

BASIS FOR ASSESSMENT

Assessment basis for plastics and other organic materials in contact with drinking water^{1,2} (KTW-BWGL)

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¹ 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).

² Notified under 2025/xxx/D

I. Amendments

The following amendments shall be made:

1. In point 2 Scope, the following paragraph is inserted after the second sentence:
'In the alternative, the requirements of Implementing Decision (EU) 2024/368 will apply to elastomers and thermoplastic elastomers from 1 March 2026. It should be noted that the requirements of the KTW assessment basis and the requirements of Implementing Decision (EU) 2024/368 are to be considered separately. It is not possible to mix or combine the regulatory documents and their specifications.'
2. In point 5.2.2 Non-listed starting substances under (a) Low use, the following is added after paragraph 1: 'Monomers with a maximum application rate of less than 0.5 % (m/m) relative to the final product of a material, which are required for regulating chain length/crosslinking and are incorporated into the polymer chain, can be used if the migration restriction $MTC_{\text{tap}} = 0.1 \mu\text{g/l}$ is complied with.'
3. In point 5.3.3 Turbidity and colouring requirements, the name of the standard 'DIN EN ISO 7027: 2016-11' is changed to 'DIN EN ISO 7027-1: 2016-11'.
4. In the second sentence of point 5.4.2 Filler requirements, 'according to DIN 53770¹⁴ Parts 1 and 13' is amended to 'according to DIN 53770¹⁴ Parts 1 and 16'. In footnote 14, Part 13 is deleted.
5. In point 5.4.2 Filler requirements, for the example of fluoride, the term 'parameter value' is replaced by the term 'limit value'.
6. In point 5.4.3 Colourant requirements, the reference to Part 13 of DIN 53770 is deleted in paragraph 4.
7. In point 5.6.3 Requirements for testing using the volumetric method (method 2), Table 4 is amended as follows:

Table 4: Evaluation of the test results of method 2 according to DIN EN 16421: 2015-05

Requirement	Information on the measurement results of method 2 according to DIN EN 16421							
	1a	1b	1c	1D optional	2a	2b optional	3a	
M1	All values $\leq (0.05 \pm 0.02) \text{ ml}/800 \text{ cm}^2$							
M2	If $1a \geq 1b$, 1a is not used for evaluation				All values $\leq (0.12 \pm 0.03) \text{ ml}/800 \text{ cm}^2$, where $1c \leq 1b$ and $3a \leq 2a$			
optional	If 1a < 1b and 1a $\leq (0.12 + 0.03) \text{ ml}/800 \text{ cm}^2$	If 1b $\geq 1c$, 1b is not used for evaluation			All values $\leq (0.12 \pm 0.03) \text{ ml}/800 \text{ cm}^2$, where $1d \leq 1c$ and $2b \leq 2a$ and $3a \leq 2a$			
M3	If $1a \geq 1b$, 1a is not used for evaluation				All values $\leq (0.20 \pm 0.03) \text{ ml}/800 \text{ cm}^2$, where $1c \leq 1b$ and $3a \leq 2a$			

Requirement	Information on the measurement results of method 2 according to DIN EN 16421		
optional	If 1a < 1b and 1a \leq (0.20 + 0.0 3) ml/800 cm ²	If 1b \geq 1c, 1b is not used for evaluation	All values \leq (0.20 \pm 0.03) ml/800 cm ² , where 1d \leq 1c and 2b \leq 2a and 3a \leq 2a

DRAFT

Comment:

An increasing trend in the measured values to be considered in accordance with Table 4 for the requirement M2 or M3 exists if the difference in the measured values to be assessed is > 0.06 ml/800 cm².

8. In point 5.7 Multilayered products, in paragraph 5, the reference to point 6.3.1 is amended to point 6.3.

9. In point 6.1 Formulation assessment, paragraph 4 is amended to: 'If polymeric starting substances with the specification 'Molar mass > 1000 Da' are used in the corresponding positive list, or if polymeric starting substances are used in accordance with 5.2.2(e), information on the molecular weight distribution and the proportions of oligomers with molecular masses below 1000 Da shall also be required in addition to the impurities to be indicated.'

10. In point 6.3.1 Execution of the migration test, the following paragraph is inserted after paragraph 3:
'The hot-water test covers the application of the products that come into contact with hot water; no additional hot-water test is necessary.'

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

Polymer-specific part

Appendix A Plastics

11. In point A.1.1 Plastics, in the first sentence, '(according to DIN EN 472:2013-06)' is replaced by '(according to DIN EN ISO 472: 2013-06 and DIN EN ISO 472/A1: 2019-03'.

12. In point A.2 Positive list of starting substances for the production of plastics, the first sentence is amended to:

'Only the authorised substances laid down in Regulation (EU) No 10/2011 (Union list) and in Regulation (EU) No 2024/3190 (Union list for plastics), the substances accepted for plastics on the 4MSI positive lists, and the starting materials listed in Table A-1 may be used for the production of plastics in contact with drinking water.'

13. In Table A-1, the following CAS number is added to the following substance entry:

'Wheat protein with CAS No 93384-22-6 under Table A-1 Additives and aids.'

Appendix B Organic coatings

14. In point B.2.2 Composition information, in the second sentence '(DIN EN ISO 4618: 2015-1)' is changed to '(DIN EN ISO 4618: 2023-05'.

15. In point B.3.1.1.9 Other monomers, the following entries are added:

Ref. No	CAS No	Substance	Restriction MTC_{tap} in µg/l	Other restrictions
	1071-93-8	adipic acid dihydrazide	2.5 0.1 for hydrazine	for powder coatings only
2008 0	2495-37-6	benzyl methacrylate	300 as methacrylic acid	

16. In point B.3.1.9 Aids to polymerisation, the following entries are added:

Ref. No	CAS No	Substance	Restriction MTC_{tap} in µg/l	Other restrictions
	34562-31-7	3,5-diethyl-1,2-dihydro-1-phenyl-2-propylpiperidine	0.1 0.1 for 2-propyl-3-ethylquinoline	for cold water only
	603-35-0	triphenylphosphine	0.1 0.1 for triphenylphosphine	

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

17. The following CAS numbers are added to the following substance entries in Table B-1:

'Maize oil fatty acids with CAS No 68308-50-9 under point B.3.1.1.8'
'Fish oil fatty acids with CAS No 91051-07-9 under point B.3.1.1.8'
'Zinc dust with CAS No 7440-06-0 under point B.3.1.2'
'Wheat protein with CAS No 93384-22-6 under point B.3.1.7'

Appendix C Lubricants

18. In Table C-1, the following CAS number is added to the following substance entry:

'Wheat protein with CAS No 93384-22-6 under point C.3.1.3'

Appendix D Elastomers

19. In Table D-1, the following CAS numbers are added to the following substance entries:

'Carbon fibres with CAS No 308063-56-1 under point D.4.1.2'
'Petroleum hydrocarbon resins, hydrogenated with CAS No 88526-47-0 under point D.4.1.3'
'Wheat protein with CAS No 93384-22-6 under point D.4.1.5'

II. Entry into force

The 6th amendment shall enter into force on xx. xx. 2025, one day after publication in the Federal Gazette.