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XXI. Commodities based on natural and synthetic rubber

As of 01.04.2022

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 XXV/1 and XXV/2: A two-year deadline applies from the date of publication within which declarations of intent to apply must be submitted. A further three-year period is set during which applications for the previously notified substances can be submitted.

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) |
| 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 | 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 | 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 anti-ageing agents. Average molecular weight: at least 350 Da, viscosity at 100 °C: at least 2.5 cSt (2,5 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with a carbon number less than 25: not more than 40 % by weight. There is a risk that the SMR will be exceeded when migrating into fatty foods or simulants assigned to them. |

| 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. |
| 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. |
| 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 | | |