Draft Regulations laid before the Scottish Parliament under regulation 7(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019, for approval by resolution of the Scottish Parliament.

DRAFT SCOTTISH STATUTORY INSTRUMENTS

2026 No.

FOOD

The Food Supplements (Magnesium L-threonate monohydrate) (Scotland) Regulations 2026

Made - - - -	*2026*
Coming into force - -	*5th March 2026*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by regulations 2(2) and 3 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(**a**) and all other powers enabling them to do so.

In accordance with regulation 7(3) of those Regulations, a draft of this instrument has been laid before and approved by resolution of the Scottish Parliament.

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(**b**).

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food Supplements (Magnesium L-threonate monohydrate) (Scotland) Regulations 2026 and come into force on 5 March 2026.

(2) These Regulations extend to Scotland only.

(**a**) S.I. 2019/651. Regulation 5 provides that the Scottish Ministers are the "appropriate authority" for regulations applying in relation to Scotland and confers powers on them to make these Regulations. Regulations made by the Scottish Ministers under regulations 2 and 3 are subject to the negative and affirmative parliamentary procedures, respectively. These Regulations are subject to the affirmative parliamentary procedure by virtue of section 33(3) of the Interpretation and Legislative Reform (Scotland) Act 2010 (asp 10).

(**b**) EUR 2002/178.

Amendment of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019

2.—(1) The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 are amended in accordance with paragraph (2).

(2) In schedule 2 (vitamin and mineral substances which may be used in the manufacture of food supplements), in Part B of the table (minerals), after the entry for "magnesium citrate malate"(**a**) insert "magnesium L-threonate monohydrate".

Setting of purity criteria for magnesium L-threonate monohydrate

3. The purity criteria for magnesium L-threonate monohydrate are set in the schedule.

Name
Authorised to sign by the Scottish Ministers

St Andrew's House
Edinburgh
Date

(**a**) Magnesium citrate malate was added to part B of the table (Minerals) in schedule 2 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 by regulation 6(3)(b) of the Food Supplements and Food for Specific Groups (Miscellaneous Amendments) Regulations 2023 (S.I. 2023/28).

SCHEDULE

Regulation 3

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(**b**)
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(**c**) (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(**d**)
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 https://www.cas.org/cas-data/cas-registry

(**b**) The dalton ('Da'), or unified atomic mass unit, is a unit of mass defined as one twelfth of the mass of an unbound neutral atom of carbon-12 in its nuclear and electronic ground state and at rest.

(**c**) 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). The USP is available at https://www.usp.org

(**d**) A part per million ('ppm') is defined as one part of a substance per one million parts of a total mixture or solution. It is equal to a milligram per kilogram ('mg/kg').

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under powers set out in regulations 2(2) and 3 of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651) ("the 2019 Regulations").

These Regulations permit the use of the mineral substance, magnesium L-threonate monohydrate, in the manufacture of food supplements. They do so by amending the list of mineral substances which is set out in schedule 2 of the 2019 Regulations, by the addition of an entry for this mineral substance (regulation 2).

These Regulations set the purity criteria for the mineral substance, as provided in the schedule of these Regulations (regulation 3).

No business and regulatory impact assessment has been prepared for these Regulations as no impact upon business, charities or voluntary bodies is foreseen.

A Policy Note has been published alongside this instrument at Legislation.gov.uk.

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