German Environment Agency

As at: 07 March 2016

RECOMMENDATION

Guideline on the hygienic assessment of organic materials in contact with drinking water (KTW Guideline)[1,2]

Only the German version of this document is legally binding.

1 Scope

1.1 Validity of this guideline

This Guideline defines hygienic requirements for plastics and silicones used in contact with drinking water.

This Guideline replaces the KTW Guideline dated 07 October 2008. It can be used for the hygienic assessment of plastics such as polyethylene, polypropylene, polybutene, polyvinylchloride, post-chlorinated polyvinyl chloride, cross-linked polyethylene, polyamide, polyurethane, polyester, and silicones. Furthermore, it contains requirements for the assessment of the testing in accordance with EN 16421 to prove the hygienic safety with regard to microbial growth.

Specific guidelines and recommendations have been published for the hygienic assessment of other organic materials:

For thermoplastic elastomers, the TPE Transitional Recommendation[3] on the hygienic assessment of products made from thermoplastic elastomers (TPEs) in contact with drinking water should be applied. In the case of non-covalent cross-linked TPEs this in turn refers back to this KTW Guideline.

[1] Notified in accordance with Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations (OJ. L 204 dated 21.07.1998, p. 37), last amended under Section 26. 2 of Regulation (EU) No. 1025/2012 of the European Parliament and the Council dated 25 October 2012 (OJ. L 316 dated 14.11.2012, p. 12)

[2] Last amended on 07 March 2016, notified under 2013/470/D

[3] Recommendation on the provisional hygienic assessment of products made from thermoplastic elastomers in contact with drinking water (TPE Transitional Recommendation): https://www.umweltbundesamt.de/sites/default/files/medien/376/dokumente/recommendation_on_the_provisional_hygienic_assessment_of_products_made_from_thermoplastic_elastomers_in_contact_with_drinking_water.pdf

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For organic coatings and similar products, such as impregnating resins, grouting material, adhesives, aqueous plastic dispersions, plastic coatings, cementitious coatings with a polymer content > 25 % on the basis of epoxy resins, polyurethanes, polyamides, polyesters, polyacrylates or their mixtures, the “Guideline for the hygienic assessment of organic coatings in contact with drinking water (Coating Guideline)”[4] has been published.
For lubricants, the “Guideline for the hygienic assessment of lubricants in contact with drinking water (sanitary lubricants) (Lubricants Guideline)”[4] has been published.
For elastomers, the “Guideline for the hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline)”[4] has been published.
Cement-bound materials are to be tested in accordance with DVGW Code of Practice W 347 “Hygiene requirements for cement-bound materials intended for use in drinking water supply systems - testing and evaluation”.

1.2 Legal status

This Guideline is a revised version of the KTW Guideline dated 07.10.2008. It is also merely a recommendation and not yet an evaluation criteria within the meaning of the German Drinking Water Ordinance (TrinkwV 2001) in the amended version of 05.12.2012. The guideline is not legally binding.
It represents the current state of scientific and technical knowledge with regard to the hygienic requirements on organic materials in contact with drinking water.
It is planned to transfer this KTW-Guideline into an evaluation criteria in accordance with Section 17 (3) of the Drinking Water Ordinance (TrinkwV 2001) in the amended version of 05.12.2012, which will be legally binding two years after its publication.
In accordance with Section 17 (5) TrinkwV 2001 it can be assumed that products and procedures meet the requirements of Section 17 if this has been confirmed by a certificate from a certifier accredited in the field of drinking water. Until completion and entry into force of the evaluation criteria for plastics und silicones in accordance with Section 17, (2) TrinkwV 2001, this Guideline relating to conformity assessment and confirmation of harmlessness of plastics and silicones to human health may be consulted.
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 the assessment of conformity or confirmation of health safety, then the following conditions have to be met:

- The testing of materials or products shall be carried out in accordance with EN test methods, where available, and shall at least comply with the level of protection for existing regulations for materials and products in contact with foodstuffs.
- The assessment system used shall be transparent.

1.3 Further requirements

Organic materials in contact with drinking water have to be suitable for their intended use. The requirements in the technical regulations shall apply independently from this Guideline. The compliance of a product in contact with drinking water made from organic materials with generally accepted rules of technology and the requirements of TrinkwV 2001 can be shown via certification by a certification body accredited in the field of drinking water.

[4] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/guidelines-evaluation-criteria

2 Organic materials in accordance with this Guideline

2.1 Plastics

Plastics are organic materials consisting mainly of polymers. These polymers are macromolecular substances produced from monomers or other substances by polymerisation processes such as poly-addition, poly-condensation, etc.

In addition to the polymers produced from the monomers as the main constituents, plastics may contain additives to ensure certain properties in the course of the production process or in the end product.

Polymerisation aids may also be contained in plastic:

- “Aids to Polymerisation (AtP)” have an influence on the polymerisation (e.g. catalysts, promoters) and are used in very small quantities. They may be present in the end product, but are not intended for it.
- “Polymer Production Aids (PPA)” are adjuvants in the production of plastics that only have a function in the manufacturing process and are not intended to have an effect in the end product. However, they may be present in the end product.

Under foodstuffs legislation, the requirements for the production of materials and articles made of plastic are regulated in the Regulation on plastic materials and articles intended to come into contact with food (Regulation (EU) No. 10/2011). The starting substances listed there can also be used for the manufacture of plastic products intended to come into contact with drinking water.

Polymerisation aids, solvents and pigments are not covered by the Regulation (EU) No. 10/2011, and they remain subject to national law. Within the scope of this Guideline, reference is made to the BfR recommendations (cf. Table 1) on the assessment of polymerisation aids.

2.2 Cross-linked plastics

Cross-linked plastics have polymer chains that are linked to one another by means of covalent bonds. The cross-linking can be formed by various procedures: Cross-linked polyethylene can be produced with the aid of peroxides (PE-X_a), with the aid of silanes (PE-X_b) or by radiation (PE-X_c). Only some of the cross-linking reagents currently used are listed in the Regulation (EU) No. 10/2011. Within the scope of this Guideline, reference is made additionally to the BfR recommendation "XLVI. Cross-linked Polyethylene" on the assessment of cross-linking materials.

2.3 Recycled plastics

The use of recycled plastics is limited to the use of recycled residues and off cuts arising in the course of production itself that have not been contaminated and have not been brought into circulation. It shall be ensured that the composition of the recycled material is known and has been notified and checked.

2.4 Silicones

2.4.1 Silicone products

Silicones intended for use in the field of drinking water consist of reactive silicone polymers, fillers, cross-linking reagents, catalysts and if necessary inhibitors, unreactive silicone polymers as plasticisers, pigments, or adhesion promoters. The cross-linking of the reactive polymer to silicone elastomers can be achieved by free-radical cross-linking with peroxide, by addition curing with platinum catalysts, or by condensation. Depending on the technology used, a distinction is made between high-temperature vulcanisation (HTV) and room-temperature vulcanisation (RTV). In the case of RTV, a further distinction is made between RTV-1 (single part) and RTV-2 (two part) types. A special case is the LSR-types (LSR = liquid silicone rubber), which are similar to the addition cured RTV-2 types, but which are vulcanised (cross-linked) at a higher temperature. All types have in common that the vulcanisation (cross-linking) produces a wide-meshed, elastic network with stable silicone-oxygen chains (siloxane structure).

Silicones used for tubing, equipment and preformed seals (without bonding) have usually been cured at higher temperatures, i.e. are of HTV or LSR types.

Within the scope of this Guideline, reference is made in the case of silicones to the positive list of the BfR Recommendation XV.[5]

2.4.2 Injectable silicone sealants

Silicone sealants are silicone formulations of the RTV-1 type. In this case, curing (vulcanisation) usually takes place at room temperature under the influence of air humidity.

Depending on the curing agent, a general distinction is made between acidic types (acetic acid) and neutral types (alcohol, oxime).

[5] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

For the assessment of the composition of RTV-1 silicone sealants, reference can be made to the positive list of the BfR Recommendation XV. An additional positive list in Annex 1 Part 2 is currently being drawn up.

2.5 Multi-layer structures

Products that are used in contact with drinking water may have a multi-layer structure. This can involve a number of layers of plastics, or one or more plastic layers in combination with layers of other materials. Where appropriate, other guidelines shall also be taken into account for the hygienic assessment, e.g. the Coating Guideline for adhesives.

If a product contains a total barrier, then hygienic assessment shall be carried out solely for the material layer that are on the side in contact with the drinking water. A total barrier prevents diffusion of all substances towards the drinking water contact side (continuous aluminium layer with a thickness of at least 9 µm or glass).

In addition to the total barrier there are also functional barriers, e.g. a layer of an ethylene-vinyl alcohol copolymer. These only slow down the diffusion of the migrating substances. Therefore, in these cases all layers are to be assessed in accordance with the relevant Guideline.

The multi-layer composite materials and the multi-layer plastic materials shall meet the requirements of this Guideline (cf. Section 3). For these products, an extended warm water migration test[6,7] is also necessary in addition to the cold water migration test in order to determine the migration behaviour of the substances from the layers under investigation into the drinking water (cf. Section 3 und 4). Multi-layer products are to be tested as such.

3 Requirements on the products within the context of this Guideline

3.1 Requirements on the composition

All substances used for the manufacture of products must be included in one of the positive lists of Table 1 or in Annex 1 according to their technological function. In the case of prematurely vulcanised or graft polymers, this requirement shall also apply for their monomers and other starting substances as well as for the starting substances of any additives. This requirement does not apply for marginal products (cf. 3.6).

For substances not included in the above-mentioned positive lists, the De Minimis Guideline can be drawn on, provided that the conditions specified therein are fulfilled. Solvents are usually not included in the positive lists (cf. Table 1). They are required as “Polymer Production Aids” for the production of plastics. They are only contained in the end product in very small amounts. For the assessment of the solvent in the formulations, the De Minimis Guideline can be drawn on.[8]

[6] Care shall be taken that substances are not extracted from the material during the warm water test.

[7] Instead of the warm water testing, the possible transfer of substances can be modelled.

[8] An extension of the *De Minimis* Guideline is planned.

For multi-layer products with a total barrier, only the layers on the drinking water side are to be assessed. The layer coming into contact with the drinking water is to be assessed in accordance with this Guideline. If further layers are to be assessed, then the corresponding Guidelines shall be drawn on for the materials in question.

For multi-layer products with a functional barrier, all layers are to be assessed. The layer coming into contact with the drinking water is to be assessed in accordance with this Guideline. For the assessment of all the other layers, the appropriate Guideline shall be drawn on according to the type of material. For the production of the layers on the side away from the drinking water substances may be used that are not contained in the positive lists if their migration into the drinking water is non detectable with a limit of detection of 0.1 µg/l. The unlisted substances shall not be mutagenic, carcinogenic or toxic to reproduction (Annex I Sections 3.5 ,3.6, and 3.7 of Regulation (EU) No. 1272/2008) and shall not have a nanostructure.

Substances used for the production of organic materials in contact with drinking water shall have a technical quality and purity that is suitable for the planned and envisaged use of the product.

Table 1 Positive lists of accepted starting substances with any limitations

Organic materials		Positive lists and evaluations
Plastics	Monomers and additives	Regulation (EU) No. 10/2011[9], German Consumer Goods Ordinance[10], European evaluations of EFSA (previously SCF)[11]
	Colourants and fillers	BfR Recommendations[12]: IX.-Colourants for plastics and other polymers used in commodities- and LII.-Fillers
	Polymerisation aids	In accordance with the evaluations of BfR for Germany (BfR Recommendations II, III, V, VI, VII, X, XI, XII, XVI, XVII, XX, XXII, XXV, XXXIII, XXXIV, XXXV, XXXVII, XXXIX, XLII, XLIII, L, and LI) Regulation (EU) 10/2011[9], German Consumer Goods Ordinance[10], assessments of EFSA (previously SCF)[11]

[9] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF

[10] https://www.juris.de/purl/gesetze/_ges/BedGgstV_!_10

[11] http://www.efsa.europa.eu/en/publications.htm

[12] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

Organic materials		Positive lists and evaluations
	Curing agent for cross-linked polyethylene	National evaluations of BfR Recommendation XLVI: “Cross-linked polyethylene” Regulation (EU) No. 10/2011, German Consumer Goods Ordinance, European evaluations of EFSA (previously SCF)
	Biocide additive[13]	Biocides evaluated by EFSA/SCF Biocides may only be used as preservatives for products during storage.
	Other starting substances	Supplementary positive list in Annex 1 of this Guideline
Silicones	Starting substances	BfR Recommendation XV. silicones, Supplementary positive list in Annex 1 of this Guideline (in preparation)

3.2 Basic requirements

The external characteristics (odour/flavour/ turbidity/colour/foaming) of the migration water in accordance with EN 12873-1 or EN 12873-2 shall not be changed.

For the ***cold water test***, the following threshold odour number (TON) and threshold flavour number (TFN) limits apply:

TON and TFN < 2	for the 3rd migration period in accordance with EN 1420-1, in the case of extension of the migration tests the 9th migration period in accordance with EN 1420-1.

For the ***warm water test***:

TON and TFN ≤ 4	for the 7th migration period in accordance with EN 1420-1, in the case of extension of the migration test the 22nd migration period in accordance with EN 1420-1.

In addition, the TON and TFN from tests in accordance with EN 1420-1 must not show an upward trend[14].

[13] Bringing the biocide onto the market is regulated in Regulation (EU) No. 528/2012.

[14] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

For the release of organic substances, measured as total organic carbon (TOC) the following applies:

For the ***cold water test:***

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$ for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$ for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

The TOC is determined as non-purgeable organic carbon (NPOC) in accordance with EN 1484.

In addition, the measured concentrations in the migration water in accordance with EN 12873-1 (or EN 12873-2) must not show an upward trend[15].

3.3 Additional requirements

The additional requirements in Table 2 for plastics and in Table 3 for silicones shall apply. These requirements do not apply for marginal products (cf. 3.6)

If the applicable additional requirement presents a migration limit in the form of a Drinking Water Positive List Limit value (definition cf. 3.4), then the migration shall be investigated in accordance with 4.3.1 and compared with the given DWPLL value.

For the ***cold water test*** the following applies:

$c_{Tap} \leq DWPLL$ for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$c_{Tap} \leq DWPLL$ for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

In addition, the measured concentrations in the migration water in accordance with EN 12873-1 (or EN 12873-2) must not show an upward trend.[15]

[15] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

Table 2 Additional requirements for plastics

Substance/substance groups	DWPLL in µg/l	Analysis method[16]
Sum of primary aromatic amines (PAAs)[17] for plastics that contain PAAs or for which PAAs may be generated in the course of their production (e.g. polyamides, polyurethane)	ND [18] (0.1 µg/l)	Specific proof with GC-ECD/GC-MS with derivatisation[19]
For the use of substances from the following substance groups:		
Heavy metal catalysts	10 % of the limit value in the TrinkwV 2001 (e.g. chromium 5 µg/l, nickel 2 µg/l)	DEV[20]
Peroxides	No peroxide on the surface of the product	58th Announcement[21]
Fillers	Purity requirements in accordance with BfR Recommendation LII[22]	
Colourants	Requirements in accordance with BfR Recommendation IX[22].	
Polymerisation aid	Requirements in accordance with the BfR Recommendations (II., III., V., VI., VII., X., XI., XII., XVI., XVII., XX., XXII., XXV., XXXIII., XXXIV., XXXV., XXXVII., XXXIX., XLII., XLIII., L. and LI. BfR Recommendation)[22]	

[16] Other equivalent analytic methods may be used.

[17] Excepting PAAs authorised in Regulation EU 10/2011.

[18] Non detectable

[19] Analysis method: Pietsch et al (1996) Fresenius j. Anal. Chem. 355:164-173 or Pietsch et. al. (1997) Vom Wasser 88: 119-135

[20] German standard methods for the examination of water, waste water and sludge (DEV)

[21] German Federal Health Gazette 40 (1997)412

[22] Compliance of the substance in question with the purity requirements can be confirmed by a conformity declaration of the supplier.

Table 3 Additional requirements for silicones

Substance/substance groups	Requirement	Analysis method
Silicone oils	Purity requirements for the given starting substances[23], Note the quantity limit with regard to the formulation and migration limits	
Silicone resins		
Silicone elastomers		
Silicone elastomers	Volatile and extractable portions of not more than 0.5 % in each case	61st Announcement[24] or GC-MS-Screening[25]
Peroxides	No peroxide on the surface of the product	58th Announcement[26]

3.4 Requirements for individual substances in formulations

The positive lists specified in Table 1 and the evaluations of EFSA may contain limits on migration. In the context of this Guideline, migration limits are expressed in the form of a Drinking Water Positive List Limit (DWPLL).

The DWPLL is a provisional drinking water limit value for material-specific substances derived from human toxicology and serves to quantify an acceptable substance migration in the test system at the time specified in the Guideline.

The DWPLL is derived from the Tolerable Daily Intake (TDI) or Acceptable Daily Intake (ADI). A daily intake of 2 l of drinking water is assumed, with a body weight of 60 kg, and a 10 % proportion of the overall exposure for given substance through drinking water (WHO Concept).

The DWPLL value can also have been calculated from a specific migration limit (SML) of Regulation (EU) No. 10/2011 using the formula DWPLL = 1/20 SML of the German Federal Environment Agency (UBA), or has been derived by the UBA in cooperation with the German Federal Institute for Risk Assessment (BfR) in accordance with the principles of the EFSA.

[23] Compliance of the substance in question with the purity requirements can be confirmed by a conformity declaration of the supplier.

[24] German Federal Health Gazette 46 (2003) 362

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

[26] German Federal Health Gazette 46 (2003) 362

The DWPLL values are calculated from the SML values as shown in Table 4.

Table 4 Deriving a DWPLL value

Level	Applicable for	Limit
0	Humans	TDI [mg/kg BW d][27]
1	Drinking water	$DWPLL = \frac{TDI \cdot 60 kgBW}{2 l/d} \cdot 0.1$ $[mg/l] = \frac{[mg/kgBW \cdot d] \cdot kgBW}{[l/d]}$ DWPLL= $^1/_{20}$ SML

If in Regulation (EU) No. 10/2011 a SML value is specified as “non detectable”, e.g. for acrylonitrile, the limit of detection is 0.1 µg/l.

All substances with a migration limit that are contained in the product shall be tested for their migration in accordance with 4.3. The concentration determined in the test shall be used to calculate the maximum concentration to be expected at the tap, c_{Tap} (cf. 4.3.3). These requirements do not apply for marginal products (cf. 3.6).

Instead of the experimental investigation, the migration can also be estimated with the aid of the Modelling Guideline[28] (cf. 4.3.2).

It is not necessary to test substances with a specific migration limit (SML) in Regulation (EU) No. 10/2011 whose SML-value multiplied by the ratio of the carbon molar mass of the substance (M_C) to the total molar mass (M_{total}) is greater than or equal to 10 mg/l. For the migration limit it is then sufficient to check the TOC parameter of the basic requirements.

$$SML \times \frac{M_C}{M_{total}} \geq 10\ mg/l$$

For substances with a QM or QMA limit in accordance with Regulation (EU) No. 10/2011, an examination of the residual content of the substance in the product is required. The QM and QMA limits apply whatever the product group of the organic material is.

If a substance with a QMA limit can be determined in the test water, then the requirement may also be tested with the aid of a migration test. In this case it is assumed that 1 kg of food is contained in a cube with a surface area of 6 dm², a SML value is then derived from the QMA value, from which in turn the DWPLL can be derived in accordance with Table 4:

$$DWPLL = {}^1/_{20} \times \text{QMA} \times {}^{6\text{dm}^2}/_{1\text{kg}}$$

[27] BW (body weight)

[28] Guideline for the mathematical estimate of the migration of individual substances from organic material in drinking water

For some substances, both a migration limit and a QM or QMA value is given. In such cases, only one limit is to be tested. However, preference should be given to the DWPLL value.

For the ***cold water test*** the following applies:

$c_{Tap} \leq$ DWPLL — for the 3rd migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 9th migration period in accordance with EN 12873-1 (or EN 12873-2).

For the ***warm water test*** the following applies:

$c_{Tap} \leq$ DWPLL — for the 7th migration period in accordance with EN 12873-1 (or EN 12873-2), or in the case of extension of the migration test the 22nd migration period in accordance with EN 12873-1 (or EN 12873-2).

In addition, the measured concentrations must not show an upward trend[29].

3.5 Requirements for the testing of the growth of microorganisms

3.5.1 Various test methods

The enhancement of microbial growth is tested in accordance with EN 16421. The test can be carried out on material plates, end products, or parts of end products (for more details see EN 16421).

In 4.4, requirements are specified for the application of the various test methods in accordance with EN 16421.

3.5.2 Requirements for testing in accordance with the biomass production potential (BPP), measured by adenosine triphosphate (ATP) - Method 1

A product shall be deemed appropriate for contact with drinking water with respect to the enhancement of microbial growth if the
biomass production potential (BPP) ≤ 1000 pg ATP /cm².

3.5.3 Requirements for tests in accordance with the volumetric method - Method 2

a) Products which, in all investigated test periods, have only a firmly adhering surface colonisation (comparison between the contact culture /the swab of the test specimen and the negative control) or surface growth ≤ (0.05 + 0.02) ml/800 cm², meet the requirements of this Guideline and are suitable for general use in connection with drinking water.

[29] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

b) For products to be used for large contact area seals[30] a limit value applies of (0.12 + 0.03) ml /800 cm². With the exception of the first month one value (1a), values shall not exceed (0.12 + 0.03) ml /800 cm². The values plus measurement limit errors shall be constant or show a declining trend, i.e. 1c ≤ 1b and 3a ≤ 2a (cf. Table 5).

c) For products to be used for small-area seals[31], the limit value is (0.20 + 0.03) ml /800 cm². With the exception of the first month one value (1a), values shall not exceed (0.20 + 0.03) ml /800 cm². The values plus measurement limit errors shall show a constant or declining trend, i.e. 1c ≤ 1b and 3a ≤ 2a (cf. Table 5).

d) For large contact area seals under b) and small contact area seals under c) the following additional assessment option applies on the basis of optional monthly values. The optional monthly values are only determined in those cases where materials or products are to be used as large contact area or small contact area seals and where the first month one value (1a) is below the relevant limit value, but the second month one value (1b) is above it (cf. Annex 6).

e) Products which show no surface growth and no surface colonisation (comparison of the contact culture /the swab of the test specimen with the negative control), do not meet the requirements of this Guideline for use in connection with drinking water.

[30] Large contact area seals and sealing filler for expansion joints; expansion units, equalisation pieces, and silencers; slides (tapered seals with seal coating); flaps, if the slider is coated; air valves if the ball is coated; membranes of pressure reducers; hydrants, if the stop valve is coated; plunger valves

[31] Other seals and adhesives (but not tile adhesives). All pipe connections not specified in D1 with elastic sealing elements, such as flange gaskets, screw-Tyton and plug-in sleeves, rolling rubber ring and rotating ring seals, fittings. All shut-off devices not specified as large contact area seals, such as slides with enclosed or surrounding seals, housing seals, spindle seals and tapered seals (with inserted profile seal). All flaps and non-return valves not specified as large contact area seals, if the flap surfaces are not coated. All valves not specified as large contact area seals

Table 5 Overview for assessment without optional monthly values

	1-Monthly samples			2-Monthly sample	3-Monthly sample
Type of material/ product	**Sample 1a**	**Sample 1b**	**Sample 1c**	**Sample 2a**	**Sample 3a**
All materials for general use in the field of drinking water (3.5.3 a)	All values ≤ (0,05 + 0,02) ml / 800 cm²				
Materials to be used as large seals (3.5.3 b, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.12 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		
Materials to be used as small seals (3.5.3 c, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.20 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		

3.6 Marginal products

Products with a conversion factor smaller than or equal to 0.001 d/dm (cf. Table 6), can be regarded as marginal products. The starting substances of these products need not be assessed or included in one of the positive lists. Requirements for the migration of individual substances as well as additional requirements do not apply to these products and a corresponding test is therefore not necessary. However, basic requirements do apply (for TOC, odour, flavour, and external characteristics). Testing the enhancement of growth of microorganisms is necessary.

4 Testing

4.1 Formulation review

The formulation shall be declared in accordance with the disclosure sheet (Annex 2). All constituents of the formulation shall be entered on the disclosure sheet. The conformity of the formulation constituents with the positive lists in Table 1 and the supplementary positive list in Annex 1 shall be confirmed. Not only the entries of substances has to be checked, but also the stated restrictions on use, e.g. in terms of the technological function. For silicones and polymerisation aids, the relevant restrictions in accordance with der BfR Recommendations are also to be examined (e.g. maximum quantity to be used, residual contents).

For the examination of the formulation of multilayer products, the formulation of each layer shall be declared separately in accordance with the disclosure sheet in Annex 2. An explanation of the layer structure shall be provided. The appropriate Guidelines shall be used for the assessment of the individual layers corresponding to the type of material in each case. For products with a total barrier, the layers not on the drinking water side of the barrier do not have to be assessed.

On the basis of the formulation presented, the test parameters shall be determined in accordance with Section 3.

4.2 Test pieces

The production process has an influence on the properties of a product. For this reason, tests of hygienic properties shall be carried out on the finished product or component.

Pipes, composite pipes, and single-layer and multi-layer hoses shall be tested by filling.

For products with the same formulation produced by the same method in a factory (e.g. injection-moulded parts, or seals of different shapes), the test can be carried out with a sample product representative of a series of products.

If it is not possible to test the finished product, the single layer materials can be tested using test plates measuring approximately 200 x 200 x 2 mm. The test plates shall have the same formulation and shall be produced according to the same temperature and time specifications as the product itself (Annex 4 of the Guideline).

Multi-layer materials, consisting of linings, intermediate layers, or inserts of individual substances, the individual components of which may have an influence by diffusion on the surface in contact with water, shall be tested as multilayer products or multilayer product components.

For testing in accordance with EN 16421, either material sheets, end products, or parts of end products may be used.

4.3 Testing migration

4.3.1 Carrying out migration tests

According to the scope of application of the product the migration test shall be performed as a cold water test at (23 ± 2) °C and if appropriate also as a warm water test (60 ± 2) °C or hot-water test (85 ± 2) °C.

The migration water samples are produced in accordance with the standards EN 1420-1, EN 12873-1, or EN 12873-2. Annex 3 provides a brief description of the migration test and includes additional requirements. The migration water samples are to be analysed for the parameters in accordance with the basic requirements, additional requirements, and formulation-specific requirements for an individual substance for the proposed product group. Careful records shall be kept of the testing process and the test results (cf. 4.3.4).

If c_{Tap} for one or more substances, the TOC value, TON or TFN in the 3rd migration period of the cold water test is above the test value (cf. 3.2) or shows an upward trend[32], then the testing can be extended to the 9th migration period in accordance with Annex 3.

If c_{Tap} for one or more substances, the TOC value, or TON and TFN in the 7th migration period of the warm water or hot water testing is above the test value (cf. 3.2) or indicates an upward trend[33], then the testing can be extended to the 22nd migration period in accordance with Annex 3.

For products made up of multiple layers, the warm water test shall be carried out with 22 migration periods[34]. This is intended to register substance migration from the outer layers.

Standardised methods shall be used to analyse the migration water samples. If no such methods currently exist for a certain substance, then an analysis method with a suitable sensitivity shall be used that allows the detection of the specified concentration. If no analytical methods are available for an individual substance, then the migration for this substance shall be estimated, e.g. in accordance with the Modelling Guideline.

4.3.2 Modelling

In place of the experimental test, migration for the formulation-dependent requirements for individual substances can also be assessed by means of the modelling guideline[35] if applicability of generally recognised diffusion models based on scientific evidence and parameters was defined.

In the report of Simoneau[36] specific parameters for the most important organic materials being in food contact are contained.

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[32] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

[33] For assessing the trend, primarily the latest measurements and possible analytical ranges of variation shall be taken into account.

[34] Care shall be taken that substances are not extracted from the material during the warm water test. Instead of the warm water test the possible substance migration can be modelled.

[35] Guideline for the mathematical estimate of migration of individual substances from organic materials in the drinking water

[36] Simoneau C. (ed) (2010), Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Report, EUR 24514 EN. "Applicability of generally recognised diffusion models for the estimation of specific

In the case of other organic materials used in contact with drinking water these parameters must be determined specifically for each material or product before modelling can be applied. Testing necessary for that purpose is also described in the above mentioned test.

A prerequisite for the modelling is the determination of the amount of the relevant substance in the product tested ($c_{P,0}$).

The method of analysis for determining $c_{P,0}$ for the polymer must be presented by the raw material supplier if there is no validated method available from the "Community Reference Laboratory for Food Contact Materials" or a standard. Alternatively $c_{P,0}$ can be used from the required quantity if the substance does not change during the manufacture and processing of the product.

Modelling must consider the respective test conditions (test temperature and test cycle) under this Guideline (see Annex 3). The concentration profile for the previous test period is used to calculate the migration for the following test period. This is described in detail in the modelling guideline.

If a product does not meet the requirements of the Guideline concerning individual substances to be tested after modelling of migration, proof can still be provided by way of experimental testing. The results of experimental tests must be weighted higher than those of the modelling.

4.3.3 Calculating the maximum concentration to be expected at the tap (c_{Tap})

The maximum concentrations to be expected at the tap (c_{Tap}) differ for the various product groups depending on the conversion factors given in Table 6:

$$c_{Tap} = \frac{F_c \times c_m}{A/V \times t}$$

where:

F_C: Conversion factor in Table 6

c_m: The concentration measured in the migration water in accordance with EN 12873-1

A/V: Surface area to volume ratio in accordance with EN 12873-1

t: Duration of the migration period in accordance with EN 12873-1

In Table 6, distinctions are made between the product groups pipes, containers, and fittings, with the requirements being further differentiated according to the place of use in the water distribution system. The fittings and seals are allocated to the relevant pipe dimensions.

migration in support of EU Directive 2002/72/EC" under
http://publications.jrc.ec.europa.eu/repository/handle/111111111/14935

Table 6 Product groups with the relevant conversion factors

Product group	Conversion factor F_C in d/dm
Pipes with DN[37] < 80 mm (service and domestic pipes)	20
Pipes with 80 mm ≤ DN < 300 mm (distribution pipes)	10
Pipes with DN ≥ 300 mm (large distribution, mains)	5
Fittings for pipes with DN < 80 mm	4
Fittings for pipes with 80 mm ≤ DN < 300 mm	2
Fittings for pipes with DN ≥ 300 mm	1
Seals for pipes with DN < 80 mm	0.4
Seals for pipes with 80 mm ≤ DN < 300 mm	0.2
Seals for pipes with DN ≥ 300 mm	0.1
Containers in the drinking water installation including repair systems	4
Containers outside the drinking water installation including repair systems	1
Repair systems for containers in the drinking water installation with 1/100 of the surface area of the container	0.04
Repair systems for containers outside the drinking water installation with 1/100 of the surface area of the container	0.01
Small contact area components of materials for pipes with DN < 80 mm that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.004
Small contact area components of materials for pipes with 80 mm ≤ DN < 300 mm, that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.002
Small contact area components of materials for pipes with DN ≥ 300 mm, that are only installed in one place in the distribution system (e.g. plain bearing of a pump)	0.001

In Annex 5 of the KTW Guideline, typical products are assigned to the product groups given in Table 6.

[37] Internal diameter - ID

4.3.4 Test report

A test report shall be produced including the complete test results in accordance with Tables 4 and 5 of Annex 3 of the Guideline and attached as Annex I to the report. Compliance with the requirements for individual substances (DWPLL values) that are subject to confidentiality are recorded as the number of substances and the note “Test value complied with”. The test report shall consist of the following annexes:

Annex I: Table with the full test results (cf. Annex 3 to the Guideline), if necessary with documentation of the modelling

Annex II: Declaration of the formulation (Annex 2 to the Guideline, completed and signed by the producer/ applicant and the test laboratory),

Annex III: Records of the production of the test specimen

Annex IV: Records of the test procedure (cf. 4.3),

Annex V: Selection and parameters for the analytical methods used or parameters for the modelling.

Confidential data are not included.

For the test on the enhancement of microbial growth, a test report shall be produced in accordance with EN 16421.

4.4 Requirements for testing in accordance with EN 16421 (microbial growth)

The test of products regarding the enhancement of microbial growth is carried out in accordance with EN 16421. The following limitations apply for the use of the three methods described in the standard.

Method 3 (MDOD method) has a limit of detection that is too high in comparison with the other methods. The method is not suitable for testing products that are to be used with drinking water that is free of disinfectant agents. In Germany, drinking water is distributed in many cases without the addition of chlorine or other disinfectant agents. For this reason, it is necessary in Germany to conduct a test using one of the other two methods (BPP method or volumetric method).

The BPP Method (Method 1) is not suitable for testing multi-layer composite products, because in the test the surface that would not normally come into contact with drinking water when in use is also exposed to the test water.

Multi-layer composite products are tested with Method 2 in the test module for pipes and hoses.

The volumetric method (Method 2) is not suitable for testing a lubricant or grease.

5 Conformity certification

5.1 General

The conformity of a product with the requirements of this Guideline may be confirmed by a test report or certificate. The confirmation of conformity is to be carried out with the

1+ System in accordance with the EU Construction Products Regulation (Regulation (EU) No. 305/2011). This requires external inspection of manufacturing plant[38].

5.2 Application

In order to receive an attestation of conformity according to this Guideline for products in contact with drinking water the applicant must provide the test laboratory with the formulation components (indication of all substances with the percentage by weight, the CAS No. and technological function (e.g. stabiliser) (template for formulation declaration in Annex 2). For products made up of multiple layers, the formulations shall be given for all layers (e.g. lining, adhesive).

The formulation details in accordance with Annex 2 can be provided separately by the producer of the product and the producer of the preparations, provided that the precise designation in each case allows a clear allocation to the product.

This shows the testing necessary for DWPLL values or the residual contents (QM, QMA) for individual substances in the product and purity requirements for the listed substances or substance groups.

In addition, the proposed product group (cf. Table 6) of the product shall be stated.

5.3 Test laboratory

Testing in accordance with this Guideline shall be carried out by a test laboratory accredited in accordance with ISO/IEC 17025 or by a certification body recognised by an accredited certifier.

5.4 Producing a test certificate

The test report or certificate shall contain the following closing paragraph:

"The product ... (precise designation) has been tested in accordance with the Guideline on the hygienic assessment of organic materials in contact with drinking water of the German Environment Agency and has passed the test for the proposed product group(s) ... in the temperature range up to ... °C."

Test certificates issued in accordance with this Guideline are valid for a period of 5 years.

Test reports or certificates for products of the same manufacturer that are produced in accordance with this Guideline may be extended for five years without further experimental testing provided that all requirements under Section 3 were met in the initial test and that the formulation of the relevant substance evaluations (restrictions in the positive lists) and the production of the product have not changed. Before extending the test certificate, the test laboratory shall ensure that the formulation, the production process, and the relevant positive list are unchanged.

[38] Implementing rules required for the external monitoring are specified in the technical regulations

Annex 1 to the KTW-Guideline

Composition of the positive lists

The positive lists include the starting substances for the production of organic materials in contact with drinking water in tabular form. For plastics und silicones, this Guideline contains only supplementary positive lists (cf. Table 1).

Column 1 The EEC packaging reference number (Ref.-No.) from the Regulation (EU) No. 10/2011.

Column 2 The Chemical Abstracts Service Number (CAS Number).

Column 3 The name of the substance.

Column 4 DWPLL values as test criteria in the migration test (cf. 4.3).

Column 5 Residual content (QM) in the plastic, or area-related residual content (QMA), relative to a surface area of 6 dm2.

For some substances, limits are included both as a DWPLL value (derived in accordance with Section 3.4) and as a QM or QMA value. In these cases, only one limit shall be tested. Preference should be given to testing the DWPLL value.

The positive lists in Table 1 also contain substances (acids, alcohols, and phenols) that can occur in the form of salts. Since the salts are normally converted in the stomach into acids, alcohols, or phenols, it is possible to use salts of the listed acids, alcohols, or phenols. This means that the salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium and zinc of the listed acids, phenols or alcohols are included. For the specified cations the migration limit shall be 10 % of the limit value under the TrinkwV 2011, Annexes 2 and 3 and the following limits as DWPLL values:

for barium	70[39] µg/l
for cobalt	1.0[40] µg/l
for zinc	300[41] µg/l

All fillers used shall comply with the purity requirements of BfR Recommendation LII[42].

All colourants used shall comply with the requirements of BfR Recommendation IX[42].

For the assessment of the aids to polymerisation used for the production of plastics and silicones, the relevant BfR Recommendations (Table 1) can be referred to (cf. Section 3.1).

[39] 10% of the WHO guidance value

[40] 10% of the LAWA-guidance value

[41] 10% of the WHO-guidance value

[42] https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp

Including new substances in the positive lists

The addition of a substance to the positive list is only permitted on application by a manufacturer (applicant) to the German Environment Agency pursuant to the rules of procedure[43] of the German Environment Agency for keeping the positive list of substances to manufacture organic materials in contact with drinking water (cf. UBA website: http://www.umweltbundesamt.de/wasser/themen/trinkwasser/verteilung.htm).

The positive list is updated approximately once per year.

To apply for an assessment of a substance to be added to the positive list a substance dossier has to be submitted containing information on transitions of the proposed substances, its contaminations and possible resulting reaction products (e.g. decomposition products of a stabiliser) into drinking water under the most unfavourable conditions. Data to be submitted are based on the questionnaire of the European Commission for plastics in contact with foodstuff ("Note for Guidance") which is divided into sections 1 to 8.

When applying for substances not only pure substances but also contaminations shall be considered. Test conditions of this Guideline have to be used for this migration test. In place of global migration the parameter "TOC " (total organic carbon) will be determined in accordance with the requirements of the Guideline.

Section 8 of the questionnaire describes the requirements for the toxicological data to be submitted, the scope of which depends on the migration level of the requested substance in deionised water. For migrations up to 2.5 µg/l it is to be shown that the substance is not mutagenic (mutagenicity test by OECD No. 471,473 and 476). For migrations exceeding 2.5 µg/l to 250 µg/l a 90-day oral feeding study and data on bioaccumulation are necessary in addition. If the migration exceeds 250 µg/l, the complete toxicological data set is required. Furthermore, all existing toxicological data must be presented.

When applying for substances to be added to the positive list for manufacture of organic materials in contact with drinking water the following 3 cases shall be distinguished. The procedure depends on which toxicological assessment is available for the substance.

1 There is no publicly available assessment of the substance by an authority or organisation.

2 There is an assessment of the substance by EFSA/SCF[44] for the use in plastics in case of food contact.

3 There is a publicly available assessment of the substance by another authority or organisation, e.g. WHO, ECHA.

In case 1 the whole questionnaire has to be filled in. In case 2 points 1 to 4 have to be filled in sufficiently and in case 3 the points 1 to 7 have to be filled in. Further details for application of substances are included in the rules of procedure of the German Environment Agency for

[43] http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien

[44] European Food Safety Authority (http://www.efsa.europa.eu/de/)/ Scientific committee on food

the management of the positive list of starting substances for organic materials in contact with drinking water.[45]

Within the framework of the mutual recognition in the 4MS process, substance assessments from other European member states may also be accepted provided that they were carried out in accordance with the requirements of the 4MS process[46]. These substances may also be added to the positive list (Annex 1 Parts 1 and 2).

Supplementary drinking-water specific positive lists for plastics and silicones in contact with drinking water

In addition to the positive lists in Table 1 in Section 3.1, Part 1 of Annex 1 contains additional starting substances for the production of plastics.

In addition to the positive list of BfR Recommendation XV. Silicones, Part 2 of Annex 1 contains further starting substances for the production of silicones.

[45] http://www.umweltbundesamt.de/sites/default/files/medien/419/dokumente/geringsfuegigkeits-leitlinie2011.pdf

[46] http://www.umweltbundesamt.de/wasser/themen/trinkwasser/4ms-initiative.htm

Part 1: Positive list of the starting substances for the production of plastics in accordance with this Guideline

Table 1 of Annex 1 Starting substances for plastics evaluated by UBA or accepted within the framework of 4MS cooperation

PM-Ref-No.	CAS-No.	Name of substance	DWPLL in µg/l	QM or QMA

Part 2: Positive list of the starting substances for the production of silicones in accordance with this Guideline

Table 2 of Annex 1 Starting substances for silicones evaluated by UBA or accepted within the framework of 4MS cooperation

PM-Ref-No.	CAS-No.	Name of substance	DWPLL in µg/l	QM or QMA

Annex 2 to the KTW-Guideline

Form for the disclosure of a formulation

Address of the manufacturer: .....

Annex to test application dated ... by the company ...

Product or brand name: ....

Declaration of the formulation of the plastic or silicone in accordance with the Guideline on the hygienic assessment of organic materials in contact with drinking water of the German Environment Agency

This declaration is to be used to determine the scope of testing and the requirements for individual substances.

Please list all starting substances /components (polymer, fillers, processing aids, etc.) required for the production of the organic material. If there is more than one supplier for a certain starting substance these must be recorded individually.

The table must be completed in full.

Starting substance / Trade name	Chemical description	CAS-Number	Function of starting substance	Percentage by weight (in %)

All information will be treated confidentially.

page ___ of __ .

Signature of producer:

The formulation shall be disclosed using the form in Annex 2. In the table, all constituents of the formulation shall be included by the producer, including for example solvent and impurities. An updated safety data sheet for the substance or formulation can as a rule provide information about the purity of the substance and other substances contained in the formulation. In individual cases, the information is to be provided by suppliers.

If a product consists of multiple layers, then the formulation of each layer shall be disclosed for the evaluation of the formulation of the product.

Annex 3 to the KTW Guideline

Performance of migration testing and odour/flavour testing of coating materials in contact with drinking water

Testing is to be done in accordance with DIN EN 1420-1 and DIN EN 12873-1, DIN EN 12873-2 by taking into account the options available in the European standards as follows:

I. Migration test at (23 ± 2) °C (cold water test) in accordance with DIN EN 12873-1 and -2

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The specimens are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with test water at (23 ± 2) °C,

   1 h flushing with tap water,

   rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{-1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each shall be used for further analyses as described below.
8. The parameters of the basic requirements (TOC, colour, turbidity and tendency to foaming) are tested on the migration waters of migration periods 1, 2 and 3.
9. Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
10. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the parameters with migration restriction stated in table 1 as additional requirements. These mixed samples are then tested. The control water from the migration periods must be tested at least once.
11. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the individual substances specific to the formulation. These mixed samples are then tested. The control water from the migration periods must be tested at least once.

12. When the cold water test is extended migration waters (mixed samples) of the fifth, seventh and ninth migration period shall be examined to determine the basic, additional and formulation-dependent requirements for individual substances (see table 1 of this Annex).

II. Migration test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 12873-1 and -2

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with test water at test temperature,

   1 h flushing with tap water,

   rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes or hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature (10 days of total contact time).
8. Migration waters of the first second, third, sixth and seventh migration periods shall be used for examining the parameters of the basic requirement (TOC, colour, turbidity and tendency to foaming). Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
9. Mixed samples are created from the tests using the migration water from migration periods 1 and 7 respectively to determine the parameters with migration restriction stated in table 1 as additional requirement. The mixed samples from the migration water from the 1st, 6th and 7th migration periods are then tested. The control water from the migration periods must be tested at least once.
10. The test for formulation-specific substances is conducted in the migrates of the 1^{st}, 6^{th} and 7^{th} test periods (mixed samples from the tests). The control water from the migration periods must be tested at least once.
11. When the migration test at elevated temperatures is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period (mixed samples from the test

runs) shall be tested to determine the basic, additional and formulation-dependent requirements of individual substances (cf. table 2).

III. Odour/flavour test at (23 ± 2) °C (cold water test) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test specimens are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with reference water at (23 ± 2) °C,

   · 1 h flushing with tap water,

   rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm^{-1} small repair systems for containers with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each are used to determine the odour/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 2 and 3 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 2nd migration periods are tested tentatively[47] in the laboratory to determine the odour/flavour limits. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 3rd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 5th, 7th and 9th migration period shall be tested. Odour and flavour threshold values of the migration waters of the 5th and 7th migration periods are determined tentatively. The results are presented in the test report and marked accordingly. The mixed sample of the migration water from the 9th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

[47] The tentative determination is a short test in which the migration water is diluted until no odour/flavour can be perceived.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622 2006.

IV. Odour/flavour test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The test specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   1 h flushing with tap water,

   24 h stagnation with reference water at test temperature,

   1 h flushing with tap water,

   rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test run and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm-1, small-scale repair systems for tanks with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature. The migration waters of the 1st, 6th and 7th test periods are used to determine the odour-/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 6 and 7 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 6th migration periods are tested tentatively in the laboratory to determine the odour/flavour threshold values. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 7th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period shall be tested. Odour and flavour threshold values of the migration waters of the 11th, 12th, 16th, 17th and 21st migration periods are determined tentatively. The results are presented in the test report and marked accordingly. The mixed sample of the migration water from the 22nd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622.

Table 1 of Annex 3 Migration cycles of extended cold water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday	1	No
1	1	4	Friday	3	Yes
2	2	7	Monday	3	Yes
2	3	10	Thursday	3	Yes
3	4	14	Monday	4	No
3	5	17	Thursday	3	Yes
4	6	21	Monday	4	No
4	7	24	Thursday	3	Yes
5	8	28	Monday	4	No
5	9	31	Thursday	3	Yes

Table 2 of Annex 3 Migration cycles of extended warm or hot water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday		No
1	1	2	Wednesday	1	Yes
1	2	3	Thursday	1	Yes
1	3	4	Friday	1	Yes
2	4	7	Monday	3	No
2	5	8	Tuesday	1	No
2	6	9	Wednesday	1	Yes
2	7	10	Thursday	1	Yes
2	8	11	Friday	1	No
3	9	14	Monday	3	No
3	10	15	Tuesday	1	No
3	11	16	Wednesday	1	Yes
3	12	17	Thursday	1	Yes
3	13	18	Friday	1	No
4	14	21	Monday	3	No
4	15	22	Tuesday	1	No
4	16	23	Wednesday	1	Yes
4	17	24	Thursday	1	Yes
4	18	25	Friday	1	No
5	19	28	Monday	3	No
5	20	29	Tuesday	1	No
5	21	30	Wednesday	1	Yes
5	22	31	Thursday	1	Yes

Table 3 of Annex 3 Minimum S/V ratio for the test runs

Test run / Area of use	Migration at 23°C	Migration at elevated temperature	Odour/flavour at 23°C	Odour/flavour at elevated temperature
Pipes DN < 80 mm	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)
Pipes 80 mm ≤ DN < 300 mm	S/V ≥ 5 dm^{-1} (fill or fill with inserted cylinder or fill pipe sections)	S/V ≥ 5 dm^{-1} (fill or fill with inserted cylinder or pipe sections)	S/V > 2.5dm^{-1} (fill)	S/V > 2.5 dm^{-1} (fill)
Pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (fill with inserted cylinder or of pipe section or immersed plates)	S/V ≥ 5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)	S/V ≥ 2.5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)	S/V ≥ 2.5 dm^{-1} (fill with inserted cylinder or pipe sections or immersed plates)
Fittings (ancillaries)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 1.5 dm^{-1} (immersion of products or test plates)	S/V ≥ 1.5 dm^{-1} (immersion of products or immersed plates)
Seals	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 5 dm^{-1} (immersion of products or test plates)	S/V ≥ 0.2 dm^{-1} (immersion of products or test plates)	S/V ≥ 0.2 dm^{-1} (immersion of products or plates)
Container, repair systems	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 2.5 dm^{-1} (immersion of test plates)	S/V ≥ 2.5 dm^{-1} (immersion of test plates)
Small contact area components for pipes DN < 300 mm	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 5 dm^{-1} (immersion of test plates)	S/V ≥ 0.2 dm^{-1} (immersion of test plates)	S/V ≥ 0.2 dm^{-1} (immersion of test plates)
Small contact area components for pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (immersion of test plates)	-	S/V ≥ 0.2 dm^{-1} (immersion of test plates)	-

Table 4 of Annex 3 Table of test results for TOC in accordance with EN 12873-1 and -2

Product:

Date of test:

Test temperature:

Surface / volume ratio:

Conversion factor for the product to be assessed:

Number of migration periods:

Analysis method:

	Sequential number of the migration period n				
	1	2	3[48]	6	7
a_n^T					
$\bar{a}_n^T$					
b_n^T					
$\bar{b}_n^T$					
$\bar{c}_n^T = \bar{a}_n^T - \bar{b}_n^T$					
$\overline{c_{Tap}}_n^T$					

where

a_n^T is the concentration of a substance measured in a migration water sample in mg/l,

b_n^T is the concentration of a substance measured in blank water in mg/l,

$\bar{c}_n^T$ the concentration of the substance to be determined,

$\overline{c_{Tap}}_n^T$ is the maximum expected tap concentration of a migrating substance,

n is the sequential number of the migration period,

T is the test temperature

[48] The cold water test ends with the 3rd or 9th test period.

Table 5 of Annex 3 Table of test results for the additional requirements and the formulation-specific individual substance requirements in accordance with EN 12873-1 and-2

Product:

Date of test:

Test temperature:

Surface area to volume ratio:

Conversion factor for the product to be assessed:

Number of the migration period:

Analysed substance:

Analysis method:

	Sequential number of the migration period n			
	1	3[49]	6	7
α_n^T				
β_n^T				
$\chi_n^T = \alpha_n^T - \beta_n^T$				
$\overline{c_{Tap\ n}}^T$				

Where:

α_n^T is the concentration of a substance measured in a mixed migration water sample in mg/l,

β_n^T is the concentration of a substance measured in the mixed blank water sample in mg/l,

χ_n^T is the concentration of the substance to be determined,

$\overline{c_{Tap\ n}}^T$ is the maximum expected tap concentration of a migrating substance

,

n is the sequential number of the migration period,

T is the test temperature

[49] The migration test at elevated temperatures ends with the 7th or 22nd test period.

For the modelled concentrations a record should be produced of all the data entered (printout of the relevant software report) which shall form part of the test report. It shall include the parameters tested and the details of the test run (temperature, surface of the specimen, volume of the migration water sample, contact time).

The formulation-specific requirements are subject to confidentiality and cannot therefore be stated in the report. Proof that a test has been carried out on these parameters and that the requirements have been met is reported in the test report as follows: ”Formulation constituent subject to confidentiality; reference value complied with.”

Annex 4 to the KTW Guideline

Disclosure sheet for recording the production of the product or test plates

The following data shall be included:

1. Address of applicant,
2. Accurate designation of the plastic/silicone (for unambiguous allocation in terms of application, formulation statement, test record, and test report),
3. Location of production of the test plates or the product (e.g. factory, laboratory, or construction site),
4. Address of producer, name of the responsible employees,
5. Date of production of the test plates or the product,
6. Method of production of the test plates or the products (e.g. injection moulding),
7. Production or curing conditions (time, temperature),
8. Mixing procedure, e.g. milling, kneading,
9. Special conditions to be observed e.g. annealing,
10. If relevant: composition of the multilayer product
11. Deviations of the test plate production from the product production (if relevant).

The products and the test plates shall be packed in suitable diffusion-resistant packaging materials (e.g. aluminium foil, glass) and stored in such a way as to avoid contamination with other substances.

Annex 5 to the KTW-Guideline

Table 1 of Annex 5 Overview of various products and their allocation to the product groups

Product group	Products
Pipes: DN < 80 mm 80 mm ≤ ID-DN < 300 mm ID-DN ≥ 300 mm	Pipes and hoses of plastics Plastic pipe lining Pipes from composite materials Cable in drinking water supply pipes Hoses in the drinking water installation (except connecting hoses for washing machines or dishwashers) Hoses for the temporary transport of drinking water
Fittings for pipes: DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Valves Stop-cocks Meters Fittings Housings for filters in a drinking water installation Power cable (e.g. for submerged pumps) Linings for slider housings Membranes for expansion vessels (ID-DN<80 mm) Connecting hoses for washing machines and dishwashers
Seals for pipes: DN<80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Seals for pipes and hoses Seals for fittings
Tanks: in a drinking water installation outside a drinking water installation Repair systems for containers and tanks	Plastic tanks and cladding in the drinking water supply system Tanks in the drinking water installation Tanks in the water works Repair systems for tanks in the waterworks
Small contact area components for pipes: DN ≥ 300 mm, only installed in one place in the distribution system	Plain bearing of a pump

Annex 6 to the Coating Guideline

Assessment of test in accordance to DIN EN 16421 – Procedure 2 (volumetric procedure) by using optional monthly values

1. General information

Optional monthly values are only determined in those cases where products are to be used as large or small seals and where the first one-month value (1a) is within the corresponding threshold values, the second one-month value (1b) is over this value (cf. table 1). Then the optional monthly values, forth one-month-value (1d) as well as second two-month-value (2b) shall be determined (cf. table 1) and used for assessment. The first one-month-value (1a) shall not be taken into account for the assessment. Assessment of the overall results shall be done without considering the value 1a (cf. table 1).

2. Large seals

With the exception of the second one-month value (1b) all values must not exceed (0.12 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

3. Small seals

With the exception of the second one-month value (1b) all values must not exceed (0.20 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

Table 1 of Annex 6 Overview of assessment by using optional monthly values

	1-Monthly samples				2-Monthly samples		3-Monthly sample
Type of material/ product	**Sample 1 a**	**Sample 1 b**	**Sample 1 c**	**Sample 1 d**	**Sample 2a**	**Sample 2 b**	**Sample 3 a**
Products to be used as large seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.12 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				
Products to be used as small seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.20 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				