As at: 16 March 2016

RECOMMENDATION

Guideline for hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline)[1,2]

Only the German version of this document is legally binding.

1 Preliminary remarks

This Guideline can be used to assess elastomers in contact with drinking water within the meaning of the Drinking Water Ordinance, Section 17 (1).

This Guideline shall not apply to thermoplastic elastomers (TPE) nor to silicones. Silicones can be assessed according to the requirements of the KTW Guideline[3] and TPE according to the TPE Transitional Recommendation[3].

This Guideline was developed by the German Environment Agency in cooperation with the KTW-AG (Joint Working Group of the Drinking Water Commission of the German Environment Agency and the Committee for Consumer Products of the Federal Institute for Risk Assessment on the hygienic assessment of plastics and other non-metal materials in contact with drinking water) and the trade association of the German Kautschukindustrie e. V. (wdk).

Like the other Guidelines of the German Environment Agency on the hygienic assessment of organic materials in contact with drinking water (KTW, Coating and Lubricants Guideline) this Guideline is [3] broken down into three parts,

- the positive list of starting substances that can be used to manufacture elastomers
- the prescribed test methods (migration test procedure) and
- the limit test values observed in the tests.

[1] Obligations resulting from Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204 of 21.7.1998, p. 37) last amended by the Directive 2006/96/EC (OJ L 363 of 20.12.2006, p. 81) have been observed.

[2] Last amended on 16 March 2016, notified under 2013/471/D

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

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1.1 Legal status of the Guideline

This guideline is a revision of the elastomer guideline of 22 december 2011. It also constitutes a recommendation and no evaluation criteria yet within the meaning of the Drinking Water Ordinance (Trinkwasserverordnung - TrinkwV 2001) amended on 05.12.2012. Hence this Guideline is non-binding. It represents the current state of scientific and technical knowledge relating to the hygienic requirements which must be met by elastomers in contact with drinking water.

Pursuant to Section 17 (3) of TrinkwV amended on 05.12.2012 it is intended to transfer this elastomer guideline into an evaluation criteria which are legally binding 2 years after being published. Pursuant to Section 17 (5) of TrinkwV 2001 it can be assumed that products and procedures meet requirements of Section 17 if this was confirmed by means of a certificate by a certifier accredited in the field of drinking water. Up to the date of completion and entry into force of the evaluation criteria for elastomers pursuant to Section 17 (2) TrinkwV 2001 this Guideline relating to conformity assessment and confirmation of harmlessness of an elstomer 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 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 method and at least comply with the level of protection for existing regulations relating to materials and products in contact with foodstuffs.
- The assessment system taken as a basis has to be trackable.

1.2 Further requirements

Elastomers in contact with drinking water must be appropriate for their intended use. Requirements in the technical regulations are valid regardless of this Guideline.

The compliance of an elastomer product in contact with drinking water with generally accepted rules of technology and the requirements of TrinkwV 2001 can be verified via certification by a certification body accredited in the field of drinking water.

2 Elastomers

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

2.1 Definition of elastomers

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

- Rubber
- Fillers
- Plasticisers
- Anti-ageing agents

- Processing aids
- Cross-linking agents

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

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

Plasticisers are added to the rubber compound, for example, to adjust the hardness of the vulcanisate or to improve flexibility in the cold.

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

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

Cross-linking agents such as sulphur, sulphur donors or peroxides allow the rubber compound to be vulcanised into elastomer. Accelerating and retarding agents are also used for vulcanisation with sulphur.

2.2 Manufacture of elastomers

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

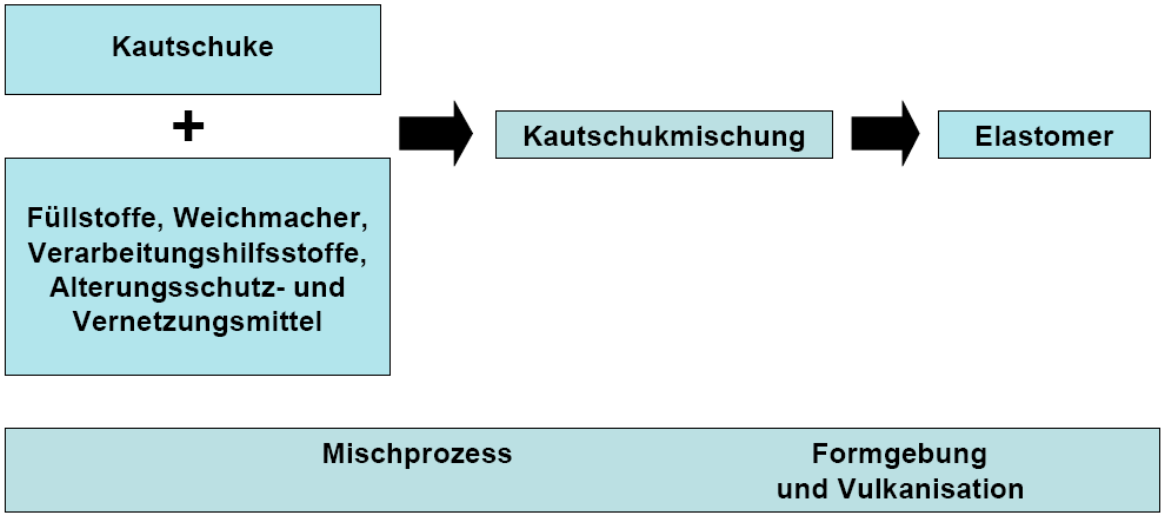

Figure 1: Manufacture of elastomers

The individual components listed in 2.1 are combined on a rolling mill or in an internal mixer with the addition of energy to produce the non-cross-linked **rubber compound**.

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

Vulcanisation cross-links the rubber compound or the rubber blank three-dimensionally with the addition of cross-linking agents and heat. This generally creates highly elastic materials, also known as elastomers.

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

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

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

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

Elastomers are used in the drinking water supply for a wide variety of applications. A summary of these can be found in Annex 5.

3 Structure of positive list for elastomers

Only the starting substances used in parts 1 + 2 of the positive list (Annex 1) should be used to manufacture the elastomers assessed under this Guideline (cf. chapter 5). In addition the use of substances under the De Minimis Guideline is also possible.

The positive list is broken down into three parts:

Part 1 of the positive list contains substances that are assessed toxicologically. The assessments were carried out by the **European Food Safety Authority** (EFSA)[4], formerly the Scientific Committee on Food (SCF), or in close cooperation of the UBA with the Federal Institute for Risk Assessment (BfR).

Part 2 of the positive list contains part-assessed substances, the use of which is accepted until December 2016. For inclusion in Part 2 and the relevant temporary applications of these substances, at least one safety assessment was required prior to a complete toxicological assessment. This involved presenting data on the migration of the substance in question and, if necessary, on its reaction and decomposition products. This information was necessary in order to assess potential exposure. The transitional rule can only be applied to substances that would normally be used to manufacture elastomers in contact with drinking water.

Part 3 contains examples of rubbers that are normally used in the manufacture of elastomers. The rubbers are listed along with their DIN ISO 1629 codes. To achieve certain product properties offcuts of rubber polymers are used with each other or with polymers that meet the KTW Guideline. The starting substances for rubbers listed (preparations) must be listed in Parts 1 or 2 of the positive list.

The starting substances for the manufacture of elastomers must be of good technical quality and purity. The rubbers must be produced in accordance with good manufacturing practice.

For Part 1 and Part 2 of the positive list the following applies:

In this positive list the "Monomers for rubbers" and "Cross-linking agents" must satisfy the **"Monomers and other starting substances"** of regulation (EU) No 10/2011[5].

Cross-linking agents are broken down into **peroxides and their co-agents, carbamates, thiocarbamates, thiurames, sulfonamides, guanidines, xantogenates, thiophosphates, mercapto accelerators and other accelerators.**

Besides the positive list contains other formulation components: **fillers, plasticisers, anti-ageing agents, processing aids and colourants.**

The use of biocide additives in drinking water materials to achieve a biocidal effect on the resulting manufactured products (biocide equipment, biocide additive) is rejected by UBA. In aqueous preparations (aqueous starting substances and intermediate products such as latex dispersions), however, it may be necessary to use biocide additives to maintain the stability of a preparation of microbiologically biodegradable substances until used (in-can-preservation). These in-can preservation agents may be contained in low-level concentrations in the preparation and are no longer active in the final product due to other elements in the

[4] http://www.efsa.europa.eu/

[5] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:DE:PDF

formulation. The in-can preservation agents must be included in the positive list (Annex 1) and must be stated in the formulation review.

The positive list is set out in table format. **Column 1** shows the "EEC Packaging Material Reference Number (Ref. No) from Regulation (EU) No 10/2011. **Column 2** contains the CAS (Chemical Abstracts Service) number.

The substance name is included in **Column 3**.

Column 4 shows the DWPLL values for several substances that are used as test criteria in the migration test (see 5.4).

The DWPLL (Drinking Water Positive List Limit) is a human-toxicologically derived temporary drinking water limit for material-specific substances and is used to quantify a substance migration to be assessed as acceptable in the text system at the point in time determined in the Guideline.

A DWPLL value corresponds to 10% of the substance-specific Tolerable Daily Intake (TDI) of a 60-kg person in 2 litres of drinking water.

The DWPLL may also have been calculated using the Specific Migration Level (SML) of Regulation (EU) No 10/2011 with the formula DWPLL = 1/20 SML of the German Environment Agency (UBA) or derived by UBA in cooperation with the Federal Institute for Risk Assessment (BfR) according to the principles of the EFSA.

The designation "TOC" in column 4 implies that the substance cannot be specifically determined but is instead covered by the basic requirement for the TOC parameter.

Column 5 shows the "QM" limit for the residual content in the vulcanised elastomer which is based on a surface area of 6 dm² (area-based residual content). These requirements have been adopted from Regulation (EU) No 10/2011. If the substance in the test water can be determined it is possible, assuming that 1 kg of food is packaged in a cube with a surface area of 6 dm², that a SML value can be derived from the QMA value and the DWPLL value can be determined.

Column 5 also contains in some cases the purity requirements for the substance input listed.

4 Inclusion of new substances in Part 1 of the Positive List

The addition of a substance to part 1 of the positive list is only permitted on application by a manufacturer (applicant) to the German Environment Agency. The positive list shall be updated approximately once per year.

The application shall be subject to the requirements of the EFSA questionnaire ("Note for guidance" (http://www.efsa.europa.eu/en/efsajournal/pub/21r.htm) that is contained in Chapter III of the European Community's questionnaire) and which is divided into sections 1 to 8).

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. Furthermore all existing toxicological data must be presented.

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.

No new substances are being added to part 2 of the positive list.

5 Requirements for elastomers

Elastomers in contact with drinking water must be appropriate for their intended use. Requirements from the technical regulations are valid regardless of this Guideline.

Assessment under this Guideline is carried out for a product that is manufactured from a vulcanised elastomer.

All of the substances used to manufacture the rubber compounds and the rubber itself must be toxicologically assessed and listed in the positive list according to their technological function (Annex 1 Parts 1 and 2). When using pre-cross-linked or plugged rubber, the additives in the starting substances must be taken into account in relation to the DWPLL values stated.

For certain substances that are not included in the positive list of the Elastomer Guideline the De Minimis Guideline can be [6] applied if the requirements stipulated therein are met.

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

The test under 6.4 indicates that the test values of the basic (5.1) and the additional requirements (5.2) as well as the formulation requirements for individual substances (5.3) are observed in the migration water samples.

5.1 Basic requirements

The **external characteristics** (odour/flavour, clarity/colour/foaming) of the migration water must not be changed.

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

TON and TNF < 2	for the third migration period pursuant to DIN EN 1420-1, in case of extension of the migration test the 9th migration period pursuant to DIN EN 1420-1.

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

TON and TNF ≤ 4	for the seventh migration period pursuant to DIN EN 1420-1, in case of extension of the migration test the 22th migration period pursuant to DIN EN 1420-1.

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

In addition TON and TFN must indicate that there is no upward trend during testing according to DIN EN 1420-1[7].

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 pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 9th migration period pursuant to DIN EN 12873-1 (or DIN 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 pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

The TOC is defined as a non-volatile organic carbon (NPOC) in accordance with DIN EN 1484.

In addition the measured concentrations in the migration waters must indicate that there is no upward trend according to DIN EN 12873-1 (or DIN EN 12873-2)7.

5.2 Additional requirements

The additional requirements laid down in table 1 shall apply. These requirements do not apply to marginal products (cf. 5.7).

The migration of the substances and substance groups listed in the table must be tested in accordance with 6.4 and checked against the DWPLL values quoted (see 5.4).

Depending on the type of cross-linking (sulphur cross-linking or peroxide cross-linking) tests are carried out either on mercaptobenzothiazole and N-nitrosamine if N-nitrosamine formers are included in the formulation or on peroxides using the methods specified in table 1.

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

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

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

$c_{Tap} \leq DWPLL$	for the 7th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the

[7] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

In addition the measured concentrations in the migration waters must indicate that there is no upward trend according to DIN EN 12873-1 (or DIN EN 12873-2)[8].

Table 1: Additional requirements for elastomers

Substances/ substance groups	DWPLL in µg/l	Test method
Zinc	3000	DEV[9]
Formaldehyde	750	50. Notification (Federal Health Gazette 30(1987)368)
Primary aromatic Amine (PAA)[10]	N. N.[11] (NWG = 2 µg/l) (Total concentrations of PAA to be tested) Notwithstanding the specific migration limits for individual amines[12]	Specific proof with GC-ECD/GC-MS with derivatisation[13]
Secondary amines[14]	250 (Total concentrations of tested amines) Irrespective of the specific migration limits for individual amines[15]	specific proof as for PAA
Types of cross-linking:		
Sulphur cross-linking		
2-mercaptobenzo-thiazole	400 µg/kg elastomer	EN 1400-3:2002
N-nitrosamine according to TRGS 552[16]	0.3 (Total concentrations of tested N-nitrosamine)	53rd Notification (Federal Health Gazette 37(1994)232), BVL L00.00-17[17]

[8] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

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

[10] The following PAA must be tested: Aniline, o-toluidine

[11] Not detectable

[12] The corresponding DWPLL values for the respective amine (see Annex 1 of the positive list in this Guideline) must be defined independently of this additional requirement.

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

[14] The following secondary amines must be tested: Dibutylamine, diethylamine, dimethylamine, dicyclohexylamine cyclohexylethylamine, diphenylamine, dibenzylamine, benzyl-N-methylamine, benzilidenbenzylamine, N-methylaniline, N-ethylaniline, N-butylaniline

[15] The corresponding DWPLL values for the respective amine (see Annex 1 of the positive list in this Guideline) must be defined independently of this additional requirement.

[16] The N-nitrosamine formers are identified in the positive list with an appropriate footnote "N" (zinc-N-dibutyldithiocarbamate, dimethyldiphenylthiuramdisulfide, tetraethylthiuramdisulfide, tetramethylthiuramdisulfide). The N-nitrosamine must be determined according to TRGS 552.

[17] Technical rule: Testing of foodstuffs; determination of nitrosamines in foodstuffs

Substances/ substance groups	DWPLL in µg/l	Test method
Peroxide cross-linking		
Peroxides	No peroxide on the surface of the product	Method to be announced

5.3 Requirements for individual substances

All substances with a limit in column 4 of the positive list which may be contained in the product must be tested in terms of their migration according to 6.4. These requirements do not apply to marginal products (cf. 5.7). The concentration determined in the test is used to calculate the maximum concentration c_{Tap}(cf. 5.4) expected at the tap.

Instead of an experimental test the migration can also be estimated using the Modelling Guideline[18] (cf. 5.5).

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

$c_{Tap} \leq$ DWPLL for the third migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 9th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2)

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

$c_{Tap} \leq$ DWPLL for the seventh migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2)

In addition the measured concentrations must not show a rising trend[19].

For substances with the indication "TOC" in column 4 of the positive list the requirement for the individual substance is observed if the basic requirements are met.

For substances with the indication "QM" or "QMA" in column 5 a review of the residual content of the substance in the vulcanised elastomer is required. The QM and QMA limits apply independently of the elastomer product group. If the substance in the test water can be determined it is possible, assuming that 1 kg of food is packaged in a cube with a surface area of 6 dm², a SML value can be derived from the QMA value and the DWPLL value can be determined for testing in place of the QMA value.

Compliance with the purity requirements of the substances used can be confirmed by a Declaration of Conformity by the supplier.

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

[19] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

5.4 Calculation of the maximum expected tap concentration (c_{Tap})

The maximum expected tap concentrations (c_{Tap}) differ for the various product groups according to conversion factors F_C stated in table 2:

$$c_{Tap} = \frac{F_c \times c_{gemessen}}{O/_V \times t}$$

Where

F_c : Conversion factor according to table 2

$c_{measured}$: Concentration measured in the migration test according to DIN EN 12873-1

S/V: Surface-to-volume ratio according to DIN EN 12873-1

t: Duration of the migration period according to DIN EN 12873-1

Table 2 lists the product groups of pipes, tanks and fittings where the requirements are further differentiated according to their place of use within the water distribution system. The product group of seals is assigned the corresponding pipe dimensions.

Table 2: Product groups with the corresponding conversion factors

Product group	Conversion factor F_c in d/dm
Pipes with DN[20] < 80 mm (domestic installation)	20
Pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	10
Pipes with DN ≥ 300 mm (main pipes)	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
Tanks in domestic installations including repair systems	4
Tanks outside domestic installations including repair systems	1
Repair systems for tanks in domestic installations with $^1/_{100}$ of the tank surface	0.04
Repair systems for tanks outside domestic installations with $^1/_{100}$ of the tank surface	0.01
Small components from materials for pipes presenting DN < 80 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.004
Small components from materials for pipes presenting 80 mm ≤ DN < 300 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.002
Small components from materials for pipes presenting DN ≥ 300 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.001

In Annex 5 to the Elastomer Guideline typical elastomer products are assigned to the product groups stated in table 2.

5.5 Modelling

In place of the experimental test, migration can also be assessed by means of the modelling guideline[21] if applicability of generally recognised diffusion models based on scientific evidence and parameters was defined.

[20] Diameter

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

The Practical Guide (Annex 1)[22] contains specific parameters for the most important organic materials being in food contact.

Additionally the report of C. Simoneau, et al. (2010)[23] is available.

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 Practical Guide (Annex 1).

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" (http://ihcp.jrc.ec.europa.eu/our_databases/eurl-fcm-ref-coll/reference-substances) or a DIN-CEN-ISO standard. Alternatively $c_{P,0}$ can be used from the required quantity if $c_{P,0}$ does not change during the manufacture and/or processing of the product.

Modelling must correspond to the respective test conditions (test temperature and test cycle) under this Guideline (see 6.4). The concentration profile for the previous test period is used to calculate the migration for the following test period. The modelling guideline contains the description of the modelling with the flow sheet to integrate modelling in the hygienic assessment of products within the framework of this Guideline.

Validated software must be used for modelling. The requirements for the software solutions to be used are detailed in the modelling guideline.

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

5.6 Requirements for the testing of propagation of microorganisms

5.6.1 Different test methods

Testing with respect to promotion of microbial growth is done according to DIN EN 16421. The test can be performed on material sheets, end products or parts of end products (cf. DIN EN 16421).

In 6.5 requirements for the application of the different test procedures according to DIN EN 16421 are specified.

[22] Practical Guide was withdrawn by EU Commission. Annex 1, Mathematical Models, however, continues to be accessible.
http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/files/PRACTICAL%20GUIDE%20_2003.04.15__annex%201%20modelling.pdf/view

[23] "Applicability of generally recognised diffusion models for the estimation of specific migration in support of EU Directive 2002/72/EC" under http://publications.jrc.ec.europa.eu/repository/handle/111111111/14935

5.6.2 Requirements for tests in accordance with the potential of biomass production (BPP) measured by ATP (procedure 1)

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

5.6.3 Requirements for tests in accordance with the volumetric procedure (procedure 2)

a) Products that demonstrate a firmly adherent surface colonisation (comparison of contact culture/abrasion of specimen to negative control) or surface growth ≤ (0.05 + 0.02) ml/800 cm², meet the requirements of this Guideline and are suitable for use in connection with drinking water.

b) For products to be used as large seals[24] a threshold value of (0.12 + 0.03) ml /800 cm² applies. With the exception of the first one-month value (1a) 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 1c must be ≤ 1b and value 3a must be ≤ 2a (cf. table 5).

c) For products to be used as small sealings[25] a threshold value of (0.20 + 0.03) ml /800 cm² applies. With the exception of the first one-month value (1a) 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 1c must be ≤ 1b and value 3a must be ≤ 2a (cf. table 5).

d) For large sealings under b) and small sealings under c) the following additional possibility of assessment applies by including optional monthly values. Optional monthly values are only determined in those cases where materials or products are to be used as large or small sealings 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. Annex 7).

e) Products not showing any surface growth nor surface colonisation (comparison of contact culture/abrasion of specimen to negative control) do not meet the requirements of this Guideline for use in connection with drinking water.

[24] Large sealings and casting compounds for expansion joints, expansion units, compensating joints and silencers; slides (wedge seals with tight coating); flaps if the slide is coated; air valves if the ball is coated; membranes of pressure reducers; hydrants if the stop valve is coated; plunger valves

[25] Other sealings and adhesives (no tile adhesives). All pipe connections not stated in D1 with elastic sealing elements such as flange gaskets, TYTON® socket joints, rolling rubber ring and rotating mechanical seals, surface-mounted fittings. All isolating valves not stated as large sealings such as slides with inserted or surrounding sealing, housing, spindle and wedge sealing (with inserted profile gasket). All flaps and check valves not stated as large sealings if the valve discs are not coated. All valves not stated as large sealings

Table 1 Overview of evaluation 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 (5.6.3 a)	All values ≤ (0.05 + 0.02) ml / 800 cm²				
Materials to be used as large seals (5.6.3 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 (5.6.3 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		

5.7 Marginal products

Products for which a conversion factor smaller than or equal to 0.001 d/dm shall apply (cf. table 2), may be considered as marginal products. The starting substances of these products need not be assessed or mentioned in a positive list. 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. Basic requirements (TOC, odour, flavour and external characteristics) do, however, apply. Furthermore testing the propagation of microorganisms is necessary.

6 Requirements for the award of a test certificate

6.1 Applications

In order to receive a test certificate for elastomers in contact with drinking water the applicant must provide the test laboratory with the formulation components of the elastomer (indication of all components with the percentage by weight, the CAS No and material group according to the positive list for elastomer materials (formulation declaration in Annex 2).

The formulation information according to Annex 2 can be given separately by the elastomer manufacturer and the manufacturer of the preparations if the exact designation of the respective products clearly indicates their unique assignment to the elastomer.

This clarifies the extent of the DWPLL values to be tested and the residual contents (QM QMA) for individual substances in the finished elastomer and the purity requirement for the listed substances or substance groups.

Furthermore the proposed product group (according to 5.4 table 2) of the elastomer must be stated. In the case of multi-layer structured products the formulations of all layers must be provided (e.g. for multi-layer hoses). In layers made from different materials the corresponding Guidelines must be applied.

6.2 Test laboratory

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

6.3 Manufacture of specimens

6.3.1 Elastomers

The test shall in principle be carried out on the elastomer products.

Single-layer hoses are tested by filling.

For product groups with the same formulation (see table 2) which are manufactured using the same process, the test laboratory can select a mixed sample for testing (e.g. O-rings of one size group with different diameters).

If it is not possible to test the finished product, testing can be carried out on test plates with dimensions approx. 200 mm x 200 mm x 2 mm for single-layer elastomers. The test plates must have the same formulation and be vulcanised under the same temperature and time constraints as the product (Annex 4 of the Guideline).

6.3.2 Multi-layer products

Multi-layer materials consisting of ply, layers or deposits of individual substances the individual components of which have an influence on the surface in contact with water by diffusion, are tested as multi-layer products or multi-layer product components in consultation with the test laboratory.

Multi-layer hoses are tested by filling and must be tested in accordance with the KTW Guideline[3] with an extended warm water migration test.

6.4 Testing

Testing must be carried out in accordance with the standards DIN EN 1420-1:1999, DIN EN 12873-1:2004 or DIN EN 12873-2:2005. Annex 3 contains the test conditions in abridged form. The test method and test results must be carefully recorded (Annex III of the test report). The test laboratory should examine whether the basic requirements, additional requirements and formulation-dependent requirements for individual substances for the proposed product group have been fulfilled.

The migration waters for the first three test periods must be tested in the migration test at (23 ± 2) °C and in the odour-flavour test at (23 ± 2) °C.

In the migration test and the odour/flavour test at higher temperatures the test samples from the first, sixth and seventh migration periods should be examined. The TOC parameter, however, should be determined in the first, second, third, sixth and seventh migration periods.

If the maximum expected tap concentration (c_{Tap}) of the third (cold water) or seventh (hot water) migration period observes the specific migration limit (SML value) of Regulation (EU) No 10/2011 defined in the calculation for the substance, but the calculated DWPLL value is exceeded, a fixed-term 5-year test certificate can be issued (without possibility of extension).

Standardised analytic procedures should normally be followed in testing the migration samples. Where no suitable analytic method currently exists for a particular substance an analytic method of suitable accuracy which enables an assessment of the recorded concentration to be made, may be applied until a standardised method is developed. Any hitherto unavailable analytic methods for substances in list 1 of the Positive List (list of assessed substances in Annex 1) should be developed by the manufacturer and test laboratories and notified to the German Environment Agency. The test laboratory should enter the analytic procedures applied in table 5 in Annex 3 to the Guideline.

The complete test results must be entered in tables in accordance with the tables 4 and 5 of Annex 3 and be attached as Annex 1 of the test report. Compliance with the formulation requirements for individual substances (DWPLL values) which are subject to confidentiality are recorded by the test laboratory with the number of substances and the note "Test value observed".

A mathematical estimate of the migration of individual substances from elastomers in drinking water can be used in place of analytical proof to verify compliance with DWPLL values. If modelling is used appropriate documentation must be presented (see 5.5).

6.5 Testing in accordance with DIN EN 16421 (microbial growth)

Testing of the products with respect to promotion of microbial growth is done according to DIN EN 16421. For using the three procedures described in the standard the following restrictions apply.
Procedure 3 (MDOD method) shows a too high detection limit compared to other procedures. The procedure is not suitable to assess products intended to be used with disinfectant-free drinking water. In Germany many drinking waters are distributed without the addition of chlorine or other disinfectants. For this reason testing according to another of the two procedures (BPP procedure or volumetric procedure) is necessary for the use in Germany.

The BPP procedure (procedure 1) is not suitable for the testing of multi-layer composite products as also surfaces not being in contact with drinking water normally will get in touch with the test water.
Multi-layer composite products are tested with procedure 2 in the test module for pipes and hoses.
The volumetric procedure (procedure 2) is not suitable to test lubricants and greases.

6.6 Test report and test certificate

If the test is passed a test report is to be prepared by the test laboratory which should include information specified in the tables 4 and 5 of Annex 3. This consists of the test certificate and the following annexes:

Annex I: Table including the full test results (cf. Annex 3 of the Guideline),

Annex II: Formulation Declaration (Annex 2 of the Guideline, completed and signed by the manufacturer/applicant and the test laboratory),

Annex III: Record of the performance of the test (see 6.4)

Annex IV: Selection and indicators for the test methods used.

The test certificate must contain the closing paragraph:

"The product (precise designation) has been tested in accordance with the Guideline on the hygienic assessment of elastomers in contact with drinking water by 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.

For products manufactured using substances from part 2 of the positive list the test certificate shall cease to be valid at the latest on 31 December 2016.

Test certificates for products of the same manufacturer that are produced in accordance with this Guideline may, if they complied with all requirements under chapter 5 in the initial test, be extended for 5 years without further experimental testing, providing that there has been no change in the formulation, in the relevant substance assessments (restrictions in the positive lists) and in the manufacturing process. Prior to extending the test certificate the test laboratory must check that the formulation, the manufacturing process and the underlying positive list have not changed.

On the test certificate it must be clearly noted if it was issued by way of an exception (use of limited substances, exceedance of DWPLL values) and therefore cannot be extended.

7 Feedback to the German Environment Agency

The test centres accredited for tests on organic materials in contact with drinking water report to the German Environment Agency once a year on the applicability of this Guideline.

As part of this the following information must be reported in anonymous format pursuant to Annex 6:

- number of all test certificates for elastomers for which this Guideline was applied

- number of test certificates for which one of the exceptions mentioned under 6.4 applies
- number of test certificates for which the substances from part 2 have been used
- which substances are used from part 2 of the positive list

Based on the feedback the German Environment Agency will decide whether or not changes and/or additions to this Guideline are necessary.

Annex 1 to the Elastomer Guideline

Positive list for elastomers in contact with drinking water

The former positive list comprising parts 1, 2 and 3 has been deleted. The currently valid positive list for elastomers has been transferred to the KTW evaluation criteria document as part of Annex D Elastomers of the polymer-specific part of the KTW evaluation criteria and is accessible via the following link:

- Polymer-specific annexes to the Evaluation criteria document for plastics and other organic materials

Annex 2 to the Elastomer Guideline

Formulation disclosure sheet

Address of the manufacturer: .....

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

Product or brand name: ....

Declaration on the formulation of elastomers in accordance with the Guideline on the hygienic assessment of elastomers in contact with drinking water of the German Environment Agency to the test laboratory

This declaration must be used by the test laboratory to determine the scope of testing and the requirements for individual substances.

Please list all starting substances/components (polymers, fillers, processing aids, etc.) required to manufacture the elastomer material. If there is more than one supplier for certain starting substances these must be recorded individually.

The table must be completed in full.

Starting substance/Trade name	Chemical description	CAS No.	Description of the starting substance	Percentage by weight (in %)	Supplier (Address, phone, fa email, contact)

All information is treated as confidential.

Page of .

Signature of manufacturer:

Annex 3 to the Elastomer Guideline

Performance of migration test and odour/flavour test for the testing of elastomers in contact with drinking water

Testing is to be done in accordance with DIN EN 1420-1 and DIN EN 12873-1 or DIN EN 12873-2 by taking into account the options left open 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 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 2 and 3 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) or (85 ± 2) °C (hot water test)) in accordance with DIN EN 12873-1 and -2

1. The 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 period 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, 6 and 7 respectively to determine the parameters with migration restriction stated in table 2 and 7 as additional requirements. 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 individual substances is conducted in the 1st, 6th and 7th migration period (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, 21th and 22th migration period (mixed samples from the tests) are 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 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 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 test periods of three days contact time each are used to determine the odour/flavour threshold values.. If the threshold odour number fails to meet the requirements the threshold flavour number 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[26] in the laboratory to determine the odour/flavour limits. The results are presented in the test report and marked accordingly.

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

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

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

1. The 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 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 S/V ratio to be met at least in test runs with elastomers

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, fill with cylinder inserted or fill pipe segment)	S/V ≥ 5 dm^{-1} (fill, fill with cylinder inserted or fill pipe segment)	S/V > 2.5 dm^{-1} (fill)	S/V > 2.5 dm^{-1} (fill)
Pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)
Fittings	S/V ≥ 5 dm^{-1} (immerse products or plates)	S/V ≥ 5 dm^{-1} (immerse products or plates)	S/V ≥ 1.5 dm^{-1} (immerse products or plates)	S/V ≥ 1.5 dm^{-1} (immerse products or plates)
Seals	S/V ≥ 5 dm^{-1} (immerse products or plates)	S/V ≥ 5 dm^{-1} (immerse products or plates)	S/V ≥ 0.2 dm^{-1} (immerse products or plates)	S/V ≥ 0.2 dm^{-1} (immerse products or plates)
Tanks, repair systems	S/V ≥ 5 dm^{-1} (immerse plates)	S/V ≥ 5 dm^{-1} (immerse plates)	S/V ≥ 2.5 dm^{-1} (immerse plates)	S/V ≥ 2.5 dm^{-1} (immerse plates)
Small components for pipes DN < 300 mm	S/V ≥ 5 dm^{-1} (immerse plates)	S/V ≥ 5 dm^{-1} (immerse plates)	S/V ≥ 0.2 dm^{-1} (immerse plates)	S/V ≥ 0.2 dm^{-1} (immerse plates)
Small components for pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (immerse plates)	-	S/V ≥ 0.2 dm^{-1} (immerse plates)	-

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

Product:

Date of the test:

Test temperature:

Surface/volume ratio:

Conversion factor for the tested product:

Number of migration periods:

Test method:

	Sequential number of the migration period n				
	1	2	3[27]	6	7
a_n^T					
$\overline{a}_n^T$					
b_n^T					
$\overline{b}_n^T$					
$\overline{c}_n^T = \overline{a}_n^T - \overline{b}_n^T$					
$\overline{\overline{c_{Tap}}}_n^T$					

Where
a_n^T is the concentration of a substance measured in the migration water in mg/l,
b_n^T is the concentration of a substance measured in the migration water in mg/l,
$\overline{c}_n^T$ is the concentration of the substance detected
$\overline{\overline{c_{Tap}}}_n^T$ is the maximum expected tap concentration of a migrating substance,
n is the sequential number of the migration period,
T is the test temperature

[27] The cold water test ends with the third or ninth test period.

Table 5 of Annex 3 — Specified table of the test results for the additional requirements and the formulation-specific requirements for individual substances in accordance with DIN EN 12873-1 and -2

Product:

Date of the test:

Test temperature:

Surface/volume ratio:

Conversion factor for the tested product:

Number of migration periods:

Tested substance:

Test method:

	Sequential number of the migration period n			
	1	3[28]	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 the migration water of the mixed sample in mg/l,

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

χ_n^T is the concentration of the substance detected

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

n is the sequential number of the migration period,

T is the test temperature

For the modelled concentrations a record should be produced of all the data entered (printout of the relevant software report) which shall constitute part of the test report. The recorded values shall include the characteristic values used and the details of the test run (temperature, surface of the specimen, volume of the migration water, 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

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

requirements have been met is reported in the test report as follows: "Formulation component subject to confidentiality; reference value observed."

Annex 4 to the Elastomer Guideline

Template for the recording of the manufacture of test plates or the product

The following data should be included:

1. Address of applicant,
2. accurate description of the elastomer (for unequivocal classification in terms of application, recipe statement, test record and test certificate),
3. Location of test plate or product manufacture (e.g. production facilities, laboratory, construction site),
4. Address of manufacturer, name of responsible employees,
5. Date of test plate or product manufacture,
6. Procedures for the manufacture of the test plates or products (e.g. injection moulding)
7. Vulcanisation conditions (time, temperature)
8. Mixing procedure, e.g. mill, mixer
9. Special conditions to be observed e.g. annealing
10. Differences between test plate manufacture and product manufacture (if relevant).
11. The products and the test plates must be packaged in suitable diffusion-resistant packaging materials (e.g. aluminium film, glass) ad must be stored accordingly to avoid contamination with other substances.

Annex 5 to the Elastomer Guideline

Overview of different products and their assignment to product groups

Table 1 Overview of different products and their assignment to product groups

Product group	Typical elastomers
Pipes DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	- Hoses in the drinking water installation (excluding connection hoses for washing machines and dishwashers) - Hoses for time-limited transport of drinking water - Pipe liners - Inliners for reinforced hoses
Fittings for pipes DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	- Connecting hoses for washing machines and dishwashers - Connecting hoses in waterworks - Membranes for expansion vessels (DN<80mm) - Bellows in straight-way form (dimension-dependent) - Bellows in side lock (DN<80 mm) - Rubberised housing (valve housing) - Rubberised gate valve - Rubberised flap (DN>300mm) - Lines routed through drinking water (e.g. electricity and control lines for submersible pumps)
Seals for pumps DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	- Flat seals - O-rings - Seal profiles - Sleeves/profile seals (inserted or circumferential seals for valves/flaps) - Pressure regulator membranes - Sleeve seals - Tyton sealing rings - Floating ring seals - Steel rings
Tanks In the drinking water installation Outside the drinking water installation	- Tank cladding - Elastomer sheets
Repair systems for containers and tanks	Repair systems for tanks in the waterworks
Small components for pipes DN ≥ 300 mm, installed only at one position in the distribution system	

Annex 6 to the Elastomer Guideline

Form for feedback to the German Environment Agency in accordance with the Elastomer Guideline

Number of test certificates issued based on this Guideline in the last 12 months	

For the tested products test certificates have been issued in accordance with the Elastomer Guideline which cannot be extended due to the exemptions defined in the Guideline.

Exemptions	Number of test certificates
Missing test method for a substance with a DWPLL value	
Exceeding of a DWPLL value	
Use of a substance from Part 2 of the positive list	

Which substances from Part 2 are used?		
PM Ref No.	**CAS No.**	**Name**

Suggestions to change the Guideline	yes ☐	no ☐
If yes, please specify:		

Annex 7 to the Elastomer 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 sealings 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 of Annex 7). Then the optional monthly values, forth one-month-value (1d) as well as second two-month-value (2b) shall be determined (cf. table 1 of Annex 7) 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 of Annex 7).

2. Large sealings

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 7).

3. Small sealings

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 7).

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 (5.6.3 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 (5.6.3 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				