II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/1461
of 28 September 2018

(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 Articles 10(3) and 14 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,

Whereas:

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

(2) Only food additives included in the Union list in Annex II to Regulation (EC) No 1333/2008 may be placed on the market as such and used in foods under the conditions of use specified therein.


(4) The Union list and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(5) On 21 October 2016 an application was submitted for the authorisation of the use of low-substituted hydroxypropyl cellulose (L-HPC) as a food additive in food supplements in tablet form falling under the food category 17.1 'Food supplements supplied in a solid form’ in Part E of Annex II to Regulation (EC) No 1333/2008. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(6) The European Food Safety Authority evaluated the safety of L-HPC as a food additive and in its opinion (4) of 20 January 2018 concluded that there was no safety concern from the proposed use in food supplements in solid form (tablet), at a maximum use level of 20 000 mg/kg and a typical use level of 10 000 mg/kg.

(4) EFSA Journal 2018;16(1):5062.
Low-substituted hydroxypropyl cellulose (L-HPC) is water insoluble cellulose that facilitates the manufacturing of solid food supplements in tablet form due to its good compressibility and binding properties. Being insoluble in water, it absorbs water while increasing in volume. The increased volume makes the tablet disintegrating rapidly providing a fast release of the nutrients in the stomach.

It is therefore appropriate to include low-substituted hydroxypropyl cellulose (L-HPC) in the Union list of food additives and to assign E 463a as E-number to that additive to enable its authorisation as a glazing agent in food supplements in solid form (tablet) at a maximum use level of 20 000 mg/kg.

The specifications for low-substituted hydroxypropyl cellulose (L-HPC) (E 463a) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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 September 2018.

For the Commission
The President
Jean-Claude JUNCKER
ANNEX I

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

(1) in Part B, point 3 ‘Additives other than colours and sweeteners’, the following new entry E 463a for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 463 Hydroxypropyl cellulose:

| ‘E 463a’ | Low-substituted hydroxypropyl cellulose (L-HPC) |

(2) in Part E, in food category 17.1 ‘Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms’, the following new entry for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 459 Beta-cyclodextrin:

| ‘E 463a’ | Low-substituted hydroxypropyl cellulose (L-HPC) | 20 000 | only food supplements in tablet form |
In the Annex to Regulation (EU) No 231/2012 the following entry for E 463a (Low-substitued hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 463 (Hydroxypropyl cellulose):

**E 463a LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (L-HPC)**

<table>
<thead>
<tr>
<th><strong>Synonyms</strong></th>
<th>Cellulose hydroxypropyl ether, low substituted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>L-HPC is a low-substituted poly (hydroxypropyl) ether of cellulose. L-HPC is manufactured by partial etherification of the anhydroglucose units of pure cellulose (wood pulp) with propylene oxide/hydroxypropyl groups. The resulting product is then purified, dried and milled to yield low-substituted hydroxypropyl cellulose. L-HPC contains not less than 5,0 % and not more than 16,0 % of hydroxyprooxy groups, calculated on the dried basis. L-HPC differs from hydroxypropyl cellulose (E 463) with respect to the degree of molar substitution with hydroxyprooxy groups of the glucose ring unit (0,2 for L-HPC vs 3,5 for E 463) of the cellulose backbone.</td>
</tr>
<tr>
<td><strong>IUPAC name</strong></td>
<td>Cellulose, 2-hydroxypropyl ether (low substituted)</td>
</tr>
<tr>
<td><strong>CAS number</strong></td>
<td>9004-64-2</td>
</tr>
<tr>
<td><strong>Einecs number</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>Hydroxypropyl ether of cellulose, low-substituted</td>
</tr>
</tbody>
</table>
| **Chemical formula** | The polymers contain substituted anhydroglucose units with the following general formula:

\[
C_6H_7O_2(OR_1)(OR_2)(OR_3)
\]

where \( R_1, R_2, R_3 \) each may be one of the following:

- \( H \)
- \( CH_2CHOHCH_3 \)
- \( CH_2CHO(CH_2CHOHCH_3)CH_3 \)
- \( CH_2CHO(CH_2CHO(CH_2CHOHCH_3)CH_3)CH_3 \)

**Molecular weight** | From about 30 000 to 150 000 g/mol |
| **Assay** | The average number of hydroxyprooxy groups \((-OCH_2CHOHCH_3)\) corresponds to 0,2 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis |
| **Particle size** | by laser diffraction method — Not less than 45 μm (not more than 1 % in weight of particles of less than 45 μm) and not more than 65 μm  by size-exclusion chromatography (SEC) — Average (D50) particle size between 47,3 μm and 50,3 μm; D90 value (90 % below given value) between 126,2 μm and 138 μm |
| **Description** | Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder |
| **Identification** | Passes test |
| **Solubility** | Insoluble in water; swelling in water. It dissolves in a solution of 10 % sodium hydroxide producing a viscous solution. |
### Assay

Determination of the degree of molar substitution by gas chromatography

### pH

Not less than 5.0 and not more than 7.5 (1 % colloidal suspension)

### Purity

<table>
<thead>
<tr>
<th>Test</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss on drying</td>
<td>Not more than 5.0 % (105 °C, 1 hour)</td>
</tr>
<tr>
<td>Residue on ignition</td>
<td>Not more than 0.8 % determined at 800 °C ± 25 °C</td>
</tr>
<tr>
<td>Propylene chlorohydrins</td>
<td>Not more than 0.1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS))</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Not more than 2 mg/kg</td>
</tr>
<tr>
<td>Lead</td>
<td>Not more than 1 mg/kg</td>
</tr>
<tr>
<td>Mercury</td>
<td>Not more than 0.5 mg/kg</td>
</tr>
<tr>
<td>Cadmium</td>
<td>Not more than 0.15 mg/kg</td>
</tr>
</tbody>
</table>