RECOMMENDATION

30. November 2010

Umwelt Bundes Amt
Für Mensch und Umwelt

Guideline for the Hygienic Assessment of Lubricants in Contact with Drinking Water (Sanitary Lubricants), (Lubricants Guideline) [1]

1 Preliminary remarks

Recommendation XV.I Silicone Oils published by the Federal Institute for Risk Assessment (BfR, formerly BgVV) has so far been used for the hygienic assessment of lubricants in contact with drinking water.

Due to the technical advances made in the development of lubricants for contact drinking water and the use of other base oils in addition to silicone oils, Recommendation XV.1 is no longer adequate. Consequently, KTW-AG (joint working group of the Drinking Water Commission of the German Federal Ministry of Health (BMG) within the Federal Environment Agency and the BfR Commission for Commodities for the Hygienic Assessment of Plastics and Other Non-metal Materials in Contact with Drinking Water) ruled at its 8th conference to develop a guideline on the hygienic assessment of lubricants in contact with drinking water, including lubricants used in domestic installations.

The Verband Schmierstoff-Industrie e.V. (VSI) formed a working group consisting of representatives from the industries in question in order to obtain an overview of the lubricants in current use and presented a draft for a white list. Representatives from KTW-AG formed a separate working group to discuss the hygienic requirements and the proposals of the industrial working group with its representatives.

Like KTW recommendations, the Guideline is composed of three parts: the white list of raw materials that can be used to manufacture substances and materials, the prescribed testing procedure (migration test procedure), and the limit values to be observed in the tests. This also corresponds to the principal structure of the future "European Acceptance Scheme (EAS) for construction products in contact with drinking water".

The progress made in the development of the EAS has enabled test values to be defined for Total Organic Carbon (TOC) and for individual substances in accordance with the current level of development of the EAS. The future gradings of the requirements have been taken into account based on the applications of the lubricants in the domestic installation. The migration test procedure developed by the European Committee for Standardization (CEN) is the prescribed test procedure. This aims to ensure that when the EAS enters into force, the lubricants that have been successfully tested in accordance with this Guideline will generally meet the new requirements.

[1] The obligations under 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 21.7.1998, p. 37), last amended by Directive 2006/96/EC of 20 November 2006 (OJ L 363 20.12.2006, p. 81) are observed.

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 scientific and technical knowledge relating to the hygienic requirements which must be met by sanitary lubricants in contact with water intended for human consumption (drinking water) in the sense of the Drinking Water Ordinance (Trinkwasserverordnung 2001 - TrinkwV 2001).

Article 17 of TrinkwV states that for the new construction or maintenance of installations for processing or distributing water for human consumption, “only those materials [may] be used, which when in contact with water, do not release substances in concentrations which exceed limits that are counted as unavoidable according to generally acknowledged technical standards, or 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 sanitary lubricants in contact with drinking water which comply with the requirements of these guidelines also satisfy the hygienic requirements of TrinkwV.

2 Definition of lubricants within the meaning of this Guideline

Lubricants reduce friction and wear in a tribological system in which the surfaces of two components are in moving contact with one another. Lubricants within the meaning of this Guideline can come into direct contact with drinking water. Lubricants are broken down into liquid, plastic rigid and solid types. These lubricants must be classified as a building element/component in a drinking water or sanitary installation. Sliding or fitting lubricants, metal machining lubricants and other lubricants are not covered by this Guideline.

Food technology lubricants, which demonstrate compliance with DIN V 10517: 2001-04 or other international regulations, are not exempt from a hygienic assessment before use in drinking water in accordance with this Guideline.

3 General information on the composition of lubricants

Lubricants for use with fittings are generally composed of the base oil, the thickener and if necessary a low dose of additives or adjuvants.

Base oils are the principal component and account for more than 50% of the lubricant. In relation to silicone oils, refer to the oil recommended in Recommendation XV.1 of the BfR.

Thickeners account for approximately 20% of lubricants.

The additives and adjuvants stipulated in the white list are used to create specific properties such as corrosion protection and account for 2% of lubricants.

4 Structure of the white list (Annex 1)

The white list only contains substances that have undergone a toxicological assessment. These assessments were taken from the "Scientific Committee on Food" (SCF, now the European Safety Authority - EFSA) of the European Commission and from Recommendation XV. Silicones

(http://bfr.zadi.de/kse/) or were carried out in cooperation with the BfR and its Plastics Commission.

The white list is set out in table format. It is broken down into base oils, thickeners, additives and adjuvants. Column 1 contains the "EEC packaging material reference number" taken from the Plastics Directive 2002/72/EC. Column 2 contains the Chemical Abstracts Service Registry Number (CAS No.). The substance name is stated in Column 3. Column 4 contains the values for the maximum permissible migration rates, which must be checked in the migration test or any other requirements (specifications) for this substance. Substances for which there is no entry in Column 4 must comply with the migration rate for the TOC (parameters of the basic requirements).

5 Acceptance of new substances on the white list

An application can be made to the Federal Environment Agency to add new substances on the white list.

The application must comply with the requirements of the questionnaire "Note for guidance" (http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm). Chapter III contains the questionnaire, which is broken down into points 1 to 8.

Point 8 of the questionnaire describes the requirements for the toxicological data being presented, the scope of which depends on the migration level of the requested substance in deionised water. All existing toxicological data must be presented.

The corresponding migration test must be carried out on a model lubricant. The migration behaviour of the requested substance is observed.

The model lubricant must only contain substances that are already included in the white list. The number of components in the model lubricant should remain restricted to a minimum. Consequently, no additive or adjuvants should be included. The requested substance must be contained in the model lubricant with the maximum required quantity. As a result, the white list shows that the maximum required quantity for the requested basis oils is at least 50%, thickener types at least 20%, additives and adjuvants at least 2%.

The migration test must be conducted at a temperature of 40 °C and with a surface-volume ratio of 5 dm^{-1} with 10 days contact time. This test method corresponds to the test carried out in Annex 3.

Suitable analysis methods must be presented for checking the maximum permissible migration rates.

When applying for substances that have already undergone toxicological assessment to be added to the white list, the requirements of points 1 to 5 only of the questionnaire must be met. The white list will be updated once a year with new accepted substances.

6 Requirements for lubricants in contact with drinking water

Lubricants in contact with drinking water must only be manufactured from the substances stipulated in the white list.

Article 17(1) of TrinkwV 2001 states that lubricants in contact with water must not release substances in concentrations which exceed limits that are counted as unavoidable according to generally acknowledged technical standards, or 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.

6.1 Basic requirements

The external characteristics (odour/flavour; clarity/colour; foaming) of the migration water must not be modified at a surface-volume ratio of 0.2 dm^{-1}. For the cold water test, the required threshold odour number (TON) and threshold flavour number (TFN) is TON, TFN < 2, for the warm water test TON, TFN ≤ 4.

The release of organic substances measured as (TOC), must not exceed the maximum permissible migration rate $M_{max,\ TOC}$ = 1,25 mg/ (dm^2 d) at a surface-volume ratio of 5 dm^{-1}.

The lubricants must not promote bacterial regrowth in the drinking water in the mains network. There are currently no suitable test procedures available to verify this requirement. If necessary, these will be introduced at a later date.

6.2 Formulation-dependent requirements for individual substances

The maximum permissible migration rates must be verified for all substances with a limit in Column 4 of the white list.

The maximum permissible migration rates stipulated here were calculated from a "Drinking Water Positive List Limit" (DWPLL) by dividing this by the conversion factor 0.4 (product group for sealing rings and other small products in domestic installation). The DWPLL values were derived from the Tolerable Daily Intake (TDI) assuming a daily consumption of 2 litres of drinking water, a body weight of 60 kg and a 10% share of total exposure.

Migration rates can be calculated by experimental determination or modelling.

Compliance with the specific migration test values can also be checked by defining the quantity of a substance in the product being assessed ($c_{P,0}$), if the ratio between this quantity and the value of the specific migration of the substance in question has been determined by applying generally recognised, scientifically-proven diffusion models and parameters.

In the case of food contact materials, the migration for individual substances can already be modelled in accordance with EU Regulation 2002/72. The Practical Guide (Annex 1) contains specific parameters for the most important organic materials (http://ec.europa.eu/food/food/chemicalsafety/foodcontact/practical_guide_en.pdf).

In the case of other organic materials used in contact with drinking water, these parameters must be determined specific to each material or product before modelling can be applied. The tests required for this are also described in the Practical Guide (Annex 1).

In the case of lubricants, these polymer-specific constants must be calculated before mathematic modelling can be applied.

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.

Modelling must correspond to the migration of the individual test periods and with the respective test conditions (test temperature and test cycle) under this Guideline (see 7.3). 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 after modelling, verification can still be carried out by experimental testing, since the results of this must always be weighted higher than the results of the modelling.

The relevant documents for the requested specifications in Column 4 of the white list must be presented (e.g. confirmation by the raw material supplier).

For substances without an entry in Column 4 of the white list, the individual substance requirements are deemed to have been met if the maximum permissible migration rate for the TOC (basic requirement) is observed.

7 Requirements for the granting of a test certificate

7.1 Applications

In order to obtain a test certificate for a lubricant in contact with drinking water, the applicant must provide the test laboratory with the complete formulation (specifying all components with CAS No.). This indicates the scope of the maximum permissible migration rates (M_{max}) for the individual substances to be tested.

7.2 Test laboratory

Testing in accordance with this Guideline shall be done by an accredited test laboratory. In addition, the test laboratory must be recognised by a certification body (e.g. the DVGW certification body) which is itself accredited for the certification of products in contact with drinking water.

7.3 Testing

The lubricant to be tested is applied to a glass plate measuring 200 mm x 200 mm at a thickness of 1 mm. The odour-flavour test is conducted for a surface-volume ratio of 0.2 dm^{-1}, the migration test at 5 dm^{-1}.

Testing is to be done in accordance with DIN EN 1420-1: 1999 and DIN EN 12873-1: 2004 and DIN EN 12873-2: 2005, taking account of experiences with the KTW Recommendation (Annex 3 to the Guideline contains an abridged version of the test conditions). The test method and test results must be carefully recorded (Annex 2 of the test report).

The test laboratory must verify compliance with the basic requirements and the formulation-dependent requirements for individual substances as well as the specifications in Column 4 of the white list.

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. The parameter TOC must be determined for the 1st, 2nd, 3rd, 6th and 7th migration periods in the migration test at elevated temperatures. The specific migration of individual substances and the odour-flavour threshold values at elevated temperatures must be tested for the migration waters in the 1st, 6th and 7th test period.

The test results should indicate that there is no increasing trend and the test results for the last period must meet the requirements applicable for the intended application.

The complete test results must be entered in tables in accordance with DIN EN 12873-2, point 11.5 and must be included as Annex 3 of the test report.

A mathematical estimate of the migration of individual substances from lubricants 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.

7.4 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 DIN EN 12873-1 and DIN EN 12873-2, point 11. This consists of the test certificate and the following annexes:

Annex 1: Formulation Declaration (Annex 2 of the Guideline, completed and signed by the manufacturer/applicant and the test laboratory)

Annex 2: Record of the realisation of the test (see 7.2)

Annex 3: Table with the complete test results (see 7.2), with modelling documentation if applicable

Annex 4: Selection and indicators for the test methods used

The test certificate must contain the closing paragraph:

"The lubricant (precise designation, batch number) has been tested in accordance with the Guideline on the hygienic assessment of lubricants in contact with drinking water by the Federal Environment Agency and has passed the test for the temperature range up to ...°C.

A copy of the test certificate including all annexes has been presented to the Federal Environment Agency".

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

Test certificates for products of the same manufacturer that are produced in accordance with this Guideline may, if they complied with the requirements under 7.3 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.

8 Feedback to the Federal Environment Agency

Until a national regulatory group is set up within the framework of the EAS, the Federal Environment Agency shall receive a test report including all of the annexes listed under 7.4 from the test laboratory on completion of the test. The test report is used by the Federal Environment Agency for scientific assessment to update the white list, to prepare the EAS and to improve the hygienic safety of the drinking water supply. The formulation declaration (Annex 1 of the test report) and the test results (Annex 2 and Annex 3 of the test report) will be treated with the strictest confidence.

Any scientific publications or collations of test results used by the Federal Environment Agency to further develop the test procedure will be carried out anonymously and without details of the formulation.

The Federal Environment Agency shall keep a list of lubricants that have passed the test in accordance with this Guideline, which will be updated as quickly as possible once the documents have been reviewed, but at least once a year, as Annex 4 to the Guideline.

Annex 1: White list for lubricants

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max, D}$ in µg/dm² d or specifications
1. Base oils			
		Cyclic organopolysiloxane with methyl groups alone or n-Alkyl (C_2-C_{32})groups**	Composition in accordance with BfR Recommendation XV
	70131-67-8	Hydroxy-terminated dimethylsiloxane**	Composition in accordance with BfR Recommendation XV
14411/ 42880	8001-79-4	Castor oil	
14440/ 42960	64147-40-6	Castor oil, dehydrated	
	68083-14-7, 73138-88-2, 68440-81-3	Silicone oils with methyl and phenyl groups, linear and branched**	Composition in accordance with BfR Recommendation XV
76520	9003-29-6	Polybutene**	Composition in accordance with BfR Recommendation XXXVII
76530	68937-10-0	Polybutene, hydrogenated**	Composition in accordance with BfR Recommendation XXXVII
76685	68037-01-4	Poly 1-Decen / hydrogenated (SCF opinion: http://ec.europa.eu/food/fs/sc/scf/out95_en.pdf)	Contamination of hydrocarbons with a carbon number of less than 30: No more than 1.5%, free of naphthenes, aromatic compounds, PAHs
76721	63148-62-9	Polydimethylsiloxane	MW>6800, minimum viscosity 100x10-6 m²/s (=100 centistokes) at 25 °C
76721	9016-00-6, 63148-62-9, 68037-74-1	Methylsilicone oils: linear and branched**	Composition in accordance with BfR Recommendation XV
76950/ 80000	9002-88-4	Polyethylene**	Composition in accordance with BfR Recommendation III

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max, D}$ in µg/dm² d or specifications
80360	9003-27-4	Polyisobutylene**	Composition in accordance with BfR Recommendation XX
95883	-	White mineral oils, paraffinic, which can be extracted from hydrocarbons with a crude oil base	Content of mineral hydrocarbons with a carbon number of less than 25: No more than 5% weight; minimum viscosity 8.5 x 10^{-6} m^2/s (= 8.5 centistokes) at 100°C; average molecular weight at least 480 Da
	68604-46-6	Lithium salt of fatty acids (castor oil) hydrogenated*	75 as lithium
2. Thickeners			
10090/ 30000	64-19-7	Acetic acids	
10599/56	-	Calcium salts of straight-chain aliphatic saturated univalent carbon acids C_{10}-C_{20}**	
13090/ 37600	65-85-0	Benzoic acids	
18900/ 61840	3159-62-4, 106-14-9	12-hydroxystearic acids	
24550/ 89040	57-11-4	Stearic acid	
34720	1344-28-1	Aluminium oxide	
44280	1305-62-0	Calcium hydroxide	
54450	-	Fatty acids of animal and plant origin	
54480	-	Hydrogenated fatty acids of animal and plant origin	
66240	9004-67-5	Methyl cellulose (gelling agent)	

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max, D}$ in µg/dm² d or specifications
69885	68988-56-7	Silicium dioxide, reaction product with trimethylchlorsilane and isopropyl alcohol**	Composition in accordance with BfR Recommendation XV
81160	9002-84-0	Polytetrafluorethylene	6.25 as tetrafluorethylene
83560	68953-58-2	Dialkyl-dimethyl-ammonium, ... sodium aluminium silicate (Bentone)*	
86240	1343-98-2	Silicic acid	Purity requirements in accordance with BfR Recommendation LII
86240	7631-86-9	Silicium dioxide (this CAS number also includes silylated silicic acids)	
86285	68611-44-9	Silicium dioxide, reaction product with dimethyldichlorosilane	
86285	68909-20-6	Silicium dioxide, reaction product with hexamethyldisilazane	
86285	67762-90-7	Silicium dioxide, reaction product with polydimethylsiloxane	
-	54326-11-3	Aluminium stearoyl benzoyl hydroxide*	
-	71011-24-0	Quaternary ammonium compounds, benzyl (hydrogenated tallow alkyl) salts with bentonite*	
-	-	Reaction product of sebacin acids with stearylamide, neutralised with calcium hydroxide*	
	7620-77-1	Octadecanoic acid, 12-hydroxy, lithium salt*	75 as Li
3. Additives			
40320	10043-35-3	Boric acid	750
40400	10043-11-5	Boron nitride	

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max, D}$ in µg/dm² d or specifications
40720	25013-16-5	*tert*-Butyl-hydroxy-anisol (BHA), hexamethylene-bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)	TOC
45940/ 15095	334-48-5	n-decanoic acid	
46640	128-37-0	2,6-Di-*tert*-butyl-4-methyl-phenol (BHT), butylhydroxytoluol	375
52800/ 16780	64-17-5	Ethanol	
53600	60-00-4	Ethylenediaminetetraacetic acids (EDTA)	
59200	35074-77-2	1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	750
66655/ 21827	78-93-3	Methyl ethyl ketone	TOC
68320	2082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	750
71680	6683-19-8	Pentaerythritol tetrakis[3-3,5-di-tert-butyl-4-hydroxyphenyl)-propionate], Tetrakis[methylene(3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate)]methane	
74240	31570-04-4	Tris(2,4-di-*tert*-butylphenyl)phosphite	
85030/ 24280	111-20-6	Sebacin acid	
86160	409-21-2	Silicium carbide	Purity requirements in accordance with BfR Recommendation LII

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max, D}$ in µg/dm² d or specifications
92880/ 92900	41484-35-9	Thiodiethylenbis(3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate)	300
96240	1314-13-2	Zinc oxide	Purity requirements in accordance with BfR Recommendation LII
4. Adjuvants:			
-	108-32-7	Propylene carbonate*	
42500	-	Carbonate	Purity requirements in accordance with BfR Recommendation LII
52720	112-84-5	Erucic acid amide	
53520	110-30-5	N,N-Ethylenebisstearamide	
72640/ 23170	7664-38-2	Phosphoric acid	Purity requirements in accordance with BfR Recommendation LII
81840/ 23740	57-55-6	1,2-Propandiol, propylene glycol	
83440	2466-09-3	Pyrophosphoric acid	Purity requirements in accordance with BfR Recommendation LII
83470	14808-60-7	Quartz	Purity requirements in accordance with BfR Recommendation LII
92080	14807-96-6	Magnesium silicate (talcum)	Purity requirements in accordance with BfR Recommendation LII
93440	13463-67-7	Titanium dioxide	Purity requirements in accordance with BfR Recommendation LII
96320	1314-98-3	Zinc sulphide	Purity requirements in accordance with BfR Recommendation LII

The list of acids includes the corresponding sodium, potassium and calcium salts without a separate listing.

Footnotes:

* Substances that have been assessed nationally within the framework of this Guideline.

** Polymers and substances that have been assessed nationally in other recommendations.

Annex 2: Formulation Declaration

Address of the manufacturer: .....

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

Product or brand name: ....

Declaration on the Formulation of Lubricants in accordance with the Guideline for the Hygienic Assessment of Lubricants in Contact with Drinking Water of the Federal Environment Agency

To the Test Laboratory.... and the Federal Environment Agency

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

Until a national regulatory group is set up within the framework of the European Acceptance System (EAS), the test laboratory this must be notified to the Federal Environment Agency together with the complete test results and a copy of the test certificate (test report).

The Table contains all formulation agents (without details of the required quantities) that are used to manufacture the requested lubricant.

Details of the formulation

	Formulation component*		Test according to Guideline ***	
	Chemical name**	CAS No.	Test method*	Detection limit
Base oil				
Thickener				
Additive				
Adjuvant				

* To be completed by the applicant/raw material supplier

** If using a subcomponent, which is obtained from a raw material supplier, its name (brand name, code) must be entered.

*** To be completed by the test laboratory

Signature of the manufacturer, date: .....,
Signature of the test laboratory, date: .....

Annex 3: Test procedure

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

The test for clarity, colour and foaming is conducted by sight on undiluted migration waters.

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 and the experiences with KTW recommendations as follows:

I. Migration test at (23 ± 2)°C in accordance with DIN EN 12873-1: 2004 and -2: 2005

1. The test plates 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 (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 identical contact tests and two blank tests are to be performed simultaneously.
5. The test is conducted on glass plates coated with the lubricant. The lubricant must be applied on the glass plate with a thickness of approximately 1 mm. The S/V ratio must be approximately 5 dm^{-1}.
6. The migration waters of the first three test periods of three days contact time each are used for further analyses.
7. The three test results must indicate that there is no upward trend and the third test result must lie below the maximum permissible migration rate calculated for the intended application.

II. Migration test at elevated temperatures ((60 ± 2)°C and (85 ± 2)°C) in accordance with DIN EN 12873-1: 2004 and -2: 2005

1. The test plates 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 test water.

3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two identical contact tests and two blank tests are to be performed simultaneously.
5. The test is conducted on glass plates coated with the lubricant. The lubricant must be applied on the glass plate with a thickness of approximately 1 mm. The S/V ratio must be approximately 5 dm^{-1}.
6. After pre-treatment, the test involves 7 migration periods at the test temperature (see diagram showing the test procedure for migration testing at elevated temperatures). The migration waters of the first three and last two test periods, each with 24 hours contact time, are used for the parameter TOC. The test for relevant individual substances is conducted in the migrates of the 1^{st}, 6^{th} and 7^{th} test periods.
7. The test results must indicate that there is no upwards trend and the 7^{th} test result must lie below the maximum permissible migration.

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

1. The test plates 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 (23 ± 2)°C, ,
   - 1 h flushing with tap water,
   - rinsing with reference water.
3. The reference water must be in accordance with 6.3.1 DIN EN 1420-1.
4. At least two identical contact tests and two blank tests are to be performed simultaneously.
5. The test is conducted on glass plates coated with the lubricant. The lubricant must be applied on the glass plate with a thickness of approximately 1 mm. The S/V ratio must be approximately 0.2 dm^{-1}.

6. 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.
7. The odour/flavour threshold numbers are determined in accordance with DIN EN 1622 using one of the methods described. A slight odour or flavour is permitted in the undiluted sample but not in the next dilution level (1:1).
8. The test results for the odour/flavour-free characteristic are stated as "nna" (not noticeably affected).

IV. Odour/flavour test at elevated temperatures ((60 ± 2)°C and (85 ± 2)°C) in accordance with DIN EN 1420-1: 1999 and DIN EN 1622: 2006

1. The test plates 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 reference water.
3. The reference water must be in accordance with 6.3.1 DIN EN 1420-1.
4. At least two identical contact tests and two blank tests are to be performed simultaneously.
5. The test is conducted on glass plates coated with the lubricant. The lubricant must be applied on the glass plate with a thickness of approximately 1 mm. The S/V ratio must be approximately 0.2 dm^{-1}.
6. After pre-treatment, the test involves 7 migration periods at the test temperature (see diagram: showing the test procedure for migration testing at elevated temperatures). The migration waters of the 1^{st}, 6^{th} and 7^{th} test periods 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.
7. The odour/flavour threshold numbers are determined in accordance with DIN EN 1622 using one of the methods described. A slight odour or flavour is permitted in the undiluted sample but not in the next dilution level (1:1).
8. The test results for the odour/flavour-free characteristic are stated as "nna" (not noticeably affected).

Diagram for 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
1. Migration test water, 60/85°C, 24 h	⟶ **Sample 1**	Wednesday
2. Migration test water, 60/85°C, 24 h	⟶ **Sample 2**	Thursday
3. Migration test water, 60/85°C, 24 h	⟶ **Sample 3**	Friday
4. Migration test water, 60/85°C, 72 h	⟶ **Sample 4** discard	Monday
5. Migration test water, 60/85°C, 24 h	⟶ **Sample 5** discard	Tuesday
6. Migration test water, 60/85°C, 24 h	⟶ **Sample 6**	Wednesday
7. Migration test water, 60/85°C, 24 h	⟶ **Sample 7**	Thursday