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►**B**

COMMISSION IMPLEMENTING DECISION

of 19 March 2014

authorising the placing on the market of (6S)-5-methyltetrahydrofolic acid, glucosamine salt as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2014) 1683)

(Only the Italian text is authentic)

(2014/154/EU)

(OJ L 85, 21.3.2014, p. 10)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision 2014/916/EU of 15 December 2014	L 360	58	17.12.2014

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Article 1

(6S)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate as specified in the Annex may be placed on the market in the Union as a novel food ingredient to be used in food supplements without prejudice to the specific provisions of Directive 2002/46/EC.

Article 2

The designation of (6S)-5-methyltetrahydrofolic acid, glucosamine salt, authorised by this Decision on the labelling of the foodstuffs containing it shall be '(6S)-5-methyltetrahydrofolic acid, glucosamine salt' or '5MTHF-glucosamine'.

Article 3

This Decision is addressed to Gnosis SpA, Via Lavoratori Autobianchi 1, 20832 Desio (MB), Italy.

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ANNEX

SPECIFICATION OF (6S)-5-METHYLTETRAHYDROFOLIC ACID, GLUCOSAMINE SALT

Definition:

Chemical name	N-[4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl]methyl]amino]benzoyl]-L-glutamic acid, glucosamine salt
Chemical formula	$C_{32}H_{51}N_9O_{16}$
Molecular weight	817,80 g/mol (anhydrous)

Description: Creamy to light-brown powder.

Identification:

CAS No.	1181972-37-1

Purity:

Diastereoisomeric purity	At least 99 % of (6S)-5-methyltetrahydrofolic acid
▼M1 Glucosamine assay	34-46 % in dry basis
▼B 5-Methyltetrahydrofolic acid assay	54-59 % in dry basis
Water content	Not more than 8,0 %
Lead	Not more than 2,0 ppm
Cadmium	Not more than 1,0 ppm
Mercury	Not more than 0,1 ppm
Arsenic	Not more than 2,0 ppm
Boron	Not more than 10 ppm

Microbiological criteria:

Total aerobic microbial count	Not more than 100 cfu/g
Total combined yeast and moulds	Not more than 100 cfu/g
Escherichia coli	Absent in 10 g