

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

XIV. Polymer Dispersions

As of 01.09.2017

There are no objections to the use of plasticizer-free polymer dispersions for coating commodities in the sense of § 2, Para. 6, No. 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch) (refer to part A of this Recommendation) and for cheese coatings not meant to be eaten (refer to part B of this Recommendation), provided that the coated commodities and cheese coatings are suitable for their intended purpose and the following conditions are met:

Part A: Polymer dispersions for coating commodities intended to come into contact with foods (e.g. adhesives or paper coatings)

The aforementioned restrictions of this Recommendation do not apply to container sealing material, which when properly used does not come into contact with foodstuffs (double-fold seals).

A number of the dispersions manufactured in accordance with this Recommendation can be cross-linked via vulcanisation, in which case Recommendation XXI¹ applies.

Linear polyurethanes, provided they comply with amended Recommendation XLI², may be mixed with polymer dispersions, whereby the proportion of polymer dispersion in the total mixture must predominate.

This Recommendation is valid for coatings that are intended to be used at temperatures up to 90 °C.

1. The following monomers for polymer dispersions may be used:

Monomers listed in the Commission Regulation (EU) No. 10/2011 may be used. Specific limits have to be obeyed.

In addition, the following substances may be used:

- a) Acrylic and methacrylic acid esters of alcohols of chain length C₁-C₁₈ which are monohydric saturated and linear (H-(CH₂)₁₋₁₈-OH), and ether alcohols of chain length C₁-C₁₈, which are monohydric saturated and linear (H-(CH₂)₁₋₁₈-O-(CH₂)₁₋₁₈-OH)
- b) Vinyl esters of aliphatic saturated carboxylic acids of chain length C₁-C₁₈
- c) Esters of maleic acid and fumaric acid with monohydric aliphatic saturated alcohols of chain length C₁-C₁₈ or with monohydric aliphatic unsaturated alcohols of chain length C₃-C₁₈
- d) Esters of aliphatic carboxylic acids of chain length C₃-C₁₂ with unsaturated alcohols of chain length C₃-C₁₈,
- e) Esters of unsaturated aliphatic dicarboxylic acids with polyethylene glycols and/or polypropylene glycols
- f) Vinyl ethers of monohydric aliphatic saturated alcohols of chain length C₁-C₁₈
- g) Vinylsulfonic acid. Commodities which shall comply with this Recommendation have to meet the following recommended migration limit: 0.05 mg/kg foodstuff or food simulant.

¹ Recommendation XXI. "Commodities based on natural and synthetic rubber"

² Recommendation XLI. "Linear polyurethanes for paper coatings"

- h) Half-esters of maleic acid or fumaric acid and itaconic acid with monohydric aliphatic saturated alcohols of chain length C₁-C₁₈, max. 8 %, if cross-linking in the film is assured through subsequent treatment, the proportion may be increased to max. 25 %.
- i) Esters of acrylic acid and methacrylic acid with dihydric aliphatic alcohols of chain length C₂-C₁₈
- j) Divinyl and diallyl esters of saturated and unsaturated aliphatic dicarboxylic acids of chain length C₃-C₁₈
- k) Vinyl ester of acrylic acid
- l) Allyl ester of acrylic acid
- m) Vinyl ester of crotonic acid
- n) Allyl ester of crotonic acid
- o) Triallyl cyanurate
- p) 2-Sulfoethylmethacrylate, max. 1.5 %.
Coatings made using this monomer must not be used for in the packaging of liquid foodstuffs. The specific limit laid down in the Commission Regulation (EU) No 10/2011 has to be obeyed.
- q) 2-(Dimethylamino)ethyl acrylate with a residual content in the finished coating of max. 0.01 mg/dm².
- r) N-[3-(Dimethylamino)propyl]methacrylamide
- s) (2-(Methacryloyloxy)ethyl)trimethylammonium chloride

If single substances that are listed in Commission Regulation (EU) 10/2011 are included in the generic terms stated above specific limits for these substances of the Commission Regulation (EU) 10/2011 have to be obeyed.

2. The following production aids may be used:

Additives already permitted by the Commission Regulation (EU) No 10/2011 may be used in accordance with the restrictions laid down therein. In addition to these, the following substances may also be used, but only in the maximum amounts given:

- a) Catalysts:
 - Hydrogen peroxide
 - Benzoyl peroxide
 - Cyclohexanone peroxide
 - Isopropylcumyl hydroperoxide
 - Peroxysulfates of potassium, sodium and ammonium
 - Peroxides of straight-chain saturated aliphatic monocarboxylic acids of chain length C₈-C₁₂
 - tert-Butyl-hydroperoxide
 - Di-tert-butyl peroxide
 - Diisopropyl-peroxy carbonate
 - Azobisisobutyronitrile
 - Acetylcyclohexane sulfonyl peroxide
 - tert-Butyl-perbenzoate
 - tert-Butylperoxy-(2-ethylhexanoate)
 - Bis-(3,5,5-trimethyl)-hexanoylperoxide
 - tert-Butyl peroxyvalate, max. 0.15 %; using max. 0.05 % dibutyl phthalate as pasting agent
 - Hydroperoxy-pinane, max. 0.2 %
 - Iron-III-chloride, max. 0.06 %
 - p-Menthane hydroperoxide, max. 0.1 %
 - tert-Butyl peroxyacetate, max. 0.2 %

Mixture of

2-Hydroxy-2-sulfonato acetic acid, di-sodium salt	35 - 60 %
2-Hydroxy-2-sulfonatoacetic acid, di-sodium salt	10 - 60 % and
Sodium sulfite	0 - 40 %, max. 0.5 %.

The commodities must not test positively for peroxides³.

b) Polymerisation regulators:

Normal and tertiary mercaptanes of chain length C₁₀-C₁₄⁴

Butene-(1)-ol-(3)

Hydroxylamine salts

Sodium dialkyldithiocarbamate

Sodium bisulfite

Ammonium bisulfite

Sodium dithionite

Isoascorbic acid

Urea⁵

Propionaldehyde⁵

Dispersion films must not contain more than 0.7 % residue or conversion products from a polymerisation regulator, and no detectable levels of butene-(1)-ol-(3) or salts of hydroxyl amine.

Alkali metal salts of oxymethane sulfinic acid, max. 0.5 %, based on the dispersion film.

Diisopropylxanthogene disulfide, max. 0.5 %, however, only for dispersions of polyvinylidene chloride.

Boric acid, max. 0.07 %⁶

2,2'-Dibenzamido-diphenyl-disulfide, max. 3.0 % in the dispersion

1-Methyl-4-(1-methylethylidene)-cyclohexene. Commodities which shall comply with this Recommendation have to meet the following recommended migration limit: 0.05 mg/kg foodstuff or food simulant

c) Protective colloids and thickening agents for further processing:

Polyvinyl alcohol (viscosity of 4 % aqueous solution at 20 °C when used as a protective colloid, min. 2 cP; when used as a thickening agent, min. 4 cP).

Polymers and copolymers of monomers listed under No. 1, the restrictions set out therein have to be complied with.

Polyacrylic acid, modified with isopropanol.

d) Emulsifying agents:

Sodium hydroxyoctadecane sulfonate

Sodium, potassium and ammonium salts of hydroxy fatty acids of chain length C₁₂-C₂₀ and their sulfation or acetylation products

Alkyl sulfates, also as salts of triethanolamine

Alkyl(C₁₀-C₂₀) sulfonates

Alkyl(C₁₀-C₂₀)-aryl sulfonates⁷

Dimethyldialkyl(C₈-C₁₈) ammonium chloride, max. 0.005 %, based on the dispersion film

Acyl-, alkyl-, oleyl- and alkylaryloxyethylates and their sulfation products⁷

Sulfosuccinic acid-4-esters with polyethylene glycol nonylphenyl ether (di-sodium salt)

Lignosulfonic acid, as well as its calcium, magnesium, sodium and ammonium salts, in total, max. 0.04 mg/dm²

Disodium dodecyl diphenylether disulfonate

³ Test method: 58th Communication on the testing of plastics in Bundesgesundheitsblatt 40 (1997) 412

⁴ These substances are completely incorporated into the polymer during polymerisation.

⁵ The specific limits laid down in the Commission Regulation (EU) No 10/2011 apply to the use of this substance.

⁶ For the purpose of reducing residual monomer content. Only in dispersions based on N-hydroxymethyl acrylamide used in the manufacture of material for wiping cloths that may come into contact with foodstuffs.

⁷ In part permitted as an additive in accordance with the Commission Regulation (EU) No 10/2011.

- Copolymers of ethylene oxide and propylene oxide with a minimum ethylene oxide content of 10 %
- Lecithine, max. 1 %
- Disodium-4-[1-methyl-2-[(1-oxo-9-octadecenyl)amino]ethyl]-2-sulfosuccinate, max. 0.8 mg/dm².
- Sulfosuccinic acid-4-esters with polyethylene glycol ethers of monohydric aliphatic alcohols of chain length C₁₀-C₁₂ (di-sodium salt). Migration into foodstuff or food simulants, respectively must not exceed 2 mg/kg.
- Sulfosuccinic acid-bis-cyclohexylester, sodium salt. Migration into foodstuff or food simulants, respectively must not exceed 5 mg/kg.
- Alkali metal salts of esters of sulfosuccinic acid with aliphatic saturated monohydric alcohols of chain length C₄-C₂₀. Migration into foodstuff or food simulants, respectively must not exceed 5 mg/kg.
- Migration of emulsifying agents from the coating of the finished product under normal condition of use must not exceed 5 mg/dm².
- e) Stabilisers (neutralising agents and complexing agents):
- Alkali metal salts of N-(2-hydroxyethyl)ethylenediamine-triacetic acid, in total max. 0.4 % in the dispersion film
- Homopolymer of 2-acrylamido-2-methylpropanesulfonic acid and its sodium, potassium and ammonium salts, max. 2 % in the dispersion film
- f) Substances which protect the dispersion against putrefaction:
- The use of these substances must not result in the finished dispersion film having a preserving effect on foodstuffs.
- o-Phenylphenol and its sodium and potassium salts, max. 0.3 %
- 3,5-Dimethyl-tetrahydro-1,3,5-thiadiazine-2-thione, max. 0.05 %.
- 1-(3-Chloroallyl)3,5,7-triazo-1-azonia-adamantane chloride⁸; no more than 0.05 mg/dm² of this substance may be present in the dispersion film.
- 2-Bromo-2-nitropropane-1,3-diol, max. 0.032 mg/dm² in dispersion film,
- p-Chloro-m-cresol, max. 0.2 %
- Titanium dioxide/silver chloride with 80 % titanium dioxide and 20 % silver chloride, max. 0.005 %
- Adduct of 70 % benzyl alcohol and 30 % formaldehyde, max. 0.4 mg/dm²
- 3-Iodine-2-propinyl-butyl-carbamate, max. 0.02 %
- 1,2-Dibromo-2,4-dicyanobutane, max. 0.058 %
- 2,2-Dibromo-3-nitrilo-propionamide, max. 0.02 mg/dm²
- Dodecylguanidine-hydrochloride, max. 0.03 %.
- 1,2-Benzisothiazolin-3-one⁹. No more than 80 µg/dm² of this substance may be present in the dispersion film.
- As pasting agent no more than 0.6 mg/dm² 1,2-propandiole and dipropylene glycol together, and no more than 0.005 mg/dm² xanthane, may be used.
- Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one (3 parts) and 2-methyl-4-isothiazolin-3-one (1 part)⁹, in total max. 4 µg/dm² in dispersion film
- 2-Methyl-4-isothiazolin-3-one⁹, max. 40 µg/dm² in dispersion film

⁸ Migration of this substance into foodstuffs and aqueous simulants is regulated by the Commission Regulation (EU) No 10/2011

⁹ The restrictions refer to the application in dispersions. An additional contribution from other applications (e. g. as slimicide or as preservative in the paper production or in printing inks) must comply with the restrictions laid down for these fields. In the extracts of the final products the following levels must not exceeded:

Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one (approx. 3 parts) and 2-methyl-4-isothiazolin-3-one (approx. 1 part): 25 µg/dm²

1,2-Benzisothiazolin-3-one: 80 µg/dm²

2-methyl-4-isothiazolin-3-one: 80 µg/dm²

2,2'-dithiobis[N-methylbenzamide] and its hydrolysis products 2-methyl-1,2-benzothiazol-3(2H)-one and 2-mercapto-N-methylbenzamide in total no more than 30 µg/dm², determined in dimethyl sulfoxide extract.

- 1,6-dihydroxy-2,5-dioxahexane, max. 29 µg/dm²,
 Besides the aforementioned restrictions, in total dispersion films must contain no more than 0.5 % of these substances.
- Tetrahydro-1,3,4,6-tetrakis-(hydroxymethyl)-imidazo(4,5-d)imidazole-2,5(1H,3H)-dione as formaldehyde donator system with an average ratio of formaldehyde: acetylene diurea of 3.1:1 to 3.5:1, max. 0.5 mg/dm² dispersion film, equivalent to a total formaldehyde content of 0.22 mg/dm².¹⁰
- Zinc pyrithione, max. 8 µg/dm²
- N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine. No more than 10 µg/dm² of this substance must be detectable in the extract of the finished product.
- 2,2'-dithiobis[N-methylbenzamide]⁹, max. 30 µg/dm²
- g) Slip agents:
 Paraffin DAB
 Polyethylene, provided that it complies with Recommendation III¹¹.
 Butyl stearate
 Altogether, the aforementioned slip agents present in dispersion films must not exceed 1.0 %.
- h) Defoaming agents:
 Triisobutyl phosphate
 Organopolysiloxanes with methyl and/or phenyl groups (silicone oil), inasmuch as their viscosity at 20 °C is no less than 100 Centistokes.
 Condensation product of linear or branched organopolysiloxane polyalkyleneglycol mono-alkyl ethers according to Section I, No. 1 of amended Recommendation XV, max. 0.04 %.
 Bis-stearoyl ethylene diamine may be used up to a maximum of 0.015 mg/dm² in the dispersion film as stabiliser for the aforementioned defoaming agents.
 The dispersion films must not contain in total more than 0.1 % of the above defoaming agents.
- i) Antioxidants:
 Bis-[(3-cyclohexyl-5-methyl-2-hydroxy)phenyl]-methane
 Bis-[3-(1-methylcyclohexyl)-5-methyl-2-hydroxy-phenyl]-methane
 2,2'-Methylene-bis-(4-methyl-6-tert-butylphenol)
 2,6-Di-tert-butyl-4-methylphenol
 2,2'-Methylene-bis-(4-ethyl-6-tert-butylphenol)
 Phenol and/or cresols, converted with styrene or methylstyrene and/or olefins of chain length C₃-C₁₂
 Styrenated diphenylamine
 Tris(nonylphenyl)phosphite⁸, i.e. tris-(mono-nonylphenyl)-phosphite⁸, also mixed with tris-(di-nonylphenyl)-phosphite^{8, 12}
 Triethyleneglycol-bis[3-(3-tert-butyl-4-hydroxy-5-methyl-phenyl)propionate], max. 0.25 %
 The dispersion films must not contain in total more than 1.0 % of the above antioxidants.
- j) Antistatic agents:
 N,N-Bis(2-hydroxyethyl)alkyl-(C₁₂-C₁₈)amines⁸, max. 2.0 mg/dm² coated commodity surface made from dispersions of vinylidene chloride copolymer. Commodities treated with this antistatic agent must not come into contact with liquid foodstuffs.

¹⁰ brief description: Tetramethylolacetylenediurea (tetramethylolglycoluril) in chemical equilibrium with trimethylolacetylenediurea, dimethylolacetylenediurea, monomethylolacetylenediurea and formaldehyde.

¹¹ Recommendation III. "Polyethylene"

¹² Purity requirements for tris(nonylphenyl)phosphite: see 76th Communication in Bundesgesundheitsblatt 15 (1972) 139.

Part B: Polymer dispersions for the manufacture of cheese coatings not meant to be eaten

If the following Recommendations are fully complied with, it may be assumed that the obligatory care necessary in the manufacture, treatment and putting into circulation of polymer dispersions for cheese coatings has been taken.

It is recommended that only the following substances be used in the manufacture of polymer dispersions:

1. Monomers

Ethylene

Vinyl esters of saturated fatty acids of chain length C_2 - C_{18}

Esters of maleic acid and fumaric acid with monohydric aliphatic saturated alcohols of chain length C_4 - C_8

Acrylic acid esters of monohydric aliphatic saturated alcohols of chain length C_4 - C_8

Mixture of α -olefins C_{14} - C_{16}

2. Catalysts

Hydrogen peroxide

Potassium, sodium and ammonium peroxydisulfate

Peroxides of even-numbered saturated aliphatic monocarboxylic acids of chain length C_8 - C_{12}

tert-Butyl-hydroperoxide

Di-tert-butyl peroxide

Diisopropyl peroxydicarbonate

tert-Butylperoxy-(2-ethylhexanoate)

Iron-III-chloride, max. 0.06 %

The finished cheese coating material must not test positively for peroxides³.

3. Emulsifying agents

Sodium lauryl sulfate

Sodium laurylethersulfate, ethoxylated (3 ethylene oxide groups)

Polyethylene glycol ether of oleyl alcohol (4 - 20 ethylene oxide groups)

4. Defoaming agents

Dimethylpolysiloxanes ($M_w > 6,800$ D)

5. pH regulator and polymerisation aids

Alkali metal salts of oxymethane sulfinic acid, max. 0.25 %

Sodium and ammonium bisulfite

Sodium dithionite

Isoascorbic acid

Urea, max. 0.75 %

Formic acid

Acetic acid

Citric acid

Tartaric acid

Hydrochloric acid

Ascorbic acid

Ammonia
Sodium hydroxide
Potassium hydroxide
Sodium and potassium carbonate and hydrogencarbonate

6. Protective colloids and thickening agents

Lactose
Silicon dioxide
Hydroxyethyl cellulose
Methylcellulose
Hydroxyethylmethyl cellulose
Carboxymethyl cellulose
Polyvinyl alcohol (viscosity of 4 % aqueous solution at 20 °C, when used as a protective colloid, min. 2 cP; when used as a thickening agent, min. 4 cP)
Polyvinyl pyrrolidone
Xanthane

7. Dyes, alone or in combination, which are permitted in the Regulation on Food Additives (Verordnung zur Neuordnung lebensmittelrechtlicher Vorschriften über Zusatzstoffe), as well as naturally coloured foodstuffs.

8. Preserving agents, which are permitted in the Regulation on Food Additives (Verordnung zur Neuordnung lebensmittelrechtlicher Vorschriften über Zusatzstoffe).