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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

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

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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 new entry is inserted after the entry for food additive E 343 Magnesium phosphates:

‘E 345(i)	Trimagnesium dicitrate’
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1) 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 new entry is inserted after the entry for E 432-436 Polysorbates:

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

ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

The following entry for E 345(i) is inserted after the entry for E 343 (ii) DIMAGNESIUM PHOSPHATE:

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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	$(C_6H_5O_7)_2 Mg_3$
Molecular weight	451,12 (anhydrous)
Assay	15 – 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 $180 \pm 10^\circ C$ for 5 h
Oxalic/oxalate	≤ 280 mg/kg (0,028%) as oxalic acid
Sulfates	$\leq 2\,000$ mg/kg (0,2%)
Calcium	$\leq 2\,000$ mg/kg (0,2%)
Iron	≤ 100 mg/kg

Mercury	$\leq 0,1 \text{ mg/kg}$
Lead	$\leq 0,1 \text{ mg/kg}$
Cadmium	$\leq 0,1 \text{ mg/kg}$
Arsenic	$\leq 0,1 \text{ mg/kg}$
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.