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XXI. Commodities based on natural and synthetic rubber

As of 01.09.2024

The purpose of this Recommendation is to explain the structure of the Recommendations on commodities based on natural and synthetic rubber and on commodities based on natural and synthetic rubber latices, the procedure for the inclusion of new substances and the clarification of the related terms. Furthermore, the Annex to this Recommendation lists the evaluated substances for the manufacture of the products according to Recommendations XXI/1 and XXI/2.

There are no objections to the use of natural and synthetic rubber and of latices made of natural and synthetic rubber in the manufacture of commodities in the sense of § 2, Para 6 No. 1 or 3 and 5 of the German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch, LFGB), provided the commodities are suitable for the intended purpose and the requirements described in Recommendation XXI and Recommendation XXI/1 or XXI/2 are met.

Attention is drawn to the obligation to comply with the requirements of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

In addition to the positively listed substances, materials and articles made of natural and synthetic rubber may contain unintentionally introduced substances (impurities in the substances used or reaction intermediates formed in the manufacturing process, or degradation or reaction products). Their transfer to food shall be assessed in accordance with internationally accepted scientific principles on risk assessment.

For silicone rubber, Recommendation XV "Silicones" applies.

Thermoplastic elastomers (TPE) produced from the monomers and additives listed in the Plastics Regulation (EU) No 10/2011 fall within the scope of the Regulation and are not the subject of this Recommendation.

It is planned to develop a separate recommendation for the use of cross-linked TPEs in food contact.

Structure of the recommendations:

The concrete requirements for the respective consumer goods are listed in the following recommendations:

Recommendation XXI:	Explanatory notes, Annex: Evaluated starting materials, additives and manufacturing aids
Recommendation XXI/1:	Elastomeric commodities in contact with foodstuffs in accordance with § 2 para. 6 sentence 1 no. 1 of the German Food and Feed Code
Recommendation XXI/2:	Special commodities made of elastomers according to § 2 para. 6 sentence 1 no. 3 or 5 of the German Food and Feed Code (formerly special category)
In preparation:	
Recommendation XXI/3:	Consumer goods made of cross-linked thermoplastic elastomers.

Recommendations XXI/1 and XXI/2 each list the recommended rubbers and latices (Tables 1). The monomers used for the production as well as additives and production aids are divided into evaluated substances (evaluations of the European Food Safety Authority, the former Scientific Committee on Food of the EU Commission, the BfR for the inclusion of substances in the BfR Recommendations after 1991), listed in the Annex of Recommendation XXI (Table 1) and substances not yet conclusively evaluated (Tables 2 of Recommendations XXI/1 and XXI/2).

The Annex to this Recommendation (Table 1) lists the substances with the migration guidance values (SMRs) established as a result of the assessment.

The substances listed in Tables 2 of Recommendations XXI/1 and XXI/2 have been used for a long time in the manufacture of elastomers for food contact; however, there is no up-to-date risk assessment for them. The maximum quantities to be used as recommended by the BfR are listed for these substances.

It is planned to establish migration guide values for all substances listed in the Recommendations commodities based on natural and synthetic rubber and to transfer the substances currently listed in Tables 2 of Recommendations XXI/1 and XXI/2 to the list of evaluated additives and auxiliaries. For the inclusion of substances from Table 2 in the above-mentioned list of evaluated substances, an application must be submitted to the BfR.

The following deadlines apply to the deletion of substances from Tables 2 of Recommendations XXI/1 and XXI/2:

Since July 1, 2021, a two year deadline has applied within which letters of intent to submit an application had to be submitted. Substances for which no letter of intent was submitted were removed from Recommendations XXI/1 and XXI/2. From now on, a further three years will be set as the deadline (until 30.09.2027) within which applications for the previously notified substances can be submitted. Thereafter, a continuation of Tables 2 in Recommendations XXI/1 and XXI/2 is not planned.

Inclusion of substances in the list of evaluated substances (Annex to this Recommendation)

For the inclusion of substances in the list of evaluated substances, an application must be submitted to the BfR, as for a new inclusion. The form of the application must comply with the "Note for Guidance" of the European Food Safety Authority

(<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2008.21r/epdf>).

Information on the application procedure can be found at:

https://www.bfr.bund.de/en/bfr_recommendations_on_food_contact_materials-1711.html

Terms

Elastomers (hard and soft rubber) are materials that undergo substantial, elastic (reversible) deformation under strain and which consist of three-dimensionally linked, flexible polymers. The linkage points are chemical bonds in rubber (natural or synthetic rubber incl. silicone rubber) created by cross-linking or physical, thermoreversible fixing points in thermoplastic elastomers (TPE) or a combination of both (thermoplastic vulcanisates, TPE-V).

Elastomers are multi-material systems and can consist of the following main components:

- Rubbers
- Fillers
- Plasticisers
- Anti-ageing agents
- Processing aids
- Cross-linking agents

Rubber is the term for non-cross-linked but cross-linkable (vulcanisable) polymers with rubber-elastic properties at 20 °C. Rubbers are systematically divided into natural and synthetic rubbers. Natural rubber consists almost exclusively of the raw material obtained from certain plant juices (latex). Synthetic rubbers are artificially produced polymers obtained by polymerisation of the monomers. According to the many different fields of application and requirements for thermal and chemical resistance, there is a multitude of synthetic rubber types. Through mixed polymerisation of different monomers, the material properties can be varied within wide limits.

Latex is a colloidal aqueous dispersion of a polymeric material, in the sense of this Recommendation a rubber. Latices can be of natural (natural rubber latex) or synthetic origin. In the case of synthetic latices, a distinction is made between emulsion polymerisates left in aqueous dispersion (e.g. styrene-butadiene rubber latex) and re-dispersed polymerisate (e.g. polyisoprene latex).

Fillers, e.g. carbon black or fine-particle silica, can have a reinforcing effect on the polymer matrix and serve, among other things, to increase the tear strength and abrasion resistance of the product.

Plasticisers are added to the rubber compound, for example to adjust the hardness of the vulcanisates or to improve flexibility at low temperatures.

Anti-ageing agents protect elastomers against external influences. They counteract the harmful effects of oxidation, heat, light or ozone on the elastomer, for example.

Processing aids have a variety of functions in a rubber or latex compound. These include improving the dimensional stability of rubber blanks, easier processability during the mixing process and/or during moulding, and much more.

Cross-linking agents such as sulphur, sulphur donors or peroxides enable the cross-linking (vulcanisation) of the rubber to become an elastomer. Accelerators and retarders are also used for cross-linking (vulcanisation) with sulphur.

Annex**Explanations to the tables**

Table 1:	Evaluated starting materials, additives and production aids
Table 2:	Sum migration guide values SMR(T)
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.
SMR:	Specific migration reference value expressed in mg of substance per kg of food or food simulant. Unless otherwise stated, a migration guideline value of 60 mg/kg food or food simulant applies for the respective substance.
SMR(T):	Migration guide value for the sum of certain substances, given in mg substances per kg food or food simulant, listed in Table 2.
NN:	Not detectable with a detection limit of 0.01 mg substance per kg food or food simulant, unless otherwise stated. The verification shall also be carried out for consumer articles for repeated use in the first migration.

Table 1: Evaluated starting materials, additives and production aids

Starting materials (monomers)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR(T), cf. tab. 2	Requirements/restrictions
225	0000107-13-1	Acrylonitrile	X		NN		
621	0016219-75-3	5-Ethylidene-bicyclo[2,2,1]heptene (ethylene norbornene)	X		0.05		Unless a suitable analytical method is available, compliance testing may be carried out by measuring the residual content per food contact surface area (QMA). Based on the application of the actual surface area to volume ratio in the actual or intended use, the transfer to the food shall not exceed 0.05 mg/kg.
223	0000106-99-0	Butadiene	X	X	NN		1 mg/kg in the finished product according to Regulation (EU) No 10/2011
125	0000074-85-1	Ethene	X				
276	0000115-11-7	2-methylpropene (isobutene)	X				
144	0000078-79-5	2-methyl-1,3-butadiene (isoprene)	X	X	NN		1 mg/kg in the finished product according to Regulation (EU) No 10/2011
275	0000115-07-1	Propene	X				
193	0000100-42-5	Styrene	X	X			There is a risk that the migration of the substance will affect the organoleptic properties of the food in contact with it and thus the finished product will not comply with Article 3(1)(c) of the framework Regulation (EC) No 1935/2004.
522	0007782-50-5	Chlorine	X				
	0007446-09-5	Sulphur dioxide	X		8		
Fillers							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
Fillers shall meet the purity requirements specified in Recommendation LII.							
XXI/2: Fillers shall not contain additives as defined in section 2 of Recommendation LII. With the exception of silica, fillers shall not be used for bottle teats, soothers and nipples.							
417	0001343-98-2	Silicic acid	X	X			
616	0014808-60-7	Quartz	X	X			
142		Vinyltriethoxysilane	X	X	0.05		For silylation of silicic acid
377		3-Aminopropyltriethoxysilane	X	X	0.05		For silylation of silicic acid

Fillers (continued)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
453		Trimethoxyvinylsilane	X	X	0.05		For silylation of silicic acid
788		[3-(Methacryloxy)propyl]trimethoxysilane	X	X	0.05		For silylation of silicic acid
	0012068-56-3 0012141-46-7 0014504-95-1 0058425-86-8 0001332-58-7	Aluminium silicate	X	X		(1)	Also known as mixed silicates of sodium, potassium, calcium, magnesium and aluminium, but excluding asbestos.
	0001344-95-2 0010034-77-2 0012168-85-3	Calcium silicate	X	X			
	0001343-88-0 0013776-74-4 0014987-04-3	Magnesium silicate	X	X			
	0001344-09-8 0006834-92-0 0013472-30-5	Sodium silicate	X	X			
	0001312-76-1 0010006-28-7	Potassium silicate	X	X			
418	0001344-28-1	Aluminium oxide	X	X		(1)	Also as mixed oxides of calcium, magnesium, aluminium and silicon.
395	0001305-78-8	Calcium oxide	X	X			
397	0001309-48-4	Magnesium oxide	X	X			
504	0007631-86-9 0011126-22-0	Silicon oxide	X	X			
402	0001314-13-2	Zinc oxide	X	X		(2)	
629	0021645-51-2	Aluminium hydroxide	X	X		(1)	Also as mixed hydroxides of calcium, magnesium and aluminium.
394	0001305-62-0	Calcium hydroxide	X	X			
396	0001309-42-8	Magnesium hydroxide	X	X			
21	0014455-29-9	Aluminium carbonate	X	X		(1)	Also as mixed carbonates of calcium, magnesium and aluminium
	0000471-34-1 0001317-65-3	Calcium carbonate	X	X			
	0000546-93-0	Magnesium carbonate	X	X			

Fillers (continued)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
411	0001333-86-4	Carbon black	X				Toluene solubles: maximum 0.1 %, determined according to ISO method 6209. UV absorption of the cyclohexane extract at 386 nm: < 0.02 AU for a cell of 1 cm or < 0.1 AU for a cell of 5 cm, determined by a generally recognised analytical method. Benzo(a)pyrene content: max. 0.25 mg/kg carbon black.
521	0007782-42-5	Graphite	X				For linings only.
Other fillers according to recommendation LII. "Fillers for consumer articles made of plastics".			X				
Vulcanising agent							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
514	0007704-34-9	Sulphur	X	X			
Vulcanisation accelerator							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
Vulcanisation retarder							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
158	0000085-44-9	Phthalic anhydride	X	X			
116	0000065-85-0	Benzoic acid	X	X			
106	0000057-11-4	Stearic acid	X	X			
Accelerator activators							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
402	0001314-13-2	Zinc oxide	X	X		(2)	
	0003486-35-9	Zinc carbonate	X	X		(2)	
	0000557-05-1	Zinc stearate	X	X		(2)	

Anti-ageing agents							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
163	0000088-24-4	2,2'-Methylene-bis-(4-ethyl-6-tert-butylphenol)	X			(3)	
285	0000119-47-1	2,2'-Methylene-bis-(4-methyl-6-tert-butylphenol)	X	X		(3)	For teats and teething rings only for pre-stabilising natural rubber latex, max. 0.4 %
472	0004066-02-8	2,2'-Methylene-bis-(4-methyl-6-cyclohexylphenol)	X			(4)	
137	0000077-62-3	2,2'-Methylene-bis[4-methyl-6-(α -methylcyclohexyl)-phenol]	X			(4)	
756	0110553-27-0	2,4-Bis(octylthiomethyl)-6-methyl-phenol	X	X		(5)	For teats and teething rings only for pre-stabilising natural or synthetic rubber latex or as a stabiliser for copolymers of butadiene or isoprene and styrene in the form of sequence polymers, max. 1.0 %
758	0110675-26-8	2,4-Bis-dodecylthiomethyl-6-methylphenol	X	X		(5)	Not for teats and teething rings
384	0000991-84-4	2,4-Bis-n-octylthio-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	X	X	30		For teats and teething rings only for pre-stabilising synthetic rubber latex or as a stabiliser for copolymers of butadiene or isoprene and styrene in the form of sequence polymers, max. 0.2 %
762	0123968-25-2	2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxy-phenyl)ethyl]phenyl acrylate	X		5		
700	0061167-58-6	2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl acrylate	X		6		
315	0000128-37-0	2,6-Di-tert-butyl-4-methylphenol	X	X	3		For teats and teething rings only for pre-stabilising synthetic rubber, max. 1.0 %
178	0000096-69-5	4,4'-Thiobis-(3-methyl-6-tert-butylphenol-1)	X		0.48		
732	0068610-51-5	Reaction product of 4-methylphenol with isobutylene and dicyclopentadiene	X	X	5		For teats and teething rings only for pre-stabilising natural rubber latex, not more than 0,7 %, and as a stabiliser for copolymers of butadiene or isoprene and styrene in the form of sequence polymers, max. 1.4 %.
433	0002082-79-3	Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	X		6		
496	0006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]	X	X			Not for teats and teething rings
671	0031570-04-4	Tris(2,4-di-tert-butyl-phenyl)phosphite	X	X			For 2,4-di-tert-butylphenol, which is formed as a degradation product, an SMR of 5 mg/kg applies. For teats and teething rings only for pre-stabilising synthetic rubber or as a stabiliser for mixed polymers of butadiene or isoprene and styrene in the form of sequence polymers, max. 0.5 %
428	0001709-70-2	1,3,5-Trimethyl-2,4,6-tris-(3,5-di-tert-butyl-4-hydroxybenzyl)-benzene	X				

Anti-ageing agents (continued)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
294	0000123-28-4	thiodipropionic acid, didodecyl ester	X	X	5		Expressed as the sum of the substance and its oxidation products
Processing aids							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
		Zinc salts of saturated and/or unsaturated higher-molecular fatty acids (chain length predominantly C ₁₇ , but not below C ₁₄)	X	X		(2)	
535	0008050-09-7	Rosin	X	X			
638	0025322-68-3	Polyethylene glycol	X	X			The purity requirements in accordance with Regulation (EU) No 231/2012 shall be complied with.
107	0000057-13-6	Urea	X	X			
	0008023-79-8	Palm kernel oil	X	X			
103	0000056-81-5	Glycerine	X	X			
53	-	Esters of glycerol with stearic acid	X	X			
528	0008002-43-5	Lecithin	X	X			Peroxide value must not exceed 10.
105	0000057-10-3	Palmitic acid	X	X			
884	0091082-17-6	Alkyl(C ₁₀ -C ₂₁)sulfonic acid esters of phenol	X	X	0.05		Not for commodities which come into contact with fatty foodstuffs to which the test simulants D1 or D2 are assigned in accordance with Regulation (EU) No 10/2011, except milk.
207	0000103-23-1	Di-(2-ethylhexyl)adipate	X	X	18	(6)	
798	0006422-86-2	Bis(2-ethylhexyl) terephthalate	X			(6)	
880		Fatty acids (C ₈ -C ₂₂), esters with pentaerythritol	X	X			
93		Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks, low viscosity	X				As processing aids for antioxidants. There is a risk that the SMR will be exceeded when migrating into fatty foods or simulants associated with these. Specifications according to the EFSA opinion "Safety assessment of 'waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock, low viscosity' for use in food contact materials" (https://www.efsa.europa.eu/en/efsajournal/pub/7761).

Processing aids (continued)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
94		Waxes, refined, derived from petroleum-based or synthetic hydrocarbon feedstocks, high viscosity	X				As processing aids for anti-ageing agents. Average molecular weight: at least 500 Da, viscosity at 100 °C: at least 11 cSt ($11 \times 10^{-6} \text{ m}^2/\text{s}$). Content of mineral hydrocarbons with a carbon number less than 25: not more than 5 % by weight. There is a risk that the SMR will be exceeded when migrating into fatty foods or simulants assigned to them.
95		White mineral oils, paraffinic, obtained from petroleum-based hydrocarbon feedstocks	X	X			Average molecular weight: at least 480 Da, viscosity at 100 °C: at least 8.5 cSt ($8.5 \times 10^{-6} \text{ m}^2/\text{s}$). Content of mineral hydrocarbons with a carbon number less than 25: not more than 5 % by weight. There is a risk that the SMR will be exceeded when migrating into fatty foods or simulants assigned to them.
569	0009005-65-6	Polyethyleneglycol sorbitan monooleate	X	X			The purity requirements in accordance with Regulation (EU) No 231/2012 shall be complied with.
Lubricant and mould release agent							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
575	0063148-62-9	Polydimethylsiloxanes (Mw> 6800)	X	X			Viscosity at 25 °C: at least 100 cSt ($100 \times 10^{-6} \text{ m}^2/\text{s}$)
	0000557-05-1	Zinc stearate	X	X		(2)	
		Fatty acids, C12-C20, Na and/or K salts	X	X			
561	0009004-67-5	Methylcellulose	X	X			
638	0025322-68-3	Polyethylene glycol	X	X			Must not contain more than 0.2 % monoethylene glycol. Determination method see 28. Communication on the examination of plastics, Bundesgesundheitsblatt 16 (1973) 362.
639	0025322-69-4	Polypropylene glycol	X	X			
250	0000110-30-5	N,N'-ethylene-bis-stearamide	X	X			Only for butadiene-styrene sequence polymers.

Organic and inorganic colour pigments							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. Tab. 2	Requirements/restrictions
			X	X			In so far as they do not transfer to foodstuffs. The purity requirements set out in Recommendation IX "Colorants for Plastics and other Polymers Used in Commodities". apply. XXI/2: Organic and inorganic colour pigments shall not be used for teats and teething rings.

Protective colloids, thickeners and plasticisers (for latices only)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
561	0009004-67-5	Methylcellulose	X	X			
558	0009004-62-0	Hydroxyethylcellulose	X	X			
542	0009000-11-7	Carboxymethylcellulose	X	X			
565	0009005-27-0	Hydroxyethyl starch	X	X			
545	0009000-65-1	Traganth	X	X			
566	0009005-32-7	Alginic acid	X	X			
547	0009000-70-8	Gelatine	X	X			
548	0009000-71-9	Casein	X	X			
552	0009003-39-8	Polyvinylpyrrolidone	X	X			Viscosity of the 5% aqueous solution at 20 °C 34 - 38 mPa·s.
	0009002-89-5	Polyvinyl alcohol	X	X			Viscosity of the 4 % aqueous solution at 20 °C at least 5 mPa·s. Must meet the purity requirements according to Regulation (EU) No 231/2012.
538	0008050-31-5	Rosin, ester with glycerine	X	X			As well as their hydrogenation products. Must meet the purity requirements of Regulation (EU) No 231/2012.
537	0008050-26-8	Rosin, ester with pentaerythritol	X	X			As well as their hydrogenation products. The colophony esters mentioned must meet the purity requirements as a food additive.

Emulsifiers and dispersants (for latices only)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
		Fatty acids, C ₁₂ -C ₂₀ , sodium, potassium and ammonium salts	X	X			
346	0000514-10-3	Abietic acid	X	X			
		Ammonium dehydroabietate	X	X			
		Potassium dehydroabietate	X	X			
	0028161-39-9	Sodium dehydroabietate	X	X			
		Ammonium hydroabietate	X	X			
		Potassium hydroabietate	X	X			
		Sodium hydroabietate	X	X			
	0000151-21-3	Sodium lauryl sulphate	X	X			
642	0025736-61-2	Styrene-maleic anhydride copolymer, sodium salt	X	X			The molecular weight fraction below 1 000 Da shall not exceed 0.05 % (w/w).
578	0009046-01-9	Polyoxyethylene tridecyl ether phosphate	X	X	5		Polyethylene glycol (EO ≤11) tridecyl ether phosphate (mono- and dialkyl esters) containing not more than 10 % polyethylene glycol (EO ≤11) tridecyl ether. Consumer goods manufactured with this emulsifier must not come into contact with fat or foodstuffs in which fat is the external phase.
799	68439-49-6 68439-50-9 68920-66-1 69011-36-5 160875-66-1 157627-86-6 78330-20-8 71060-57-6 68551-12-2 26183-52-8	Polyethylene glycol ethers (EO = 1-50) of linear and branched primary alcohols (C8-C22)	X	X	1.8		In compliance with the maximum level of ethylene oxide according to the purity criteria for food additives referred to in Commission Regulation (EU) No 231/2012.
802	146340-15-0	Secondary alcohols, C12-C14, beta-(2-hydroxyethoxy), ethoxylated	X	X	5		
78	68891-38-3 150413-26-6 63428-87-5 1146116-43-9 68585-40-0	Polyethylene glycol (EO = 1-50)-monoalkyl ether (linear and branched, C8-C20)-sulfate, salts	X	X	5		

Protective agent against rot (Only for latices)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
252	0000110-44-1	Sorbic acid	X	X			
	0002634-33-5	1,2-Benzisothiazolin-3-one	X	X	0.5		
109	0000057-55-6	1,2-Propanediol	X	X			
257	0000110-98-5 0025265-71-8	Dipropylene glycol	X	X			
Defoaming agent (Only for latices and rubber dispersions)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
118	0000067-63-0	2-Propanol	X	X			
575	0063148-62-9	Polydimethylsiloxanes (molecular weight > 6800 Da)	X	X			Viscosity at 25 °C: at least 100 cSt (100 × 10 ⁻⁶ m ² /s)
Neutralising agents, pH regulating substances (Only for latices)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
510	0007664-41-7	Ammonia	X	X			
400	0001310-73-2	Sodium hydroxide	X	X			
399	0001310-58-3	Potassium hydroxide	X	X			
307	0000124-38-9	Carbon dioxide	X	X			
115	0000064-19-7	Acetic acid	X	X			
161	0000087-69-4	Tartaric acid	X	X			
139	0000077-92-9	Citric acid	X	X			
Precipitant (Only for latices and rubber dispersions)							
FCM substance no.	CAS No.	Chemical name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), cf. tab. 2	Requirements/restrictions
	0010043-01-3	Aluminium sulphate	X	X		(1)	
	0010043-67-1	Potassium aluminium sulphate (alum)	X	X		(1)	
	0012125-02-9	Ammonium chloride	X	X			
	0000631-61-8	Ammonium acetate	X	X			
	007783-20-2	Ammonium sulphate	X	X			
585	0010043-52-4	Calcium chloride	X	X			

	0010124-37-5	Calcium nitrate	X	X			
	0006484-52-2	Ammonium nitrate	X	X			

Table 2: Sum migration guide values

Sum migration guide values	FCM substance no.	CAS No.	Chemical name	SMR (T) (mg/kg)	Comments
(1)		0012068-56-3 0012141-46-7 0014504-95-1 0058425-86-8	Aluminium silicate	1	calculated as Al
	418	0001344-28-1	Aluminium oxide		
	629	0021645-51-2	Aluminium hydroxide		
	21	0014455-29-9	Aluminium carbonate		
		0010043-01-3	Aluminium sulphate		
		0010043-67-1	Potassium aluminium sulphate (alum)		
(2)	402	0001314-13-2 0003486-35-9 0000557-05-1	Zinc oxide Zinc carbonate Zinc stearate	25	calculated as Zn
			Zinc salts of saturated and/or unsaturated higher-molecular fatty acids (chain length predominantly C ₁₇ , but not below C ₁₄)		
(3)	163	0000088-24-4	2,2'-Methylene-bis-(4-ethyl-6-tert-butylphenol)	1.5	calculated as the sum of the substances
	285	0000119-47-1	2,2'-Methylene-bis-(4-methyl-6-tert-butylphenol)		
(4)	472137	0004066-02-8 0000077-62-3	2,2'-Methylene-bis-(4-methyl-6-cyclohexylphenol) 2,2'-Methylene-bis[4-methyl-6-(α -methylcyclohexyl)-phenol]	3	calculated as the sum of the substances
(5)	756758	0110553-27-0 0110675-26-8	2,4-Bis(octylthiomethyl)-6-methyl-phenol 2,4-Bis-dodecylthiomethyl-6-methylphenol	5	calculated as the sum of the substances
(6)	207	0000103-23-1	Di-(2-ethylhexyl)adipate	60	calculated as the sum of the substances
	798	0006422-86-2	Bis(2-ethylhexyl) terephthalate		