German Environment Agency

As at: 30 January 2025

UBA RECOMMENDATION

Transitional recommendation on provisional assessment of drinking water hygiene of silicones in contact with drinking water (Silicone Transitional Recommendation)

Version 6

English translation – only the German document version is binding

Amendments:

1. Change of attestation of conformity

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1 Preliminary remarks

The KTW Guideline was withdrawn on 21st march 2021 with the binding validity of the evaluation criteria document for plastics and other organic materials in contact with drinking water (KTW-BWGL). But the evaluation criteria document currently does not contain any arrangements relating to silicones.

This transitional recommendation alternatively applies to silicones in contact with drinking water and may be used for assessment in regard to drinking water hygiene of silicones in contact with drinking water.

The transitional recommendation does not constitute any evaluation criteria yet within the meaning of the Drinking Water Ordinance (TrinkwV). Hence it is not legally binding. It represents the current state of scientific and technical knowledge relating to the hygienic requirements for silicones in contact with drinking water.

It is intended to implement the hygienic requirements for contact with drinking water of this transitional recommendation into the KTW-BWGL.

Pursuant to Section 16 of TrinkwV it shall be presumed that products and procedures meet requirements of Section 15 TrinkwV if this was confirmed by means of a certificate by a certification body accredited in the field of drinking water. If certificates from another Member State of the European Union, a signatory to the Agreement on the European Economic Area or from Turkey are consulted for conformity assessment and confirmation of harmlessness to human health the following conditions have then to be met:

- Material or product testing, if any, has to be done in accordance with EN standard test methods and at least comply with the level of protection for existing arrangements relating to materials and products in contact with food (Regulation (EC) No 1935/2004).
- The assessment system taken as a basis has to be trackable.

2 Scope of application

This transitional recommendation shall apply to silicones, silicone-based coatings, sprayable silicone sealants and other silicone-based products (for e.g. silicone-based sealing compounds) in contact with drinking water.

3 Information about silicones

Silicones for use in the drinking water sector consist of reactive silicone polymers, fillers, crosslinkers, catalysts and inhibitors if applicable, inert silicone polymers as plasticisers, colourants or adhesives. Crosslinking of reactive polymers to form a silicone elastomer may be done radically via peroxides, through addition-curing by means of platinum catalysts or via condensation. Depending on technology, HTV (high-temperature vulcanisation) and RTV (room-temperature vulcanisation) can be distinguished. The RTV distinguishes between RTV-1 (one-component) and RTV-2 (two-component) types. The product class of LSR (Liquid Silicone Rubber) grades which have a similar structure in terms of technology as addition-curing RTV-2 grades but are vulcanised (crosslinked) at high temperatures, has a special status. All types have in common that a wide-meshed, elastic network with stable silicon-oxygen chains (siloxane structure) is formed during vulcanisation (crosslinking).

Silicone hoses, equipment and preformed gaskets (not glued) are mostly silicones that are crosslinked at high temperatures, i.e. HTV or LSR types.

Sprayable silicone sealants are silicone formulations of the RTV-1 type. Crosslinking (vulcanisation) in this case usually takes place at room temperature under the action of atmospheric moisture.

Depending on the type of crosslinker, a distinction is essentially made between acidic (acetic acid) and neutral (alcohol, oxime) types.

4 Inclusion of new substances on the positive list

The UBA evaluates the starting substances for the production of organic materials at the request of a manufacturer or association (applicant). The application procedure shall be defined in accordance with the rules of procedure of the German Environment Agency for the management of the positive list of starting substances for organic materials in contact with drinking water[1].

Evaluation shall be done according to the principles of EFSA to assess food contact materials. These are described in the “Note for Guidance”[2].

For the evaluation of the starting substances not only pure substances but also impurities as well as possible reaction and decomposition products shall be considered.

For the evaluation of the starting substances a migration test shall be carried out in order to obtain information on a possible substance transfer into the drinking water. This should be done as far as possible according to the test conditions of the evaluation criteria for plastics and other organic materials. In addition, instead of global migration, the parameter "TOC" (Total Organic Carbon) shall be determined in accordance with the test specifications of the mentioned evaluation criteria document.

On the basis of the migration determined, the applicant must submit the following toxicological studies for the assessment of the migration substances of drinking water contact materials:

- For a migration leading to c_{tap} up to 2,5 µg/l, it must be shown that the substance is not genotoxic.
- For a migration leading to c_{tap} exceeding 2,5 µg/l and up to 250 µg/l, a 90-day oral feeding study and bioaccumulation data are required in addition.
- If migration leads to c_{tap} exceeding 250 µg/l, the complete toxicological dataset shall be required.

The appropriate studies required are mentioned in the “Note for Guidance”[2].

Furthermore, the applicant must provide ancillary toxicological examinations available in addition to the required studies, with a reference to the source.

When applying for substances that have already undergone toxicological assessment (e.g. by EFSA) the requirements of points 1 to 4 only must be met.

[1] https://www.umweltbundesamt.de/en/document/rules-of-procedure-of-the-german-environment-agency-0

[2] https://www.efsa.europa.eu/en/efsajournal/pub/rn-21

5 Requirements for silicones

Silicones in contact with drinking water must be appropriate for their intended use. Requirements of the technical arrangements are valid regardless of this recommendation.

5.1 Positive list required for the manufacture of silicones

All of the substances used to manufacture silicones must be toxicologically assessed and listed on the positive list according to their technological function.

For certain substances that are not mentioned in the positive lists below, the rule according to 5.2.2 of the Evaluation criteria for plastics and other organic materials in contact with drinking water can be applied if the requirements stipulated therein are met.

The substances used when manufacturing silicones in contact with drinking water must be of a technical quality and purity that is fit for the planned and intended purpose of silicones.

In addition to the positive list of the BfR Recommendation XV. Silicones[3] and the 4MSI positive list (Core and Combined List)[4] the following complementary positive list may be used for silicones.

Table 1: Complementary positive list for silicones

Polymer starting substances

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
		No entry so far		

Other starting substances (e.g. co-monomers)

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
12786	919-30-2	3-Aminopropyltriethoxysilane	2.5	
14450/1		Castor oil fatty acids, dehydrated		
26320	07/02/2768	Vinyltrimethoxysilane	2.5	
26305	78-08-0	Vinyltriethoxysilane	2.5	
21498	2530-85-0	[3-(Methacryloxy)propyl]-trimethoxysilane	2.5	
		Peroxides according to BfR recommendation XV	0.1	

[3] https://www.bfr.bund.de/cm/343/XV-Silicone.pdf

[4] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative

Additives

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
37520	2634-33-5	1,2-Benzisothiazol-3(2H)-one	25	Only in-can preservation
43760	26172-55-4	5-Chloro-2-methyl-2H-isothiazol-3-one	0.5	Only in-can preservation
53600	60-00-4	Ethylenediamine tetra acetic acid (EDTA)	60	
66930	68554-70-1	Methylsilsesquioxane		Methyltrimethoxysilanes ‹ 1 mg/kg of methylsilsesquioxanes
76721	63148-62-9	Polydimethylsiloxane MW › 6800 Da		Viscosity › 100 cSt
80160	37349-34-1	Polyglyceryl-5-stearate		
86285		Silicon dioxide, silanated		for synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0.1–1 µm and may form agglomerates within the size distribution of 0.3 µm to the mm size.
95870		Wheat protein		
	1313-59-3	Sodium oxide		
	7631-86-9	Silicon dioxide		In case of synthetic amorphous silicon dioxide: Primary particles of 1 nm - 100 nm, aggregated to 0.1 µm - 1 µm, which can form agglomerates of 0.3 µm to millimetre size
	7782-99-2	Sulfurous acid	0.5 as SO_2	

Fillers

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
		Fillers according to CR (EU) No. 10/2011 and KTW-BWGL		Purity requirements according to 5.4.2 of KTW-BWGL

Colourants

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
		Colourants according to 5.4.3 of KTW-BWGL		Purity requirements according to 5.4.3 of KTW-BWGL

Solvents

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
53255	100-41-4	Ethylbenzene	30	
48030	112-34-5	Diethylene glycol monobutyl ether (DEGBE)	150 as sum of 48030 and 53765	as sum for (di)ethylene glycol, monoalkyl (C1,C2,C4,C6) ethers and acetic acid, 2-ethoxy-ethyl ester
53765	111-76-2	Ethylene glycol monobutyl ether		
18115/57520	31566-31-1	Glycerol monostearate		
66655	78-93-3	Methylethylketone	250	
66725	108-10-1	Methylisobutyl ketone	250	
93540	108-88-3	Toluene	60	
26945 95945	1330-20-7	Xylene	50	

Polymer production aids

Ref. No.	CAS No.	Substance	MTC_{tap} in µg/l	other restrictions
	7681-65-4	Copper (I) iodide	50 for iodine 200 for copper	

5.2 Basic requirements for silicones

The test values of the evaluation criteria for organic materials (see 5.3 of KTW-BWGL) shall apply.

5.3 Additional requirements for silicones

The additional requirements laid down for silicones in Table 2 shall apply. Chapter 5.4 of the evaluation criteria for organic materials (KTW-BWGL) and the risk-based approach (5.1 of KTW-BWGL) shall be considered

Table 2: Additional requirements for silicones

Substances/substance groups	Requirement		Analytic method
Silicone oils	Purity requirements concerning the mentioned starting substances[5], Consideration of quantitative limit in relation to formulation and migration restrictions		
Silicone resins			
Silicone elastomers			
Silicone elastomers	Volatile	0.5% based on the silicone	amended BfR method[6], HS-GC/MS[7]

5.4 Formulation-dependent requirements for individual substances for silicones

All substances with a limit in one of the positive lists which may be contained in the product must be tested in terms of their migration according to 5.5 of the evaluation criteria for organic materials (KTW-BWGL), the risk-based approach (5.1 of KTW-BWGL) shall be considered. The concentration determined in the test is used to calculate the maximum concentration (cf. 6.3.3 of KTW-BWGL) expected at the tap c_{tap}.

[5] Compliance with the purity requirements of the substances used can be confirmed by a declaration of conformity by the supplier.

[6] https://www.bfr.bund.de/cm/343/bestimmung-von-fluechtigen-verbindungen-in-bedarfsgegenstaenden-aus-silikon.pdf

Note on the BfR method: Silicones that decompose at 200 °C are subjected to high-temperature treatment at 60 °C instead of 200 °C.

[7] KOCH, Andreas: Gaschromatographische Verfahren zum Nachweis der Freisetzung von Inhaltsstoffen aus Polymermaterialien im Trinkwasserkontakt. 1. Aufl. Osnabrück: Der Andere Verlag, 2004 -ISBN 3-89959-225-5

5.5 Requirements for the testing the enhancement of microbial growth

The requirements of chapter 5.6 according to the evaluation criteria for organic materials (KTW-BWGL) for elastomers shall apply. Especially, the requirement according to 5.6.3 c):

M1	≤ (0.05 + 0.02) ml/800 cm²
M2	≤ (0.12 + 0.03) ml/800 cm²
M3	≤ (0.20 + 0.03) ml/800 cm²

is set as for all silicones.

6 Testing

The specifications of chapter 6 according to the evaluation criteria for organic materials (KTW-BWGL) shall apply.

The test shall show that the test values comply with the basic and the additional requirements as well as the formulation-dependent requirements for individual substances and the requirements pertaining the enhancement of microbial growth.

7 Attestation of conformity

The attestation of conformity of the drinking water hygienic suitability of silicones can be carried out in accordance with the UBA recommendation "Attestation of conformity of the drinking water hygienic suitability of products".
Currently valid test certificates, which were issued on the basis of the previous publications of the "Transitional recommendation on provisional assessment of drinking water hygiene of silicones in contact with drinking water (Silicone Transitional Recommendation)" can still be used to prove the drinking water hygienic suitability until 28 February 2025. An extension of these test certificates is possible until 28 February 2025.