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III. Polyethylene

As of 01.04.2021

There are no objections to the use of polyethylene 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:

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) Monomer: Ethylene
- b) Comonomers:

higher α -olefines such as

*Propylene } in total
Butylene } max. 10 %*

If 1-octene is used exclusively as comonomer it may be used up to 21 %.

4-Methylpentene-1, max. 22 %

Vinylacetate, max. 10 %

Acrylic acid-n-butylester, max. 20 %

Acrylic acid-methylester, max. 10 %

The melt flow index (see DIN ISO 1133) of the polymer must not exceed 100 (2.16 Kp, 190 °C).

2. Additives permitted by the Commission Regulation (EU) No 10/2011 may be used in compliance with the restrictions laid down therein. In addition to these, the raw polymer or finished products may contain only the following production aids, used during manufacture and processing of the polymer, in the maximum amounts given¹:

- a) Catalyst residues²:

Oxides³ of calcium, magnesium, aluminium, silicon, titanium, chromium, vanadium, zirconium and hafnium, in total max. 0.1 %.

The finished products may contain max. 10 ppm chromium, max. 20 ppm vanadium, max. 100 ppm zirconium and max. 100 ppm hafnium.

Ethylene-bis-(4,5,6,7-tetrahydroindenyl)zirconium dichloride, supported on silica/methylalumoxane support, max. 250 mg/kg polymer

6-Methyl indacene, the migration of this substance must not exceed 0.05 mg/kg foodstuff or food simulant.

Bis(C₁₆-C₁₈-alkyl)methylamine, max. 30 mg/kg.

¹ Apart from the substances listed under this number, copolymers of ethylene oxide and propylene oxide may be used as lubricants for high-pressure compressors; however, finished products must not contain more than 0.1 % of these copolymers.

² Catalysts, as such or in the form of their decomposition products, not contained in the finished product are not considered.

³ Aluminium oxide, calcium oxide, silicon dioxide, magnesium oxide and titanium dioxide are permitted as additives in accordance with the Commission Regulation (EU) No 10/2011.

- 6'',6''''-(propane-1,3-diylbis(oxy))bis(3,3'',5-tri-tert-butyl-5'-methyl-[1,1':3,1''-terphenyl]-2'-ol), the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant⁴
- 2',2''-(propane-1,3-diylbis(oxy))bis(3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-3'-methyl-5-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2-ol), max. 1.5 mg/kg polymer.
- 2',2''-((((1R,2R)-cyclohexane-1,2-diyl)bis(methylene))bis(oxy))bis(3-(9H-carbazol-9-yl)-5-methyl-[1,1'-biphenyl]-2-ol), the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant.⁴
- 3'',5,5''-tri-tert-butyl-5'-methyl-[1,1':3,1''-terphenyl]-2,2'-diol, the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant.
- 3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-2'-(3-((3'-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5-fluoro-2'-hydroxy-5'-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2-yl)oxy)propoxy)-5'-fluoro-3'-methyl-5-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2-ol, max. 2.3 mg/kg polymer.
- 3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-5-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2,2'-diol, the migration of this substance must not exceed 0.05 mg/kg food stuff or simulant.⁴
- 3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-3'-methyl-5-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2,2'-diol, the migration of this substance must not exceed 0.05 mg/kg food stuff or simulant.⁴
- 2,2,6,6-Tetramethyl-3,5-heptanedione, tautomeric mixture with 5-hydroxy-2,2,6,6-tetramethylhept-4-en-3-one, the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant.

b) Residual decomposition products of the following initiating agents:

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

- | | | |
|--|---|---------------------------|
| Aliphatic diacyl(C ₈ -C ₁₂)peroxides | } | in total
max.
0.1 % |
| tert-Butylperoxy-(2-ethylhexanoate) | | |
| tert-Butyl perbenzoate | | |
| Di-tert-Butyl peroxide | | |
| tert-Butyl perpivalate | | |
| Dicyclohexyl peroxydicarbonate | | |
| Ethylhexyl peroxydicarbonate | | |
| tert-Butyl perisononate | | |
| tert-Butyl peracetate, max. 0.01 % | | |
| 2,2-Di(tert-butylperoxy)butane | | |
| tert-Butyl-hydroperoxide, max. 0.0013 % | | |
| tert-Amyl perpivalate, max. 0.2 % | | |
| tert-Butyl perneodecanoate, max. 0.15 % | | |
| tert-Butyl peroxy isobutyrate, max. 0.2 % | | |
| Methylisobutylketone peroxide, max. 0.05 % | | |
| Bis(C ₁₆ -C ₁₈ -alkyl)methylamine, max. 30 mg/kg | | |
| 1,1,3,3-Tetramethylbutylperoxyperpivalate, max. 0.007 %, for films with a thickness of max. 0.05 mm, only | | |
| 1,1,3,3-Tetramethylbutylperoxy-2-ethylhexanoate, max. 0.03 % | | |
| 3,6,9-Triethyl-3,6,9-trimethyl-1,2,4,5,7,8-hexoxonane, max. 0.05 %, for films with a thickness of max. 0.12 mm, only | | |
| tert-Amyl perneodecanoate, max. 560 mg/kg of polymer. In the manufacture of graft polymers made from polyethylene and maleic acid anhydride may be used beyond the catalysts and initiators listed in this recommendation also dicumylperoxide or 2,5-dimethyl-2,5-di(tert-butylperoxy)hexane. | | |

⁴ For the inspection of the compliance with the recommended migration limit it is feasible to use the fat reduction factor following the conditions defined in annex V of Commission Regulation (EU) No 10/2011.

2,2-di(tert-amylperoxy)butane, max. 0.01%, for films with a thickness of max. 0.25 mm, only.

Furthermore, a migration guidance value for methylethylketone and tert-amylalcohol is established with a maximum of 5 mg/kg foodstuff and 0.54 mg/kg foodstuff, respectively.

c) Emulsifying agents, or their residues:

Addition products of ethylene oxide to natural fatty acids, max. 0.2 %

n-Alkylaryl sulfonates, max. 0.2 %

Alkyl(C₁₄H₂₉)polyglycol ether oxyacetic acid, whereby the number of glycol ether groups in this compound must be 3 - 5, max. 0.25 %⁵

3. Surfaces of finished products must not test positively for peroxides.⁶

⁵ Departing from its use being limiting to 0.25 %, this substance may also be used as an antifogging agent, provided that the following conditions are met:

a) For thin plastic films (up to 12 µm) the amount used must not exceed 1.0 %.

b) For films between 12 and 50 µm in thickness, less than 1.0 % must be used. The maximum amount is obtained from film thickness (in µm) and the amount used (in %), the product of which must not exceed 12 (for example, max. 0.6 % may be used in a film with a thickness of 20 µm).

c) In the cases previously described under "a" and "b" this substance must **not** at the same time be used as an emulsifying agent.

d) If this substance is used as an antifogging agent for films thicker than 50 µm, whereby experience shows only small amounts to be necessary, it must be remembered that in total no more than 0.25 % may be contained in the finished product.

⁶ 58th Communication on the testing of plastics, Bundesgesundheitsblatt 40 (1997) 412.