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ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted: *[OP, please insert in the EN version in alphabetical order.]*

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | Data protection |
|--|---|-----------------------|--|--------------------|---|
| Magnesium potassium trichloride hexahydrate | Specified food category | Maximum levels | <p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘magnesium potassium trichloride hexahydrate’.</p> <p>2. Where the novel food is added to final product that contain an amount of potassium and magnesium that is considered significant in accordance with Point 2 of Part A of Annex XIII to</p> | | <p>Authorised on [...] [OP please insert the date dd.mm.yyyy - 20th day following its publication].</p> <p>This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: BK Guilini, GmbH, member of ICL Group, Am Hafen 2, 68526 Ladenburg, Germany.</p> |
| | Raw cured (or seasoned) meat | 1050 mg/100 g | | | |
| | Cooked cured (or seasoned) meat | 700 mg/100 g | | | |
| | Pastas and rice (or other cereal)-based dishes | 600 mg/100 g | | | |
| | Preserved or partly preserved sausages | 1050 mg/100 g | | | |

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|--|--|--|--|--|--|
| | | | Regulation (EU) No 1169/2011, the nutrition declaration shall contain the amount of potassium and magnesium. | | <p>During the period of data protection, the novel food magnesium potassium trichloride hexahydrate is authorised for placing on the market within the Union only by BK Guilini GmbH, member of ICL Group, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of BK Guilini GmbH, member of ICL Group.</p> <p>End date of the date protection: [...] [OP please insert the date dd.mm.yyyy – after 5 years]</p> |
|--|--|--|--|--|--|

(2) in Table 2 (Specifications), the following entry is inserted: [OP, please insert in the EN version in alphabetical order.]

| Authorised Novel Food | Specifications |
|---|---|
| <p>Magnesium potassium trichloride hexahydrate</p> | <p>Description / Definition: The novel food is a mineral salt containing potassium and magnesium. It is a white, off-white crystalline, fine granular, slightly hygroscopic product with a characteristic saline taste. It is exclusively originating from water of the Dead Sea (Israel) and produced by fractional precipitation.</p> <p>Synonym: Potassium magnesium chloride hydrate</p> <p>Identity: Positive by X-ray diffraction</p> <p>Characteristics: Melting point (range): 149.6 - 160.2°C Solubility: <ul style="list-style-type: none"> - pH 1.94: 4.13 and 6.80: freely soluble - pH 8.06: slightly soluble - Insoluble parts: ≤ 0.3% (w/w) Water at 180°C (water of crystallisation plus moisture): 32%–40%</p> <p>Main constituents: Chloride: 40% - 42% (w/w) Potassium: 11.0% - 13.6% (w/w) Magnesium: 7.9% - 8.9% (w/w) Calcium: ≤ 0.2% (w/w) Sodium: ≤ 2.75% (w/w)</p> |

Heavy metals:

Arsenic < 0.1 mg/kg

Cadmium < 0.1 mg/kg

Mercury < 0.05 mg/kg

Lead < 0.1 mg/kg

Trace elements:

Bromide (Br⁻): ≤ 0.40% (w/w)

Strontium: ≤ 25 mg/kg

Manganese: ≤ 3.0 mg/kg

Iron: ≤ 4.0 mg/kg

Copper: ≤ 0.5 mg/kg

Boron: ≤ 10 mg/kg

Aluminium: ≤ 1.0 mg/kg

Total phosphorous: ≤ 5 mg/kg

Sulfate: < 500 mg/kg

Nitrite: < 10 mg/kg

Nitrate: < 400 mg/kg

Chlorate: < 0.2 mg/kg

Bromate: < 1 mg/kg

Fluoride: ≤ 5 mg/kg

Iodine: < 0.1 mg/kg

Microbiological parameters:

Total plate count: < 100 CFU/g

E. coli: not detected in 1 g

Salmonella: not detected in 25 g

| | |
|--|--|
| | <p>Salt-tolerant microorganisms: < 100 CFU/g</p> <p>Sum parameters:</p> <p>Total organic carbon: < 0.10% (w/w)</p> <p>CFU: colony forming units</p> |
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