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### III. Polyethylene

As of 01.09.2017

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  $\alpha$ -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 given<sup>1</sup>:

- a) Catalyst residues<sup>2</sup>:

Oxides<sup>3</sup> 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(C<sub>16</sub>-C<sub>18</sub>-alkyl)methylamine, max. 30 mg/kg

Bis(tetraalkyl(C1-C4)hydroxytriphenyl)propane ether, the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant<sup>4</sup>

<sup>1</sup> 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.

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

<sup>3</sup> 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.

- Bis[(dialkyl(C1-C4)carbazole)-(fluorodialkyl(C1-C8)-hydroxydiphenyl)]-1,3-propane ether, max. 1.5 mg/kg polymer
- Bis(alkyl(C1-C4)hydroxyl-carbazole biphenyl)1,2-dimethylcyclohexane ether, the migration of this substance must not exceed 0.05 mg/kg foodstuff or simulant<sup>4</sup>
- 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.

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|--|---|------------------------------------|
| <ul style="list-style-type: none"> <li>Aliphatic diacyl(C<sub>8</sub>-C<sub>12</sub>)peroxides</li> <li>tert-Butylperoxy-(2-ethylhexanoate)</li> <li>tert-Butyl perbenzoate</li> <li>Di-tert-Butyl peroxide</li> <li>tert-Butyl perpivalate</li> <li>Dicyclohexyl peroxydicarbonate</li> <li>Ethylhexyl peroxydicarbonate</li> <li>tert-Butyl perisononate</li> <li>tert-Butyl peracetate, max. 0.01 %</li> <li>2,2-Di(tert-butylperoxy)butane</li> <li>tert-Butyl-hydroperoxide, max. 0.0013 %</li> <li>tert-Amyl perpivalate, max. 0.2 %</li> <li>tert-Butyl perneodecanoate, max. 0.15 %</li> <li>tert-Butyl peroxy isobutyrate, max. 0.2 %</li> <li>Methylisobutylketone peroxide, max. 0.05 %</li> <li>Bis(C<sub>16</sub>-C<sub>18</sub>-alkyl)methylamine, max. 30 mg/kg</li> <li>1,1,3,3-Tetramethylbutylperoxyperpivalate, max. 0.007 %, for films with a thickness of max. 0.05 mm, only</li> <li>1,1,3,3-Tetramethylbutylperoxy-2-ethylhexanoate, max. 0.03 %</li> <li>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</li> <li>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.</li> <li>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.</li> </ul> | } | <p>in total<br/>max.<br/>0.1 %</p> |
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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(C<sub>14</sub>H<sub>29</sub>)polyglycol ether oxyacetic acid, whereby the number of glycol ether groups in this compound must be 3 - 5, max. 0.25 %<sup>5</sup>

<sup>4</sup> 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.

<sup>5</sup> 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 %.

3. Surfaces of finished products must not test positively for peroxides.<sup>6</sup>

### Applications for the inclusion of new substances in Recommendation III. Polyethylene:

The following is stated in respect to the problem presented by the dependency of migration on the type of polyethylene used (LDPE/HDPE) and the results of specific migration studies that must be presented with an application for inclusion of a new substance in the Recommendation:

Specific substance migration is related to polymer type. In the case of polyethylene, specific migration generally increases with decreasing density. However, current knowledge does not permit deduction of a strict relationship.

Thus, for the inclusion of a new substance for polyethylene in Recommendation III, migration values must be determined for a type of polyethylene from which migration is greatest. Applications that comply with this condition lead to the establishment of the maximum amount that may be used. Based on studies of substance migration behaviour from various types of polyethylene and on the current state of technological development, it can be assumed that the highest migration rates of migration are from polyethylene with a density of 0.88 - 0.90 g/cm<sup>3</sup>.

In the case of applications that do not comply with this condition, limits for specific migration of the particular substance will be determined on the basis of the submitted and toxicologically accepted migration data. If the substance has already been conclusively evaluated by the European Commission's Scientific Committee for Food, the migration limit they have established will be adopted.

If the migration value does not exceed this limit, it can be assumed to be safe in the sense of § 31 (1) of the Food and Feed Code (Article 3 Regulation (EG) 1935/2004).

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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.

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