
W E L S H S U B O R D I N A T E L E G I S L A T I O N

WG25-89**FOOD, WALES****REGULATED PRODUCTS, WALES****NOVEL FOODS**

Determination of authorisation status: authorisation of magnesium L-threonate monohydrate as a novel food

Explanatory note

(this note is not part of the determination)

This determination is made in relation to Wales by the Welsh Ministers in exercise of the powers conferred by Article 12 of Regulation [\(EU\) 2015/2283](#) of the European Parliament and of the Council on novel foods (EUR 2015/2283).

It authorises magnesium L-threonate monohydrate as a novel food for use in food supplements. The terms of the authorisation and the conditions, requirements and specification upon which the novel food is authorised are set out in the Schedule.

This determination comes into force on the date on which magnesium L-threonate monohydrate is added to Schedule 2 to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, in relation to Wales..

There has been consultation as required by Article 9 of Regulation [\(EC\) No 178/2002](#) of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (EUR 2002/178).

Determination

Application and coming into force

1. This determination applies in relation to Wales, and comes into force on [the date on which magnesium L-threonate monohydrate is added to Schedule 2 to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, in relation to Wales.

Interpretation

2. Any expression used both in this determination and in Regulation (EU) No 2015/2283 of the European Parliament and of the Council on novel foods (Regulation (EU) No 2015/2283) has the same meaning as it has in that Regulation.

Determination of authorisation status of magnesium L-threonate monohydrate

3. Magnesium L-threonate monohydrate is authorised as a novel food to be placed on the market in Wales, and to be used in or on food, in accordance with the conditions, requirements and specification set out in the Schedule.

Name: Sarah Murphy MS

Minister for Mental Health and Wellbeing, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers

Date: 15 December 2025

SCHEDULE

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Data protection
	<i>Specified food category</i>	<i>Maximum levels</i>		
Magnesium L-threonate monohydrate	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, for persons aged 18 years or above, excluding pregnant women and lactating women	250 mg magnesium/day	<ol style="list-style-type: none"> 1. The designation of the novel food on the labelling of the food containing it is: "Magnesium L-threonate" 2. The labelling of food supplements containing magnesium L-threonate monohydrate must bear a statement that the food supplement is not to be consumed by persons under 18 years, pregnant women and lactating women. <p>The food information must be presented in accordance with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (EUR 2011/1169) which apply to mandatory food information.</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: AIDP Inc. 19535 East Walnut Drive South, City of Industry CA 91748 USA</p> <p>During the period of data protection, the use of magnesium L-threonate monohydrate [within food supplements is authorised for placing on the market, within Wales, only by AIDP Inc. 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)</p>

				2015/2283 or with the agreement of AIDP Inc. The data protection will expire at the end of 5 years from the coming into force of this determination.
Specification				
<p>Description/Definition:</p> <ul style="list-style-type: none"> Magnesium L-threonate monohydrate is a water-soluble white powder which is manufactured via a chemical synthetic process <p>Chemical Identity:</p> <ul style="list-style-type: none"> Chemical formula: C₈H₁₆MgO₁₁ Chemical name: Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate CAS No.: 500304-76-7 Molecular weight: 312.51 Da <p>Characteristics/composition:</p> <ul style="list-style-type: none"> Solubility: Soluble in water at 1% concentration at 25°C and clear in solution at 1% concentration Magnesium: 7.2 to 8.3 % L-Threonate: 82 to 91 % Oxalic acid/oxalate: ≤ 0.5 % (as oxalic acid) Loss on drying (105°C, 4 hours): ≤5.0 % Colour (solid): White pH (USP (1% in H₂O)): 5.8 - 7.0 <p>Heavy metals:</p> <ul style="list-style-type: none"> Arsenic: ≤ 1 ppm Lead: ≤ 0.5 ppm Cadmium: ≤ 0.2 ppm 				

- Mercury ≤ 0.1 ppm