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EN

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 L-threonate	Specified food category	Maximum levels	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Magnesium L-threonate’. 2. The labelling of food supplements containing magnesium L-threonate shall bear a statement that the food supplements should not be consumed by infants, children, pregnant and lactating women.		Authorised on [<i>OP please insert the date dd.mm.yyyy - 20th day following its publication</i>]. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: AIDP Inc., 19535 East Walnut Drive South City of Industry, CA 91748, the United States. During the period of data protection, the novel food magnesium L-threonate is authorised for placing on the market within the Union only by AIDP Inc., unless a subsequent applicant obtains authorisation for the novel food
	Food supplements as defined in Directive 2002/46/EC for adults, excluding pregnant and lactating women	In accordance with Directive 2002/46/EC			

					<p>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 AIDP Inc.</p> <p>End date of the date protection: <i>[OP please insert the date dd.mm.yyyy – after 5 years]</i></p>
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(2) in Table 2 (Specifications), the following entry is inserted: [*OP, please insert in the EN version in alphabetical order.*]

Authorised Novel Food	Specification
Magnesium L-threonate	<p>Description/Definition: The novel food is produced by chemical synthesis and consists of magnesium L-threonate.</p> <p>Chemical identity: Chemical (IUPAC) name: Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate Common name: magnesium L-threonate Molecular formula: C₈H₁₆MgO₁₁ CAS number: 500304-76-7 Molecular weight: 312.5 Da</p> <p>Characteristics/composition: Appearance: White powder Mg L-threonate monohydrate: 98%–102% Magnesium: 7.2%-8.3% L-Threonate: 82%-91% Oxalic acid: ≤ 1% Ethanol: ≤ 5000 ppm Loss on drying: ≤ 5.0%</p> <p>Microbiological criteria: Total aerobic microbial count: ≤ 100 CFU/g Total yeast and moulds count: ≤ 100 CFU/g <i>E. coli</i>: Not detected in 10 g <i>Salmonella</i>: Not detected in 25 g</p>

	Abbreviations: CAS: chemical abstracts service, IUPAC: International Union of Pure and Applied Chemistry, CFU: colony forming unit
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