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LII. Fillers

As of 01.01.2012

This Recommendation for fillers applies to the following materials:

1. Plastics Dispersions according to Recommendation XIV
2. Silicones according to Recommendation XV
3. Commodities based on Natural and Synthetic Rubber according to Recommendation XXI
4. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials according to Recommendation XXVIII
5. Linear Polyurethanes for Paper Coatings according to Recommendation XLI
6. Artificial Sausage Casings according to Recommendation XLIV
7. Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking Utensils according to Recommendation LI
8. Processing aids listed under 2.2 of this Recommendation also apply to additives used in glass fibre sizing, which are used in plastics in the sense of Regulation (EU) No 10/2011. (Apart from that fillers are exclusively regulated in the Regulation itself.)

However where the use of particular fillers is specifically regulated in one of the BfR Recommendations mentioned above, the requirements in these specific Recommendations apply for these particular fillers.

In so far as the present Recommendation contains substances from the list of additives in Regulation (EU) No 10/2011, these have been labelled. For these substances the specific migration limits given in this Regulation must be met.

There are no objections to the use of fillers in the manufacture of commodities in the sense of § 2, Para. 6, No 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch), made of plastics, provided they are suitable for their intended purpose and comply with the following conditions:

1. The following substances may be used as fillers:

Silicic acid, also in silylated form^{1,2}

Quartz flour¹

Silicates or mixed silicates of sodium, potassium, calcium, magnesium, aluminium, iron and zirconium (including bentonite)³, but not including asbestos⁴

Oxides or mixed oxides of calcium, magnesium, aluminium, silicon and zinc³, zinc content of the finished product must not exceed 1.0 %

Hydroxides or mixed hydroxides of calcium, magnesium and aluminium³

Carbonates or mixed carbonates of calcium⁵, magnesium and aluminium³

¹ Permitted as an additive in compliance with the Regulation (EU) No 10/2011.

² The treatment of silicic acids with silylating agents, e.g. dimethyl-dichloro-silane, serves the creation of silicic acids with hydrophobic properties. The agents are not detectable in the silylated silicic acids (detection limit: 100 mg/kg).

³ In part permitted as an additive in compliance with the Regulation (EU) No 10/2011.

⁴ Only in the case of seals or gaskets exposed to thermal stress may chrysotile asbestos be used.

Sulfates or mixed sulfates of calcium, and barium¹ (see purity requirements under 3.2)³
Calcium sulfoaluminate¹
Aluminium powder¹ and aluminium bronze
Graphite¹
Glass fibres¹ with a diameter greater than 1 µm (mean diameter: 5 - 30 µm)
Glass microballs¹ with a mean diameter of 5 - 100 µm
Cellulose¹
Cotton fabric¹, untreated
Carbon fibres
Sawdust from untreated wood¹
Polytetrafluoroethylene, provided its melting viscosity at 380 °C is more than 50 Pa • s.
Dialuminium-hexamagnesium-carbonate-hexadecahydroxide-tetrahydrate
Magnesium-sodium-fluoride-Silicate¹

2. Additives for fillers

- 2.1 The following coating agents may be used for fillers – except for glass fibres, carbon fibres and glass micro balls:
Microcrystalline waxes in compliance with Recommendation XXV (Part I, Section B)
Low-molecular polyolefins in compliance with Recommendation XXV (Part I, Section E, No 3), max. 12 %
Esters of montanic acids with ethanediol and/or 1,3-butanediol and/or glycerol and mixtures of these esters with unesterified montanic acids, as well as with their calcium salts¹, max. 2.0 %
Bis-stearoyl- and/or bis-palmitoyl ethylenediamine^{1, 6}
Saturated and unsaturated fatty acids of chain length C₁₂-C₁₈, as well as their calcium and magnesium salts¹, in total max. 4.0 %
Siloxanes³, max. 5 %
Alkoxysilanes with functional groups, e.g. vinyl, methacryl, amino or glycidyl groups, in total max. 0,5 %
The total amount of coating agent used must not exceed 5.0 %, based on the filler.
- 2.2 Processing aids for glass fibres, carbon fibres and glass microballs
The total amount of processing aids used, based on surface area of the filler, must not exceed 0.25 g/m². The following processing aids may be used:
- 2.2.1 Adhesion promoters:
Alkoxysilanes with functional groups, e.g. vinyl, methacryl, amino or glycidyl groups, max. 0.5 %, based on the filler, or max. 0.3 %, based on the plastic component.
For fillers to be used in materials for contact with drinking water γ-aminopropyl triethoxysilane⁷ may be used up to 0.7 %.
Chromium(III)methacrylates, max. 0.3 %, based on these fillers, but only for unsaturated polyester resins in compliance with Recommendation XII
Poly-(Chromium(III)acetylacetonate) and/or poly-(titanium acetylacetonate), in total max. 0.3 %, based on this filler.

⁵ As dispersing and grinding agent for calcium carbonate, polyacrylic acid (mol. wt. 3 000-10 000) or its sodium salt may be used in amounts of max. 0.8 %, based on the calcium carbonate, or max 0.2 %, based on the plastic component.

⁶ Fillers treated with this substance may only be used in plastics for which bis-stearoyl and/or bis-palmitoyl-ethylenediamine are listed in the BfR Recommendations that apply to them. The limits for these substances stipulated therein must not be exceeded through the addition of treated fillers.

⁷ Permitted as a monomer in compliance with the Regulation (EU) No 10/2011.

- The total amount of adhesion promoters used, based on these fillers, must not exceed 1.0 %. Chromium(VI) must not be detectable⁸.
- 2.2.2 Film-forming preparations:
Plastic dispersions in compliance with Recommendation XIV, Part A
Polymers of acrylic and methacrylic acid ester in compliance with Recommendation XXII
Unsaturated polyester resins in compliance with Recommendation XII
Diol esters of polyterephthalic acid in compliance with Recommendation XVII
Polyurethanes in compliance with Recommendation XXXIX
Total solids content, based on these fillers, must not exceed 3 %.
- 2.2.3 Wetting agents:
Emulsifiers in compliance with Recommendation XIV, No 2 d, max. 0.05 %, based on the fillers.
- 2.2.4 Neutralising agents:
Acetic acid¹
Lactic acid¹
Formic acid¹
Propionic acid¹
Malonic acid¹
Hydrochloric acid¹
Citric acid¹
Ammonia¹
Phosphoric acid¹
Malic acid¹
Tartaric acid¹
Hydroxyacetic acid
β-Hydroxypropionic acid
- 2.2.5 Antistatic finish:
Alkali metal chlorides³
Ammonium chloride¹
The total amount used, based on solids content of the processing aids, must not exceed 20 %.
- 2.2.6 Other processing aids:
Protective colloids in compliance with Recommendation XIV, Part A, No 2 c
Antifoam agents in compliance with Recommendation XIV, Part A, No 2 h
Slip agents in compliance with Recommendation XIV, Part A, No 2 g

3. Purity requirements

- 3.1 General purity requirements:
Filler contaminants soluble in 0.1 N hydrochloric acid, determined according to DIN 53 770⁹ must not exceed the following:
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|----------|----------|
| Lead | 0.01 % |
| Arsenic | 0.01 % |
| Mercury | 0.0005 % |
| Cadmium | 0.01 % |
| Antimony | 0.005 % |
- 3.2 Purity requirements for barium sulfate:
The barium content soluble in 0.1 N hydrochloric acid, determined according to

⁸ Testing is conducted after DIN 53 770, "Testing of pigments and fillers; determination of matter soluble in hydrochloric acid, Part 1 and 8", (method A, diphenylcarbacid method).

⁹ See DIN 53 770, Part 1, 2, 3, 5, 6 and 13.

DIN 53 770¹⁰, must not exceed 0.01 %.

The water-soluble filler components, determined according to DIN-ISO 787¹¹, must not exceed 0.4 %.

¹⁰ See DIN 53 770, Part 1 and 4.

¹¹ See DIN EN ISO 787 "General methods of test for pigments and fillers - Part 3: Determination of matter soluble in water; hot extraction method".