



2024/346

23.1.2024

COMMISSION REGULATION (EU) 2024/346

of 22 January 2024

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of trimagnesium dicitrate in food supplements

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives including colours and sweeteners that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union lists in Annexes II and III to Regulation (EC) No 1333/2008 may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) An application for authorisation of the use of trimagnesium dicitrate anhydrous as a stabiliser and anti-caking agent in food supplements in solid and chewable forms was submitted on 24 June 2015 and was made available to the Member States.
- (5) Trimagnesium dicitrate anhydrous is intended for use in food supplements in solid and chewable forms for binding small amounts of residual water during processing and inside the packaging.
- (6) The European Food Safety Authority ('the Authority') evaluated the safety of trimagnesium dicitrate anhydrous ⁽⁴⁾ when used as an additive in food supplements in solid and chewable forms and concluded that its use in solid food supplements at the proposed typical use level of 50 000 mg/kg is of no safety concern, whereas at the proposed maximum use level of 120 000 mg/kg, the resulting dietary exposure estimate of magnesium for adults and the elderly for high percentiles would be above the tolerable upper intake level ('UL') of 250 mg/day for supplemental magnesium set by the Scientific Committee on Food, based on a mild, transient laxative effect which is easily reversible and to which the body can easily adapt within days. Provided that dietary exposure estimates of magnesium from the use of the food additive trimagnesium dicitrate anhydrous in the food supplement were below the UL, the Authority considered that there would not be a safety concern from the proposed typical use levels of trimagnesium dicitrate anhydrous as a stabiliser and anticaking agent in food supplements.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA Journal 2016; 14(11):4599.

- (7) Following the Authority's opinion, the applicant lowered the requested maximum use levels to 100 000 mg/kg so that the resulting exposure to magnesium in adults and the elderly at the high-level under the instructions of use provided by the manufacturer for the normal use of the food supplement would not be above the UL authorised as nutrient in food supplements.
- (8) It is, therefore, appropriate to authorise the use of trimagnesium dicitrate anhydrous as a stabiliser and anti-caking agent in solid food supplements and to assign E 345(i) as E-number to that additive.
- (9) The specifications for trimagnesium dicitrate (E 345(i)) should be included in Regulation (EU) No 231/2012 as it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 January 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) in Part B, point 3 'Additives other than colours and sweeteners', the following entry is inserted after the entry for food additive E 343 Magnesium phosphates:

'E 345(i)	Trimagnesium dicitrate'
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- (2) in Part E, in food category 17.1 'Food supplements supplied in a solid form, excluding food supplements for infants and young children', the following entry is inserted after the entry for E 432-436 Polysorbates:

	'E 345(i)	Trimagnesium dicitrate	100 000	(97)	
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(97): In conformity with Directive 2002/46/EC'

ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry for E 345(i) is inserted after the entry for E 343 (ii) DIMAGNESIUM PHOSPHATE:

E 345 (i) TRIMAGNESIUM DICITRATE	
Synonyms	Magnesium citrate; trimagnesium citrate
Definition	
Einecs	222-093-9
Chemical name	Trimagnesium bis (2-hydroxypropane-1,2,3- tricarboxylate), anhydrous
Chemical formula	(C ₆ H ₅ O ₇) ₂ Mg ₃
Molecular weight	451,12 (anhydrous)
Assay	15,0-16,5 % Mg on dry substance/matter equal to 92,8-102,1 % trimagnesium dicitrate anhydrous
Description	White or almost white, fine, slightly hygroscopic powder
Appearance of a solution	Not more opalescent than ref. susp. III and not more intensely coloured than ref. sol. Y7 or BY6
Identification	
Test for citrate	Positive
Test for magnesium	Positive
pH (5 % solution)	6,0-8,5
Solubility	Soluble in water, practically insoluble in ethanol (96 %), it dissolves in diluted hydrochloric acid.
Particle size	by STEM method – Median (D ₅₀) particle size (number-based) not below 130 nm by laser diffraction method – Median (D ₅₀) particle size (mass-based) not below 50 µm
Purity	
Loss on drying	Maximum 3,5 %, determined on 1 000 g by drying in an oven at 180 ± 10 °C for 5 h
Oxalic/oxalate	≤ 280 mg/kg (0,028 %) as oxalic acid
Sulfates	≤ 2 000 mg/kg (0,2 %)
Calcium	≤ 2 000 mg/kg (0,2 %)
Iron	≤ 100 mg/kg
Mercury	≤ 0,1 mg/kg
Lead	≤ 1 mg/kg
Cadmium	≤ 0,1 mg/kg
Arsenic	≤ 1 mg/kg
Not identified material	No process or product related impurities. The unintended presence of hydrated forms of trimagnesium dicitrate such as the nonahydrate cannot be excluded.'