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XXI. Commodities based on Natural and Synthetic Rubber

As of 01.07.2016

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1. Preamble

There are no objections to the use of rubber in the manufacture of commodities in the sense of § 2, Para. 6, No. 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch (LFGB)), provided they are suitable for their intended purpose and comply with the conditions described below. The same applies for commodities in the sense of § 2, Para. 6, No. 3, 5 and 6 of the aforementioned Act, which are dealt with in a special section (Special category) of this Recommendation.

The majority of food-contact commodities made of rubber do not come into contact with foodstuffs over their entire surface or over an extended period of time, but usually only with a part of their surface and for just a limited period of time. This must be taken into account when evaluating a particular commodity, and test conditions for determining migration chosen accordingly. Based on their different conditions of use and contact with food in practice, rubber articles are divided into four categories, plus a special category:

Prolonged contact

Medium contact

Short contact

Insignificant contact.

Commodities intended, or can be expected, to be put in the mouth are placed in a special category.

In order to illustrate the various categories, a number of commodities are given as examples. Commodities that come into contact with foodstuffs for different periods of time, depending on their particular use, are placed in the category with the longest contact time¹.

Specific test conditions are allocated to each category. If the actual conditions of use differ significantly from the test conditions, these are to be adapted according to the practical use. The choice of test foodstuff for determining migration is made under the same considerations as when testing other polymers². In particular cases testing may be carried out with the foodstuff itself.

Test conditions for contact at elevated temperatures (short-time heat treatment, sterilisation, etc.) are not included in a separate category, because global migration determined under these conditions is generally no greater than migration determined in a 10-day test at 40 °C. Thus, determination of global migration need not be carried out under conditions of short contact at high temperatures, but can be conducted under conditions of extended contact at room temperature (10 days at 40 °C). Migration values are usually given in mg/dm², but in

¹ This does not exclude the possibility of test conditions being based on the conditions of actual use. This is valid for particular cases (e.g. arbitrary tests) in which the actual contact time differs considerably from that specified for the classification in an individual category.

² Amtliche Sammlung von Untersuchungsverfahren nach § 64 LFGB, B. 80.30-1 bis 3

special cases³ also in ppm. The limits for global migration given for the individual categories in mg/dm² must, however, always be complied with. For the determination of both global and specific migration the following test conditions apply:

Commodities belonging to

Category 1:	10 days at 40 °C
Category 2:	24 hours at 40 °C
Category 3:	10 minutes at 40 °C
Category 4:	-
Special category:	24 hours at 40 °C

The limits for global migration are given in the relevant sections on the individual categories.

2. Substances used in manufacturing commodities made of rubber

The recommended polymers (starting substances) and additives are listed in the individual categories. Category 1 substances are included in the basic list, which are referred to in the other categories. For Category 1, only substances included in the basic list may be used, while for Categories 2 - 4 the list is supplemented with additional substances.

Restrictions and additions applicable to particular commodities are to be taken into account in all categories.

2.1 Category 1

2.1.1 Definition:

This category contains commodities (articles and materials) which as a result of their intended use come into contact with foodstuffs for periods of between 24 hours and up to several months.

Examples:

1. Storage containers
2. Container linings
3. Large-area seals
4. Sealing rings for cans, jars, bottles and the like

2.1.2 Migration:

Test period for migration:

10 days at 40 °C.

Limits for global migration:

Distilled water: max. 50 mg/dm²

10 % vol. ethyl alcohol: max. 50 mg/dm²

3 % wt. acetic acid: max. 150 mg/dm², of which max. 50 mg/dm² organic components⁴

The limit for global migration in test fat will be announced at a later date.

³ When small surface areas come into contact with large amounts of foodstuffs, migration values in mg/dm² based on the prescribed test procedure would represent an incorrect basis for the evaluation. In such cases, in order to obtain a closer correlation with actual conditions, it is better to give the value for migration in ppm, based on the actual exposed area and the amount of foodstuffs coming into contact with it.

⁴ Max-von-Pettenkofer-Institut des Bundesgesundheitsamtes (Hrsg.), 1978. 4.5.3 Bestimmung der Globalmigration in 3gew.%ige Essigsäure mit anschließender Isolierung organischer Anteile. In: Ostromow, H., Hofmann, W.: Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 25 (MvP-Berichte; 2/78)

2.1.3 Basic list of substances used

2.1.3.1 Solid rubber

2.1.3.1.1 Starting materials

The following starting materials may be used:

2.1.3.1.1.1. Natural rubber; light-coloured, non-smoked sorts⁵.

2.1.3.1.1.2 Pre-cured, natural rubber, as well as graft polymers of natural rubber with acrylic and/or methacrylic acid esters of monohydric alcohols, C₁-C₄⁵.

The amount of pre-cured rubber used is to be limited so that the total amount of substances permitted under 2.1.3.1.2 of this basic list is not exceeded; if 2-mercaptobenzothiazole is used, its specific taste needs to be taken into account.

2.1.3.1.1.3 Polymers of butadiene⁶ and isoprene.

2.1.3.1.1.4 Polymers and copolymers of mono- and dichlorobutadiene, where appropriate with styrene or acrylonitrile⁶ (chloroprene rubber).

2.1.3.1.1.5 Copolymers of butadiene⁶ or isoprene and styrene, also in the form of sequential polymers (the latter may contain lithium salts with up to 100 mg lithium/kg) and/or acrylonitrile⁶ (nitrile rubber) and/or divinyl benzene⁶ and/or 5 - 8 % acrylic or methacrylic acid.

Blend of sequential polymers of butadiene⁶ or isoprene and styrene or of hydrogenated sequential polymers of butadiene⁶ and styrene with no more than 50 % liquid paraffins and in combination with polymers that comply with Recommendation III for polyethylene, V for polystyrene, VI for styrene copolymers and VII for polypropylene, in total, max. 20 %

Additives:

Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.25 %

1,3,5-Trimethyl-2,4,6-tris-(3,5-di-tert-butyl-4-hydroxy-benzyl)benzene, max. 0.3 %

Tris(2,4-di-tert-butyl-phenyl)phosphite, max. 0.2 %

Thio-bis-(dodecylpropionate), max. 0.25 %

Erucamide, max. 0.1 %

2,4-Bis-dodecylthiomethyl-6-methylphenol, max. 0.3 %

As catalyst 1,2-Diethoxypropane, max. 0.08 %, may be used.

No contact with fat or foodstuffs in which fat forms the external phase.

2.1.3.1.1.6 Copolymers of isobutylene and isoprene (butyl rubber), provided they comply with amended Recommendation XX⁷.

2.1.3.1.1.7 Copolymers of ethylene and α -olefins of chain length C₃-C₄ and/or acyclic (e.g. 1,4-hexadiene) or cyclic (e.g. dicyclopentadiene, alkenyl norbornenes, cyclo-octadiene) monomers (so-called ethylene-propylene rubber).

2.1.3.1.1.8 Chlorosulfonated polyethylene, but only for rubberised textiles and linings.

Methanol extract from the chlorosulfonated polyethylene must not exceed 2.0 %⁸.

The aforementioned starting materials may be used on their own or in combination with copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, as well as with their salts and esters, provided they comply with Sections A and B of amended Recommendation XXXV⁹. Nitrile rubber may also be used in combination with polyvinyl chloride

⁵ They must contain no p-nitrophenol, boric acid or sodium salt of pentachlorophenol; hydroxylamine must not be detectable in the finished product. Testing for these substances is conducted in accordance with sections 2.3.1, 3.7, 3.8 and 3.9 of the methods for "Testing commodities made of rubber", see. Part B II, XXI.

⁶ For their use the specific limits laid down in the Commission Regulation (EU) No 10/2011 apply.

⁷ Butyl rubber, see Recommendation XX. "Polyisobutylene copolymers and mixtures of polyisobutylene with other polymers"

⁸ These requirements serve to ensure sufficiently high qualities of natural and synthetic rubber. Testing is conducted in accordance with Sections 2.1 and 2.2 of methods, see. Part 1. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78)

homopolymer, provided it complies with the amended Recommendation II¹⁰. In both cases the rubber content must predominate.

Commodities (articles or materials) made from copolymers of butadiene or isoprene and styrene in the form of sequential polymers (see 2.1.3.1.1.5) and classified in Category 1 must not come into contact with foodstuffs in which fat forms the external phase. They may be used in combination with polymers that comply with Recommendation III for polyethylene, VI for styrene co- and graft polymers, and VII for polypropylene. However, these blends must not contain more than 15 % of the aforementioned sequential polymers when they come into contact with foodstuffs in which fat forms the external phase.

The starting materials can be pre-stabilised and/or pre-cured. Only the antioxidants listed under 2.1.3.1.2.3 (in total, max 1.5 %) and the vulcanising agents listed under 2.1.3.1.2.2 of the basic list may be used for this purpose.

The acetone extract of natural rubber must not exceed 3.5 %, while the methanol extract of grafted natural rubber or of synthetic rubber types must not exceed 8.0 %⁸.

2.1.3.1.2 Additives, processing aids

In the manufacture of finished products only the following substances and in the given maximum amounts (based on the finished product)¹¹, may be added to the starting materials, including any that are pre-stabilised. When pre-cured or grafted rubber is used the amounts of additives already contained in these must also be taken into account.

2.1.3.1.2.1 Fillers

Carbon black¹², graphite, but only for linings; for rubberised materials for silos and flexible containers for powdered foodstuffs only acetylene carbon black.

Other fillers in compliance with Recommendation LII¹³.

2.1.3.1.2.2 Vulcanising aids

2.1.3.1.2.2.1 Vulcanising agents

Sulfur

⁹ Ethylene-vinylacetate rubber: compare Recommendation XXXV. "Copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, as well as their salts and esters"

¹⁰ Recommendation II. "Plasticizer-free polyvinyl chloride,"

¹¹ In the present Recommendation, when applied to commodities of non-homogeneous composition, "finished product" refers only to the part made of rubber which, and to the extent, during normal use is expected to come into direct contact with foodstuffs.

¹² The carbon blacks used must comply with the "Purity requirements for carbon blacks" laid down in Communication 82 of Bundesgesundheitsblatt, 15 (1972) 268. Acetylene black must comply with DAB purity requirements for medical grade carbon.

¹³ Compare Recommendation LII "Fillers"

2.1.3.1.2.2.2 Vulcanising accelerators

2.1.3.1.2.2.2.1 Accelerators

o-Tolylbiguanide, max. 1.0 %

Zinc-N-dialkyl-dithiocarbamates¹⁴or zinc-N-ethylphenyldithiocarbamate,
max. 0.4 %

Tetramethylthiuram monosulfide

Zincdibenzoyldithiocarbamate, max. 0.5 %^{16, 17}
 } in total
 max.
 1.2 %¹⁵

 } in total max.
 3.0 % zinc content
 according to 3.1
 of this Recommendation

Tetramethylthiuram disulfide

Tetraethylthiuram disulfide

Dimethyldiphenylthiuram disulfide

Dipentamethylene thiuram tetrasulfide

Caprolactam disulfide¹⁹, max. 1.0 %
 } in total
 max.
 3.0 %¹⁸

2.1.3.1.2.2.2.2 Secondary accelerators:

2-Mercaptobenzothiazole

Dibenzothiazyl disulfide

 } in total
 max. 0.05 %

2.1.3.1.2.2.2.3 Surface hardeners:

Pentamethylene-ammonium-N-pentamethylene-dithiocarbamate

Cyclohexylethylamine

These both substances must not be detectable in the finished product.²⁰

Dibutylamine

2.1.3.1.2.2.2.4 Vulcanisation retarders:

Phthalic anhydride, max. 0.5 %

Benzoic acid, max. 1.0 %

Stearic acid, max. 1.5 %

} in total max. 2.5 %

2.1.3.1.2.2.2.5 Accelerator activators:

Zinc oxide

Zinc carbonate

Zinc stearate

Zinc peroxid

 } zinc content acc. to 3.1 of
 this Recommendation

¹⁴ Here "alkyl" refers to methyl, ethyl, butyl and pentamethylene groups.

¹⁵ According to available test results, it can be expected that, under the conditions of this Recommendation, no more than traces of zinc dithiocarbamates or their decomposition products, which are harmless to human health, transfer to foodstuffs.

¹⁶ See 3.5.

¹⁷ The requirements laid down in Annex 4 of the Commodities Regulation (Bedarfsgegenständeverordnung) apply to the release of N-nitrosamines and N-nitrosable substances that derive from these accelerators.

¹⁸ This dosage is necessary for the production of heat-resistant vulcanisates.

¹⁹ For the release of ϵ -caprolactam, a limit of 100 mg/kg elastomer must not be exceeded. Commodities manufactured using caprolactam disulfide must be washed for one hour at 90 °C.

²⁰ Testing is conducted in accordance with Section 2.5.2.2.6 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78)

2.1.3.1.2.3 Anti-aging agents:

- 2,2'-Methylene bis(4-methyl-6-cyclohexylphenol)
- 2,2'-Methylene bis[4-methyl-6-(α -methylcyclohexyl)-phenol]
- 2,2'-Methylene bis(4-methyl-6-tert-butylphenol)
- Bis(3,5-dimethyl-2-oxyphenyl)-isobutane
- Phenol and/or methylphenols, converted with styrene or α -methylstyrene and/or olefins of chain length C₃-C₁₂
- 2,6-Di-tert-butyl-4-methyl-phenol
- Tris(nonylphenyl)phosphite²¹, i.e., tris(mono-nonylphenyl)-phosphite, also mixed with tris(di-nonylphenyl)-phosphite
- 2,4-Di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxy-phenyl)-ethyl]phenylacrylate, max. 0.5 %
- Mixture of 2,2'-methylene bis(4-methyl-6-nonyl-phenol), approx. 2 parts, and 2,6-bis(2-hydroxy-3-nonyl-5-methylbenzyl)-p-cresol, approx. 1 part, max. 0.3 % of the mixture²²
- Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.25 %²²
- 2,4-Bis-n-octylthio-6(4'-hydroxy-3',5'-ditert-butyl-anilino)-1,3,5-triazine, max. 0.2 %²³
- 2,4-Bis(octylthiomethyl)-6-methylphenol, max. 0.5 %²⁴
- 2-tert-Butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)4-methylphenyl acrylate, max. 0.5 %²²
- Styrenated diphenylamine²²
- Tris(2,4-ditert-butylphenyl)-phosphite, max. 0.4 %²²
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate⁶
- Reaction product of 4-methylphenol with isobutylene and dicyclopentadiene, max. 1.4 %
- 2,4-Bis-dodecylthiomethyl-6-methylphenol, max. 0.5 %

in total
max. 1 %

Commodities manufactured using this anti-aging agent must not come into contact with fatty foodstuffs.

For ethylene-propylene rubber acc. to 2.1.3.1.1.7 of the basic list for Category 1 of this Recommendation, only the following anti-aging agents may be used:

- 4,4'-Thio-bis(3-methyl-6-tert-butyl-phenol), max. 0.25 %
- Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.2 %

However, these anti-aging agents must not be used in products made of ethylene-propylene rubber expected to come into contact with foodstuffs in which fat forms the external phase.

Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate⁶.

Antioxidants may also be used in mixtures containing hard paraffins and microcrystalline waxes, provide these comply with Part I, Sections A, B and C of amended Recommendation XXV²⁵ and provided the content of hard paraffins and microcrystalline waxes in the finished products does not exceed 3.0 %.

²¹ Purity requirements for tris(nonylphenyl)phosphite, see 76th Communication on the "Evaluation of plastics in respect to health, within the framework of the Food and Other Commodities Act ", Bundesgesundheitsblatt, 15 (1972) 139

²² Commodities manufactured using this antioxidant must not come into contact with fatty foodstuffs.

²³ Suitable for contact with fatty foodstuffs; no more than 0.5 % of this antioxidant may be used in commodities which do not come into contact with fatty foodstuffs.

²⁴ When this antioxidant is used, contact with fatty foodstuffs is only permitted for commodities made from acrylonitrile-butadiene rubber.

²⁵ Recommendation XXV. "Hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics"

2.1.3.1.2.4 Processing aids:

Zinc salt of pentachlorothiophenol, max. 0.3 %
 Zinc salts of saturated and/or unsaturated high-molecular fatty acids (chain length mainly over C₁₇, but not below C₁₄), max. 3.0 %
 Colophony, max. 2.0 %
 Polyethylene glycols²⁶ and their fatty alkyl ethers, max. 2.0 %
 Urea, max. 3.0 %

} zinc content acc. to 3.1 of this Recommendation

Xylene-formaldehyde resins (comp. 3.3.3 of this Recomm.)
 Liquid paraffins²⁷
 Palm kernel oil
 Lecithins, whose peroxide value does not exceed 10

} in total max. 5.0 %, incl. any paraffin oils contained in factice

Melamine-resorcinol-formaldehyde resins and resorcinol-formaldehyde resins (compare 3.4.3 of this Recommendation), as adhesion promoter, only, max. 5.0 %

Palmitic acid, max. 1.5 %

Factice²⁸, max. 20 %

provide that the following conditions are met:

In the production of factice, only natural and/or hydrogenated fats and oils of vegetable and/or animal origin, but no blown fats or oils, may be used as raw materials.

Only aliphatic or cycloaliphatic secondary amines may be used as regulator in the production of factice. The regulators must be completely reacted²⁹.

Other factice additives and the amounts used must comply with this Recommendation.

Regenerated rubber, provided its composition complies with this Recommendation.

Glycerol

Glycerol, esters with stearic acid

Acids, fatty (C₈-C₂₂), esters with pentaerythritol⁶

2.1.3.1.2.5 Slip agents and mould release agents:

Silicone oils (organopolysiloxanes), provided they comply with Section I of amended Recommendation XV³⁰.

Zinc stearate; zinc content of the finished product must comply with 3.1 of this Recommendation

Sodium and/or potassium salts of fatty acids of chain length C₁₂-C₂₀

Alkyl sulfonates

Methyl cellulose

Polyethylene glycol²⁶

Polypropylene glycol

Bis-stearoyl-ethylenediamine, max. 0.2 %, only for butadiene-styrene sequence polymers

Acids, fatty (C₈-C₂₂), esters with pentaerythritol⁶

²⁶ Polyethylene glycol may contain no more than 0.2 % monoethylene glycol. For method of determination see Communication 28 on the testing of plastics in Bundesgesundheitsblatt, 16 (1973) 362.

²⁷ The liquid paraffins used must comply with the purity requirements laid down in the Regulation on Food Additives (Zusatzstoffverkehrsverordnung). Testing for carcinogenic polycyclic hydrocarbons is conducted as prescribed in the 38th Communication on the testing of plastics (see Bundesgesundheitsblatt, 19 (1976) 231). Liquid paraffin, refined by hydrogenation, may also be used, provided it complies with the aforementioned purity requirements.

²⁸ Factice: unsaturated vegetable or animal oils reacted with sulfur, disulfur dichloride or hydrogen sulfide.

²⁹ Testing for secondary aliphatic and cycloaliphatic amines is conducted in compliance with Section 2.5.2.2.5 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 20 (MvP-Berichte; 2/78)

³⁰ Recommendation XV. "Silicones"

2.1.3.1.2.6 Organic and inorganic pigments, provided they do not transfer to foodstuffs³¹

2.1.3.2 Latexes and rubber dispersions

2.1.3.2.1 Starting materials:

As starting materials may be used latexes and dispersions of the rubber types listed under 2.1.3.1.1, as well as rubber types containing up to 15 % free carboxyl groups and acrylic and/or methacrylic esters of monohydric aliphatic alcohols C₁-C₄.

Natural latex may be stabilised with ammonia and additionally with zinc or sodium dialkyldithiocarbamate and tetramethyl or tetraethyl thiuram disulfide and zinc oxide.

Latexes preserved with boric acid and sodium pentachlorophenol may not be used³².

The acetone extract from dried (not precipitated) natural latex must not exceed 3.5 %³³. The methanol extract from dried (not precipitated), grafted, natural rubber latex and from synthetic rubber latexes must not exceed 8 %⁸. The KOH number³⁴ of natural rubber latex must not exceed 0.7 %. The natural rubber latex must not contain more volatile fatty acids than correspond with a VFA number of 0.2³⁵.

The finished products manufactured from natural latex must contain no hydroxyl amine³⁶.

The synthetic latexes and dispersions included in this basic list may contain the additives, in the maximum amounts given³⁷, permitted in accordance with amended Recommendation XIV³⁸.

2.1.3.2.2 Additives, processing aids:

Unless otherwise stated, finished products¹¹ may contain only the following processing aids, or their conversion products, in the maximum amounts given (in weight percent based on the finished product).

2.1.3.2.2.1 Fillers

as specified under 2.1.3.1.2.1.

2.1.3.2.2.2 Vulcanising aids:

in addition to those listed under 2.1.3.1.2.2, the following accelerators are permitted:

Sodium dialkyl dithiocarbamates³⁹

Sodium ethylphenyl dithiocarbamates
(in total max. 0.4 %)

Sodium alkyl xanthogenates³⁹

Zinc alkyl xanthogenates

} in total max. 1.2 %,
zinc content acc. to 3.1 of
this Recommendation

³¹ Recommendation IX. "Colorants for plastics and other polymers used in commodities".

³² Testing for boric acid is conducted according to section 3.7, testing for sodium pentachlorophenol according to section 3.8 of the methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78)

³³ Drying the latex is conducted according to ISO 124 or DIN 53 563 "Testing of latex - Determination of total solids content". The extraction of dry material with acetone is conducted according to section 5.1.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 26 (MvP-Berichte; 2/78)

³⁴ KOH number refers to the amount of potassium hydroxide (in grams) equivalent to the ammonia bound acids in 100 g of latex dry substance. Thus, the determination of KOH number can only be conducted with natural latex that has been preserved solely with ammonia and formaldehyde. It is carried out according to ISO 127 "Rubber, natural latex concentrate - Determination of KOH number".

³⁵ VFA number (VFA = Volatile Fatty Acid) refers to the amount of potassium hydroxide (in grams) that is equivalent to the volatile fatty acids contained in 100 g of latex dry substance. Determination of VFA number is conducted according to ISO 506 "Rubber latex, natural, concentrate - Determination of volatile fatty acid".

³⁶ Testing for hydroxylamine is conducted according to section 3.9 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 23 (MvP-Berichte; 2/78)

³⁷ These aids are largely removed through washing processes involved in manufacture, and thus do not occur in detectable amounts in finished products.

³⁸ Recommendation XIV "Plastics dispersions".

³⁹ Here "alkyl" refers to methyl, ethyl, isopropyl, butyl and pentamethylene groups.

2.1.3.2.2.3 Anti-aging agents:

in addition to those listed under 2.1.3.1.2.3 the following substances may be used:

2,2-Methylene-bis(4-ethyl-6-tert-butylphenol)

The total amount of antioxidant used must not exceed 1.0 %.

2.1.3.2.2.4 Processing aids:

2.1.3.2.2.4.1 Protective colloids, thickeners and plasticisers:

Methyl, hydroxyethyl and carboxymethyl cellulose

Hydroxyethyl starch

Tragacanth gum

Sodium alginate

Gelatine

Casein

Polyvinyl alcohol (viscosity of 4 % aqueous solution at 20 °C min. 5 mPa · s)

Polyvinyl ether according to Recommendation XVI⁴⁰

Polyvinyl pyrrolidone (viscosity of 5 % aqueous solution at 20 °C 34-38 mPa · s)

Alkali metal salts and amides of polymers of acrylic acid, metacrylic acid, crotonic acid, maleic acid, fumaric acid, itaconic acid, vinylsulfonic acid

Esters of glycerol and pentaerythritol with resin acids of colophony and their hydrogenation products⁴¹

Liquid paraffins²⁷, max. 5.0 %

2.1.3.2.2.4.2 Emulsifying and dispersing agents:

Sodium, potassium and ammonium salts of fatty acids of chain length C₁₂-C₂₀

Alkyl sulfonates of chain length C₁₀-C₂₀

Alkylaryl sulfonates

Alkyl-, alkylaryl- and acyloxethylates and their sulfation products

Alkyl or alkylphenyl polyglycol ether

Condensation products of naphthalene sulfonic acid sodium salt with formaldehyde (compare 3.4.3 of this Recommendation)

Sodium, potassium and ammonium dehydroabietate, hydroabietate and abietate

Sodium dodecyl sulfate

Styrene-maleic acid anhydride-copolymer, sodium salt, residual amount in the finished article max. 100 mg/kg

Polyoxyethylene tridecylether phosphatate, residue in polymer max. 300 mg/kg

Polymers manufactured with this emulsifier must not come into contact with foodstuffs in which fat forms the external phase.

2.1.3.2.2.4.3 Anti-fouling agents:

Potassium sorbate

1,2-Benzisothiazolin-3-one, max. 0.02 %

} in total
max. 0.4 %⁴²

If 1,2-propanediol and dipropylene glycol are used as pasting agents for the last named anti-fouling agent, dispersion films must not contain more than 0.15 mg/dm² of the two substances, in total.

⁴⁰ Recommendation XVI. "Polyvinyl ethers".

⁴¹ The named colophony esters must comply with the purity requirements of the Regulation on Food Additives (Zusatzstoffverkehrs-Verordnung).

⁴² The maximum amount given is based on the latex.

2.1.3.2.2.4.4 Defoaming agents:

Triisobutyl phosphate

Isopropanol

Silicone oils (Organopolysiloxanes), provided they comply with Section I of amended Recommendation XV³⁰

2.1.3.2.2.4.5 Neutralising agents, pH-regulating substances:

Ammonia

Sodium and potassium hydroxide

Sodium and potassium carbonate

Carboxylic acid

Acetic acid

Tartaric acid

Citric acid

2.1.3.2.2.4.6 Precipitating agents:

Aluminium sulfate

Potassium aluminium sulfate (alum)

Ammonium chloride, sulfate, nitrate or acetate

Calcium chloride or nitrate

Polyvinylmethyl ether

Ethoxylated and propoxylated organopolysiloxanes with methyl groups (viscosity at 20 °C approx. 97 mPa · s), provided they comply with Section I of amended Recommendation XV³⁰

2.1.3.2.2.5 Slip and mould release agents:

Polyethyleneglycol²⁶ and/or polypropyleneglycol

Silicone oils (organopolysiloxanes), provided they comply with Section I of amended Recommendation XV³⁰.

2.1.3.2.2.6 Organic and inorganic pigments, provided they do not transfer to foodstuffs³¹.

2.2 Category 2

2.2.1 Definition:

This category contains commodities (articles and materials) that, when used as intended, come into contact with foodstuffs for no more than 24 hours.

Examples:

1. Flexible tubing for conducting foodstuffs
2. Stoppers and caps for bottles
3. Sealing rings for pressure cookers, tubing for coffee machines
4. Lid seals, e.g. for milk churns
5. Valve balls

2.2.2 Migration:

Test period for migration:

24 hours at 40 °C

Limits for global migration:

Distilled water: max. 20 mg/dm²
 10 % vol. ethyl alcohol: max. 20 mg/dm²
 3 % wt. acetic acid: max. 100 mg/dm², of which max. 20 mg/dm² organic components
 The limit for global migration in test fat will be announced at a later date.

2.2.3 Substances which may be used in addition to those in the basic list

The materials named in the basic list under 2.1.3, as well as the maximum concentrations given for them, are also valid for Category 2 commodities. In addition, the following substances may also be used:

Carbon black¹², max. 30 %

Esters of alkyl sulfonic acids (C₁₀-C₂₁) with phenol, but only for chloroprene rubber (2.1.3.1.1.4), nitrile rubber (2.1.3.1.1.5) and ethylene-propylene rubber (2.1.3.1.1.7) in compliance with the basic list of this Recommendation, max. 10.0 %.

Bis-(tert-butylperoxy-isopropyl)-benzene, max. 1.5 %, as cross-linking agent. This substance must not be detectable on the surface of the finished product.

2.3 Category 3

2.3.1 Definition:

This category contains commodities (articles and materials) that, when applied as intended, come into contact with foodstuffs for no more than 10 minutes (short contact).

Examples:

1. Rubbers teats⁴³
 2. Tubing for milking machines⁴³
 3. Seals for milk processing machines
 4. Membranes, plungers, mountings and the like
 5. Pump stators
 6. Roller coatings
 7. Conveyor belts
 8. Gloves, aprons, worn in food processing industry
- } for fatty foodstuffs, in which
} fat forms the external phase

2.3.2 Migration:

Test period for migration:

10 Minutes at 40 °C

Limits for global migration:

Distilled water: max. 10 mg/dm²
 10 % vol. ethyl alcohol: max. 10 mg/dm²
 3 % wt. acetic acid: max. 50 mg/dm², of which max. 10 mg/dm² organic components
 The limit for global migration in test fat will be announced at a later date.

2.3.3 Substances which may be used in addition to those in the basic list

The products named in the basic list under 2.1.3, as well as under 2.2.3, and the maximum concentrations given for them, are also valid for Category 3 commodities. In addition, the following substances, or altered concentrations of already permitted substances, may be used: Carbon black¹², max. 30 %, but only for commodities corresponding to examples No. 1 to 5 under 2.3.1

⁴³ Cleaning instructions are given under 3.4.4.

Cyclohexyl aminoacetate, but only for rubber gloves. The amount added must be limited so that migration is no more than 2 mg per dm² ⁴⁴.

Dibenzothiazyl disulfide, max. 1.0 %, or zinc-2-mercaptobenzothiazole, max. 1.0 %

Diphenylguanidine, max. 0.3 %

N-Phenyl-N'-(1,3-dimethylbutyl)-p-phenylenediamine, max. 1.5 % (test, see under 3.4.4)

2- α -Methylcyclohexyl-4,6-dimethylphenol, max. 1.0 %

Di-2-ethylhexylphthalate, max. 10.0 % or

Di-2-ethylhexyladipate, max. 10.0 %, but only for chloroprene rubber according to 2.1.3.1.1.4, nitrile rubber according to 2.1.3.1.1.5 and ethylene-propylene rubber according to 2.1.3.1.1.7 of the basic list of this Recommendation.

2,4-Bis-dodecylthiomethyl-6-methylphenol, max. 0.5 %.

Di-(2-ethylhexyl) terephthalate⁶

2.4 Category 4

2.4.1 Definition:

In this category are placed all those commodities (articles and materials) whose intended use involves conditions under which no migration into foodstuffs is to be expected. This is particularly the case when the article is in contact with food for just a very short period of time or with a very small part of its surface, and does not belong in Categories 1 to 3.

Examples:

1. Conveyor belts and roller coatings
2. Suction and pressure lines (e.g. for filling and emptying tanker ships and railway tankers)
3. Seals for conduits, pumps, cocks and inclined-seat valves etc. for liquid foodstuffs

2.4.2 Migration:

In respect to migration no requirements are laid down.

2.4.3 Substances which may be used in addition to those in the basic list

In addition to the products included in the basic list (2.1.3), as well as under 2.2.3, and 2.3.3, the following may also be used:

All substances used in the manufacture of technical rubber articles, with the following restrictions:

In conveyor belts and suction lines for transporting potatoes, beets, vegetables, bananas, unshelled nuts, cereals etc., and in roller coatings for dried, non-fatty foodstuffs (e.g. rice polishing rollers), abrasion resistant rubber types containing carbon black may be used, provided that the transported goods are subsequently washed, peeled or otherwise cleaned. The amount of abrasion permitted, in accordance with DIN 53 516, is $\leq 225 \text{ mm}^3$.

For rubber seals in conduits, pumps, cocks, inclined-seat valves and the like, used for liquid foodstuffs, provided that they are fitted in such a way that during normal use they have no contact with the liquid foodstuff, or if they do, only with a very small part of their surface or for a very short period of time, the carbon blacks must comply with the purity requirements (see footnote 12). For other seals, Categories 1 – 3 apply.

⁴⁴ Testing is conducted in compliance with section 8 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 31 (MvP-Berichte; 2/78)

2.5 Special category (commodities in the sense of § 2, Para. 6, No. 3 and 5, and in part also § 2, Para. 6, No. 1 of the Food and Feed Code)

2.5.1 Definition:

Commodities intended for use as eating utensils or which may be expected to be placed in the mouth (e.g. toys), are placed in this special category.

Examples:

1. Toys acc. to Recommendation XLVII^{45, 46}
2. Toy balloons⁴⁶
3. Bottle teats⁴⁶
4. Dummies (pacifiers)⁴⁶
5. Nipple cups
6. Teething rings
7. Gum shields

2.5.2 Migration:

Test period for migration:

24 hours at 40 °C

Limits for global migration:

Examples 1 and 2:

Distilled water: max. 50 mg/dm²

Examples 3 - 7:

Distilled water: max. 20 mg/dm²

2.5.3 List of substances used:

In the manufacture of toys and toy balloons (examples No. 1 and 2), only the substances included in the basic list under 2.1.3 and the substances listed under 2.5.3.1 and 2.5.3.2 may be used. In addition, as plasticizer for toy balloons, the n-butyl esters of a mixture of natural, partially modified, vegetable fatty acids, predominantly of chain lengths C₁₆ and C₁₈, may be used, max. 5.0 %.

In the manufacture of commodities included in examples No. 3 to 7, only the following substances may be used:

2.5.3.1 Starting materials:

Natural rubber; light-coloured, non-smoked, also pre-cured sorts⁵

cis-1,4-Polyisoprene

In addition, natural rubber latex and sequential polymers of butadiene or isoprene and styrene. Latexes containing boric acid and sodium pentachlorophenol as preservatives must not be used⁴⁷.

Mixtures of sequence polymers of butadiene or isoprene and styrene, or of hydrogenated sequence polymers of butadiene and styrene with max. 50 % liquid paraffin²⁷ and in combination with polymers in compliance with Recommendation III for polyethylene, V for polystyrene, VI for styrene copolymers and VII for polypropylene, in total max. 20 %.

Additives:

Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1 %,

Thio-bis-(dodecylpropionate), max. 0.25 %,

⁴⁵ Recommendation XLVII. "Toys made from plastics and other polymers, and from paper and paperboard"

⁴⁶ The release of N-nitrosamines or of substances that can be converted to N-nitrosamines is regulated in Annex 4 and 5, respectively of the Commodities Regulation (Bedarfsgegenständeverordnung).

⁴⁷ Testing for boric acid is conducted according to section 3.7, for the sodium pentachlorophenol according to section 3.8 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78)

Erucamide, max. 0.1 %.

There must be no contact with fat or with foodstuffs in which fat forms the external phase.

2.5.3.2 Additives, processing aids:

2.5.3.2.1 Fillers:

Fillers in compliance with Recommendation LII¹³, section 1, may only be used as follows:

Silicic acid, also silylated⁴⁸

Quartz powder

Silicates or mixed silicates of sodium, potassium, calcium, magnesium and aluminium, but not including asbestos

Oxides or mixed oxides of calcium, magnesium, aluminium and silicon

Hydroxides or mixed hydroxides of calcium, magnesium and aluminium

Carbonates or mixed carbonates of calcium, magnesium and aluminium

These fillers must contain no additives included in section 2 of Recommendation LII; in addition, they must comply with the purity requirements given under section 3. of that Recommendation⁴⁹.

2.5.3.2.2 Vulcanising additives

2.5.3.2.2.1 Vulcanising agent:

Sulfur

2.5.3.2.2.2 Vulcanisation accelerator:

Zinc-N-dialkyl dithiocarbamates^{14, 17}

Zinc-N-ethylphenyl dithiocarbamate, max. 0.4 %¹⁷

Zinc-N-dibenzyl dithiocarbamate, max. 0.5 %¹⁷

Zinc-N-diisononyl dithiocarbamate, max. 0.5 %¹⁷

Tetramethyl thiuram mono and disulfide

Dimethyldiphenyl thiuram disulfide

Dipentamethylene thiuram tetrasulfide

Caprolactam disulfide, max. 1.0 %¹⁹

The amounts added are to be dosed so that no sulfur containing accelerator is detectable in extract from the finished products.⁵⁰

2-Mercaptobenzothiazole⁵¹

2.5.3.2.2.3 Surface hardener:

as under 2.1.3.1.2.2.2.3 of the basic list in this Recommendation

2.5.3.2.2.4 Vulcanisation retarders:

as under 2.1.3.1.2.2.2.4 of the basic list in this Recommendation

2.5.3.2.2.5 Accelerator activators:

as under 2.1.3.1.2.2.2.5 of the basic list in this Recommendation

⁴⁸ The treatment of silicic acids with silylating agents, e.g. dimethyl-dichlorosilane, gives them hydrophobic properties. The starting materials are no longer detectable in the silylated material (detection limit: 100 mg/kg).

⁴⁹ Except for silicic acid in compliance with section 1 of Recommendation LII for bottle teats and dummies (pacifiers) and for nipple cups, fillers are not used.

⁵⁰ Testing is conducted in accordance with section 7.1.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 31 (MvP-Berichte; 2/78)

⁵¹ The content in 2-Mercaptobenzothiazole in commodities must be reduced as far as technically achievable, so that it is detectable in the extract of the finished articles only in technically unavoidable amounts. The Scientific Committee on Food of the EC has expressed an opinion in this respect (SCF/CS/PM/GEN/M83 of 13.11.2000). Concerning the analysis, please note DIN EN 1400-3.

2.5.3.2.3 Anti-aging agents:

Apart from the following exceptions, antioxidants must not be used in the manufacture of bottle teats, dummies (pacifiers) and teething rings:

As pre-stabiliser in synthetic rubber (A):

2,6-Di-tert-butyl-4-methylphenol, max. 1.0 %.

As pre-stabiliser in natural rubber latex (B):

2,2'-Methylene-bis-(4-methyl-6-tert-butylphenol), max. 0.4 %.

Reaction product of 4-methyl phenol with isobutylene and dicyclopentadiene, max. 0.7 %

As stabiliser for copolymers of butadiene, or isoprene and styrene in the form of sequential polymers (C):

1,3,5-Trimethyl-2,4,6-tris-(3,5-ditert-butyl-4-hydroxybenzyl)-benzene, max. 0.3 %.

Reaktion product of 4-methyl phenol with isobutylene and dicyclopentadiene, max. 1.4 %

For A or B or C:

2,4-Bis(octylthiomethyl)-6-methylphenol, max. 1.0 %

For A or C:

2,4-Bis-(n-octylthio)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine, max. 0.2 %

Tris-(2,4-di-tert-butylphenyl)phosphite, max. 0,5 %

2.5.3.2.4 Processing aids:

as under 2.1.3.2.2.4 of the basic list of this Recommendation

Zinc salt of pentachlorothiophenol

Zinc salts of saturated and unsaturated long-chain fatty acids (chain length predominantly greater than C₁₇, but not under C₁₄) } in total max 0.3 %

The addition of zinc compounds is to be restricted so as not to exceed the 1.0 % limit for zinc content in teats, dummies (pacifiers) and teething rings, in accordance with section 3.1.

Acids, fatty (C₈-C₂₂), esters with pentaerythritol⁶

2.5.3.2.5 Slip and mould release agents:

as under 2.1.3.1.2.5 of the basic list of this Recommendation. If zinc stearate is used, the 1 % limit for zinc content, according to section 3.1 of this Recommendation, must be complied with.

2.5.3.2.6 Organic and inorganic pigments:

provided they do not transfer to foodstuffs³¹. Organic or inorganic pigments must not be used in teats, dummies (pacifiers) and teething rings.

3. Finished products

In addition to the conditions laid down in the individual sections of this Recommendation, commodities (articles and materials) must also comply with the following further requirements:

3.1 The zinc content of Categories 1, 2 and 3 commodities must not exceed 3.0 %, while the zinc content of Special category commodities must not exceed 1.0 %.

3.2 Based on the finished products, Categories 1, 2 and 3 commodities must contain no more than 0.003 %, Special category commodities no more than 0.001 % lead impurities⁵².

⁵² The determination of zinc and lead content is conducted according to section 2.5.4 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78).

3.3 When testing commodities in Categories 1, 2 and 3 of this Recommendation, a limit of 1.0 µg/dm² for N-nitrosamines⁵³ must not be exceeded.

Commodities are tested in distilled water, in 3 % wt. acetic acid, and in 10 % vol. ethyl alcohol under the following conditions of time and temperature:

Category 1 = 10 days at 40 °C

Category 2 = 24 hours at 40 °C

Category 3 = 10 minutes at 40 °C.

When testing commodities in accordance with section 2.5 (Special category) of this Recommendation (With the exception of bottle teats, dummies (pacifiers), toy balloons and toys for children < 36 month which are taken into the mouth as intended or in a foreseeable way. For these commodities the release of N-nitrosamines and nitrosatable substances is regulated by law⁵⁴) for N-nitrosamines a limit of 10 µg per kg commodity must not be exceeded.

Migration is determined following Commodities Regulation (Bedarfsgegenständeverordnung), Annex 10 No. 6.

When testing commodities in accordance with section 2.5, the limit laid down in annex 4 of the Commodities Regulation (Bedarfsgegenständeverordnung) for the migration of nitrosatable substances (0.1 mg/kg commodity) must also be complied with, except in the case of toys that are neither intended nor likely to be put in the mouth...

3.4 For Categories 1 - 3 and Special category commodities the following also applies:

3.4.1 The extracts obtained in accordance with the prescribed test procedure⁵⁵ must contain a total of no more than 20 µg/l primary aryl amine, calculated as aniline hydrochloride, and/or 1 mg/l secondary N-alkylaryl amine, calculated as N-ethylphenyl amine. In aqueous extracts from teats, dummies (pacifiers) and teething rings (manufactured from latex), N-ethylphenyl amine content must not exceed 0.5 µg/ml.

3.4.2 For the migration of secondary aliphatic and cycloaliphatic amines from Category 1 - 3 commodities, a limit of 5 mg/dm² is valid.

3.4.3 1 ml of aqueous extract obtained in accordance with the stipulated test procedure⁵⁶ must contain no more than 3 µg formaldehyde.

3.4.4 Before performing migration testing, components of milking clusters have to be pretreated according to "Beurteilungsgrundlage für die Migration von primären aromatischen Aminen aus Gummi-Bauteilen von Melkanlagen"⁵⁵.

Following 10 minutes contact with milk or water at 40 °C, the content of N-phenyl-N'-(1,3-dimethylbutyl)-p-phenylene diamine in these liquids must not exceed 0.3 mg/l⁵⁷.

The migration of primary aromatic amines from the entire cluster shall not exceed 50 µg/l. This migration limit is tested corresponding to: „Beurteilungsgrundlage für die Migration von primären aromatischen Aminen aus Gummi-Bauteilen von Melkanlagen“⁵⁸.

⁵³ The determination of nitrosamines is conducted in accordance with the method published in the 53rd Communication on the testing of plastics (Bundesgesundheitsblatt, 37 (1994) 232).

⁵⁴ The Commodities Regulation (Bedarfsgegenständeverordnung)

⁵⁵ Testing is conducted according to section 4 and according to Sections 6.1 and 7.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78), please also consider: 62. Mitteilung über die "Untersuchung von Kunststoffen, sowie sie als Bedarfsgegenstände im Sinne des Lebensmittel-, Bedarfsgegenstände und Futtermittelgesetzbuches verwendet werden", Bundesgesundheitsblatt 50 (2007) 524

⁵⁶ Testing is conducted according to section 2.7.1 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, 21 (MvP-Berichte; 2/78)

⁵⁷ Testing is conducted according to sections 6.1.1, 6.2.2 and 6.2.3 of methods. In: Ostromow, H., Hofmann, W., 1978. Untersuchung von Bedarfsgegenständen aus Gummi. Berlin: Reimer, (MvP-Berichte; 2/78)

3.5 For the migration of zinc dibenzyl dithiocarbamate from Category 1 - 4 commodities a limit of 0.1 mg/kg elastomer is valid.

3.6 In order to prevent the risk of allergic reactions, the content of soluble proteins must be reduced to a minimum in Special category commodities, as well as in other commodities in the sense of § 2, Para.6, No. 3 - 6 of the Food and Feed Code (LFGB) made of natural rubber materials. Finished products made from natural rubber latex, or their packaging, must be provided with the following label: "Natural rubber latex, which may cause an allergic reaction, has been used in the manufacture of this product." In the case of teats and soothers this instruction for possible cause of allergies may be dropped if a release of latex proteins can not be detected (< 20 ppm referring to the method published in the 59th communication on the testing of plastics "Determination of extractable protein from commodities made from natural rubber" (Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 43 (2000) 77) and accordingly < 0.15 ppm referring to ASTM D7427-08 "Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Natural Rubber and Its Products Derived from Latex").

Finished products made from natural rubber, or their packaging, must be provided with the following label: "Natural rubber has been used in the manufacture of this product".

3.7 Some of the substances listed in this Recommendation may cause an antimicrobial effect in the finished product. However, no substances (including those quoted in this Recommendation) may be used to obtain an intended antimicrobial proofing of the finished product.

⁵⁸ Testing is conducted according to methods for "Testing foodstuffs - the determination of primary aromatic amines in aqueous test foodstuffs" in the Official Collection of Testing Methods (Amtliche Sammlung von Untersuchungsverfahren nach § 64 LFGB, L. No. 00.00-6. See 62. Mitteilung zur Untersuchung von Kunststoffen [Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 50 (2007) 524].