

## 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)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients <sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

(1) On 28 July 2011, the company Gnosis SpA made a request to the competent authorities of Ireland to place (6S)-5-methyltetrahydrofolic acid, glucosamine salt on the market as a novel food ingredient for use in food supplements.

(2) On 26 October 2011, the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that (6S)-5-methyltetrahydrofolic acid, glucosamine salt meets the criteria set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 28 February 2012, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 14 September 2012 and on 5 March 2013 the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for (6S)-5-methyltetrahydrofolic acid, glucosamine salt as food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 11 September 2013, EFSA adopted a Scientific Opinion on (6S)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate added for nutritional purposes to food supplements <sup>(2)</sup>, concluding that (6S)-5-methyltetrahydrofolic acid, glucosamine salt is not of safety concern as a source of folate.

(7) The opinion gives sufficient grounds to establish that (6S)-5-methyltetrahydrofolic acid, glucosamine salt as a source of folate complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) Directive 2002/46/EC of the European Parliament and of the Council <sup>(3)</sup>, lays down specific provisions for the use of vitamins and minerals in food supplements. The use of (6S)-5-methyltetrahydrofolic acid, glucosamine salt should be authorised without prejudice to the requirements of this legislation.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

<sup>(2)</sup> *EFSA Journal* 2013;11(10):3358.

<sup>(3)</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

HAS ADOPTED THIS DECISION:

*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 Laboratori Autobianchi 1, 20832 Desio (MB), Italy.

Done at Brussels, 19 March 2014.

*For the Commission*

Tonio BORG

*Member of the Commission*

## 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-pteridiny]methyl]amino]benzoyl]-L-glutamic acid, glucosamine salt
Chemical formula	C <sub>32</sub> H <sub>51</sub> N <sub>9</sub> O <sub>16</sub>
Molecular weight	817,80 g/mol (anhydrous)

**Description:** Creamy to light-brown powder.

**Identification:**

CAS No.	1181972-37-1
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**Purity:**

Diastereoisomeric purity	At least 99 % of (6S)-5-methyltetrahydrofolic acid
Glucosamine assay	34-36 % in dry basis
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
<i>Escherichia coli</i>	Absent in 10 g