German Federal Institute for Risk Assessment

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XV. Silicones

As of 01.08.2024

There are no objections to the use of silicones (organopolysiloxanes) in the manufacture of commodities in the sense of § 2, Para. 6, No. 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch), provided they are suitable for their intended purpose and comply with the following conditions. The same applies for commodities in the sense of § 2, Para.6, No. 3 of the same act, which are dealt with in Section III (Silicone elastomers) No. 4 of this Recommendation:

I. Silicone oils[1]

1. The following starting materials may be used:
   a) Linear or branched and/or cyclic[2] organopolysiloxanes with methyl groups alone or with n-alkyl(C_2-C_{32}), phenyl[2] and/or hydroxyl groups attached to the silicon atom, and their condensation products with polyethylene and/or polypropyleneglycol and/or polyalkylene(C_2-C_4)glycolmonoalkyl(C_1-C_4)ether.
   b) Linear or branched organopolysiloxanes as mentioned under a) but in addition with up to max. 5 % hydrogen and/or alkoxy(C_2-C_4) and/or carboalkoxyalkyl (-$(CH_2)_{2\text{-}17}$-C(O)-O-$(CH_2)_{0\text{-}17}CH_3$)- and/or hydroxyalkyl(C_1-C_3) groups attached to the silicon atom.

2. Finished products may contain only the following production aids, used in manufacturing the raw polymer, in the maximum amounts given:
   a) Condensation agents:
      Residues of condensation accelerators and their conversion products:
      Sodium hydroxide
      Potassium hydroxide
      Hydrochloric acid
      Sulfuric acid
      Phosphoric acid
      Acetic acid
      } in total max. 0.01 %
      Conversion products of phosphonitrile chloride, max. 0,001 %
   b) Thickening agents:
      Calcium salts of straight-chain aliphatic saturated monocarboxylic acids C_{10}-C_{20}
      12-Hydroxystearic acid, calcium salt
      Carboxymethylcellulose
      Pulped Starch[3]
   c) Emulsifying agents, provided that the oils are used as aqueous emulsions[4], in total

[1] Silicone fats or pastes are silicone oils to which fillers or extenders (see Section I. No. 2 b) with a thickening effect have been added, and for which the same requirements apply.

[2] There must be no cyclic polysiloxanes included, which besides a phenyl group also have a hydrogen atom or a methyl group attached to the same silicon atom.

[3] Because the viscosity of natural starch is too high, it is partially broken down through dextrinisation (treatment with acids at moderate temperature, or without acid, at elevated temperature), through oxidation (with hypochlorite in alkaline medium) or with the help of enzymes.

max. 10 %, based on the silicone content:
Alkyl(C_8-C_{18}) dimethylbenzyl ammonium chloride, max. 1.5 %, but only for coating paper
Sodium dodecyl sulfate, max. 0.5 %
Polyethyleneglycol ethers of monohydric aliphatic alcohols C_{12}-C_{20} and of C_2-C_9 alkyl phenols
Polyethyleneglycol esters of natural fatty acids C_8-C_{22} and vegetable oils
Semi-acetylated polyvinyl alcohol with less than 20 % acetyl groups and a K-value greater than 40

3. Preserving agents:
   The following preserving agents may be added to silicone oil emulsions:
   Sorbic acid, max. 0.1 %.

4. Kinematic viscosity of the silicone oils, measured according to DIN 51 562 at 20 °C, must be min. 100 $mm^2 \bullet s^{-1}$.

II. Silicone resins

1. The following starting materials may be used:
   Linear and branched organopolysiloxanes with methyl groups alone and/or n-alkyl(C_2-C_{32})-, and/or phenyl-[2], and/or vinyl-, and/or hydroxyl-, and/or alkoxy(C_1-C_4)-, and/or hydrogen-, and/or carboalkoxyalkyl(-$(CH_2)_{2\text{-}17}$-C(O)-O-$(CH_2)_{0\text{-}17}CH_3$)-, and/or hydroxyalkyl(C_1-C_3)-groups attached to the silicon atom also in combination with polycondensation products (esters) of:
   Isophthalic acid
   Terephthalic acid
   Ethandiol
   Trimethylol propane
   Glycerol
   Pentaerythrite

2. Finished products may contain only the following production aids, used in manufacturing and processing the raw polymer, in the maximum amounts given:
   a) Condensation agents:
      Residues of hydrochloric acid and its conversion products with fillers and hardeners, in total max. 0.1 %
   b) Hardeners:
      α) Zinc-di-2-ethylhexoate, Di-n-octyl-tin-maleinate } in total max. 1.5 %
      β) Conversion products[5] of hardeners named under α), plus the following:
      Butyltitanate and/or butylpolytitanate, as necessary, with the monoethyl ether of ethanediol (ethyleneglycol) in the ratio 1:1 [6]
      Aluminium acetylacetonate
      Zirconium acetylacetonate

[4] Silicone emulsions are used to produce coatings and films. As a result of heat treatment (e.g. the hydrophobing of glass at 280 °C) or of strong dilution of the aqueous phase prior to use (e.g. as slip agent for corks, artificial guts (sausage casings), or as release agent for rubber stoppers and seals), as a rule, they only contain a fraction of the emulsifying agents present in the emulsion.

[5] The conversion products are either incorporated into the resin or occur as oxides. Thus, a quantitative limit is not deemed necessary.

[6] To be used at temperatures of at least 180 °C.

c) Emulsifying agents:
In so far as the resins are used in the form of aqueous emulsions[4], the substances listed above under 1, No. 2 c may be used, however, max. 7.0 %, based on silicone content.

3. The following substances may be added to silicone resins used for coating paper:
Carboxymethyl cellulose
Pulped starch[3]
Alginates
Casein
Dispersions of hard paraffin and wax[7]
Dispersions based on copolymers of acrylic and methacrylic acid esters, butadiene and styrene, provided they comply with Recommendation XIV[8].
Polyvinyl alcohol (viscosity of 4 % aqueous solution at 20 °C min. 5 cP).
Hydroxyethyl cellulose, max. 2 % in the resin.

III. Silicone elastomers (Silicone rubber)

1. The following starting materials may be used:
Polymers complying with Section I, No.1 of this Recommendation
Organopolysiloxanes with vinyl groups attached to the silicon atom
Addition products of trivinyl cyclohexane and α,ω-Dihydrogenpolyhydrogen-methyldimethyl-siloxanes, max. 10 %
1-Dodecene, max. 20 %
Polydimethyl- siloxanes and -silicones, 3-aminopropyl-group terminated, polymers with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane[9]
Polydimethyl- siloxanes and -silicones, 3-aminopropyl-group terminated, polymers with bis(4-isocyanatocyclohexyl)methane[10]

2. Finished products may contain only the following production aids, used in manufacturing and processing the raw polymer, in the maximum amounts given:
a) Residues of condensation accelerators and their neutralising agents:
Sodium hydroxide
Potassium hydroxide
Hydrochloric acid
Sulfuric acid
Phosphoric acid
Acetic acid
} in total max. 0.1 %
Conversion products of phosphorus nitrile chloride, max. 0.001 %
Sodium hydrogen carbonate, max. 0.5 %

[7] The waxes and paraffins must comply with Recommendation XXV. "Hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics", Part I.
[8] Recommendation XIV. "Plastics dispersions"
[9] Specifical restrictions for 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane and 1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane, laid down in the Commission Regulation (EU) No 10/2011, must be complied with.
[10] Specifical restrictions for bis(4-isocyanatocyclohexyl)methane and bis(4-aminocyclohexyl)methane, laid down in the Commission Regulation (EU) No 10/2011, must be complied with.

b) Conversion products of following cross-linking agents:

Benzoyl peroxide Bis-(2,4-Dichlorobenzoyl) peroxide[11] Dicumyl peroxide tert-Butyl-cumyl peroxide 2,5-Bis(tert-butylperoxy)-2,5-dimethylhexane Methyl-tris-cyclohexyl-aminosilane[12] Methyl-tris-sec-butylaminosilane[12] Methyl-tris-acetoxysilane Ethyl-tris-acetoxysilane Methyl-tris-butanoximosilane[12] Di-(4-methyl-benzoyl)peroxide	in total max. 0.2 %

Esters of alkyl-C_1-C_8-silicic acid or orthosilicic acid with aliphatic monohydric alcohols C_2-C_4 and the monomethyl ether of ethanediol (methylglycol) and their condensation products[13], in total max. 3 %.

c) Hardener or catalysts and their conversion products:

Di-n-octyl-tin-dimaleinate Di-n-octyl-tin-dilaurate Esters of titanic acid with isobutyl alcohol, n-butanol and the enolate of acetoacetic ester Amides of aliphatic carboxylic acids, C_8-C_{22}	max. 1.5 %, based on finished product

Coordination compounds of platinum, max. 50 mg platinum per kg finished product[14]. The following substances may be used as inhibitors for these coordination compounds: 1-ethinyl-cyclohexanol and 2-methylbutine-3-ol-2, in total max. 0.1 %.

d) Emulsifying agents:
Apart from the emulsifying agents[4] listed above under Section I, No. 2 c, the following may be used only in silicone elastomers for coating paper:

Sodium alkyl(C_8-C_{22})-sulfates Sodium alkyl(C_8-C_{22})-sulfonates Sodium alkylaryl sulfonates	in total max. 4 % based on silicone content

The total amount of emulsifying agents used must not exceed 10 %.

e) Reclaimed silicone rubber, provided it complies with this Recommendation.

3. To the extent that the silicone elastomers are intended for coating paper or plastic films, the following may be used:
   a) the substances listed above under Section II, No. 3
   b) as hardener or catalyst – departing from No. 2, c) of this Section -, coordination compounds of platinum, max. 120 mg platinum per kg finished coating
   c) 1,2-dibromo-2,4-dicyanobutane, max. 2.7 µg/dm² of finished coating, as preservative.
   d) 2-Bromo-2-nitropropane-1,3-diol, max. 1,25 µg/dm² of finished coating, as preservative.

4. To the extent that silicone elastomers in compliance with this recommendation are used in the manufacture of bottle teats, dummies (pacifiers), nipple caps, teething rings or dental guards, the

[11] The migration of 2,4-dichloro benzoic acid formed as decomposition product must not exceed 5 mg/kg food resp. food simulant.

[12] The reaction products, cyclohexylamine, sec-butylamine or Butanonoxime and their conversion products must not be detectable in the finished products. For method of analysis, see 43rd Communication on the testing of plastics in Bundesgesundheitsblatt 22 (1979) 339

[13] The conversion products are incorporated into the elastomers or hydrolysed to silicic acid.

[14] Hexachloroplatinic acid and its conversion products with vinyl-containing siloxanes are the catalysts of choice.

finished products may only contain the following production aids, used during manufacture and processing of the raw polymer, in the maximum amounts given:

a) Conversion products of the following cross-linking agents:
   Dicumyl peroxide
   Benzoyl peroxide } in total max. 0.2 %
   tert-Butyl-cumyl peroxide
b) Hardener or catalysts and their conversion products:
   Coordination compounds of platinum, max. 50 mg platinum per kg of finished product[14]
c) The following may be used as inhibitors:
   1-Ethinyl-cyclohexanol and 2-methylbutine-3-ol-2, in total max. 0.1 %
d) Fillers:
   Silicic acid[15].

Dummies (pacifiers) and bottle teats made of silicone elastomers must comply with the requirements laid down in the Commodities Regulation (Bedarfsgegenständeverordnung).

5. The silicone elastomers must release no more than 0.5 % volatile organic components.[16]

6. The finished products must not test positively for peroxides.[17]

7. The silicone elastomers must contain not more than 3 % titanium dioxide or titanium dioxide with 1-3 % iron(III) oxide as heat stabilizing agent. The material is characterized as follows:
   The size of the primary particles is 5-100 nm, at least 90 % of primary particles have a size below 50 nm.

[15] Recommendation LII. "Fillers"

[16] Test method: https://www.bfr.bund.de/cm/343/bestimmung-von-fluechtigen-verbindungen-in-bedarfsgegenstaenden-aus-silikon.pdf; articles that do not withstand thermal testing according to the above method shall be tested according to the temperature/time conditions specified in Table 3 in Annex V of Regulation (EU) No 10/2011. Sample conditioning is to be carried out according to the method specified in the 61st Communication of Bundesgesundheitsblatt 46 (2003) 362. This applies to composite materials or articles with plastic or textiles such as conveyor belts, coated textiles or two-component injection molded parts for seals.

[17] 58th Communication on testing of plastics in Bundesgesundheitsblatt 40 (1997) 412