

This is an unofficial translation. Only the German version is binding.

XXI/1. Commodities based on natural and synthetic rubber in contact with food

As of 01.09.2024

1. Preliminary remarks

Recommendation XXI. Consumer goods based on natural and synthetic rubber must be observed.

- a) The majority of articles made of natural and synthetic rubber intended for food contact does not come into contact with food with its entire surface and for a long period of time, but mostly only with a part of the surface and also only for a limited time. These special conditions of use must be taken into account in the assessment. Accordingly, the test conditions for determining the migration of substances from consumer goods into food or food simulants are to be oriented to the practical use of the consumer goods.

According to the different conditions of use that occur in practice, the consumer goods made of natural and synthetic rubber are divided into four categories:

- Category 1: Long-term contact
- Category 2: Medium contact time
- Category 3: Short-term contact
- Category 4: Insignificant contact.

- b) In order to characterise the individual categories, a few consumer goods are listed as examples in each case. Materials and articles which may come into contact with foodstuffs at different contact times have been assigned to the category with the longer contact time. Certain test conditions are assigned to the categories. If the actual conditions of use in a specific case differ significantly from the test conditions, these must be adapted to the respective conditions of practical use.
- c) The specific migration test shall be carried out in the foodstuff, by derogation the simulants listed in 2.5 may be used. If it is found that the performance of the tests causes physical or other changes in the sample which do not occur under the worst foreseeable conditions of use of the material or article under test, the migration tests shall be performed under the worst foreseeable conditions of use under which these physical or other changes do not occur.
If a test is carried out in the foodstuff milk, it must have a fat content of 3.5 %.
The assignment of simulants to foodstuffs shall be made in accordance with Table 2 in Annex III to Regulation (EU) No 10/2011, with the exception of tests where water is required.
- d) If migration guide values are given, the results of migration experiments must be converted, if necessary, taking into account the actual contact area and food quantity.
If such a calculation is not possible, assume a surface-to-volume ratio of 1 dm²/200 ml.
- e) Unless otherwise specified in the Annex to Recommendation XXI, a migration guideline value of 60 mg/kg food or food simulant applies for the respective substance.

2. Categories and test conditions

Whether the specified test conditions are sufficient for longer contact and/or at higher temperatures can be checked via the Arrhenius correlation, which describes the dependence of the migration rate of substances from polymers on temperature. From this, the simplified rule can be derived that an increase in temperature by 10 °C leads to a doubling of the migration rate.¹ For testing times of 24 hours or less, compliance with the temperature in the food or food simulant must be checked.

2.1 Category 1

2.1.1 Definition

This category includes commodities that come into contact with food for longer than 24 hours up to several months when used as intended.

Examples:

1. storage containers
2. container linings
3. sealing rings for cans, jars, bottles and the like
4. stoppers and caps for bottles

2.1.2 Migration testing

Test conditions: 10 days at 40°C.

Contact at higher temperatures (short-term heating, sterilisation, etc.) in conjunction with long-term storage at room temperature is not included in a separate category because the transitions occurring under these conditions are generally no greater than those determined in the 10-day test at 40°C.

2.2 Category 2

2.2.1 Definition

This category includes commodities that come into contact with the food for a maximum of 24 hours when used as intended.

Examples:

1. hoses for conveying food
2. sealing rings for pressure cookers, hoses for coffee machines
3. lid seals, e.g. for milk cans
4. valve balls

2.2.2 Migration testing

Test conditions: 24 hours at 40 °C

2.2 Category 3

2.3.1 Definition

This category includes consumer articles that come into contact with the food for a maximum of 10 minutes during intended use (short-term contact).

Examples:

1. Liners in milking systems
2. Milking machine hoses
3. Seals for milk processing machines
4. Diaphragms, pistons, fittings and the like

¹ This context can in principle be used to assess whether the test conditions specified in the individual categories cover the worst foreseeable conditions of use.

5. Pump stators
6. Roller covers for greasy food
7. Conveyor belts for fatty foods
8. Gloves, aprons worn during the processing of foodstuffs

2.3.2 Migration testing

Test conditions: 10 minutes at 40 °C

2.4 Category 4

2.4.1 Definition

This category includes commodities which, when used as intended, are only used under such conditions that no transfer to the food is to be expected. This applies in particular if the article only comes into contact with the food at temperatures up to room temperature and only for a very short time and/or only with a very small surface area and cannot be classified in categories 1 to 3.

Examples:

1. Conveyor belts and roller covers for solid foodstuffs, e.g. harvested goods
2. Suction and pressure lines for solid foodstuffs, e.g. for filling and emptying ship tanks, wagons and the like
3. Seals for pipelines, pumps, taps and angle seat valves and the like for liquid foodstuffs

2.4.2 Migration testing

The migration test can be waived.

2.5 Simulants for migration testing

The simulants must represent the substance transfers to food that are to be expected in the worst case. The following can be used:

- deionised water
- 10 % ethanol by volume
- 20 % ethanol by volume
- 3 % acetic acid by weight
- 50 % ethanol by volume
- Poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, Pore size 200 nm
- any vegetable oil with less than 1 % unsaponifiable matter.

2.6 Testing migration from commodities for repeated use

If the material or article is intended to come into repeated contact with foodstuffs, the migration tests shall be carried out three times on the same sample, each time using a different portion of the food (simulant). Conformity shall be checked on the basis of the migration value found in the third test.

If there is conclusive evidence that the migration value does not increase in the second and third tests and the migration benchmarks are not exceeded in the first test, no further testing is required.

2.7 Migration benchmark "not detectable"

If not detectable (NN) is specified for the specific migration benchmark, a detection limit of 0.01 mg substance per kg foodstuff shall apply, unless otherwise specified for an individual substance. For these substances, the material or article must already comply with the specific migration guideline value in the first migration test.

2.8 Migration values for closures

Migration values for caps, gaskets, stoppers and similar closures as well as membranes are expressed in:

- a) mg/kg of food using the actual contents of the container for which the closure is intended, provided that the intended use of the article is known,
- b) mg/item, if the intended use of the item is not known. To estimate a transfer to food, the most unfavorable foreseeable surface-to-volume ratio should be assumed. If such an estimation is not possible, a surface-to-volume ratio of 1 dm²/kg (equivalent to 1 L simulant) is assumed.

3. Substances for the manufacture of commodities from natural and synthetic rubber or from the corresponding latices

Only the substances listed in the Annex to Recommendation XXI and in Table 2 may be added to the raw materials for the manufacture of the finished products. The quantities indicated (calculated on the finished products) must be complied with².

If the starting materials are pre-crosslinked or pre-stabilised with anti-ageing agents, only the substances listed in the Annex to Recommendation XXI and in Table 2 may be added for this purpose.

All substances used shall be considered in their total quantity.

3.1 Starting materials

Rubbers are listed in Table 1.

3.1.1 Solid rubbers

The rubber types listed in Table 1 may be pre-stabilised and/or pre-cured. For this purpose, only the anti-ageing agents listed in the Annex to Recommendation XXI and those listed in Table 2 may be used, in quantities not exceeding 1.5 % in total, or the vulcanising agents listed in these tables (vulcanisation accelerators, accelerator activators and vulcanisation retarders).

² In the case of commodities of non-uniform composition, the term "finished product" is used in this Recommendation to mean the part of the finished commodity consisting of rubber, and this in turn only to the extent that it comes into direct contact with foodstuffs during the foreseeable use of the material and article.

3.1.2 Rubber dispersions (latices)

Dispersions of the rubber types listed in Table 1 may be used as starting materials.

The latices may contain the excipients listed in the respective applicable version of Recommendation XIV (Polymer Dispersions) in the quantities listed therein.

3.2 Monomers, additives, production aids

Within Table 2, columns have been introduced for the individual categories. Based on the assignment, it can be read for each substance for which category it can be used. The use for category 1 (long-term contact) basically also includes the shorter contact of categories 2-4. In these cases, the cells have been linked in Table 2. Conversely, however, substances that are only recommended in categories 2-4 may not be used in consumer articles for prolonged contact. Therefore, in these cases, the cells of the categories for which the substance must not be used have been crossed out.

Article-related restrictions and extensions are to be observed in all categories.

In the manufacture of commodities according to category 4, in addition to the substances listed in the Annex to Recommendation XXI and the substances listed in Table 2, all substances commonly used for the manufacture of technical elastomeric products may be used with the following restrictions:

For conveyor belts and suction lines for conveying e.g. potatoes, beets, vegetables, bananas, unpeeled nuts, grains, as well as for roller covers for dry non-greasy foodstuffs (e.g. rice peeling rollers), soot-containing, abrasion-resistant rubber types may be used, provided that the goods to be transported are subsequently washed, peeled or otherwise cleaned. The abrasion limit according to DIN 53 516 $\leq 225 \text{ mm}^3$ applies as a requirement for these technical compounds.

For seals in pipelines, pumps, taps, angle seat valves and the like for liquid foodstuffs, the carbon blacks must meet the purity requirements specified in Table 1 of the Annex to Recommendation XXI for the use of carbon black as a filler.

Explanations to Tables 1 and 2

Table 1: List of rubbers / latices

Table 2: List of not conclusively evaluated starting materials, additives and production aids

For the rubbers and latices listed in Table 1, only the substances listed in Table 2 and in Table 1 of the Annex to Recommendation XXI may be used as starting materials (monomers).

FCM substance no.: Identification number of the substance according to the Regulation (EU) No 10/2011

CAS No.: Registration number of the Chemical Abstracts Service (CAS)
If CAS numbers are specified, only substances with the specified CAS numbers may be used.

Rubbers can be used alone or in combination.

The rubbers listed in Table 1 can also be used in combination with copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids as well as their salts and esters, provided

they comply with sections A and B of the current version of Recommendation XXXV³. Nitrile rubber can also be used in combination with polyvinyl chloride homopolymer, provided it complies with the current version of Recommendation II⁴. In both cases, the proportion of rubber in the mixture must be predominant. Products manufactured in this way are to be regulated in future in Recommendation XXI/3.

³ Recommendation XXXV: "Mixed polymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their salts and esters"

⁴ Recommendation II: "Plasticizer-free polyvinyl chloride, plasticizer-free copolymers of vinyl chloride and mixtures of these polymers with other copolymers and chlorinated polyolefins containing mainly vinyl chloride in the total mixture"

Table 1: List of rubbers / latices

Table 1. Rubbers / latices			
FCM substance no.	Chemical name	Comments	Requirements/restrictions
	Copolymer of ethene and propene (EPM)		
	Mixed polymers of butadiene and acrylonitrile (nitrile rubber) (NBR)		
	Mixed polymers of butadiene and styrene (SBR)	Also in the form of sequence polymers. These may contain lithium salts, based on lithium up to 100 mg/kg.	
	Interpolymers of isobutene and isoprene (butyl rubber) (IIR)		Insofar as they comply with recommendation XX "Polyisobutylene, isobutylene copolymers and mixtures of polyisobutylene with other polymers".
574	Natural rubber (NR) and latices, including all polyisoprenes from natural sources	Light-coloured, non-smoked varieties.	Where pre-cross-linked rubber is used, the quantity used shall be limited so that the total permitted quantity of additives and processing aids as set out in the Annex to Recommendation XXI and Table 2 of this Recommendation is not exceeded; where 2-mercaptobenzothiazole is used, the inherent flavour of this compound shall be taken into account. p-Nitrophenol, boric acid and pentachlorophenol sodium shall not be present. Natural latex may be stabilised with ammonia and additionally with zinc or sodium dialkyldithiocarbamate and tetramethyl or tetraethylthiuram disulphide and zinc oxide. Hydroxylamine shall not be detectable in the finished product. Testing for these substances shall be carried out in accordance with sections 2.3.1, 3.7, 3.8 and 3.9 of the publication referred to in footnote ⁵ .
	Polymers of butadiene (polybutadiene) (BR)		
	Polymers of isoprene (polyisoprene) (IR)		
	Quatropolymer of ethene, propene, dicyclopentadiene and ethylidene norbornene (EPDM)		
	Terpolymer of ethene, propene and dicyclopentadiene (EPDM)		
	Terpolymer of ethene, propene and ethylidene norbornene (EPDM)		

⁵ Franck, R., Kunststoffe im Lebensmittelverkehr. Cologne: Carl Heymanns Verlag - loose-leaf edition, Part B II XXI: Investigation of consumer goods made of rubber, ISBN: 978-3-452-16045-4. Other validated analytical methods can also be used to check the guideline values.

Table 2: Not conclusively evaluated raw materials, additives and processing aids

For the use levels of the substances listed in Table 2, in addition to the limits specified in the category columns, sum use limits shall apply to each of the substances marked (1), (2), (3), (4) or (5)⁶:

- (1) total max. 1.2 %
- (2) total max. 3.0 %
- (3) total max. 0.05 %
- (4) total max. 1.0 %
- (5) total max. 1.0 %.

Starting materials (monomers)						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0000077-73-6	Dicyclopentadiene					
Vulcanisation accelerator						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0000137-30-4	Zinc-(N-N-dimethyl-dithiocarbamate)		(1) (2)			
0014324-55-1	Zinc-(N-N-diethyl-dithiocarbamate)		(1) (2)			
0000136-23-2	Zinc-(N-N-dibutyl-dithiocarbamate)		(1) (2)			
0084604-96-6	Zinc-N-diisononyl-dithiocarbamate		Max. 0.5 % (1) (2)			
0014634-93-6	Zinc-N-ethylphenyl-dithiocarbamate		Max. 0.4 % (1) (2)			
0000097-74-5	Tetramethylthiuram monosulphide		(1) (2)			
0014726-36-4	Zinc dibenzyl-dithiocarbamate		Max. 0.5 % (1) (2)			The following guideline value for the release of zinc dibenzyl-dithiocarbamate must be observed in consumer articles according to categories 1 - 4: 0.1 mg/kg elastomer content.
0000137-26-8	Tetramethylthiuram disulphide		(2)			Maximum transfer into food or food simulant: 0.6 mg/kg
0000097-77-8	Tetraethylthiuram disulphide		(2)			Maximum transfer into food or food simulant: 0.6 mg/kg
0053880-86-7 0010591-84-1	Dimethyldiphenylthiuram disulphide		(2)			
0000120-54-7	Dipentamethylenethiuram tetrasulphide		(2)			

⁶ If several limitations are assigned to a substance, all of them must be observed. Zinc-N-diisononyl-dithiocarbamate e.g. may be used up to a maximum of 0.5 %. If other substances of group (1) are used, their sum must not exceed 1.2 %. If substances of group (2) are also used, their sum must not exceed 3 %.

0023847-08-7	Caprolactam disulphide	Max. 1.0 % (2)	Consumer articles manufactured using caprolactam disulphide must be washed at 90 °C for 1 hour. Regulation (EU) No 10/2011 sets a SML of 15 mg/kg for caprolactam.
--------------	------------------------	----------------	--

Vulcanisation accelerator (continued)						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0025155-25-3	Bis(tert-butylperoxy-isopropyl)-benzol			höchstens 1,5 %		Auf der Oberfläche des Fertigerzeugnisses darf die genannte Verbindung nicht nachweisbar sein.
0000102-06-7	Diphenylguanidin			höchstens 0,3 %		
0000149-30-4	2-Mercaptobenzothiazole	(4)		(4) (5)		Maximum transfer of 2-mercaptobenzothiazole into food or food simulant: 2 mg/kg
0000120-78-5	Dibenzothiazyl disulphide	(4)		(5)		
0000155-04-4	Zinc-2-mercaptobenzothiazole			(5)		
Accelerator activators						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0001314-22-3	Zinc peroxide					The total transfer of zinc according to 4.2 of this recommendation must be observed.
Anti-ageing agent						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
7786-17-6 17201-15-9	Mixture of 2,2'-methylene-bis-(4-methyl-6-nonylphenol), about 2 parts, and 2,6-bis-(2-hydroxy-3-nonyl-5-methylbenzyl)-p-cresol, about 1 part.	Not more than 0.3 % of the mixture (6)				Consumer goods in the manufacture of which these anti-ageing agents are used must not come into contact with fatty foods.
0033145-10-7	Bis(3,5-dimethyl-2-oxyphenyl)-isobutane	(6)				
0068442-68-2	Diphenylamine, styrolised	(6)				Consumer goods in the manufacture of which these anti-ageing agents are used must not come into contact with fatty foods.
0000793-24-8	N-phenyl-N'-(1,3-dimethylbutyl)-p-phenylenediamine			Max. 1.5 %		Test see 4.9
0000077-61-2	2- α -Methylcyclohexyl-4,6-dimethylphenol			Max. 1 %		
063231-60-7	Microcrystalline waxes	Max. 3.0% in the finished product				Antioxidants may also be used in mixtures with hard paraffins and micro-crystalline waxes, provided that they comply with Part I, Sections A, B and C of the current version of Recommendation XXV.
008002-74-2	Paraffine					

Processing aids						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
	Polyethylene glycol, fatty alkyl ether	maximum 2.0 %				Limitation together with polyethylene glycol
0009006-24-0	Xylene formaldehyde resins					see 4.8 of this Recommendation
024969-11-7	Resorcinol-formaldehyde resins	maximum 5.0 %				only as an adhesion promoter, see 4.8 of this Recommendation
0068153-37-7	Rapeseed oil, sulphurized	maximum 20.0 %				Only natural and/or hydrogenated fats and oils of vegetable origin, but not blown oils and fats, may be used as raw materials for the production of factice. Only aliphatic or cycloaliphatic secondary amines may be used as factice regulators. The factoring regulators must be fully converted. The test for secondary aliphatic and cycloaliphatic amines shall be carried out in accordance with section 2.5.2.2.5 of the publication referred to in footnote 5 of Table 1. Other factice additives must comply with this Recommendation in terms of type and quantity.
0068153-36-6	Rapeseed oil, chlorosulphurized					
0070025-20-6	Rapeseed oil, chlorosulphurized, magnesium salt					
0070025-21-7	Rapeseed oil, reaction products with hydrogen sulphide and sulphur					
0068952-47-6	Rapeseed oil, polymer with soybean oil, sulphur cross-linked					
0068604-22-8	Rhizinus oil, sulphurized					
0068152-90-9	Soybean oil, sulphurized					
0070025-27-3	Soybean oil, chlorosulphurized, magnesium salt					
Protective colloids, thickening and softening agents (only for latices)						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0009003-19-4	Polyvinyl ether					According to Recommendation XVI "Polyvinyl ether"; only for Latices
Emulsifiers and dispersants (only for latices)						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0104376-75-2	Distyrylphenol, ethoxylated					
0068130-72-3	Benzylated hydroxybiphenyl, ethoxylated					
0009084-06-4	Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt					see 4.8 of this Recommendation
Precipitating agent (only for latexes and rubber dispersions)						
CAS No.	Chemical name	Category 1	Category 2	Category 3	Category 4	Requirements/restrictions
0009003-09-2	Polyvinyl methyl ether					
0067762-90-7 0068957-00-6 0063148-62-9	Organopolysiloxanes with methyl groups, ethoxylated and/or propoxylated					insofar as they correspond to Section I of the applicable version of Recommendation XV "Silicones", viscosity at 20 °C approx. 97 mPa · s

Finished products

In addition to the requirements and specifications already mentioned in the individual sections, the commodities (articles and materials) must comply with the following further requirements:

- 4.1 The total migration of substances from commodities in categories 1, 2 and 3 of this Recommendation into food simulants shall not exceed 10 mg/dm² of the commodity.⁷
For caps, seals, stoppers and similar closures as well as membranes, a value of 60 mg/dm² applies. For latex disposable gloves, a value of 30 mg/dm² applies when tested in 3 % acetic acid, of which a maximum of 10 mg/dm² is organic content. The test is carried out in accordance with section 4.5.3 of the publication cited in footnote 5.
- 4.2 The total transfer of zinc from finished products of categories 1, 2 and 3 shall not exceed 25 mg/kg food or food simulant.
- 4.3 The total transfer of aluminium from finished products of categories 1, 2 and 3 shall not exceed 1 mg/kg food or food simulant.
- 4.4 A transfer of lead from finished products of category 1, 2 and 3 shall not be detectable with a detection limit of 0.01 mg/kg food or food simulant. The test shall be carried out in the first migration.
- 4.5 For consumer articles according to categories 1, 2 and 3 of this recommendation, the release of *N-nitrosamines* must not be detectable with a sum detection limit of 1 µg/dm² elastomer. The testing of the articles has to be carried out under the time and temperature conditions specified for the respective categories. Testing with deionised water must not be omitted. The test shall be carried out in the first migration.
- 4.6 For consumer goods of categories 1, 2 and 3, the following also applies:
The extracts prepared according to the test specification⁸ shall not contain primary aromatic amines classified as carcinogenic substances of categories 1A and 1B according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures in a detectable amount. The detection limit is 0.002 mg/l. In total, primary aromatic amines must not be detectable above 0.01 mg/l. Testing with deionised water shall not be waived. The test shall be carried out in the first migration.
The amount of secondary N-alkyl-arylamines shall not exceed 0.25 mg/l in total.
- 4.7 For the release of secondary aliphatic and cycloaliphatic amines from consumer articles of categories 1 - 3, a guide value of 5 mg/dm² applies.
- 4.8 The total transfer of formaldehyde from finished products of categories 1, 2 and 3 must not exceed 6 mg/kg food or food simulant.

⁷ Tests have shown that 50 % ethanol by volume may be an overestimating simulant for milk in contact with rubber. It is therefore not mandatory to use it for milk with regard to the total migration test.

⁸ The examination shall be conducted in accordance with Section 4 of the publication indicated in footnote 5 of Table 1.

4.9 By way of derogation from the publication referred to in footnote⁹, the components of milking installations shall be pre-treated as follows before the migration and sensory test is carried out:

1. rinse with tap water for 5 minutes
2. fill with a tempered cleaning solution (75 °C), allow to cool for 10 minutes at room temperature and pour out.
3. rinse with tap water for 10 minutes

For the 2nd step of sample pre-treatment, use an aqueous 0.25 wt.% nitric acid as cleaning solution. For teat rubbers, the rinsing processes shall be carried out according to Fig. 2 (see publication footnote⁹) to avoid rinsing shadows.

The time between pre-treatment and migration test is 60 ± 10 minutes.

The transfer of primary aromatic amines shall not exceed 0.05 mg/l for the entire cluster.

After contact with milk or water at 40 °C for 10 minutes, the content of N-phenyl-N'-(1,3-dimethylbutyl)-p-phenylenediamine in these liquids must not exceed 0.3 mg/l¹⁰.

4.10 Some of the substances listed in this Recommendation may cause an antimicrobial effect in the finished product. However, no substances, including those listed in the Recommendation, may be used in articles in accordance with this Recommendation for the purpose of intentionally imparting antimicrobial activity to finished articles.

4.11 In order to prevent the risk of allergies, the soluble protein content of materials and articles made of natural rubber materials in accordance with this Recommendation, which may also come into contact with the skin, shall be reduced to a minimum. In the case of products manufactured from natural rubber latex, the materials and articles or their packaging shall bear a statement to the effect that the product is manufactured using natural rubber latex which may cause allergies. In the case of products made of natural rubber, the materials and articles or their packaging shall bear the indication that the product has been manufactured using natural rubber.

⁹ 62nd Communication regarding "Untersuchung von Kunststoffen, sowie sie als Bedarfsgegenstände im Sinne des Lebensmittel-, Bedarfsgegenstände und Futtermittelgesetzbuches verwendet werden", Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 50 (2007) 524.

¹⁰ The test shall be carried out in accordance with sections 6.1.1, 6.2.2 and 6.2.3. of the publication indicated in footnote 5 to table 1.