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II. Plasticizer-free Polyvinyl Chloride, Plasticizer-free Copolymers of Vinyl Chloride and Mixtures of these Polymers with other Copolymers and Chlorinated Polyolefins Containing Mainly Vinyl Chloride in the Total Mixture

As of 01.01.2012

The monomers and other starting substances as well as additives used in the production of plasticizer-free polyvinyl chloride, plasticizer-free copolymers of vinyl chloride containing mainly vinyl chloride, mixtures of these polymers with other copolymers, and chlorinated polyolefins containing mainly vinyl chloride in the total mixture are subject to the requirements of the Commission Regulation (EU) No 10/2011.

Otherwise, there are no objections to the use of these plastics for 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:

1. The use of monomers and other starting materials for polyethylene is subject to the stipulations of the Commission Regulation (EU) No 10/2011.

The evaluation presented in the following refers to polymers from the following monomeric starting substances:

- a) Vinyl chloride
- b) Vinylidene chloride
- c) Trans-dichloroethylene
- d) Vinylesters of aliphatic carbonic acids C_2-C_{18} , in so far as covered by the positive list of the Commission Regulation (EU) No 10/2011
- e) Esters of acrylic acid, methacrylic acid and/or maleic acid or fumaric acid with alcohols C_1-C_{18} , monohydric, aliphatic, saturated, and alcohols C_3-C_{18} , monohydric, aliphatic, unsaturated, in so far as covered by the positive list of the Commission Regulation (EU) No 10/2011
- f) Vinylethers of C_1-C_{18} , monohydric, aliphatic, saturated, in so far as covered by the positive list of the Commission Regulation (EU) No 10/2011
- g) Propylene
- h) Butadiene
- i) Maleic acid, fumaric acid, itaconic acid, acrylic acid, methacrylic acid, in total maximum 8 %

The following mixed polymers may be added to the polymers and/or mixed polymers, provided that the proportion of polyvinyl chloride in the total mixture predominates:

Chlorinated polyolefines with a content in chlorine up to 56 %

Mixed polymers from butadiene and acrylonitrile in accordance with Recommendation XXI¹.

¹ Recommendation XXI "Commodities based on Natural and Synthetic Rubber"

2. Plastics for food contact materials can be produced and processed with the substances regulated by the Commodities Regulation. The respective restrictions have to be followed. Additionally, the raw polymer and finished products must not contain other than the following production aids² and their residues or conversion products (from manufacturing and processing) respectively, in the maximum amounts given:

a) Residues of decomposition products from the following catalysts:

For the catalysts mentioned below isododecane may be added as phlegmatizing agent. The transfer from the final product may not exceed 5 mg isododecane/kg foodstuff.

- Azobisisobutyronitrile
- Azodicyclohexyl carboxylic acid dinitrile
- 2,2'-Azobis-(2,4-dimethylvaleronitrile), max. 0.07 %
- Benzoyl peroxide
- Diacyl(C₈-C₁₂) peroxide
- Acetyl cyclohexane sulfonyl peroxide
- Potassium peroxydisulfate
- Diisopropyl peroxydicarbonate
- Bis(2-ethylhexyl)peroxydicarbonate
- Bis(4-tert-butylcyclohexyl)peroxydicarbonate
- Sodium hydrogen sulfite
- tert-Butyl perpivalate
- Dicyclohexyl peroxydicarbonate
- Dicetyl peroxydicarbonate
- Tert-butyl peroxyneodecanoate
- Dimyristyl-peroxydicarbonate
- Bis(2-methylbenzoyl)peroxide
- 1,3-Di(isopropylperoxyneodecanoyl)benzene, max. 0.02 %
- 3-Hydroxy-1,1-dimethylbutylperoxyneodecanoate, max. 0.05 %
- tert-Butylhydroquinone, max. 0.002 %
- 2,4,4-Trimethylpentyl-2-peroxyneodecanoate, max. 0.06 %
- Diisobutyryl peroxide, max. 0.15 %
- 4-Hydroxy-2,2,6,6-tetramethylpiperidin-1-oxyl

in total
max.
0.2 %

The following substances may be used as pasting agent for the above listed peroxide catalysts

- Di-n-butylphthalate³
- Diisobutylphthalate⁴
- Dicyclohexylphthalate

in total
max.
0.5%

The following may be used to stabilise aqueous peroxide solutions:

- Nonylphenoxypoly-(ethylenoxy)-ethanol (degree of ethoxylation 4 - 14), max. 0.04 %
- Polysaccharide, based on macromolecules of the monosaccharides glucose and mannose, as well glucuronic acid, max. 0.004 %

b) Residues of the following emulsifying agents, in total max. 3.0 %:

- Sodium hydroxyoctadecane sulfonate

² Such production aids also include polymerisation regulators which are occasionally used, e.g. dodecyl mercaptane, trichloroethylene or 2-mercaptoethanol, max. 0.02 %, N,N-Diethylhydroxylamine, max. 0,012 %, as well as cross-linking agents. These substances are incorporated into the polymer during polymerisation.

³ Permitted in accordance with the Commission Regulation (EU) No 10/2011. Migration of this substance into foodstuffs is regulated by the Commission Regulation (EU) No 10/2011.

⁴ Restrictions applying to di-n-butylphthalate also apply to diisobutylphthalate.

- Sodium, potassium and ammonium salts of hydroxy fatty acids of chain length C₁₂-C₂₀, as well as their sulfation and acetylation products
- Alkyl sulfates C₁₂-C₂₀⁵
- Alkyl sulfonates C₁₂-C₂₀
- Alkylaryl sulfonates
- Alkylacyloxyethylates and their sulfation products
- Disodium dodecyl diphenylether disulfonate
- Nonylphenoxypoly-(ethyleneoxy)-ethanol (degree of ethoxylation 4 - 14), max. 0.2 %
- Alkylmonoethylene glycolether from monohydric saturated aliphatic alcohols C₁₆-C₁₈ with predominantly one ethylene oxide unit⁵, max. 1.0 %⁶
- c) Protective colloids, in total max. 1.0 %:
- Polyvinyl alcohol, manufactured by saponification of polyvinyl acetate with a degree of saponification of at least 20 mol %
- Copolymers of vinyl ester and maleic anhydride
- Copolymers of vinylmethyl ether and maleic anhydride
- Copolymer of 30 % vinyl acetate and 70 % vinyl pyrrolidone
- Block polymers of propylene oxide and ethylene oxide based on ethylenediamine (mean mol. wt. c. 11 200), max. 0.5 %
- d) Mixture of 89.5 % rapeseed oil⁷, 5 % polyether-modified siloxane⁵ according to Section I, No 1a of amended Recommendation XV, 2.5 % silicone dioxide⁷ and 3 % of an emulsifying agent⁸, in total max. 0.03 %, as defoaming agent.
3. Sulfate ash of the finished commodity must not exceed 4.0 % of the plastic content (i.e. not including any added pigments or filler).
4. The surface of finished products must not test positively for peroxides.⁹

⁵ In part permitted as additives in accordance with the Commission Regulation (EU) No 10/2011.

⁶ The emulsifying agent has the following composition: monoethoxylate = c. 24 %, diethoxylate = c. 13 %, higher ethoxylates = c. 15 %, monohydric aliphatic saturated C₁₆-C₁₈ fatty alcohols = c. 50 %.

⁷ Permitted as an additive in compliance with the Commission Regulation (EU) No 10/2011.

⁸ The emulsifying agent consists of (additives, some of which are regulated by the Commission Regulation (EU) No 10/2011) polyoxyethylene oleylether, stearins, aliphatic alcohols, fatty acid esters, waxes and purified saturated hydrocarbons.

⁹ See the 58th Communication on the examination of plastics, Bundesgesundheitsblatt 40 (1997) 412.