DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2016/1344

of 4 August 2016

authorising the placing on the market of organic silicon (monomethylsilanetriol) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2016) 4975)

(Only the English text is authentic)

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 ([1]), and in particular Article 7 thereof,

Whereas:

(1) On 27 March 2013, the company LLR-G5 Ltd made a request to the competent authorities of Ireland to place organic silicon (monomethylsilanetriol) on the market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97.

(2) On 17 April 2013, the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that an additional assessment was required in line with Article 6(3) of the novel food Regulation (EC) No 258/97.

(3) On 26 April 2013, the Commission forwarded the initial assessment report to the other Member States.

(4) On 10 October 2013, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for organic silicon (monomethylsilanetriol) as novel food ingredient in accordance with Regulation (EC) No 258/97.

(5) On 9 March 2016, EFSA concluded in its opinion on the safety of organic silicon (monomethylsilanetriol, MMST) as a novel food ingredient for use as a source of silicon in food supplements and bioavailability of orthosilicic acid from the source ([2]), that organic silicon (monomethylsilanetriol) is safe under the proposed conditions of use.

(6) That opinion gives sufficient grounds to establish that organic silicon (monomethylsilanetriol) as a novel food ingredient complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(7) Directive 2002/46/EC of the European Parliament and of the Council ([3]) lays down requirements on food supplements. The use of organic silicon (monomethylsilanetriol) should be authorised without prejudice to the requirements of this legislation.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) EFSA Journal 2016;14(4):4436
([3]) 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).

HAS ADOPTED THIS DECISION:

Article 1

Organic silicon (monomethylsilanetriol) as specified in the Annex to this Decision may be placed on the market in the Union as a novel food ingredient to be used in food supplements in liquid form intended for the adult population with a maximum dose of 10,40 mg silicon per day as recommended by the manufacturer without prejudice to the specific provisions of Directive 2002/46/EC.

Article 2

The designation of organic silicon (monomethylsilanetriol) authorised by this Decision for the labelling of the foodstuffs shall be 'organic silicon (monomethylsilanetriol)'.

Article 3

This Decision is addressed to LLR-G5 Ltd, Golden Mile Industrial Park, Breaffy Road, Castlebar, Co. Mayo, F23 VX58, Ireland.

Done at Brussels, 4 August 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

SPECIFICATION OF ORGANIC SILICON (MONOMETHYLSILANETRIOL)

Identity of organic silicon (monomethylsilanetriol)

Chemical name	Silanetriol, 1-methyl-
Chemical formula	CH_6O_3Si
Molecular weight	94,14 g/mol
CAS No	2445-53-6

Organic silicon (monomethylsilanetriol) preparation (aqueous solution)

Parameters	Specification value
Acidity (pH)	6,4-6,8
Silicon	100-150 mg Si/l
Lead	Not more than 1 µg/l
Mercury	Not more than 1 µg/l
Cadmium	Not more than 1 µg/l
Arsenic	Not more than 3 µg/l
Methanol	Not more than 5 mg/kg (residual presence)