Draft Regulations laid before Parliament under regulation 6(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No.

FOOD, ENGLAND

The Food Supplements Purity Criteria (Magnesium L-threonate monohydrate) (England) Regulations 2026

Made - - - -	***
Coming into force - -	*13th August 2026*

The Secretary of State makes these Regulations in exercise of the powers conferred by regulation 3 and in accordance with regulation 5(1) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 ("the 2019 Regulations")(**a**).

There has been open and transparent consultation in accordance with Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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(**b**).

In accordance with regulation 6(3) of the 2019 Regulations, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Food Supplements Purity Criteria (Magnesium L-threonate monohydrate) (England) Regulations 2026 and come into force on 13th August 2026.

(2) These Regulations extend to England and Wales.

(3) These Regulations apply to England only.

Purity criteria for magnesium L-threonate monohydrate

2. The purity criteria for magnesium L-threonate monohydrate are set out in the Schedule to these Regulations.

(**a**) S.I. 2019/651, amended by S.I. 2026/412. There are other amending instruments but none are relevant. These powers are exercised by the Secretary of State who is the "appropriate authority" for regulations applying in relation to England, as defined in regulation 5(4)(a).

(**b**) EUR 2002/178, to which there are other amending instruments but none are relevant.

Signed by authority of the Secretary of State for Health and Social Care

Name
Parliamentary Under-Secretary of State
Date Department of Health and Social Care

SCHEDULE

Regulation 2

PURITY CRITERIA FOR MAGNESIUM L-THREONATE MONOHYDRATE

Synonym	Magnesium L-threonate
Definition	
Chemical name	Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate
CAS number	500304-76-7(**a**)
Chemical formula	$C_8H_{16}MgO_{11}$
Molecular weight	312.51 Da
Colour (solid)	White
Assay	Magnesium: 7.2% to 8.3% L-threonate: 82% to 91%
Description	A water-soluble white powder which is manufactured via a chemical synthetic process.
Identification	
Solubility	Soluble in water at 1% concentration at 25℃ and that is clear in solution at 1% concentration.
pH USP(**b**) (1% in H_2O)	5.8 to 7.0
Purity	
Loss on drying	Not more than 5.0% (105℃/4 hours)
Oxalic acid/oxalate	Not more than 0.5% (as oxalic acid)
Arsenic	Not more than 1 ppm
Lead	Not more than 0.5 ppm
Cadmium	Not more than 0.2 ppm
Mercury	Not more than 0.1 ppm

(**a**) This is a reference to the CAS Registry Number assigned to this preparation by the Chemical Abstracts Service. This is available at https://www.cas.org/cas-data/cas-registry

(**b**) United States Pharmacopoeia (USP), published by the United States Pharmacopeial Convention in Rockville, Maryland, USA. General Chapter 791 pH of the USP was revised in 2014 by a Supplement to the USP, published on 1st December 2014 (ISBN number 1936424223). USP is a nonprofit scientific organisation that develops and disseminates public compendial quality standards for medicines and other articles. The USP is available at https://www.usp.org

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations set the purity criteria for the mineral substance magnesium L-threonate monohydrate, as a source of magnesium, as set out in the Schedule to these Regulations (regulation 2).

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

An Explanatory Memorandum has been published alongside this instrument at www.legislation.gov.uk.

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ISBN 978-0-34-828257-3

£6.40

http://www.legislation.gov.uk/id/ukdsi/2026/9780348282573

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