German Federal Institute for Risk Assessment

This is an unofficial translation. Only the German version is binding.

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

As of 01.07.2025

There are no objections to the use of hard paraffins, microcrystalline waxes and mixtures of these with waxes, resins and plastics as well as natural waxes 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 and low-viscosity/high-viscosity waxes and mixtures of these with waxes, resins and plastics as well as natural waxes 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[1]

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.[2] 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 type 1: low viscosity waxes[3]

1. The composition and physicochemical properties must correspond to those in the EFSA opinion of 2023 (doi: 10.2903/j.efsa.2023.7761). This concerns in particular:
    a) Composition:[4]
        - The wax consists mainly of *n*-alkanes. The content is usually over 80%, but should be at least 60%. The content of branched and cyclic alkanes is correspondingly low (differentiation from section I.B. microcrystalline waxes).
        - The average molecular weight of the compounds contained is typically around 400 g/mol, but should not be less than 350 g/mol and should not exceed 600 g/mol.
        - The content of hydrocarbons with carbon number less than 25 should not exceed 40%.

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

[2] By way of derogation, finished products coated exclusively with low viscosity waxes according to Part I point A that meet the definition of FCM 93 from Table 1 of Regulation (EU) No 10/2011 as laid down in the EFSA opinion of 2023 (doi: 10.2903/j.efsa.2023.7761) may also be used in contact with fats and oils or fatty foodstuffs in which fat forms the external phase. However, a maximum of 5 mg of the low-viscosity wax per kg of food may migrate.

[3] The term “hard paraffins type 1: low viscosity waxes” refers to mixtures of solid, purified, mainly straight-chain, saturated hydrocarbons derived from petroleum-based or synthetic hydrocarbon feedstock.

[4] The following parameters should be determined using a suitable method. The BfR recommends the use of an online coupled high-performance liquid chromatography-gas chromatography method with a flame ionization detector (LC-GC/FID). Compare e.g. JRC (2023): https://publications.jrc.ec.europa.eu/repository/bitstream/JRC133174/JRC133174_01.pdf. A version of this method was used in the above-mentioned EFSA opinion.

- At least one process step to reduce the amount of aromatic mineral oil hydrocarbons (MOAH) – e.g. a hydrogenation step – should be included in the production of the low-viscosity wax.
- The content of MOAH in the low-viscosity wax should be as low as possible and must not exceed 3.9%.

b) Physicochemical parameters:
- The kinematic viscosity measured according to DIN 53000-1 at 100 °C is typically around 3 - 5 $mm^2 \bullet s^{-1}$, but must not be lower than 2.5 $mm^2 \bullet s^{-1}$ at 100 °C and must not exceed a value of 9.9 $mm^2 \bullet s^{-1}$ at 100 °C (differentiation from section I.C. hard paraffins type 2: high-viscosity waxes).
- The solidification (congealing) temperature determined in accordance with DIN ISO 2207 must not be lower than 45 °C and must not exceed 92 °C (differentiation from section I.C. hard paraffins type 2: high-viscosity waxes). However, the solidification (congealing) temperature of products used to coat or impregnate packaging for liquids, in particular for milk, must not be lower than 52 °C.

2. When testing for alkaline or acidic reacting impurities, the low-viscosity waxes must fulfil the requirements specified in the test specifications[5].

3. When tested with sulphuric acid (90% ± 0.5%), the low-viscosity waxes must fulfil the requirements specified in the test specifications[5].

4. Iodine colour number of the fused low viscosity wax, determined according to DIN 6162, must not exceed 1 (= 1 mg iodine in 100 ml aqueous potassium iodide solution).

5. The following antioxidants may be added to low-viscosity waxes:
   a) 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-di-tert-butyl-4-methylphenol (BHT), in total max. 0.01%
   b) Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1%

6. Migration into food must not exceed 5 mg/kg food.

B. Microcrystalline waxes ("micro waxes")[6]

1. The solidification temperature, determined according to DIN ISO 2207, must be between 50 °C and 90 °C.

2. Kinematic viscosity, according to DIN 53000-1 at 100 °C, must be between 10.0 and 35 $mm^2 \bullet s^{-1}$.

3. Iodine colour number of the fused microcrystalline wax, determined according to DIN 6162, must not exceed 60 (= 60 mg iodine in 100 ml aqueous potassium iodide).

4. The microcrystalline waxes must comply with the test requirements[5] laid down under 6. ("Purity test of microcrystalline waxes") in the 38th Communication on the testing of plastics.

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

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

5. The following antioxidants may be added to microcrystalline waxes:
    a) In total, max. 0.01% 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-di-tert-butyl-4-methyl phenol (BHT)
    b) Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.1%

C. Hard paraffins type 2: high viscosity waxes[7]

1. The solidification temperature, determined according to DIN ISO 2207, must be between 92 °C and 105 °C (differentiation from section I.A. hard paraffins type 1: low-viscosity waxes).

2. Kinematic viscosity, according to DIN 53000-1 at 120 °C, must be between 9 and 30 $mm^2 \bullet s^{-1}$ (differentiation from section I.A. hard paraffins type 1: low-viscosity waxes).

3. In testing for alkaline or acidic impurities, they must comply with the requirements laid down in the testing procedures[5].

4. In testing with sulfuric acid (90% ± 0.5%), they must comply with the requirements laid down in the testing procedures[5].

5. The following antioxidants may be added to the high-viscosity waxes:
    a) In total, max. 0.01% 2- and 3-tert-butyl-4-hydroxyanisole (BHA) and/or 2,6-di-tert-butyl-4-methyl phenol (BHT)
    b) 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)]:	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 mg iodine

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

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

[7] "Hard paraffins type 2: high-viscosity waxes" 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.

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. Natural waxes[8]

1. Bees wax
2. Candelilla wax
3. Carnauba wax

F. 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[9].
2. Polypropylene, provided it complies with Recommendation VII[10].
3. Low-molecular polyolefins[11]
   a) Kinematic viscosity, according to DIN 53000-1 at 120 °C, of min. 50 $mm^2 \bullet s^{-1}$.
   b) Oxygen content of max. 1.0%.
   c) The iodine colour number of the fused low-molecular polyolefins, determined according to DIN 6162, must not exceed 2 (= 2 mg iodine in 100 ml aqueous potassium iodide).
4. Polyterpenes[12]
   a) The softening point (ring and ball method according to DIN 1995 U4) must be between 50 °C and 130 °C.
   b) Kinematic viscosity of a 50% solution of the polyterpenes in toluene, according to DIN 53000-1 at 20 °C, must be between 10 and 30 $mm^2 \bullet s^{-1}$
   c) The iodine colour number of a 10% solution of the polyterpenes in toluene, according to DIN 6162, 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%

[8] The substances must comply with the relevant purity requirements of Regulation (EU) No. 231/2012.
[9] Recommendation III. "Polyethylene".
[10] Recommendation VII. "Polypropylene".
[11] 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.
[12] Here, polyterpenes refers to mixtures of aliphatic and cycloaliphatic hydrocarbons produced through polymerisation of monomeric terpenoid hydrocarbons.

5. Polyisobutylene and isobutylene-isoprene copolymers (butyl rubber), provided they comply with Recommendation XX[13].

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 products [14]
   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
   Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydrocinnamate)]methane, max. 0.4 %
   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 XXXV[15].

9. Polyolefin resins[16]
   a) Dynamic viscosity, according to DIN 53019-1 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, 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%
      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 VI[17].

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

[13] Recommendation XX. "Polyisobutylene, Isobutylene Copolymers and Mixtures of Polyisobutylene with other Polymers".
[14] These must comply with the purity requirements of the Regulation on Food Additives (Zusatzstoffverkehrsverordnung).
[15] Recommendation XXXV. "Copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, as well as their salts and esters".
[16] Here, “polyolefine resins” refers to copolymers of unsaturated monomers containing 4 or more C-atoms, particularly olefines, diolefines and dienes.
[17] Recommendation VI. "Styrene co- and graft polymers, and mixtures of polystyrene with other polymers".

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 resin[18]
    a) Dynamic viscosity, according to DIN 53019-1 at 140 °C, min. 2 Pa • s.
    b) The softening point (ring and ball method according to DIN 1995 U4), min. 95 °C.
    c) The iodine colour number of a 50 % solution of the resin in toluene, according to DIN 6162, max. 10 (= 10 mg iodine in 100 ml aqueous potassium iodide).
    d) 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 dm^2.

12. Copolymer of C_5/C_6 mono and diolefins, styrene and cyclic olefins with the composition $C_{10}H_{16}$
    a) Kinematic viscosity, according to DIN 53000-1 at 160 °C, min. 300 $mm^2 • s^{-1}$.
    b) The softening point (ring and ball method according to DIN 1995 U4), min. 93 °C.
    c) The iodine colour number of the fused copolymer, according to DIN 6162, max. 2 (= 2 mg iodine in 100 ml aqueous potassium iodide).
    d) Mean molecular weight: 1200 g/mol
    e) 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 C_8-C_9 aromatic olefins, dicyclopentadiene and isobutene
    a) Dynamic viscosity, according to DIN 53019-1 at 150 °C, min. 1 Pa • s.
    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, 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 %

[18] Here, "hydrogenated polycyclopentadiene resins" refers to mixtures produced through thermal polymerisation of a mixture of mainly dicyclopentadiene with methylcyclopentadiene, isoprene and piperylene and C_8-C_{10} aromates (latter mainly composed of vinyl aromates, indene and methylindene) and subsequent hydrogenation of the copolymer.

G. 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 $mm^2 \bullet s^{-1}$), 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/dm^2

H. 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 type 1: low viscosity waxes in compliance with Section I.A
   For use in cheese coatings, kinematic viscosity, according to DIN 53000-1 at 100 °C, min. 2.5 $mm^2 \bullet s^{-1}$.

2. Microcrystalline waxes in accordance with Section I.B

3. Hard paraffins type 2: high viscosity waxes in accordance with Section I.C

4. Bees wax[8]

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[9], up to 10%

2. Low-molecular polyolefins[11], up to 10%

3. Polyisobutylene, up to 10%, or isobutylene-isoprene copolymers, up to 3%, provided they comply with Recommendation XX[13]

4. Copolymers of ethylene, vinyl esters and esters of unsaturated aliphatic acids, provided they comply with Recommendation XXXV[15]

5. Esters of glycerol and pentaerythritol with resin acids of colophony and their hydrogenation products[14]
   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)[8]

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

2. Hydrogenated castor oil

D. Colorants

Colorants, on their own or mixed, permitted by Regulation (EC) No 1333/2008 on food additives for edible cheese rind, as well as naturally coloured foodstuffs.

E. Preserving agents

Preserving agents permitted by Regulation (EC) No 1333/2008 on food additives for cheese and cheese products.