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XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics

As of 01.09.2017

There are no objections to the use of hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics in the manufacture of impregnations, coatings and contact adhesives for foodstuff packaging and other 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 the following conditions are met.

Part I. Hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics in the manufacture of impregnations, coatings and contact adhesives for foodstuff packaging and other commodities in the sense of § 2, Para. 6, No. 1 of the Food and Feed Code¹

Finished products coated with substances or mixtures of substances dealt with in this Recommendation must not be used with fats and oils or with fatty foodstuffs in which fat forms the external phase. This restriction of use also applies to such finished products for which no direct contact between food and coating is given as long as in the packaging no barrier for the transfer of substances from the coating to the food exists.

A. Hard paraffins of natural origin²

1. Solidification temperature, determined according to DIN 51 556, must be between 43 °C and 75 °C. However, the solidification temperature of paraffins and mixtures containing paraffin used to coat or impregnate packaging for liquids, particularly milk, must not be below 52 °C.
2. Kinematic viscosity, measured according to DIN 51 562 at 100 °C, must not exceed 5.8 mm² • s⁻¹ (delimitation in respect to microcrystalline waxes).
3. Iodine colour number of the fused paraffin, determined according to DIN 6162 (Dec. 1981), must not exceed 1 (= 1 mg iodine in 100 ml aqueous potassium iodide solution).
4. Hard paraffins must comply with the following purity requirements:
 - a) In the test with sulfuric acid and
 - b) in the test for alkaline or acidic impurities they must comply with the test requirements³.
 - c) They must contain no fluorescence-quenching substances.

¹ The substances dealt with here are mainly used to coat, impregnate and laminate packaging material made from paper.

² The term "hard paraffins of natural origin" refers to mixtures of solid, purified, mainly straight-chain, saturated hydrocarbons produced from petroleum, lignite or shale tar oil.

³ See "Testing liquid paraffins, hard paraffins and microcrystalline waxes" in the 38th Communication on testing plastics in Bundesgesundheitsblatt 19 (1976) 231.

- d) When observed under a low-pressure UV quartz analysis lamp (wave length, 254 nm) in the fused state, they must show no stronger fluorescence than a solution of quinine sulfate in 0.1 N sulfuric acid, which in 1 ml contains 0.1 μg ($= 10^{-7}$ g) quinine sulfate (based on 8-hydrate)³.
 - e) In the test for 3,4-benzpyrene, determined according to method No. 4 in Communication 38 on the testing of plastics ["Halbquantitative papierchromatographische Bestimmung (Rundfilterchromatographie) von 3,4-Benzpyren"] no more than 0.1 mg/kg ($=10^{-7}$ g) 3,4-benzpyrene may be detected³.
5. The following antioxidants may be added to hard paraffins:
In total, max. 0.01 % 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-ditert-butyl-4-methyl phenol (BHT)
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1 %.

B. Microcrystalline waxes ("micro waxes")⁴

1. The solidification temperature, determined according to DIN 51 556, must be between 50 °C and 90 °C.
2. Kinematic viscosity, according to DIN 51 562 at 100 °C, must be between 5.8 and 35 $\text{mm}^2 \cdot \text{s}^{-1}$.
3. Iodine colour number of the fused microcrystalline wax, determined according to DIN 6162 (Dec. 1981), must not exceed 60 ($= 60$ mg iodine in 100 ml aqueous potassium iodide).
4. The microcrystalline waxes must comply with the following purity requirements:
 - a) They must contain no fluorescence quenching substances.
 - b) They must comply with the test requirements laid down under 6. ("Purity test of microcrystalline waxes") in the 38th Communication on the testing of plastics³.
5. The following antioxidants may be added to microcrystalline waxes:
In total, max. 0.01 % 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-ditert-butyl-4-methyl phenol (BHT)
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1 %.

C. Synthetic hard paraffins⁵

1. The solidification temperature, determined according to DIN 51 556, must be between 92 °C and 105 °C.
2. Kinematic viscosity, according to DIN 51 562 at 120 °C, must be between 9 and 30 $\text{mm}^2 \cdot \text{s}^{-1}$.
3. In testing for alkaline or acidic impurities, they must comply with the requirements laid down in the testing procedures³.

⁴ Microcrystalline waxes are mixtures of solid, purified, mainly branched, saturated microcrystalline hydrocarbons derived from petroleum.

⁵ Synthetic hard paraffins are mixtures of high-molecular, solid, purified, mainly straight-chain hydrocarbons. They have not, up until now, been shown to contain carcinogenic, polycyclic aromatic hydrocarbons.

4. In testing with sulfuric acid (90 % \pm 0.5 %), they must comply with the requirements laid down in the testing procedures³.
5. The following antioxidants may be added to the synthetic hard paraffins:
In total, max. 0.01 % 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-ditert-butyl-4-methyl phenol (BHT)
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1 %.

D. Low-molecular polypropylene

Low-molecular polypropylene must comply with the following requirements:

Softening point [ring and ball method according to DGF-M-III 13 (75), based on DIN 1995]:	ca. 160 °C
Density (20 °C):	0.86-0.88 g/cm ³
Viscosity (180 °C):	1000-30 000 mPa • s
Mol. wt. (numerical mean), determined by GPC:	2500-6000
Acid number:	0
Iodine colour number according to DIN 6162:	less than 2

The following antioxidants may be added to low-molecular polypropylene:

- In total, max. 0.01 % 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-ditert-butyl-4-methyl phenol (BHT)
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1 %.

Mixtures

The substances dealt with under A, B, C and D above may be mixed with one another, whereby each must comply with the specific purity requirements laid down for it.

E. Additives

The substances dealt with under A, B, C and D and mixtures of the same may have the following substances added to them, whereby in the overall mixture A, B, C and D must predominate:

1. Polyethylene, provided it complies with Recommendation III.⁶
2. Polypropylene, provided it complies with Recommendation VII.⁷
3. Low-molecular polyolefins⁸
 - a) Kinematic viscosity, according to DIN 51 562 at 120 °C, of min. 50 mm² • s⁻¹.
 - b) Oxygen content of max. 1.0 %.
 - c) The iodine colour number of the fused low-molecular polyolefins, determined according to DIN 6162 (Dec. 1981), must not exceed 2 (= 2 mg iodine in 100 ml aqueous potassium iodide).

⁶ Recommendation III. "Polyethylene".

⁷ Recommendation VII. "Polypropylene"

⁸ Here, low-molecular polyolefins refers to mixtures of solid aliphatic hydrocarbons produced through the polymerisation of monomeric olefins. In their manufacture, the production aids listed in Recommendation III for polyethylene may be used. Oxidised or partially oxidised polyolefins comply neither with this Recommendation nor with Recommendation III.

4. Polyterpenes⁹
 - a) The softening point (ring and ball method according to DIN 1995 U 4) must be between 50 °C and 130 °C.
 - b) Kinematic viscosity of a 50 % solution of the polyterpenes in toluene, according to DIN 51 562 at 20 °C, must be between 10 and 30 mm² • s⁻¹
 - c) The iodine colour number of a 10 % solution of the polyterpenes in toluene, according to DIN 6162 (Dec. 1981), must not exceed 4 (= 4 mg iodine in 100 ml aqueous potassium iodide solution).
 - d) The density of the polyterpenes at 20 °C must be between 0.98 and 1.01.
 - e) The following antioxidants may be used:
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %, or
2,4-bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.
5. Polyisobutylene and isobutylene-isoprene copolymers (butyl rubber), provided they comply with Recommendation XX¹⁰.
6. Dammar resin, provided it complies with the purity requirement of the German Pharmacopoeia.
7. Esters of glycerol and pentaerythritol with resin acids of colophony, as well as their hydrogenation products¹¹.
The following antioxidants may be used:
2,4-Bis(octylthio-6-(4-hydroxy-3,5-di-tert-butyl-anilino)-1,3,5-triazine, max. 0.4 %, or
or
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %, or
or
2,4-bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.
8. Copolymers of ethylene, vinyl esters and esters of unsaturated aliphatic acids, provided they comply with Recommendation XXXV¹².
9. Polyolefin resins¹³
 - a) Dynamic viscosity, according to DIN 53018 at 140 °C, min. 3 Pa • s.
 - b) The softening point (ring and ball method according to DIN 1995 U4), min. 90 °C.
 - c) The iodine colour number of the fused polyolefin resin, according to DIN 6162 (Dec.1981), max. 40 (= 40 mg iodine in 100 ml aqueous potassium iodide).
 - d) The content of monomeric starting materials, max. 0.2 %.
 - e) Ash content, max. 0.1 %.
 - f) The following antioxidants may be added to the polyolefin resins:
either
2,6-ditert-butyl-4-methylphenol (BHT), max. 0.1 %, or
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, max. 0.4 %,

⁹ Here, polyterpenes refers to mixtures of aliphatic and cycloaliphatic hydrocarbons produced through polymerisation of monomeric terpenoid hydrocarbons.

¹⁰ Recommendation XX. "Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers"

¹¹ These must comply with the purity requirements of the Regulation on Food Additives (Zusatzstoffverkehrsverordnung).

¹² Recommendation XXXV. "Copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, as well as their salts and esters"

¹³ Here, "polyolefine resins" refers to copolymers of unsaturated monomers containing 4 or more C-atoms, particularly olefines, diolefines and dienes.

or
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %,
or
2,4-bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.

10. Copolymers of α -methylstyrene and vinyl toluene, provided they comply with Recommendation VI¹⁴.

Copolymers of α -methylstyrene and vinyl toluene, manufactured using max. 0.23 % borium trifluoride as catalyst.

Copolymers of α -methylstyrene and styrene. As catalyst, boron trifluoride, max. 0.23 %, or an addition compound of boron trifluoride and phenol, max. 1.2 %, may be used.

As antioxidants the following may be used:

Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %,
or
2,4-bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.

11. Hydrogenated polycyclopentadiene resin¹⁵

- Dynamic viscosity, according to DIN 53018 at 140 °C, min. 2 Pa • s.
- The softening point (ring and ball method according to DIN 1995 U4), min. 95 °C.
- The iodine colour number of a 50 % solution of the resin in toluene, according to DIN 6162 (Dec. 1981), max. 10 (= 10 mg iodine in 100 ml aqueous potassium iodide).
- The following may be added to the hydrogenated polycyclopentadiene resin as antioxidants
2,6-ditert-butyl-4-methylphenol (BHT), max. 0.3 %,
or
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, max. 0.4 %,
or
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %,
or
2,4-bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.

Zinc dibutyl dithiocarbamate, max. 0.45 %, may also be added to the hydrogenated polycyclopentadiene resin, in which case, however, the finished product must contain no more than 70 mg of the resin per dm².

12. Copolymer of C₅/C₆ mono and diolefins, styrene and cyclic olefins with the composition C₁₀H₁₆

- Kinematic viscosity, according to DIN 51 562 at 160 °C, min. 300 mm² • s⁻¹.
- The softening point (ring and ball method according to DIN 1995 U4), min. 93 °C.
- The iodine colour number of the fused copolymer, according to DIN 6162 (Dec. 1981), max. 2 (= 2 mg iodine in 100 ml aqueous potassium iodide).
- Mean molecular weight: 1200.
- The following antioxidant may be added to this copolymer:
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, max. 0.4 %.

13. Hydrogenated hydrocarbon resins based on C₈-C₉ aromatic olefins, dicyclopentadiene and isobutene

- Dynamic viscosity, according to DIN 53018 at 150 °C, min. 1 Pa • s.

¹⁴ Recommendation VI. "Styrene co- and graft polymers, and mixtures of polystyrene with other polymers"

¹⁵ Here, "hydrogenated polycyclopentadiene resins" refers to mixtures produced through thermal polymerisation of a mixture of mainly dicyclopentadiene with methylcyclopentadiene, isoprene and piperylene and C₈-C₁₀ aromates (latter mainly composed of vinyl aromates, indene and methylindene) and subsequent hydrogenation of the copolymer.

- b) The softening point (ring and ball method according to DIN 1995 U4), min. 97 °C.
- c) The iodine colour number of the fused resin, according to DIN 6162 (Dec. 1981), max. 1 (= 1 mg iodine in 100 ml aqueous potassium iodide).
- d) The following antioxidants may be used:
 - Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate, max. 0.4 %
 - Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.5 %.

F. Auxiliary substances

In total max. 10.0 % of the overall mixture:

1. Esters of montanic acids with ethanediol and/or 1,3-butanediol and mixtures of these esters with unesterified montanic acids and their calcium salts.
2. Hydrogenated castor oil
3. Organopolysiloxanes with methyl and/or phenyl groups (silicone oil), (viscosity at 20 °C, min. 100 cSt), max. 1.0 %.
4. Stearic acid
5. Oleic acid amide and/or stearic acid amide, in total, max. 0.2 %
6. Mixture of ammonium salts of sulfosuccinic acid-diisodecylester and sulfosuccinic acid-isodecyl-isononyl-diester, max. 0.008 mg/dm².

G. Anti-fouling agents

3-Iodine-2-propinyl-butyl-carbamate, max. 0.033 %.

Addition of this agent must not result in the finished product having a preserving effect on foodstuffs.

Part II. Paraffins, microcrystalline waxes and bees wax, used in the manufacture of cheese coatings not meant to be eaten

If the following Recommendation is complied with, it may be assumed that the duty of care, required in the manufacture, treatment and marketing of cheese coatings made of paraffins, microcrystalline waxes or bees wax, has been complied with.

It is recommended that only the following substances be used in their manufacture:

A. Starting materials

1. Hard paraffins of natural origin in compliance with Section I.A
For use in cheese coatings, kinematic viscosity, according to DIN 51 562 at 100 °C, min. $2.5 \text{ mm}^2 \cdot \text{s}^{-1}$.
2. Microcrystalline waxes in accordance with Section I.B
3. Synthetic hard paraffins in accordance with Section I.C
4. Bees wax¹⁶.
The above components 1. to 4. can be mixed with one another.

B. Additives for the substances A. 1. – 3. :

1. Polyethylene, provided it complies with Recommendation III, up to 10 %⁶
2. Low-molecular polyolefins⁸, up to 10 %
3. Polyisobutylene, up to 10 %, or isobutylene-isoprene copolymers, up to 3 %, provided they comply with Recommendation XX¹⁰.
4. Copolymers of ethylene, vinyl esters and esters of unsaturated aliphatic acids, provided they comply with Recommendation XXXV¹².
5. Esters of glycerol and pentaerythritol with resin acids of colophony and their hydrogenation products¹¹
The following may be used as antioxidants:
2,4-bis(octylthio-6-(4-hydroxy-3,5-di-tert-butyl-anilino)-1,3,5-triazine, max. 0.4 %,
or
Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %
or
2,4-Bis(octylthiomethyl)-6-methylphenol, max. 0.5 %.
6. Edible fatty acids, as well as mono, di, and triglycerides, also when esterified (E 471, E 472 a-f).

C. Auxiliary substances

1. Esters of montanic acids with ethanediol and/or 1,3-butanediol and mixtures of these esters with unesterified montanic acids and their calcium salts.

¹⁶ Purity in compliance with the European Pharmacopoeia

2. Hydrogenated castor oil.

D. Colorants

Colorants, on their own or mixed, permitted by the "Verordnung zur Neuordnung lebensmittelrechtlicher Vorschriften über Zusatzstoffe" (regulation reorganising the legislation on foodstuff additives), as well as naturally coloured foodstuffs.

E. Preserving agents

Preserving agents permitted by the "Verordnung zur Neuordnung lebensmittelrechtlicher Vorschriften über Zusatzstoffe" (regulation reorganising the legislation on additives) for cheese.