

RECOMMENDATION

Guideline for the hygienic assessment of lubricants in contact with drinking water (sanitary lubricants), (lubricants guideline)^{1,2}

Only the German version of this document is legally binding.

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 the contact with drinking water and the use of other base oils in addition to silicone oils, Recommendation XV.1 is no longer adequate. As a result KTW-AG (joint working group of the Drinking Water Commission of the German Federal Ministry of Health (BMG) within the German 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 positive 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 positive list of starting substances 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.

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

² Last amended on 16 March 2016, notified under 2013/473/D

1.1 Legal status

This Guideline is a revision of the lubricants guideline of 30 November 2010. It also constitutes a recommendation and no evaluation criteria yet within the meaning of the Drinking Water Ordinance (Trinkwasserverordnung - TrinkwV 2001) amended on 05.12.2012. Hence this Guideline is non-binding. It represents the current state of scientific and technical knowledge relating to the hygienic requirements which must be met by sanitary lubricants in contact with drinking water.

Pursuant to Section 17 (3) of TrinkwV amended on 05.12.2012 it is intended to transfer this lubricants guideline into an evaluation criteria which are legally binding 2 years after being published. Pursuant to Section 17 (5) of TrinkwV 2001 it can be assumed that products and procedures meet requirements of Section 17 if this was confirmed by means of a certificate by a certifier accredited in the field of drinking water. Up to the date of completion and entry into force of the evaluation criteria for lubricants pursuant to Section 17 (2) TrinkwV 2001 this Guideline relating to conformity assessment and confirmation of harmlessness of a lubricant to human health may be consulted.

If certificates from another Member State of the European Union, a signatory to the Agreement on the European Economic Area or from Turkey are consulted for conformity assessment and confirmation of harmlessness to human health the following conditions have then to be met:

- Material or product testing, if any, has to be done in accordance with EN standard test method and at least comply with the level of protection for existing regulations relating to materials and products in contact with foodstuffs.
- The assessment system taken as a basis has to be trackable.

2 Definition of lubricants within the meaning of this guideline

Lubricants reduce friction and wear in a tribiological 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 EN ISO 21469 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 positive list are used to create specific properties such as corrosion protection and account for 2% of lubricants.

4 Structure of the positive list (Annex 1)

The positive 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 - EFSA³) of the European Commission and from Recommendation XV. Silicones⁴ or were carried out in cooperation with the BfR.

The positive 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 (Ref No.)

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 positive list

In accordance with the rules of procedure of the German Environment Agency for the management of the positive list of starting substances of organic materials in contact with drinking water an application has to be made to add new substances on the positive list.⁵ The application must comply with the requirements of the questionnaire "Note for guidance" (<http://www.efsa.europa.eu/de/efsajournal/pub/21r>). 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. Furthermore 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 additives or adjuvants should be included. The requested substance must be contained in the model lubricant with the maximum required quantity. As a result the positive

³ <http://www.efsa.europa.eu/de/>

⁴ <https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp>

⁵ <http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien>

list shows that the maximum required quantity for the requested base 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.

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

When applying for substances that have already undergone toxicological assessment (e. g. by EFSA) the requirements of points 1 to 5 only must be met (cf. rules of procedure⁶).

The positive list shall be updated at least once a year with new accepted substances.

6 Requirements for lubricants in contact with drinking water

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

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

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, TNF < 2, for the warm water test TON, TNF ≤ 4.

The release of organic substances measured as TOC must not exceed the maximum permissible migration rate $M_{\max, \text{TOC}} = 1.25 \text{ mg}/(\text{dm}^2 \text{ d})$ 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 positive list.

The maximum permissible migration rates stipulated here were calculated from a "temporary drinking water limit for material-specific substances" (Drinking Water Positive List - DWPLL) by means of division by the conversion factor 0.4 d/dm (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.

⁶ <http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien>

Migration can be assessed by means of the modelling guideline⁷ if applicability of generally recognised diffusion models based on scientific evidence and parameters was defined.

The Practical Guide (Annex 1)⁸ contains specific parameters for the most important organic materials being in food contact.

Additionally the report of C. Simoneau, et al. (2010)⁹ is available.

Material- or product-specific parameters have to be determined for further organic materials used in contact with drinking water in order to use modelling. Testing necessary for that purpose is also described in the Practical Guide (Annex 1).

A condition for modelling is the determination of the quantity of the substance concerned in the product to be assessed ($c_{p,0}$).

The method of analysis for determining $c_{p,0}$ for the polymer must be presented by the raw material supplier if there is no validated method available from the "Community Reference Laboratory for Food Contact Materials"

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

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

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

If a product does not meet the requirements of the Guideline concerning individual substances 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 positive list must be presented (e.g. confirmation by the raw material supplier).

For substances without an entry in Column 4 of the positive 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 Guideline relating to mathematical estimate of migration of individual substances from organic materials into drinking water

⁸ Practical Guide was withdrawn by EU Commission. Annex 1, Mathematical Models, however, continues to be accessible.

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

⁹ "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>

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.) (cf. Annex 2). 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 or by a certification body recognised by an accredited certifier.

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 the standards of DIN EN 1420 and DIN EN 12873-1 or DIN EN 12873-2 by taking account of the experiences with the KTW recommendations (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 positive 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 trend¹⁰ 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 12873-1, 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.

¹⁰ For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

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 -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 performance of the test (see 7.3)
- Annex 3: Table with the complete test results (see 7.3) 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 German 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 German 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.

Annex 1 to the lubricants guideline

Positive list of assessed starting substances required for the manufacture of products within the meaning of this Guideline

Table 1 of Annex 1

positive list of assessed starting substances required for the manufacture of products within the meaning of this Guideline

1 List of assessed substances

1.1 Base oils

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max,D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
-	-	Cyclic organopolysiloxane with methyl groups alone or n-Alkyl (C ₂ -C ₃₂)groups**	Composition in accordance with BfR Recommendation XV ⁴
-	70131-67-8	Polydimethylsiloxane, hydroxy terminated**	Composition in accordance with BfR Recommendation XV ⁴
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 ⁴
17200	68308-53-2	Soya fatty acids	
-	61790-37-2	Tallow fatty acids	
76520	9003-29-6	Polybutene**	Composition in accordance with BfR Recommendation XXXVII ⁴
76530	68937-10-0	Polybutene, hydrogenated**	Composition in accordance with BfR Recommendation XXXVII ⁴
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 naphtenes, aromatic compounds, PAHs

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{\max D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
76721	63148-62-9	Polydimethylsiloxane MW > 6800 Da	requirements in table 1 of Regulation 10/2011
76721	9016-00-6, 63148-62-9, 68037-74-1	Methylsilicone oils: linear and branched**	Composition in accordance with BfR Recommendation XV ⁴
76950 80000	9002-88-4	Polyethylene**	Composition in accordance with BfR Recommendation III ⁴
80360	9003-27-4	Polyisobutylene**	Composition in accordance with BfR Recommendation XX ⁴
95858	-	Waxes paraffinic, refined, extracted from crude oil-based or synthetic hydrocarbons, low viscosity	6.25 requirements in table 1 of Regulation 10/2011
95883	-	White mineral oils, paraffinic, which can be extracted from hydrocarbons with a crude oil base	requirements in table 1 of Regulation 10/2011
-	68604-46-6	Lithium salt of fatty acids (castor oil) hydrogenated*	75 as lithium

1.2 Thickeners

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{\max D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
10090 30000	64-19-7	Acetic acid	
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	

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{\max. D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
54480	-	Hydrogenated fatty acids of animal and plant origin	
66240	9004-67-5	Methyl cellulose (gelling agent)	
69885	68988-56-7	Silicium dioxide, reaktion product with trimethylchlorsilane and isopropyl alcohol**	Composition in accordance with BfR Recommendation XV ⁴
81160	9002-84-0	Polytetrafluorethylene	6.25 as tetrafluorethylene
83560	68953-58-2	Dialkyl-dimethyl-ammonium, - sodium aluminium silicate (Bentone)*	
85680	1343-98-2	Silicic acid	Purity requirements in accordance with BfR Recommendation LII ⁴
86240	7631-86-9	Silicium dioxide (this CAS number also includes silylated silicic acids)	requirements in table 1 of Regulation 10/2011
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 dimethyl), salts with bentonite*	
-	-	Reaction product of sebacin acids with stearylamide, neutralised with calcium hydroxide*	
-	7620-77-1	Lithium salt of 12-hydroxystearic acids	75 as lithium

1.3 Additives

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{\max. D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
-	637-12-7	Aluminium tristearate	
40320	10043-35-3	Boric acid	750 as boron
40400	10043-11-5	Boron nitride	
40720	25013-16-5	tert-butyl-4-hydroxy-anisole (BHA)	TOC

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max. D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
45940 15095	334-48-5	n-decanoic acid	
46640	128-37-0	2,6-Di-tert-butyl-4-kresol (BHT)	375
52800 16780	64-17-5	Ethanol	
53600	60-00-4	Ethylenediamintetraacetic 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]	
74240	31570-04-4	Tris(2,4-di-tert-butylphenyl)phosphite	
85030 24280	111-20-6	Sebacic acid	
86160	409-21-2	Silicium carbide	Purity requirements in accordance with BfR Recommendation LII ⁴
92880 92900	41484-35-9	Thiodiethylen-bis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	300
95858	-	Waxes paraffinic, refined, extracted from crude oil-based or synthetic hydrocarbons, low viscosity	6.25 requirements in table 1 of Regulation 10/2011
95859	-	Waxes, refined, extracted from crude oil-based or synthetic hydrocarbons, high viscosity	requirements in table 1 of Regulation 10/2011
96240	1314-13-2	Zinc oxide	Purity requirements in accordance with BfR Recommendation LII ⁴

1.3 Adjuvants

PM Ref No.	CAS No.	Class / Substance	Migration rates $M_{max,D}$ in $\mu\text{g}/\text{dm}^2 \text{ d}$ or specifications
-	108-32-7	Propylene carbonate*	
16960	107-15-3	Ethylenediamine	1500
42500	-	Carbonate	Purity requirements in accordance with BfR Recommendation LII ⁴
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 ⁴
81840 23740	57-55-6	1,2-Propandiol, propylene glycol	
83440	03/09/2466	Pyrophosphoric acid	Purity requirements in accordance with BfR Recommendation LII ⁴
83470	14808-60-7	Quartz	
92080	14807-96-6	Magnesium silicate (talcum)	
93440	13463-67-7	Titanium dioxide	
96320	1314-98-3	Zinc sulphide	

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 to the lubricants guideline

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 German Environment Agency

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

The following 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 to the lubricants guideline

Test procedure

Performance of migration test and odour/flavour test 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 and DIN EN 12873-1, DIN EN 12873-2 by taking into account the options available in the European standards and the experiences with the KTW Recommendations as follows:

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

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 and -2

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 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 1st, 6th and 7th test periods.
7. The test results must indicate that there is no upward trend and the 7th test result must lie below the maximum permissible migration.

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

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. The reference water must be in accordance with DIN EN 1420.
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 needs 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 diluted 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 and DIN EN 1622

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. The reference water must be in accordance with DIN EN 1420.
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 1st, 6th and 7th test periods are used to determine the odour/flavour threshold values. If the threshold odour number fails to meet the requirements the threshold flavour number needs 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 diluted level (1:1).
8. The test results for the odour/flavour-free characteristic are stated as "nna" (not noticeably affected).

Diagram for Annex 3 of the lubricants guideline

Performance of 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 st Migration test water, 60/85 °C, 24 h	→ sample 1	Wednesday
2 nd Migration test water, 60/85 °C, 24 h	→ sample 2	Thursday
3 rd Migration test water, 60/85 °C, 24 h	→ sample 3	Friday
4 th Migration test water, 60/85 °C, 72 h	→ sample 4 discard	Monday
5 th Migration test water, 60/85 °C, 24 h	→ sample 5 discard	Tuesday
6 th Migration test water, 60/85 °C, 24 h	→ sample 6	Wednesday
7 th Migration test water, 60/85 °C, 24 h	→ sample 7	Thursday