*Rheoliadau drafft a osodwyd gerbron Senedd Cymru yn unol â gweithdrefn gymeradwyo'r Senedd o dan reoliad 8(3) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019 (O.S. 2019/651).*

OFFERYNNAU STATUDOL CYMRU DRAFFT

# 2026 Rhif

# Rheoliadau Atchwanegiadau Bwyd (Magnesiwm L-threonad monohydrad) (Cymru) 2026

| | |
|---|---|
| *Gwnaed* | ***** |
| *Yn dod i rym* | *5 Mawrth 2026* |

*Draft Regulations laid before Senedd Cymru in accordance with the Senedd approval procedure under regulation 8(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651).*

DRAFT WELSH STATUTORY INSTRUMENTS

# 2026 No.

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

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

*Rheoliadau drafft a osodwyd gerbron Senedd Cymru yn unol â gweithdrefn gymeradwyo'r Senedd o dan reoliad 8(3) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019 (O.S. 2019/651).*

O F F E R Y N N A U   S T A T U D O L   C Y M R U   D R A F F T

# 2026 Rhif

# BWYD, CYMRU

# Rheoliadau Atchwanegiadau Bwyd (Magnesiwm L-threonad monohydrad) (Cymru) 2026

## NODYN ESBONIADOL

*(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)*

Mae'r Rheoliadau hyn wedi eu gwneud drwy ddefnyddio pwerau a nodir yn rheoliadau 2(2), 3 a 5(1) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019 (O.S. 2019/651) ("Rheoliadau 2019").

Mae rheoliad 5 o Reoliadau Ychwanegion Bwyd (Cymru) 2003 (O.S. 2003/1719 (Cy. 186)) yn gwahardd gwerthu atchwanegiadau bwyd a weithgynhyrchwyd gan ddefnyddio fitaminau neu fwynau oni bai bod y fitamin neu'r mwyn hwnnw—

(a) wedi ei restru yn Atodlen 1 i Reoliadau 2019;

(b) ar ffurf sydd wedi ei rhestru yn Atodlen 2 i Reoliadau 2019 ac sy'n bodloni'r meini prawf purdeb perthnasol.

Mae'r mwyn, magnesiwm, eisoes wedi ei restru yn Atodlen 1 i Reoliadau 2019. Mae'r Rheoliadau hyn yn—

(a) ychwanegu'r ffurf fwynol, magnesiwm L-threonad monohydrad ("y Sylwedd") at y rhestr yn Atodlen 2 i Reoliadau 2019;

(b) gosod meini prawf purdeb ar gyfer y Sylwedd.

Mae'r Sylwedd hefyd yn fwyd newydd o fewn ystyr "novel food" yn Rheoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor dyddiedig 25 Tachwedd 2015 ar fwydydd newydd, sy'n diwygio Rheoliad (EU) Rhif 1169/2011 Senedd Ewrop a'r Cyngor ac yn diddymu Rheoliad (EC) Rhif 258/97 Senedd Ewrop a'r Cyngor a Rheoliad y Comisiwn (EC) Rhif 1852/2001 (EUR 2015/2283) ("y Rheoliad Bwyd Newydd").

Mae Gweinidogion Cymru wedi penderfynu statws awdurdodi'r Sylwedd o ran Cymru yn unol ag Erthygl 12 o'r Rheoliad Bwyd Newydd. Mae gwybodaeth am yr awdurdodiad ar gael ar y rhestr o fwydydd newydd a gynhelir gan yr Asiantaeth Safonau Bwyd (Foss House, Kings Pool, 1-2 Peasholme Green, York, YO1 7PR) yn unol ag Erthygl 3B o'r Rheoliad Bwyd Newydd.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, lluniwyd asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn. Gellir cael copi oddi wrth: Cyfarwyddiaeth Iechyd y Cyhoedd, Llywodraeth Cymru, Parc Cathays, Caerdydd, CF10 3NQ ac mae wedi ei gyhoeddi ar www.llyw.cymru.

*Rheoliadau drafft a osodwyd gerbron Senedd Cymru yn unol â gweithdrefn gymeradwyo'r Senedd o dan reoliad 8(3) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019 (O.S. 2019/651).*

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O F F E R Y N N A U   S T A T U D O L   C Y M R U   D R A F F T

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# 2026 Rhif

# BWYD, CYMRU

## Rheoliadau Atchwanegiadau Bwyd (Magnesiwm L-threonad monohydrad) (Cymru) 2026

| | |
|---|---|
| *Gwnaed* | *** |
| *Yn dod i rym* | *5 Mawrth 2026* |

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddir gan reoliadau 2(2), 3 a 5(1) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019(**1**), yn gwneud y Rheoliadau a ganlyn.

Ymgynghorwyd fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor dyddiedig 28 Ionawr 2002 sy'n gosod egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn gosod gweithdrefnau o ran materion diogelwch bwyd(**2**).

Mae'r Rheoliadau hyn wedi eu gosod gerbron Senedd Cymru yn unol â gweithdrefn gymeradwyo'r Senedd o dan reoliad 8(3) o Reoliadau Maethiad (Diwygio etc.) (Ymadael â'r UE) 2019(**3**).

**Enwi, dod i rym a rhychwant**

**1.**—(1) Enw'r Rheoliadau hyn yw Rheoliadau Atchwanegiadau Bwyd (Magnesiwm L-threonad monohydrad) (Cymru) 2026.

(2) Daw'r Rheoliadau hyn i rym ar 5 Mawrth 2026.

(3) Mae'r Rheoliadau hyn yn rhychwantu Cymru a Lloegr.

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(**1**) O.S. 2019/651. Mae'r cyfeiriad at "appropriate authority" yn rheoliad 5(1) yn golygu, ar gyfer rheoliadau sy'n gymwys o ran Cymru, Weinidogion Cymru (*gweler* rheoliad 5(4), y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn).

(**2**) EUR 2002/178, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(**3**) O.S. 2019/651. Mae'r cyfeiriad yn rheoliad 8(3) at Gynulliad Cenedlaethol Cymru bellach yn cael effaith fel cyfeiriad at Senedd Cymru, yn rhinwedd adran 150A(2) o Ddeddf Llywodraeth Cymru 2006 (p. 32). *Gweler* hefyd adran 37G o Ddeddf Deddfwriaeth (Cymru) 2019 (dccc 4) am ddarpariaeth ynghylch y weithdrefn sy'n gymwys i'r offeryn hwn.

**Diwygio Rheoliadau Maethiad (Diwygio etc.) (Ymadael â’r UE) 2019**

**2.**—(1) Mae Atodlen 2 i Reoliadau Maethiad (Diwygio etc.) (Ymadael â’r UE) 2019 (sylweddau fitaminau a mwynau y caniateir eu defnyddio wrth weithgynhyrchu atchwanegiadau bwyd)(**4**) wedi ei diwygio fel a ganlyn.

(2) Yn Rhan B (mwynau) o’r tabl, ar ôl y cofnod “magnesium citrate malate” mewnosoder “magnesium L-threonate monohydrate (in relation to Wales)”.

**Y meini prawf purdeb ar gyfer magnesiwm L-threonad monohydrad**

**3.** Mae’r meini prawf purdeb ar gyfer magnesiwm L-threonad monohydrad wedi eu nodi yn yr Atodlen.

*Enw*
Y Gweinidog Iechyd Meddwl a Llesiant, o dan awdurdod Ysgrifennydd y Cabinet dros Iechyd a Gofal Cymdeithasol, un o Weinidogion Cymru
Dyddiad

(**4**) O.S. 2019/651, a ddiwygiwyd gan reoliad 6(3)(b) o O.S. 2023/28 i ychwanegu “magnesium citrate malate”; mae diwygiadau eraill i Atodlen 2 ond nid yw’r un ohonynt yn berthnasol i’r Rheoliadau hyn.

# YR ATODLEN

Rheoliad 3

## Y meini prawf purdeb ar gyfer magnesiwm L-threonad monohydrad

| **Magnesiwm L-threonad monohydrad** | |
|---|---|
| Cyfystyr | Magnesiwm L-threonad |
| **Diffiniad** | |
| Enw cemegol | Magnesiwm (2R,3S)-2,3,4-trihydrocsibwtanoad monohydrad |
| Fformiwla gemegol | $C_8H_{16}MgO_{11}$ |
| Rhif CAS | 500304-76-7(1) |
| Pwysau moleciwlaidd | 312.51 Da(2) |
| Lliw (solid) | Gwyn |
| Prawf | Magnesiwm: 7.2 i 8.3%<br>L-threonad: 82 i 91% |
| **Disgrifiad** | Powdr gwyn sy'n hydawdd mewn dŵr, a weithgynhyrchir drwy broses synthetig gemegol. |
| **Dull adnabod** | |
| Hydoddedd | Hydawdd mewn dŵr ar grynodiad o 1% ar 25°C ac yn glir mewn hydoddiant ar grynodiad o 1%. |
| pH (USP(3) (1% mewn $H_2O$)) | 5.8 i 7.0 |
| **Purdeb** | |
| Colled wrth sychu | Dim mwy na 5.0% (105℃/4 awr) |
| Asid ocsalig/ocsalad | Dim mwy na 0.5% (ar ffurf asid ocsalig) |
| Arsenig | Dim mwy nag 1 mg/kg |
| Plwm | Dim mwy na 0.5 mg/kg |
| Cadmiwm | Dim mwy na 0.2 mg/kg |
| Mercwri | Dim mwy na 0.1 mg/kg |

(1) Y rhif a neilltuwyd i'r sylwedd hwn gan y Gwasanaeth Crynodebu Cemegol (www.cas.org/cas-data/cas-registry).
(2) Uned o fàs yw'r dalton, neu'r uned màs atomig unedig, a ddiffinnir fel un rhan o ddeuddeg o fàs atom carbon-12 niwtral di-rwym sydd yn ei gyflwr niwclear ac electronig isaf ac sy'n ddisymud.
(3) United States Pharmacopeia.

*Draft Regulations laid before Senedd Cymru in accordance with the Senedd approval procedure under regulation 8(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651).*

DRAFT WELSH STATUTORY INSTRUMENTS

# 2026 No.

# FOOD, WALES

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

### EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made using powers set out in regulations 2(2), 3 and 5(1) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651) ("the 2019 Regulations").

Regulation 5 of the Food Supplements (Wales) Regulations 2003 (S.I. 2003/1719 (W. 186)) prohibits the sale of food supplements manufactured using vitamins or minerals unless that vitamin or mineral is—

(a) listed in Schedule 1 to the 2019 Regulations;

(b) in a form which is listed in Schedule 2 to the 2019 Regulations and meets the relevant purity criteria.

The mineral, magnesium, is already listed in Schedule 1 to the 2019 Regulations. These Regulations—

(a) add the mineral form, magnesium L-threonate monohydrate ("the Substance") to the list in Schedule 2 to the 2019 Regulations;

(b) set purity criteria for the Substance.

The Substance is also a novel food within the meaning of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (EUR 2015/2283) ("the Novel Food Regulation").

The Welsh Ministers have determined the authorisation status of the Substance in relation to Wales in accordance with Article 12 of the Novel Food Regulation. Information about the authorisation is available on the list of novel foods maintained by the Food Standards Agency (Foss House, Kings Pool, 1-2 Peasholme Green, York, YO1 7PR) in accordance with Article 3B of the Novel Food Regulation.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Public Health Directorate, Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.

*Draft Regulations laid before Senedd Cymru in accordance with the Senedd approval procedure under regulation 8(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651).*

DRAFT WELSH STATUTORY INSTRUMENTS

# 2026 No.

# FOOD, WALES

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

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

The Welsh Ministers, in exercise of the powers conferred by regulations 2(2), 3 and 5(1) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(**1**), make the following Regulations.

There has been consultation as required by 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(**2**).

These Regulations have been laid before Senedd Cymru in accordance with the Senedd approval procedure under regulation 8(3) of the Nutrition (Amendment etc.) (EU Exit) Regulations 2019(**3**).

**Title, coming into force and extent**

**1.**—(1) The title of these Regulations is the Food Supplements (Magnesium L-threonate monohydrate) (Wales) Regulations 2026.

(2) These Regulations come into force on 5 March 2026.

(3) These Regulations extend to England and Wales.

(**1**) S.I. 2019/651. The reference to “appropriate authority” in regulation 5(1) means, for regulations applying in relation to Wales, the Welsh Ministers (*see* regulation 5(4), to which there are amendments not relevant to these Regulations).

(**2**) EUR 2002/178, to which there are amendments not relevant to these Regulations.

(**3**) S.I. 2019/651. The reference in regulation 8(3) to the National Assembly for Wales now has effect as a reference to Senedd Cymru by virtue of section 150A(2) of the Government of Wales Act 2006 (c. 32). *See* also section 37G of the Legislation (Wales) Act 2019 (anaw 4) for provision about the procedure that applies to this instrument.

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

**2.**—(1) Schedule 2 to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (vitamin and mineral substances which may be used in the manufacture of food supplements)(**4**) is amended as follows.

(2) In Part B (minerals) of the table, after the entry "magnesium citrate malate" insert "magnesium L-threonate monohydrate (in relation to Wales)".

### Purity criteria for magnesium L-threonate monohydrate

**3.** The purity criteria for magnesium L-threonate monohydrate are set out in the Schedule.

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

(**4**) S.I. 2019/651, amended by regulation 6(3)(b) of S.I. 2023/28 to add "magnesium citrate malate"; there are other amendments to Schedule 2 but none is relevant to these Regulations.

## SCHEDULE

Regulation 3

## Purity criteria for magnesium L-threonate monohydrate

| **Magnesium L-threonate monohydrate** | |
|---|---|
| Synonym | Magnesium L-threonate |
| **Definition** | |
| Chemical name | Magnesium (2R,3S)-2,3,4-trihydroxybutanoate monohydrate |
| Chemical formula | $C_8H_{16}MgO_{11}$ |
| CAS number | 500304-76-7[(1)] |
| Molecular weight | 312.51 Da[(2)] |
| Colour (solid) | White |
| Assay | Magnesium: 7.2 to 8.3%<br>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[(3)] (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 mg/kg |
| Lead | Not more than 0.5 mg/kg |
| Cadmium | Not more than 0.2 mg/kg |
| Mercury | Not more than 0.1 mg/kg |

(1) The number assigned to this substance by the Chemical Abstracts Service (www.cas.org/cas-data/cas-registry).
(2) The dalton, 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.
(3) United States Pharmacopeia.