II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 816/2013

of 28 August 2013

Council as regards the use of Neutral methacrylate copolymer and Anionic methacrylate
copolymer in solid food supplements and the Annex to Commission Regulation (EU)
No 231/2012 as regards the specifications for Basic methacrylate copolymer (E 1205), Neutral
methacrylate copolymer and Anionic methacrylate copolymer

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European
Union,

Having regard to Regulation (EC) No 1333/2008 of the
European Parliament and of the Council of 16 December
2008 on food additives (1), and in particular Article 10(3),
Article 14 and Article 30(5) thereof,

Having regard to Regulation (EC) No 1331/2008 of the
European Parliament and of the Council of 16 December
2008 establishing a common authorisation procedure for
food additives, food enzymes and food flavourings (2), and in
particular Article 7(5) thereof,

Having regard to Regulation (EC) No 1333/2008 of the
European Parliament and of the Council of 16 December
2008 on food additives (3), and in particular Article 10(3),
Article 14 and Article 30(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a
Union list of food additives approved for use in foods
and their conditions of use.

(2) Commission Regulation (EU) No 231/2012 (4) lays down
specifications for food additives including colours and
sweeteners that are listed in Annexes II and III to Regu-

(3) Those lists may be updated in accordance with the
common procedure referred to in Article 3(1) of Regu-
lation (EC) No 1331/2008, either on the initiative of the
Commission or following an application.

(4) Applications for authorisation of the use of Anionic
methacrylate copolymer and Neutral methacrylate
copolymer as glazing agents in solid food supplements
were submitted on 25 and 27 April 2009 and were
made available to the Member States.

(5) The European Food Safety Authority evaluated the safety
of Neutral methacrylate copolymer (5) and Anionic
methacrylate copolymer (6) when used as food additives
and concluded that their use in solid food supplements at
the proposed use levels is not of a safety concern.

(6) There is a technological need for the use of Neutral
methacrylate copolymer and Anionic methacrylate
copolymer in solid food supplements. Neutral metha-
crylate copolymer is intended to be used as a
sustained-release glazing agent. Sustained-release formu-
lations allow the continuous dissolution of a nutrient
over a defined time. Anionic methacrylate copolymer is
intended to be used as a glazing agent to protect the
stomach against irritating ingredients and/or to protect
sensitive nutrients against disintegration by the gastric
acid. It is therefore appropriate to authorise the use of
both food additives in solid food supplements and to
assign E 1206 as E-number to Neutral methacrylate
copolymer and E 1207 as E-number to Anionic metha-
crylate copolymer.

(7) Commission Regulation (EU) No 1129/2011 (7) autho-
rised the use of Basic methacrylate copolymer
(E 1205) in solid food supplements and Regulation
(EU) No 231/2012 sets out the specifications for that
food additive, including the maximum levels for
arsenic, lead, mercury and copper. Those specifications
should be updated to take into account the maximum
levels for lead, copper and cadmium in food

(4) EFSA Journal 2010; 8(7):1655.

(8) Maximum level of arsenic in food supplements has not been set at the Union level. However, specific levels are laid down in the laws of Member States. Therefore, it is appropriate to update specifications of Basic methacrylate copolymer (E 1205) in Regulation (EU) No 231/2012 as regards arsenic to take into account the laws of Member States.

(9) Maximum level of copper in food supplements has not been set at the Union level and there is no indication of copper presence at toxicologically significant levels in Basic methacrylate copolymer (E 1205). It is therefore appropriate to delete copper from the purity section for Basic methacrylate copolymer (E 1205) in Regulation (EU) No 231/2012.

(10) Specifications should be adopted for Neutral methacrylate copolymer (E 1206) and Anionic methacrylate copolymer (E 1207). The purity criteria for arsenic, lead, mercury and cadmium should follow the same approach as those for Basic methacrylate copolymer (E 1205) and the maximum levels should take into account that the commercial form of Neutral methacrylate copolymer (E 1206) and Anionic methacrylate copolymer (E 1207) is a 30% dispersion of the dry substance in water.


(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1
Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2
The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 August 2013.

For the Commission
The President
José Manuel BARROSO

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, the following entries for E 1206 and E 1207 are inserted in point 3 'Additives other than colours and sweeteners', after the entry for E 1205 Basic methacrylate copolymer:

<table>
<thead>
<tr>
<th>E 1206</th>
<th>Neutral methacrylate copolymer</th>
</tr>
</thead>
<tbody>
<tr>
<td>E 1207</td>
<td>Anionic methacrylate copolymer</td>
</tr>
</tbody>
</table>

(2) In Part E, the following entries are inserted in food category 17.1 ‘Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms’, after the entry for E 1205 Basic methacrylate copolymer:

<table>
<thead>
<tr>
<th>E 1206</th>
<th>Neutral methacrylate copolymer</th>
<th>200 000</th>
</tr>
</thead>
<tbody>
<tr>
<td>E 1207</td>
<td>Anionic methacrylate copolymer</td>
<td>100 000'</td>
</tr>
</tbody>
</table>
The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) The purity section of the entry for E 1205 (Basic methacrylate copolymer) is replaced by the following:

**Purity**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of drying</td>
<td>Not more than 2.0 % (105 °C, 3 h)</td>
</tr>
<tr>
<td>Alkali value</td>
<td>162-198 mg KOH/g of dried substance</td>
</tr>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0.1 %</td>
</tr>
<tr>
<td>Residual monomers</td>
<td>Butylmethacrylate &lt; 1 000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Methyl methacrylate &lt; 1 000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Dimethylaminoethyl methacrylate &lt; 1 000 mg/kg</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>propan-2-ol &lt; 0.5 %</td>
</tr>
<tr>
<td></td>
<td>Butanol &lt; 0.5 %</td>
</tr>
<tr>
<td></td>
<td>Methanol &lt; 0.1 %</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 3 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0.1 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 1 mg/kg</td>
</tr>
</tbody>
</table>

(2) The following entries for E 1206 and E 1207 are inserted after the entry for E 1205 (Basic methacrylate copolymer):

**E 1206 NEUTRAL METHACRYLATE COPOLYMER**

**Synonyms**

Ethyl acrylate methyl methacrylate polymer; Ethyl acrylate, methyl methacrylate polymer; Ethyl acrylate, polymer with methyl methacrylate; Methyl methacrylate, ethyl acrylate polymer; Methyl methacrylate, polymer with ethyl acrylate

**Definition**

Neutral methacrylate copolymer is a fully polymerised copolymer of methyl methacrylate and ethyl acrylate. It is produced using a process of emulsion polymerisation. It is manufactured by redox initiated polymerisation of the monomers ethyl acrylate, methyl methacrylate by using a free radical donor redox initiator system stabilised with polyethylene glycol monostearil ether and vinylic acid/sodium hydroxide. Residual monomers are removed by means of water vapour distillation.

**CAS No**

9010-88-2

**Chemical name**

Poly(ethylacrylate-co-methyl methacrylate) 2:1

**Chemical formula**

Poly[(CH₂CHCO₂CH₂CH₃)-co-(CH₂C(CH₃)CO₂CH₃)]

**Weight average molecular weight**

Approximately 600 000 g/mol

**Assay/Residue on evaporation**

28.5–31.5 %

1 g dispersion is dried in an oven for 3 hours at 110 °C.

**Description**

Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.
Identification

Infrared absorption spectroscopy
Characteristic of the compound

Viscosity
Max. 50 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)

pH-value
5.5–8.6

Relative density (at 20 °C)
1.037–1.047

Solubility
The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Not soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2.

Purity

Sulphated ash
Not more than 0.4 % in the dispersion

Residual monomers
Total of monomers (sum of methyl methacrylate and ethyl acrylate): not more than 100 mg/kg in the dispersion

Residual emulsifier
Polyethylene glycol monostearyl ether (macrogol stearyl ether 20) not more than 0.7 % in the dispersion

Solvent residues
Ethanol not more than 0.5 % in the dispersion
Methanol not more than 0.1 % in the dispersion

Arsenic
Not more than 0.3 mg/kg in the dispersion

Lead
Not more than 0.9 mg/kg in the dispersion

Mercury
Not more than 0.03 mg/kg in the dispersion

Cadmium
Not more than 0.3 mg/kg in the dispersion

E 1207 ANIONIC METHACRYLATE COPOLYMER

Synonyms
Methyl acrylate, methyl methacrylate, methacrylic acid polymer; Methacrylic acid, polymer with methyl acrylate and methyl methacrylate

Definition
Anionic methacrylate copolymer is a fully polymerised copolymer of methacrylic acid, methyl methacrylate and methyl acrylate. It is manufactured in aqueous medium by emulsion polymerisation of methyl methacrylate, methyl acrylate and methacrylic acid using a free radical initiator stabilised with sodium lauryl sulphate and polyoxyethylene sorbitan monooleate (polysorbate 80). Residual monomers are removed by means of water vapour distillation.

CAS No
26936-24-3

Chemical name
Poly (methyl acrylate-co-methylmethacrylate-co-methacrylic acid) 7:3:1

Chemical formula
Poly[(CH₂(CHCO₂CH₃)-co-(CH₂-C(CH₃)CO₂CH₃)-co-(CH₂-C(CH₃) COOH)]

Weight average molecular weight
Approximately 280 000 g/mol

Assay/Residue on evaporation
28.5–31.5 %

1 g of the dispersion is dried in an oven for 5 hours at 110 °C.
9.2–12.3 % methacrylic acid units on dry substance.

Description
Milky-white dispersion (the commercial form is a 30 % dispersion of the dry substance in water) of low viscosity with a faint characteristic odour.
### Identification

<table>
<thead>
<tr>
<th>Characteristic of the compound</th>
<th>Infrared absorption spectroscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity</td>
<td>Max. 20 mPa.s, 30 rpm/20 °C (Brookfield viscosimetry)</td>
</tr>
<tr>
<td>pH-value</td>
<td>2,0–3,5</td>
</tr>
<tr>
<td>Relative density (at 20 °C)</td>
<td>1,058–1,068</td>
</tr>
</tbody>
</table>

**Solubility**
The dispersion is miscible with water in any proportion. The polymer and the dispersion are freely soluble in acetone, ethanol and isopropyl alcohol. Soluble when mixed with 1 N sodium hydroxide in a ratio of 1:2. Soluble above pH 7,0.

### Purity

<table>
<thead>
<tr>
<th>Acid value</th>
<th>60–80 mg KOH/g of dried substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulphated ash</td>
<td>Not more than 0,2 % in the dispersion</td>
</tr>
<tr>
<td>Residual monomers</td>
<td>Total of monomers (sum of methacrylic acid, methyl methacrylate and methyl acrylate): not more than 100 mg/kg in the dispersion</td>
</tr>
<tr>
<td>Residual emulsifiers</td>
<td>Sodium lauryl sulphate not more than 0,3 % on the dry substance Polysorbate 80 not more than 1,2 % on the dry substance</td>
</tr>
<tr>
<td>Solvent residues</td>
<td>Methanol not more than 0,1 % in the dispersion</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 0,3 mg/kg in the dispersion</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 0,9 mg/kg in the dispersion</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0,03 mg/kg in the dispersion</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 0,3 mg/kg in the dispersion</td>
</tr>
</tbody>
</table>