RECOMMENDATION

22. December 2011

Umwelt Bundes Amt
Für Mensch und Umwelt

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

1. Preliminary remark

This Guideline can be used to assess elastomers in contact with drinking water within the meaning of the Drinking Water Ordinance, Section 17 (1). It replaces the KTW Recommendation part 1.3.13 "Rubber made from natural and synthetic rubbers".

This Guideline shall not apply to thermoplastic elastomers (TPE) nor to silicones. Silicones can be assessed according to the requirements of the KTW Guideline.

This Guideline was developed by the Federal Environment Agency (Umweltbundesamt - UBA) in cooperation with the KTW-AG (Joint Working Group of the Drinking Water Commission of the Federal 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 Federal Environment Agency on the hygienic assessment of organic materials in contact with drinking water (KTW, Coating and Lubricants Guideline), this Guideline is 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.

1.1 Legal status of the Guideline

This Guideline is not a legal norm and is therefore non-binding. It represents the current state of science and technology concerning the sanitary requirements for elastomers in contact with drinking water within the meaning of the Drinking Water Ordinance 2001 (TrinkwV 2001), last amended on 3 May 2011 (Federal Law Gazette 21, p. 748-774).

Article 17 (1) of TrinkwV 2001 states that for the new construction or maintenance of installations for extracting, processing or distributing water for human consumption, “only those materials [may] be used which when in contact with water, do not release substances in

[1] The obligations arising 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 and of rules on Information Society services (OJ L 204 of 21 July 1998, p. 37), as amended by Directive 2006/96/EC (OJ L 363 of 20 December 2006, p. 81), have been fulfilled.

concentrations which exceed limits deemed unavoidable according to generally acknowledged technical standards. Furthermore, materials which directly or indirectly diminish the level of protection of human health provided for by this Ordinance, or which alter the odour or flavour of the water;...".

It can therefore be assumed that elastomers in contact with drinking water which comply with the requirements of this Guideline will also satisfy the sanitary requirements of TrinkwV 2001.

1.2 Certification symbols and the tests on which they are based

To prove the hygienic safety of the respective elastomers with respect to microbiological requirements, in addition to and independently of this Guideline, the materials used must pass a test in accordance with DVGW-Arbeitsblatt W 270.

The compliance of a product with an element from elastomers with generally accepted rules of the Art[2] and the requirements of TrinkwV 2001 can be recognised by the certification symbol of an industry certification body, e.g. DVGW Cert GmbH.

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 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 carried widely in terms of their limits through the copolymerisation of various monomers.

[2] Generally accepted technical standards include, for instance, the Technical Rules of the German Technical Association for Gas and Water (DVGW).

Fillers, e.g. soot or fine silicic acid, have an strengthening effect on the polymer matrix and are used to increase the breaking strength and abrasive 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 peroxides allow the rubber compound to be vulcanised into elastomer. Accelerating and retarding agents are also used for vulcanisation with sulphur.

2.1 Manufacture of elastomers

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

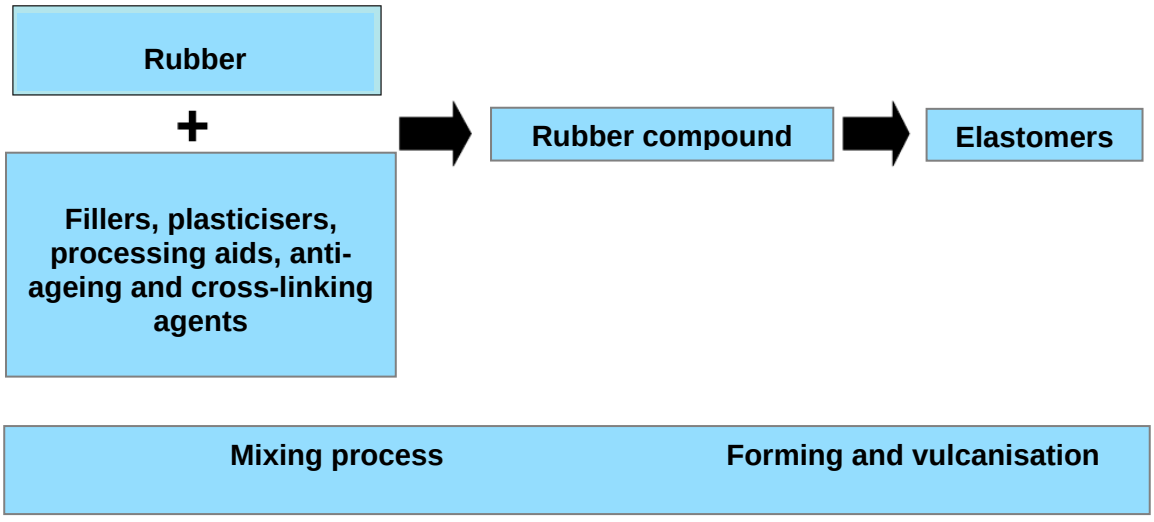

Figure 1: Manufacture of elastomers

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 preformed 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 (see 5). 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), formerly the Scientific Committee on Food (SCF), or in close cooperation 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 is required prior to a complete toxicological assessment. This involves presenting data on the migration of the substance in question and, if necessary, on its reaction and decomposition products. This information is 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[3].

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

The positive list also 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 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. **Column 3** contains the substance name.

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 Federal Environment

[3] Commission Regulation (EC) 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:2011:012:0001:01:EN:HTML

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, "QMA" contains a residual content determination of the vulcanised elastomer, which is based on a surface area of 6 dm^2 (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 dm^2, 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 Federal Environment Agency. The positive list is 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, whose extent is determined by the level of migration of the requested substance in deionised water. All existing toxicological data must be presented.

When applying for substances that have already undergone toxicological assessment (e.g. by the EFSA) only the requirements of points 1 to 4 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 fit for purpose. The requirements of the technical standard apply regardless of this Guideline.

The 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 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 additional requirements (5.2) and the formulation requirements for individual substances (5.3) are observed in the migration water samples.

5.1 Basic requirements

The external characteristics of odour, flavour, clarity, colour and foaming of the migration water may 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

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

TON and TNF < 4 For the seventh migration period

For the release of **organic substances**, measured as total organic carbon **TOC**), the following applies to the **cold water test**:

DWPLLTOC = 0.5 mg/l for the third migration period

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

DWPLLTOC = 0.5 mg/l for the seventh migration period

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

5.2 Additional requirements

The additional requirements laid down in table 1 shall apply.

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 5.3).

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.

Table 1: Additional requirements for elastomers

Substances/substance groups	DWPLL in µg/l	Test method*
Zinc	3000	DEV[4]
Formaldehyde	150	50th Notification (Federal Health Gazette 30(1987)368)
Primary aromatic Amine (PAA)[5]	N. N.[6] (NWG = 2 g/l) (Total concentrations of 5 PAA tested) Notwithstanding the specific migration limits for individual amines[7]	Specific proof with GC-ECD/GC-MS with derivatisation[8]
Substances/substance groups	DWPLL in µg/l	Test method*
Secondary amines9	250 µg/l (Total concentrations of tested amines) Irrespective of the specific migration limits for individual amines[10]	Specific proof as for PAA
Types of cross-linking:		
Sulphur cross-linking		
2-mercaptobenzothiazole	400 µg/kg elastomer	EN 1400-3: 2002
N-nitrosamine according to TRGS 552[11]	0.3 (Total concentrations of tested N-nitrosamine)	53rd Notification (Federal Health Gazette 37(1994)232), BVL L00.00-17[12]
Peroxide cross-linking		
Peroxides	No peroxide on the surface of the product	Method to be announced

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

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

[6] Not detectable

[7] 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.

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

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

[10] 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.

[11] 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.

[12] Testing of foodstuffs; determination of nitrosamines in foodstuffs

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. The concentration determined in the test is used to calculate the maximum concentration c_{Tap}(see 5.4) expected at the tap.

Instead of an experimental test, the migration can also be estimated using the Modelling Guideline[13] (see 5.5).

For the ***cold water test*** the following shall apply:

$c_{Tap} \leq$ DWPLL for the third migration period

For the ***hot water test*** the following shall apply:

$c_{Tap} \leq$ DWPLL for the seventh migration period

In addition, the measured concentrations must not show a rising trend.

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 dm^2, 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.

5.4 Calculation of the maximum expected tap concentration (cTap)

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

$$c_{Tap} = \frac{F_C \; c_{gemessen}}{S/V \quad t}$$

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

[13] Guideline for the mathematical estimation of the migration of individual substances made of organic materials into the drinking water

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 to d/dm
Pipes with DN[14] < 80 mm (domestic installation)	20
Pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	10
Pipes of diameter 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
Fittings 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

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, the migration can also be estimated using the Modelling Guideline[15] (see 5.5), insofar as the applicability of generally recognised, scientifically proven diffusion models and characteristics have been determined.

[14] Diameter

[15] Guideline for the mathematical estimation of the migration of individual substances made of organic materials into drinking water

The Practical Guide (Annex 1)[16] contains specific parameters for the most important organic materials.

The report by C. Simoneau, et al. (2010)[17] is also 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. The tests required for this are 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://crl-fcm.jrc.it/index.php?option=com_methods&Itemid=80) or a DIN 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.

The modelling must satisfy the respective test conditions (test temperature and test cycle) of 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 describes in detail modelling with the flow chart for the inclusion of modelling for the hygienic assessment of products in the framework of the 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 with regards to the individual substances to be tested after modelling the migration, proof can still be provided by way of an experimental test. The results of experimental tests must be weighted higher than those of the modelling.

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

[16] Practical Guide has been withdrawn by the EU Commission. Annex 1, Mathematical Models, can however still be downloaded from

http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/files/PRACTICAL%20GUIDE%20_2003.04.15__annex%201%20modelling.pdf/view

[17] "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

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 requirements 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

The test under this Guideline must be carried out by a test laboratory accredited in accordance with ISO/IEC 17025 or a test laboratory recognised by an accredited industry certification body.

6.3 Sample taking

6.3.1 Elastomers

The test should 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 products (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.

6.4 Testing

Testing must be carried out in accordance with the standards DIN EN 1420-1: 1999, DIN EN 12873-1: 2004 and 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 recipe-dependent requirements for individual substances for the proposed product group have been fulfilled.

In the migration test at (23 ± 2) °C and the odour/flavour test at (23 ± 2) °C, the test water samples from the first three test periods should be examined.

In the migration test and the odour/flavour test at higher temperatures, the test water 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 Federal Environmental Agency. The test laboratory should entered the analytic procedures applied in table 5 in Annex 3 to the Guideline.

The complete test results must be inserted in the tables according to tables 4 and 5 of Annex 3 and appended as Annex I to the 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".

Instead of analytical proof of compliance with the DWPLL values, mathematical methods may be used to estimate the migration rate of individual substances from the elastomer into the drinking water. If modelling is used, appropriate documentation must be presented (see 5.5).

6.5 Test report and test certificate

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

Annex I: Table with the full test results (see Annex 3 of the Guideline),

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

Annex III: Record of the testing procedure followed (cf. 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 Federal 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 the valid at the latest on 31 December 2016.

Test certificates for products from the same manufacturer which are produced in accordance with this Guideline may, if they comply with all the requirements listed in 6.4 in the initial test, be extended for 5 years without further experimental testing, providing that there has been no change in their formulation, in the relevant substance assessments (restrictions in the Positive Lists) or 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 Federal Environment Agency

The test centres accredited for tests on organic materials in contact with drinking water report to the Federal 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 Federal 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 following table contains:

Column 1: the EEC packaging material reference number

Column 2: the Chemical Abstracts Service (CAS No) registry number

Column 3: the substance name

Column 4: the "human-toxicologically derived temporary drinking water limit for material-specific substances": Drinking Water Positive List Limit (DWPLL) in µg/l

Column 5: Residual content of QM in mg/kg polymer or QMA values in mg/6 dm^2 or other requirements on purity/composition

For substances whose migration restriction is limited as a group, an appropriate number will be inserted in column 4.

N-nitrosamine formers are marked in the positive list in column 4 with an "N". For these substances the additional requirement "N-nitrosamine" must be tested.

For some substances, both a DWPLL as well as a QM or QMA value must be indicated for a restriction. In these cases, only one restriction has to be tested. Preference should be given to checking the DWPLL value.

The positive list also contains substances (acids, alcohols and phenols) that can occur in the form of salts. Since the salts in the stomach acids are normally converted into salts, alcohols or phenols, it is possible to use salts of lists 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 aforementioned cations, the migration restriction is based on the limit values of Annexes 2 and 3 of TrinkwV 2011.

For all of the fillers used, the purity requirements of the BfR Recommendation LII must be met.

For all of the colourants used, the purity requirements of the BfR Recommendation IX must be met.

For the assessment of the aids to polymerisation for manufacturing rubber, the corresponding BfR Recommendation may be used.

1 LIST OF ASSESSED SUBSTANCES

1.1 STARTING SUBSTANCES

1.1.1 MONOMERS

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
10120	108-05-4	Vinyl acetate	600	
10690	79-10-7	Acrylic acid	300	
12100	107-13-1	Acrylonitrile	0.1	
13630	106-99-0	Butadiene	0.1	1 mg/kg
13870	106-98-9	1-butene		
13900	107-01-7	2-butene		
14530	07782-50-5	Chlorine		
15030	931-88-4	Cyclooctene	2.5	
16950	74-85-1	Ethylene		
17110	16219-75-3	5-ethylidenebicyclo[2,2,1] hept-2-ene	2.5	QMA = 0.05 mg/6dm^2.
18430	116-15-4	Hexafluoropropylene	0.1	
19000	115-11-7	Isobutene		
20020	79-41-4	Methacrylic acid	300	
20410	2082-81-7	1,4-butanediol dimethacrylate	2.5	
21640	78-79-5	2-methyl-1,3-butadiene (isoprene)	0.1	1 mg/kg
22660	111-66-0	Octene-1	750	
23980	115-07-1	Propene		
24610	100-42-5	Styrene		

25120	116-14-3	Tetrafluoroethylene	2.5
26140	75-38-7	Vinylidene fluoride	250

1.1.2 Fillers

Purity requirements according to BfR Recommendation LII. Fillers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
34480		Aluminium fibres, flakes, powder	0.2 mg/l for Al	
34560	21645-51-2	Aluminium hydroxide	0.2 mg/l for Al	
34690	11097-59-9	Aluminium magnesium carbonate hydroxide	0.2 mg/l for Al	
34720	1344-28-1	Aluminium oxide	0.2 mg/l for Al	
41280	1305-62-0	Calcium hydroxide		
41520	1305-78-8	Calcium oxide		
41600	12004-14-7/ 37293-22-4	Calcium sulphoaluminate		
42080	1333-86-4	Soot	PAHs in accordance with TrinkwV 2011, Annex 2 Part II	Purity requirements in BfR Recommendation XXI
42240		Carbon fibres		
42500		Carbon dioxide salts		
43280	9004-34-6	Cellulose		
45280		Cotton fibres		
55520		Glass fibres with a diameter greater than 1µm (mean diameter: 5-30 µm		
55600		Microglass balls with a mean diameter of 5-100 µm		
58320	7782-42-5	Graphite		
64640	1309-42-8	Magnesium hydroxide		
64720	1309-48-4	Magnesium oxide		

Ref. No	CAS No	Substance name	DWPLL in ↔g/l	QM or QMA
83470	14808-60-7	Quartz		
85601		Silicates, natural (with the exception of asbestos)		
85610		Silicates, natural, silanated (with the exception of asbestos)		
85680	1343-98-2	Silicic acids		
85950	37296-97-2	Magnesium-sodium-fluoride salt	0.3 mg/l for fluoride	
86000		Silicic acid, silanated		
86240	7631-86-9	Silicon dioxide		
92000	7727-43-7	Barium sulphate according to the purity requirements of 3.2 in BfR Recommendation LII	0.7 mg/l for barium	
92080	14807-96-6	Talc		
93440	13463-67-7	Titanium dioxide		
95920		Wood flour and fibres		
96240	1314-13-2	Zinc oxide	3000	
	7778-18-9	Calcium sulphate (anhydrite)		
	10101-41-9	Calcium sulphate (dihydrate)		

1.1.3 Plasticisers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
31920	00103-23-1	Di-(2-ethylhexyl) adipate	900	
34240	91082-17-6	Alkyl C_{10} - C_{20} sulphonic acid esters with phenol	2.5	
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester		
	9003-29-6	Polybutene		Composition according to KTW Guideline, molecular weight >1000D
72081/10		Petroleum hydrocarbon resins (hydrogenated)		Requirements in Table 1 of Regulation 10/2011
75105	68515-49-1, 26761-40-0	Phthalic acid, diesters with primary, saturated C8-C10 branched alcohols, more than 60 % C9	450	
	9003-27-4	Polyisobutylene		Composition according to KTW Guideline, molecular weight >1000D
	9003-31-0	Polyisoprene		
95859		Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks		Requirements in Table 1 of Regulation 10/2011
95883		White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks		Requirements in Table 1 of Regulation 10/2011
		Silicones according to BfR Recommendation XV.3		Requirements according to BfR Recommendation XV.

1.1.4 Anti-ageing agents

1.1.4.1 Phenolic anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
38800	32687-78-8	N,N′-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	750	
40000	991-84-4	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	1500	
40020	110553-27-0	2,4-bis(octylthiomethyl)-6-methylphenol	250	
45450	68610-51-5	p-cresol-dicyclopentadiene-isobutylene, copolymer	250	
46640	128-37-0	2,6-di-tert-butyl-p-cresol	150	
66400	88-24-4	2,2′-methylene bis(4-ethyl-6-tert-butylphenol)	75 (1)	
66480	119-47-1	2,2′-methylene bis(4-methyl-6-tert-butylphenol)	75 (1)	
66560	4066-02-8	2,2′-methylenebis(4-methyl-6-cyclohexylphenol)	150 (2)	
66580	77-62-3	2,2′-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol)	150 (2)	
68320	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	300	
71680	6683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]		
74240	31570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester		
74400		Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester	1500	
92800	96-69-5	4,4′-thiobis(6-tert-butyl-3-methylphenol)	24	
95200	1709-70-2	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene		

1.1.4.2 Aminic anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.2.1 1.1.4.3 Other anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
67850	8002-53-7	Montan wax		Requirements in Table 1 of Regulation 10/2011
95859		Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks		

1.1.5 Processing aids, also applies to adhesives and additives for fillers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
15910	108-46-3	1,3 dihydroxybenzene	120	
16697	693-23-2	n-dodecanedioic acid		
17170	61788-47-4	Fatty acids, coco		
18070	108-55-4	Glutaric anhydride		
18250	115-28-6	Hexachloroendomethylenetetrahydrophthalic acid	0.1	
18280	115-27-5	Hexachloroendomethylenetetrahydrophthalic anhydride	0.1	
18880	99-96-7	p-hydroxybenzoic acid	250	
19150	121-91-5	Isophthalic acid		
19270	97-65-4	Itaconic acid		
24160	8052-10-6	Rosin tall oil		
24280	111-20-6	Sebacic acid		
24430	2561-88-8	Sebacic anhydride		
24520	8001-22-7	Soybean oil		
25960	57-13-6	Urea		
26305	78-08-0	Vinyltriethoxysilane	2.5	
26320	2768-02-7	Vinyltrimethoxysilane	2.5	
30610		Acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)		
30612		Acids, C2-C24, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters		
34240	091082-17-6	Alkyl(C10-C21)sulphonic acid, esters with phenol	2.5	
42720	8015-86-9	Carnauba wax		
44160	77-92-9	Citric acid		
45940	334-48-5	n-decanoic acid		
46720	4130-42-1	2,6-di-tert-butyl-4-ethylphenol	240	
52720	112-84-5	Erucamide		
52730	112-86-7	Erucic acid		

54450		Fats and oils, from animal or vegetable food sources		
Ref. No	**CAS No**	**Substance name**	**DWPLL in µg/l**	**QM or QMA**
55120	110-17-8	Fumaric acid		
55190	29204-02-2	Gadoleic acid		
55680	110-94-1	Glutaric acid		
55920	56-81-5	Glycerol		
56540		Glycerol, esters with oleic acid		
61840	106-14-9	12-hydroxystearic acid		
62960	50-21-5	Lactic acid		
63280	143-07-7	Lauric acid		
63760	8002-43-5	Lecithin		
64560	7786-30-3, 7791-18-6	Magnesium chloride		
64800	110-16-7	Maleic acid	1500	
64900	108-31-6	Maleic acid hydride		
65020	6915-15-7	Malic acid		
65040	141-82-2	Malonic acid		
67840		Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol and compounds of this ester with unesterified mantanic acids and their calcium salts		
67891	544-63-8	Myristic acid		
68960	301-02-0	Oleamide		
69040	112-80-1	Oleic acid		
69920	144-62-7	Oxalic acid	300	
70400	57-10-3	Palmitic acid		
76960	25322-68-3	Polyethylene glycols		
77520	61791-12-6	Polyethyleneglycol ester of castor oil		
77600	61788-85-0	Polyethyleneglycol ester of hydrogenated castor oil		
77702		Polyethyleneglycol esters of aliph. monocarb. acids (C6-C22) and their ammonium and sodium sulphates		
77708		Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols	90	Requirements in Table 1 of Regulation 10/2011
77895	68439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C16-C18) ether	2,5	Requirements in Table 1 of Regulation 10/2011

		Polyethylene wax		
80000	9002-88-4			
Ref. No	**CAS No**	**Substance name**	**DWPLL in µg/l**	**QM or QMA**
83610	73138-82-6	Resin acids		
83840	8050-09-7	Rosin		
84000	8050-31-5	Rosin, ester with glycerol		
84640	69-72-7	Salicylic acid		
88960	124-26-5	Stearamide		
89040	57-11-4	Stearic acids		
90960	110-15-6	Succinic acid		
92160	87-69-4	Tartaric acid		
93520	59-02-9 10191-41-0	α-tocopherol		
10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	2.5 (3)	
10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled	2.5 (3)	
10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), hydrogenated, dimers, distilled	2.5 (3)	
10599/93	068783-41-5	Acids, fatty, unsaturated (C18), hydrogenated, dimers, non-distilled	2.5 (3)	
	9002-88-4	Polyethylene		Composition according to KTW Guideline, molecular weight >1000D
	9003-07-0	Polypropylene		Composition according to KTW Guideline, molecular weight >1000D
	63148-62-9	Silicone oil according to BfR Recommendation XV.1		Requirements according to BfR Recommendation XV.
	9006-24-0	Xylolformaldehyde resins according to the Coating Guideline		Composition according to Coating Guideline, molecular weight >1000D
		Zinc salts of fatty acids (animal and plant origin) C14 - C20	3mg/l for Zn	
	557-05-1	Zinc stearate	3mg/l for Zn	

1.1.6 Cross-linking agents

1.1.6.1 Peroxides

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.2 Coagents for peroxide cross-linking

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
25840	3290-92-4	Trimethylolpropene trimethacrylate	2.5	

1.1.6.3 Carbamates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.4 Thiocarbamates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.2.2 1.1.6.5 Thiurames

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.6 Sulfenamides

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.7 Guanidines

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.8 Xanthogenates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

1.1.6.9 Mercapto accelerators

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
65768	149-30-4	2-mercaptobenzothiazole		Additional requirement for S cross-linking
	155-04-4	Zinc-2-mercaptobenzothiazole	3 mg/l for Zn	

1.1.6.10 Other accelerators

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
37600	65-85-0	Benzoic acids		
41280	1305-62-0	Calcium hydroxide		
41520	1305-78-8	Calcium oxide		
42500	3486-35-9	Zinc carbonate		
45760	108-91-8	Cyclohexylamine		
47680	111-46-6	Diethyleneglycol	1500	
59280	100-97-0	Hexamethylenetetramine	15 (as formaldehyde)	
64720	1309-48-4	Magnesium oxide		
76320	85-44-9	Phthalic anhydride		
76960	25322-68-3	Polyethyleneglycol		
80800	25322-69-4	Polypropyleneglycol		
84640	69-72-7	Salicylic acid		
89040	57-11-4	Stearic acids		
91840	7704-34-9	Sulphur		
94560	122-20-3	Triisopropanolamine	250	

Ref. No	CAS No	Substance name	DWPLL in µ/l	QM or QMA
96240	1314-13-2	Zinc oxide	3 mg/l for Zn	

1.1.6.11 Other cross-linking agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	9003-35-4	Phenolformaldehyde reagents according to Coating Guideline	Composition according to Coating Guideline, molecular weight >1000D	

1.1.7 Colourants — Purity requirements according to BfR Recommendation IX

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
		Colour pigments according to Recommendation IX "Colourants for dying plastics and other polymers for consumer products"		

1.1.8 Aids to polymerisation for rubber

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
		Aids to polymerisation for the manufacture of rubber in accordance with BfR Recommendations		

2 LIST OF PART-ASSESSED SUBSTANCES

2.1 STARTING SUBSTANCES

2.1.1 MONOMERS

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
14560	126-99-8	2-chloro-1,3-butadiene	0.1	
15580	1653-19-6	2,3-dichloro-1,3-butadiene	0.1	
15730	77-73-6	Dicyclopentadiene		
18370	592-45-0	Hexadiene (1,4)	0.6 (4)	
18400	592-42-7	Hexadiene (1,5)	0.6 (4)	
	7726-95-6	Bromine		
	3048-64-4	-5-Vinyl bicyclo [2,2,1] heptene (2) (VNB)		

2.1.2 Fillers

Purity requirements according to BfR Recommendation LII. Fillers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
		Aramid-copolymer fibres		

2.1.3 Plasticisers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

2.1.4 Anti-ageing agents

2.1.4.1 Phenolic anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	61788-44-1	Phenols, styrenated	TOC	

2.1.4.2 Aminic anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µ/l	QM or QMA
	101-67-7	Bis(4-octylphenyl)amine	Additional requirement of PAA sec. amines	
	68411-46-1	Octylated diphenylamine (N-phenylbenzolamine, styrenated)		
	68442-68-2	Styrenated diphenylamine		

2.1.4.3 Other anti-ageing agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	26780-96-1	2,2,4-trimethyl-1,2-dihydrochinoline (polymerised)		

2.1.5 Processing aids, also applies to adhesives and additives for fillers

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	96-76-4	2,4-Di-tert-butylphenol		
	128-39-2	2,6-Di-tert-butylphenol		
	17540-75-9	2,6-Di-tert-butylphenol-4-sec-butylphenol		

2.1.6 Cross-linking agents

2.1.6.1 Peroxides

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
38600	78-63-7	2,5-Bis(tert-butylperoxy)-2,5-dimethylhexane		
46440	94-36-0	Dibenzoyl peroxide		Additional requirement for peroxides
	80-43-3	Dicumylperoxide		
	133-14-2	2,4-dichlorbenzoylperoxide		
		Di(4-methyl-benzoyl)peroxide		
	25155-25-3	1,4-Bis(tert-butylperoxyisopropyl)-benzene		
	6731-36-8	1, 1-Di-tert-butylperoxy-3, 5,5-trimethylcyclohexane		

1.2.3 2.1.6.2 Coagents for peroxide cross-linking

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
25390	101-37-1	Triallyl cyanurate		According to BfR Recommendation XXXV.
25405	1025-15-6	Triallyl isocyanurate (2,4, 6-Triallyloxy-1, 3,5-triazin)		

2.1.6.3 Carbamates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

2.1.6.4 Thiocarbamates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	84604-96-6	Bis-bis(3,5,-trimethylhexyl)dithiocarbamate-S-S´zinc		
	14726-36-4	Zinc-N-dibenzyldithiocarbamate (ZBEC)		Additional requirement for S cross-linking
96160	136-23-2	Zinc-N-dibutyldithiocarbamate (ZDBC)	N	

2.1.6.5 Thiurames

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	53880-86-7	Dimethyldiphenylthiuram disulfide	N	Additional requirement for S cross-linking
	10591-85-2	Tetrabenzylthiuram disulfide (TBzTD)		
92400	97-77-8	Tetraethylthiuram disulfide	N	
92720	137-26-8	Tetramethylthiuram disulfide (TMTD)	N	

2.1.6.6 Sulfenamides

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	95-33-0	Benzothiazyl-2-cyclohexylsulfenamide (CBS)		Additional requirement for S cross-linking
	4979-32-2	Benzothiazyl-2-dicyclohexylsulfenamide (DSBS)		

2.1.6.7 Guanidines

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
51500	102-06-7	Diphenylguanidine (DPG)	2.5	Additional requirement for S cross-linking

2.1.6.8 Xanthogenates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

2.1.6.9 Thiophosphates

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA

2.1.6.10 Mercapto accelerators

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
46400	120-78-5	Dibenzothiazyl disulfide	Additional requirement for S cross-linking	

2.1.6.11 Other accelerators

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	17796-82-6	N-(Cyclohexylthio)phthalimide		
	23847-08-7	N,N´-Dithio-bis(hexahydro-2H-azepinon-2) (Caprolactam disulfide)	750 ↔g/l as caprolactam	

2.1.6.12 Other cross-linking agents

Ref. No	CAS No	Substance name	DWPLL in µg/l	QM or QMA
	26678-93-3	1,1,3,3-Tetramethylbutylphenol formaldehyde resin		
	112484-41-0	1,1,3,3-Tetramethylbutylphenol formaldehyde resin hydrobromate		

3 LIST OF RUBBERS

Name	Abbreviation according to DIN ISO 1629
Acrylonitrile -1, 3-butadiene rubber	NBR
Bromo-isobutene-isoprene rubber (Bromo-butyl rubber)	BIIR
Chlorinated polyethylene	CM
Chloro-isobutene-isoprene rubber (Chloro-butyl rubber)	CIIR
Chloroprene rubber	CR
Chlorosulfonated polyethylene	CSM
Copolymer of ethene and propene	EPM
Copolymers of hexafluoropropene and vinylidene fluoride	FPM
Ethylene-vinylacetate copolymers	EVM or EVA, both names allowed, EVM for VA contents >40 %, EVA for VA contents <40 %
Isobutene-isoprene rubber (Butyl rubber)	IIR
Isoprene rubber, synthetic	IR

Name	Abbreviation according to DIN ISO 1629
Natural rubber	No.
Polybutadiene	BR
Polybutylene	
Polycyclooctene	
Polyisobutene	IM or PIB both names allowed
Quatropolymer of ethene, propene, dicyclopentadiene and ethylene norbornene	EPDM
Quatropolymer of ethene, propene, vinylnorbornene and ethylene norbornene	EPDM
Styrene-butadiene rubber	SBR
Terpolymer of ethene, propene and dicyclopentadiene	EPDM
Terpolymer of ethene, propene and ethylene norbornene	EPDM
Terpolymer of ethene, propene and vinylnorbornene	EPDM
Terpolymer of ethylene, propylene and hexadiene (1,4) (EPDM-hexadiene (1,4))	EPDM
Terpolymer of ethylene, propylene and hexadiene (1,5) (EPDM-hexadiene (1,5))	EPDM
Terpolymer of ethylene, propylene and VNB	EPDM
Terpolymers of hexafluoropropylene, vinylidenfluoride and tetrafluoroethylene	FPM
Offcuts of rubber polymers and polymers according to the KTW Guideline	

Annex 2 to the Elastomer Guideline

Formulation components of the elastomer material

Address of the manufacturer: .....

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

Product or brand name: ....

Declaration on the formulation of the elastomer in accordance with the Guideline on the hygienic assessment of elastomers in contact with drinking water of the Federal Environmental Agency to the test laboratory

This declaration shall 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, Tel., Fax, Email, contact)

All information is treated as confidential.

Page ___ of __ .

Signature of manufacturer:

Annex 3 to the Elastomer Guideline

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

Testing is to be done in accordance with DIN EN 1420-1: 1999 and DIN EN 12873-1: 2004, DIN EN 12873-2: 2005, taking account of the options left open in the European standards as follows:

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

The test pieces are not subjected to a disinfection pre-treatment (superchlorination).

The test pieces 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.

Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.

At least two of the same test pieces are used in the test and two blind tests are carried out.

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).

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.

The migration water samples from the first three migration periods of three days contact time each shall be used for further analyses, as described below.

The parameters of the basic requirement (TOC, colour, turbidity and tendency to foaming) are tested on the migration waters of migration periods 1, 2 and 3.

Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.

Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the parameters stated in table 1 under 5.2 Additional requirements. These mixed samples are then tested The control water from the migration periods must be tested at least once.

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.

II. Migration testing at higher temperatures ((60 ± 2) °C and (85 ± 2) °C) in accordance with DIN EN 12873-1 and -2

1. The test pieces are not subjected to a disinfection pre-treatment (superchlorination).

The test objects are pretreated according to the following sequence:

- 1 h flushing with tap water,
- 4 h stagnation with reference water at test temperature,
- 1 h flushing with tap water,
- rinsing with test water.

Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.

At least two of the same test pieces are used in the test and two blind tests are carried out simultaneously.

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).

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.

The pre-treatment is followed by 7 migration periods at the test temperature (cf. schedule 1 to Annex 3: showing the test procedure for migration testing at elevated temperatures).

The migration water from the first three and the last two migration periods each of 24 hours contact time is used to test the parameters of the basic requirement (TOC, colour and turbidity, tendency to foaming). The test for relevant individual substances is conducted in the 1st, 6th and 7th test periods.

Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.

Mixed samples are created from the tests using the migration water from migration periods 1 and 7 respectively to determine the parameters stated in table 1 under 5.2 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.

The test for relevant individual substances is conducted in the 1st, 6th and 7th migration periods. The control water from the migration periods must be tested at least once.

III. Odour/flavour test at (23 ± 2) °C in accordance with DIN EN 1420-1:1999 and DIN EN 1622:2006

1. The test pieces are not subjected to a disinfection pre-treatment (superchlorination).
2. The test pieces 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 reference water.
3. The reference water should be in accordance with 6.3.1 DIN EN 1420.
4. At least two of the same test pieces 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 immersing the test plates with a S/V ratio of at least 1.5 dm-1 (see Table 3), small-scale repair systems for tanks with a S/V ratio of at least 0.2 dm-1 are tested (cf. Table 3).
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 threshold odour number fails to meet 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 in the laboratory to determine the odour/flavour limits. The tentative determination is a short test in which the migration water is diluted until no odour/flavour can be perceived. 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 11. The control water from the migration periods must be tested at least once.
11. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622:2006.

IV. Odour and flavour testing at higher temperatures ((60± 2) °C and (85± 2) °C) inaccordance with DIN EN 1420-1: 1999 and DIN EN 1622: 2006

1. The test pieces are not subjected to a disinfection pre-treatment (superchlorination).
2. The test objects are pretreated 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 should be in accordance with 6.3.1 DIN EN 1420.
4. At least two of the same test pieces 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 immersing the test plates with a S/V ratio of at least 1.5 dm^{-1} (see Table 3), small-scale repair systems for tanks with a S/V ratio of at least 0.2 dm^{-1} are tested (cf. Table 3).
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 pre-treatment is followed by 7 migration periods at the test temperature (cf. schedule 1 to Annex 3: showing the test procedure for migration testing at elevated temperatures). The migration water from the 1st, 6th and 7th test periods are used to determine the odour/flavour thresholds. If the threshold odour number fails to meet requirements, the threshold flavour number 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 limits. The tentative determination is a short test in which the migration water is diluted until no odour/flavour can be perceived. 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 11. The control water from the migration periods must be tested at least once.
11. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622:2006.

Schedule 1 to Annex 3:

Test procedure for migration testing at elevated temperatures

Step	Sample	Day of the week
Rinse tap water, cold, 1 h		
		Monday
Stagnation test water, 60/85 °C, 24 h		
	→ Discard	
Rinse tap water, cold, 1 h		
		Tuesday
1st migration test water, 60/85 °C, 24 h		
	→ **Sample 1**	Wednesday
2nd migration test water, 60/85 °C, 24 h		
	→ **Sample 2**	Thursday
3rd migration test water, 60/85 °C, 24 h		
	→ **Sample 3**	Friday
4th migration test water, 60/85 °C, 72 h		
	→ **Sample 4** Discard	Monday
5th migration test water, 60/85 °C, 24 h		
	→ **Sample 5** Discard	Tuesday
6th migration test water, 60/85 °C, 24 h		
	→ **Sample 6**	Wednesday
7th migration test water, 60/85 °C, 24 h		
	→ **Sample 7**	Thursday

Table 3 to Annex 3: Minimum S/V ratio required for elastomer tests

Test run / Area of use	Migration at 23 °C	Migration at higher temperature	Odour/flavour at 23 °C	Odour/flavour at higher 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)	S/V ≥ 5 dm-1 (fill, fill with cylinder inserted or fill pipe)	S/V > 2.5dm-1 (fill)	S/V > 2.5 dm-1 (fill)
Pipes DN ≥ 300 mm	S/V ≥ 5 dm-1 (fill with cylinder inserted, fill pipe segment or immerse coated plates)	S/V ≥ 5 dm-1 (fill with cylinder inserted, fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm-1 (fill with cylinder inserted, fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm-1 (fill with cylinder inserted, fill pipe segment or immerse coated plates)
Fittings	S/V ≥ 5 dm-1 (immerse products or immerse coated plates)	S/V ≥ 5 dm-1 (immerse products or immerse coated plates)	S/V ≥ 1.5 dm-1 (immerse products or immerse coated plates)	S/V ≥ 1.5 dm-1 (immerse products or immerse coated plates)
Seals and adhesives	S/V ≥ 5 dm-1 (immerse products or immerse coated plates)	S/V ≥ 5 dm-1 (immerse products or immerse coated plates)	S/V ≥ 0.2 dm-1 (immerse products or immerse coated plates)	S/V ≥ 0.2 dm-1 (immerse products or immerse coated plates)
Tanks and repair systems	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 2.5 dm^{-1} (immerse coated plates)	S/V ≥ 2.5 dm^{-1} (immerse coated plates)
Small-area repair systems for tanks	S/V ≥ 5 dm-1 (immerse coated plates)	S/V ≥ 5 dm-1 (immerse coated plates)	S/V ≥ 0.2 dm-1 (immerse coated plates)	S/V ≥ 0.2 dm-1 (immerse coated plates)

Table 4 to Annex 3 of the Elastomer Guideline

Table 4: 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[18]	6	7
_					
_					
_					
_					
_					
_					

Where

_ is the concentration of a substance measured in the migration water in mg/l,

_ is the concentration of a substance measured in the control water in mg/l,

_is the concentration of the substance,

_is the maximum expected tap concentration of a migrating substance,

n is the sequential number of the migration period,

T is the test temperature

[18] The cold water test ends with the third test period.

Table 5 to Annex 3 of the Elastomer Guideline

Table 5: 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[19]	6	7
–				
–				
–				
–				

Where

– is the concentration of a substance measured in the migration water of the mixed samples in mg/l,

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

– is the concentration of the substance,

– is the maximum expected tap concentration of a migrating substance,

– n is the sequential number of the migration period,

T is the test temperature

[19] The cold water test ends with the third test period. In the hot water test the migration water from this migration period is not tested.

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 sample, 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 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

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

Annex 5 to the Elastomer Guideline

Assignment of typical elastomers to product groups stated in section 5.4 table 2 of the Elastomer Guideline

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 pipes 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

Annex 6 to the Elastomer Guideline

Form for feedback to the Federal 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:		