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XXXV. Copolymers of Ethylene, Propylene, Butylene, Vinyl Esters and Unsaturated Aliphatic Acids, and their Salts and Esters

As of 01.06.2019

There are no objections to the use of copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their salts and esters, in a cross-linked or uncross-linked state with diluting agents (extenders), 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 that the following conditions are complied with:

A. Uncross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, their salts and esters, as well as their saponification products

1. Starting materials for uncross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, their salts and esters, as well as their saponification products, are subject to the requirements of the Commission Regulation (EU) No 10/2011.

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

Ethylene

Propylene

Butene-1

Isobutylene

Vinyl chloride

Vinylidene chloride

Vinylesters of aliphatic saturated monocarboxylic acids C₂-C₁₈ as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

Esters of aliphatic unsaturated mono- and dicarboxylic acids C₃-C₈ with monohydric saturated alcohols C₂-C₁₂ as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

Unsaturated aliphatic mono- and dicarboxylic acids C₃-C₈ as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

2. Residues of production aids:
Additives permitted by the Commission Regulation (EU) No 10/2011 may be used in compliance with the restrictions laid down therein. Apart from these, only the following residues of production aids - used in copolymer production and preparation after No 1 - may be contained in the raw polymer or in finished products made from it, in the maximum amounts given:
 - a) Residues of polymerisation aids:
Monohydric aliphatic alcohols¹, max. 0.5 %

¹ In part permitted as an additive 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.

- b) Residues of decomposition products of 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.

<p>Azobisisobutyronitrile Benzoyl peroxide Diacyl(C₈-C₁₂)peroxides Di-tert-butyl peroxide Diethyl peroxide Potassium peroxydisulfate tert-Butyl hydroperoxide tert-Butyl peroxyacetate t-Butyl peroxyisobutyrate tert-Butylperoxypivalate Diisopropyl peroxydicarbonate tert-Butyl peroxybenzoate tert-Butylperoxy-(2-ethylhexanoate) Dicyclohexyl peroxydicarbonate Ethylhexyl peroxydicarbonate tert-Butyl peroxy-3,5,5-trimethyl hexanoate tert-Butyl peroxyneodecanoate 2,2'-Azobis-(2,4-dimethylvaleronitrile), max. 0.07 % tert-Amylperpivalate, max. 0.014 % tert-Amylperneodecanoate, max. 0.02 % Oxides of calcium, magnesium, aluminium, titanium, vanadium and copper², in total max. 0.1 % (calculated as oxide). The finished products must contain no more than 0.002 % (= 20 ppm) vanadium, calculated as vanadium pentoxide (V₂O₅), and no more than 0.001 % copper (= 10 ppm).</p>	<p>} in total max. 0.2 %</p>
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- c) Residues of the following emulsifying agents:
Alkylaryl sulfonates
Alkylaryl oxethylates
In part covered by the Commission Regulation (EU) No. 10/2011. In this case the restrictions specified therein have to be obeyed. The residual content of the emulsifying agents stated above must not exceed 3,0%.

3. Finished products^{3,4}

- a) Finished products made from uncross-linked copolymers after this Recommendation must not be used for fats, oils or fatty foodstuffs in which fat forms the external phase.
b) The surface of finished products made from uncross-linked copolymers after this Recommendation must not test positively for peroxides.

² Calcium oxide, magnesium oxide, aluminium oxide, titanium dioxide, zinc oxide are permitted as additives by the Commission Regulation (EU) No 10/2011.

³ In respect to commodities of non-uniform composition (e.g. coated fabrics), here the term "finished product" only refers to the component to which this Recommendation is applicable.

⁴ In respect to articles made from uncross-linked, peroxide cross-linked and physically cross-linked copolymers containing vinyl acetate, a certain smell of acetic acid cannot always be avoided. However, this must not be so strong that it has a negative effect on taste or smell of the foodstuffs.

B. Peroxide cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, and their esters

1. The starting materials for peroxide cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, their salts and esters, as well as their saponification products, are subject to the requirements of the Commission Regulation (EU) No 10/2011.

The evaluation presented in the following refers to polymers made from the monomeric starting substances listed in Section A.

2. Residues of production aids
Apart from the additives already permitted by the Commission Regulation (EU) No 10/2011, the raw copolymers, produced and prepared after No 1 of this Recommendation, and the finished products made from them, may only contain residues of the production aids listed in Section A, No 2 above, in the maximum amounts given.
3. Additives
Apart from those additives already permitted by the Commission Regulation (EU) No 10/2011 the following additives may also be used in processing the copolymers of this Section:
 - a) Cross-linking agents:
2,5-Dimethyl-2,5-di-(tert-butylperoxy)hexane
2,2-Bis(tert-butylperoxy)butane
Di-tert-butyl peroxide
Triallyl cyanurate⁵ } in total max. 3.0 %
 - b) Anti-hydrolysis agents:
Tri-isopropyl-1,3,5-benzene-2,4-polycarbodiimide, max. 4.0 %, but not in co-polymers used in the manufacture of packaging for foodstuff. Other commodities are subject to No 4 b of this Recommendation.
4. Finished products^{3, 4}
 - a) The surface of finished products made from peroxide cross-linked copolymers after this Recommendation must not react positively for peroxides. Carbodiimide groups and their conversion products must not be detectable in foodstuffs or food simulants.
 - b) Finished products made from peroxide cross-linked copolymers after this Recommendation, which contain the anti-hydrolysis agent listed under No 3 b, must not be used for fats, oils or fatty foodstuffs in which fat forms the external phase.

C. Ionically cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, their salts and esters

1. The starting materials for ionically cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, their salts and esters are subject to the requirements of the Commission Regulation (EU) No 10/2011.

⁵ This substance must be completely incorporated in the cross-linked polymer, or reduced to a concentration that is undetectable, whether analytically, or through taste or smell.

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

Ethylene

Propylene

Butene-1

Esters of methacrylic acid with monohydric aliphatic saturated alcohols C₁-C₁₈ as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

Vinylesters of aliphatic saturated monocarboxylic acids C₂-C₁₂ - as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

Unsaturated aliphatic mono- and dicarboxylic acids C₃-C₈ as far as covered by the positive list of the Commission Regulation (EU) No 10/2011

2. Residues of production aids

From the manufacture and processing of copolymers after No 1, apart from those already permitted by the Commission Regulation (EU) No 10/2011, raw copolymer and the articles made from it may only contain the following additives:

Residues of decomposition products of the peroxide catalysts (initiators) listed in Section A of this Recommendation under No 2 b, in total max. 0.2 %.

3. Finished products^{3,4}

The surface of finished products made from ionically cross-linked copolymers after this Recommendation must not test positively for peroxide.

D. Physically (e.g. through electron beam irradiation) cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their esters

1. Starting materials for physically (e.g. through electron beam irradiation) cross-linked copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids and their esters are subject to the Commission Regulation (EU) No 10/2011.

The evaluation presented in the following refers to polymers made from the monomeric starting substances listed in Section A.

2. Residues of production aids

Apart from the additives already permitted by the Commission Regulation (EU) No 10/2011, the raw copolymers, produced and prepared after No 1 of this Recommendation, and the finished products made from them, may only contain residues of the production aids listed in Section A, No 2 above, in the maximum amounts given.

3. Finished products^{3,4}

The surface of finished products made from physically cross-linked copolymers after this Recommendation must not test positively for peroxide.