTCtap in µg/l	Test method* (The use of other equivalent methods of analysis is possible.)	
Sum of Primary Aromatic Amines (PAA) ⁵ for plastics containing PAA or which may produce PAA (e.g. polyamides, polyurethanes)	0.1	Specific proof with GC-ECD/GC-MS with derivatisation ⁶	
When substances of the following gr	oups of substances are used:		
Unlisted catalysts	Requirements according to point 5.2.2 DEV ⁷ letter (I) general part of the evaluation criteria		
Fillers	Requirements according to point 5.4.2 general part of the evaluation criteria		
Colouring matter	Requirements according to point 5.4.3 general part of the evaluation criteria		

Appendix B Organic coatings

47. In point B.2.1, the standard DIN EN 923: 2008-06 is replaced by DIN EN 923: 2016-03. The following entries are amended in Table B-1:

In the entry 'Silicon dioxide, silylated' in point B.3.1.2, CAS No 60676-86-0 is deleted.

The entry '2,4-toluene diisocyanate' with CAS No 26747-90-0 is amended to '2,4-toluene diisocyanate dimer' in point B.3.1.1.5.

The entry 'Rapeseed oil fatty acids' with CAS No 93165-31-2 is amended to 'Rapeseed oil fatty acids, low in erucic acid**' in point B.3.1.1.8.

The entry 'Xylene**' with CAS No 1330-20-7 is amended to 'Xylene isomer mixture**' in point B.3.1.5.

CAS No 61789-44-4 is added to the entry 'Castor oil fatty acids'.

In the entry 'Castor oil fatty acids, dehydrogenated**', CAS No 61789-45-5 is added in point B.3.1.1.8.

48. The following entries are added to Table B-1:

in point B.3.1.1.4 'Amine', the following is added:

Ref. no.	CAS no.	Substance	Restriction MTC _{tap} in μg/l	Other restrictions
	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	

in point B.3.1.1.9 'Other monomers', the following is added:

Ref. no.	CAS no.	Substance	Restriction MTC _{tap} in μg/l	Other restrictions
	22208-25-9	2-Ethyl-2-(hydroxymethyl)-1,3- propanediol triacetoacetate*	2.5 μg/l for a sum of 2-Ethyl-2- (hydroxy-methyl)-1,3- propanediol (mono-, di-, tri-)acetoacetate	
			300 μg/l for 1,1,1- trimethylolpropane	

⁵ Excluding PAA authorised by Regulation (EU) No 10/2011.

⁶ Test method: Pietsch et al (1996) Fresenius J. Anal. Chem. 355:164-173 or Pietsch et al. (1997) Vom Wasser 88: 119-135

⁷ German standard methods for the examination of water, waste water and sludge (DEV)



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49. In point B.3.1.2 Fillers/Colourants, the restrictions on soot are amended:

Ref. no.	CAS no.	Substance	Restriction MTC _{tap} in μg/l	Other restrictions
42080	1333-86-4	Soot	PAH and benzo(a)pyrene 10 % of the threshold of the TrinkwV	Purity requirements in Table 1 of Regulation (EU) 10/2011

50. In point B.4, in Table B-3, the entry in letter (b) Polyurethane coatings is amended to:

Substances/substance groups	Restriction MTCtap in μg/l	Test method* (The use of other equivalent methods of analysis is possible.)			
b) Polyurethane coatings					
Total of all isocyanates Alternatively, hydrolysing amines can be determined in migratory water.	QM = 1 mg/kg	DIN EN 13130-8: 2004-08			
Primary aromatic amines	0.1	Specific proof with GC-ECD/GC-MS with derivatisation			

Appendix C Lubricants

- 51. In point C.3.1, in sentence 1, 'of the substances accepted for lubricants' is replaced by 'the substances accepted for lubricants'.
- 52. In point C.3.1.2, for three substance entries, Ref No '86285' is replaced by 'included in 86285'.
- 53. The entry 'Poly-alpha-olefin from 1-dodecene and 1-octene' with CAS No 163149-29-9 is amended to 'Poly-alphaolefin from 1-dodecene and 1-octene hydrogenated' in point C.3.1.1.
- 54. The entry 'Poly-1-decene/hydrogenated' with CAS No 68037-01-4 is amended to 'Poly-1-decene, hydrogenated' in point C.3.1.1.
- 55. The entry 'Silicon dioxide, reaction product with trimethylchlorosilane and isopropyl alcohol*' with CAS No 68988-56-7 is amended to 'Silicon dioxide, reaction product with trimethylchlorosilane and isopropyl alcohol, sodium salt*' in point C.3.1.2.
- 56. In point C.4.3, 'Table 7' is amended to 'Table 8'.

Appendix D Elastomers

- 57. The entry for soot in point D.4.1.2 Fillers, pigments and colourants is amended as set out in point 49.
- 58. In the entry 'Calcium sulphate (dihydrate)', the CAS No 10101-41-9 is amended to CAS No 10101-41-4 in point D.4.1.2.
- 59. In the entry for barium sulfate in point D.4.1.2 Fillers, pigments and colourants, the entry for 'other restrictions' is deleted.
- 60. The addition 'TOC' is added to the entry '1,2-cyclohexyl dicarboxylic acid diisononyl ester' with CAS No 166412-78-8 in point D.4.1.3.
- 61. In the entry 'resin acids' in point D.4.1.5 Processing aids, adhesion agents and additives for fillers, CAS No '73318-82-6' is amended to '73138-82-6'.
- 62. CAS No 61789-45-5 is added to the entry 'Castor oil fatty acids, dehydrogenated' in point D.4.1.5.
- 63. In the entry 'Silicone oil according to the silicone transition recommendation*', the CAS number in point D.4.1.5 is deleted.
- 64. In the entry 'n-hexane* including structural isomers up to 40 % (Cyclohexane < 3 %)' in point D.4.1.7 Polymerisation aids, EC No '925-29-5' is amended to '925-292-5'.
- 65. The entries for '2,5-bis(tert-butylperoxy)-2,5-dimethylhexane' and 'dicumyl peroxide' are moved from point D.4.2.3.1 to D.4.1.6.1.
- 66. In point D.4.2.3.2 the following substance is included:

Ref. no.	CAS no.	Substance	MTC _{tap} in µg/l	Other restrictions
	95-33-0	N-Cyclohexylbenzothia-zene-2- sulfenamide* (CBS)	0.1 100 μg/l for 2- mercaptobenzothiazole (2- MBT)	Corresponding products may only be used outside the drinking water installation and only with cold water
			2.5 μg/l for 2,2'-dithio-bis- benzothiazole (di(benzothiazol- 2-yl)disulfide, MBTS)	



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	2.5 μg/l for cyclohexylamine, 0.1 μg/l for benzothiazole and 0.1 μg/l for 2-benzothiazolone (until 31.12.2026 MTC _{tap} = 2.5 μg/l applies as the sum of benzothiazole and	
	benzothiazole and	
	benzothiazolone)	

67. In point D.5, in Table D-4, the reference '**' for zinc is deleted.

II. Entry into force

These amendments shall enter into force on the day after publication in the Federal Gazette.

Dessau-Roßlau, 23 August 2024

Federal Environment Agency

In Representation Prof. Dr. Lilian Busse