European Food Safety Authority

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SCIENTIFIC OPINION

Monomethylsilanetriol added for nutritional purposes to food supplements [1]

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food

(EFSA-Q-2006-198, EFSA-Q-2006-296)

Adopted on 28 January 2009

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SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food has been asked to deliver a scientific opinion based on its consideration of the safety and bioavailability of monomethylsilanetriol (also called organic silicon) added for nutritional purposes to food supplements.

The present opinion deals only with the safety of monomethylsilanetriol as a source of silicon and with the bioavailability of silicon from this source. The safety of silicon itself, in terms of amounts that may be consumed, as well as the consideration of silicon as a nutrient are outside the remit of this Panel.

The essentiality of silicon for man has not been established and a functional role for silicon in humans has not yet been identified. No recommended intake for silicon has been set.

[1] For citation purposes: Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the European Commission on monomethylsilanetriol (organic silica) added for nutritional purposes to food supplements. *The EFSA Journal* (2009) 950, 1-12.

The Panel notes that the use of monomethylsilanetriol is proposed to provide maximum 15 mg silicon/day (equivalent to 0.84 mg monomethylsilanetriol/kg bw/day and 0.25 mg silicon/kg bw/day for a 60 kg adult). However, no adequate data on the bioavailability of silicon from monomethylsilanetriol have been provided and no data on the toxicity of monomethylsilanetriol are available.

The Panel also notes that there is presently no experimental evidence demonstrating the conversion of monomethylsilanetriol to orthosilicic acid.

Given the absence of adequate data on the bioavailability of silicon from monomethylsilanetriol and the toxicity of monomethylsilanetriol, the Panel could not assess the safety of the source and the bioavailability of silicon from this source.

KEY WORDS:

Monomethylsilanetriol, CAS No. 2445-53-6, monomethyl silanetriol (potassium salt), CAS No. 31795-24-1, silanetriol, methyl siliconate, methylsilanetriolate, methylsilanetriol, organic silicon.

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BACKGROUND AS PROVIDED BY THE COMMISSION

The European Community legislation lists nutritional substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients.

The Commission has received a request for the evaluation of monomethylsilanetriol (also called organic silicon) added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements[2].

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of monomethylsilanetriol (also called organic silicon) added for nutritional purposes in food supplements.

ACKNOWLEDGEMENTS

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[2] OJ L 183, 12.7.2002, p.51.

ASSESSMENT

1. Introduction

The present opinion deals only with the safety of monomethylsilanetriol (potassium salt) as source of silicon (Si) and with the bioavailability of silicon from this source. The safety of silicon itself, in term of amounts that may be consumed and the consideration of silicon as a nutrient are outside the remit of this Panel. Monomethylsilanetriol and so called 'organic silicon' are synonyms.

This opinion is based on information provided by two petitioners.

2. Chemical data

Two petitioners are applying for the use of monomethylsilanetriol either as such or as its potassium salt.

2.1. Chemistry

Monomethylsilanetriol is a liquid with CAS Registry Number 2445-53-6, molecular formula CH_3-Si-$(OH)_3$ and molecular weight of 94.2 g/mol. Monomethyl silanetriol (potassium salt) [Silanetriol, 1-methyl-, potassium salt (1:x)] has a CAS Registry Number 31795-24-1**.**

Synonyms: silanetriol, methyl siliconate, methylsilanetriolate, methylsilanetriol, organic silicon.

2.2. Specifications

One petitioner states that monomethylsilanetriol is a pale, straw-coloured emulsion with a slight odour. This petitioner indicates that the potassium salt is an aqueous solution containing approximately 47 % silanetriol and approximately 19 % potassium hydroxide.

The second petitioner indicates that the food supplement is an aqueous solution containing 115 mg silicon/L.

Monomethylsilanetriol is soluble in water up to 200 mg/L (as silicon) without the onset of oligomerisation.

Impurities

According to one petitioner, impurities may occur as polymeric silanols or as further methylated (e.g. di-methyl) products. It is, however, indicated that careful control of the manufacturing process and the extent of dilution minimises these impurities. No data on heavy metals or other elemental impurities have been provided by any of the petitioners.

The Panel notes that according to Commission Regulation (EC) No 629/2008, the maximum levels of lead, mercury and cadmium in food supplements as sold should be 3.0 mg/kg, 0.1 mg/kg and 1 mg/kg, respectively (EC, 2008).

2.3. Manufacturing process

For monomethylsilanetriol (potassium salt), no information is provided by the petitioner. For monomethylsilanetriol as such the petitioner only indicated that the origin of the source was an alkaline solution of potassium methyl silanetriolate which is reacted, and the pH neutralised with phosphoric acid, leading to the formation of methyl silanetriol at pH 6.6 ± 0.05.

2.4. Methods of analysis in food

No specific method for the analysis of monomethylsilanetriol in food has been provided.

2.5. Reaction and fate in foods to which the source is added

Specific information was provided by one petitioner. This petitioner only stated that the aqueous solution of monomethylsilanetriol and potassium hydroxide was chemically stable at physiological pH.

2.6. Case of need and proposed uses

One petitioner indicates that monomethylsilanetriol, as a source of silicon, is used in liquid food supplements in combination with a flavour (vanillin) and unspecified anti-oxidizing agents, or in combination with a flavour (vanillin), unspecified anti-oxidizing agents and essential oils.

This petitioner further indicates that for liquid food supplements, the initial aqueous solution of monomethylsilanetriol and potassium hydroxide is used at a final concentration of 0.215 %. Each daily intake (15 ml of solution) of the commercial product brings approximately 15 mg silicon/day (equivalent to 0.25 mg silicon/kg bw for a 60 kg adult).

The second petitioner states that monomethylsilanetriol will be supplied in liquid supplements at a level of 115 mg silicon/L. This will amount to a maximum daily intake of silicon from this source of 10.35 mg silicon (equivalent to about 0.17 mg silicon/kg bw/day for a 60 kg adult) as the maximum daily dose is 90 ml of liquid. A more typical daily dose is 60 ml liquid yielding a daily intake of 6.9 mg silicon (equivalent to about 0.12 mg silicon/kg bw/day for an adult).

2.7. Information on existing authorisations and evaluations

Monomethylsilanetriols in drinking food supplements have been marketed in France and Belgium since 1998 and in Spain since 2003. One of the petitioners did notify the monomethylsilanetriol drinking solution in Belgium and did receive the authorisation to market the product via pharmacies (Notification in Belgium: NUT/PL numbers: PL 497/1, PL 497/2, PL 497/3).

The essentiality of silicon for man has not been established and a functional role for silicon in humans has not yet been identified (EFSA, 2004). A recommended intake for silicon has not been set (SCF, 1993; IOM, 2008; FNB, 2001).

Silicon in the form of silicon dioxide (E551), silicates and dimethylpolysiloxane (E900) (SCF, 1991) is added as an excipient to foods, e.g. anti-caking and anti-foaming agent.

In 2004, EFSA concluded there were no suitable dose-response data to establish a Tolerable Upper Intake Level (UL) for silicon, and also the Institute of Medicine (IOM) reported that due to lack of data indicating adverse effects of silicon, it was not possible to establish a UL (IOM, 2000). The EFSA estimated that the typical dietary intake of 20-50 mg silicon/day, corresponding to 0.3-0.8 mg/kg bw/day in a 60 kg person, is unlikely to cause adverse effects (EFSA, 2004).

The Expert Group on Vitamins and Minerals (EVM) carried out a risk assessment and set a safe upper level for daily supplemental exposure to silicon at 700 mg silicon/day for adults over a lifetime. In terms of elemental silicon, this is equivalent to a safe upper level of 12 mg silicon/kg bw/day for a 60 kg adult for supplemental silicon (EVM, 2003).

2.8. Exposure

Based on the information provided by the petitioners on the proposed levels of use, the Panel notes that the intake level of silicon from the monomethylsilanetriol supplements will be maximum 15 mg silicon/day, which is equivalent to 50.3 mg monomethylsilanetriol/day, or to 0.84 mg monomethylsilanetriol/kg bw/day and to 0.25 mg silicon/kg bw for a 60 kg adult.

3. Biological and toxicological data

3.1. Bioavailability

Introduction

Silicon occurs in nature as silicon dioxide (SiO_2) or the corresponding silicic acids formed by the hydration of the oxide. Orthosilicic acid [$Si(OH)_4$; monomeric silicic acid] is the simplest acid and the main chemical species of silicon soluble in water (Carlisle, 1997).

The bioavailability of silicon depends on the solubility or speciation of the compound concerned (Van Dyck *et al.*, 1999).

Bioavailability of silicon from monomethylsilanetriol

One petitioner referred to a study by Varaprath *et al*. (2003), who looked at the metabolites of hexamethyldisiloxane in the urine of Fischer 344 rats. The analytical results demonstrated the presence of monomethylsilanetriol [$(CH_3\text{-}Si\text{-}(OH)_3$] next to the presence of a number of other metabolites. The study also demonstrated the occurrence of demethylation at the silicon-methyl bonds. Based on this the authors proposed an oxidative pathway by which monomethylsilanetriol can be oxidised to form orthosilicic acid [$Si\ (OH)_4$].

The Panel notes however, that the proposed conversion of monomethylsilanetriol to orthosilicic acid has, at present, not been proven experimentally.

The second petitioner indicated that no formal human absorption study has been reported, despite rat studies having shown high bio-availability of silicon from monomethylsilanetriol (Allain *et al.,* 1983; Hott *et al.,* 1993), and human intervention studies implying that bio-availability is high from this source (Schiano *et al.*, 1979; Eisinger and Clairet, 1993). Therefore, the petitioner investigated silicon absorption from monomethylsilanetriol in eight healthy volunteers (4 male and 4 female) with normal renal function. In this study, the petitioner followed the protocols of Sripanyakorn *et al.* (2004) and Jugdaohsingh *et al.* (2002). The subjects avoided high silicon-containing foods (beer, cereals, certain vegetables and fruit) 24 h before the study day. Blood, urine and elemental analysis for silicon were performed.

The minimum percentage of absorption was estimated to be 57 ± 17 %, based upon urinary silicon excretion and assuming a silicon intake of 8.75 mg (as confirmed by ICP analysis). Absorption was calculated as urinary silicon excretion at 0-3 hours plus that at 3-6 hours, following ingestion of the monomethylsilanetriol solution, minus 2 times urinary silicon excretion at 0-3 hours following control vehicle (water alone; baseline).

The petitioner concludes that the data indicated that silicon is very well absorbed from the monomethylsilanetriol. However, the Panel notes that the analytical methodology used in this study does not provide information on the form in which this silicon was taken up by the test subjects.

3.2. Subsequent metabolic fate of the source and biological distribution

The petitioner claims that monomethylsilanetriol undergoes de-methylation and hydroxylation and is excreted in urine with a small degree of tissue uptake, commensurate with physiological balance (Popplewell *et al.,* 1998). The Panel notes however, that the proposed conversion of monomethylsilanetriol to orthosilicic acid has at present not been proven experimentally.

3.3. Toxicological data

3.3.1. Acute toxicity

No data on acute toxicity were provided. One petitioner only stated that an oral acute toxicity study was performed in rats with oral administration of 2000 mg monomethylsilanetriol/kg body weight. At this level no oral toxicity was observed.

3.3.2. Subchronic and chronic toxicity

No data on subchronic and chronic toxicity were provided.

3.3.3. Genotoxicity

The petitioner only stated that no data were available for monomethylsilanetriol and that silicon dioxide is considered not to be genotoxic *in vitro* and *in vivo* (IARC, 1997).

3.3.4. Reproductive and developmental toxicity

According to both petitioners, no data were available for monomethylsilanetriol.

4. Discussion

The Panel notes that the use of monomethylsilanetriol is proposed as a source of silicon to provide maximum 15 mg silicon/day (equivalent to 0.84 mg monomethylsilanetriol/kg bw/day and to 0.25 mg silicon/kg bw/day for a 60 kg adult). However, no adequate data on the bioavailability of silicon from monomethylsilanetriol have been provided, and no data on the toxicity of monomethylsilanetriol are available.

The Panel also notes that there is presently no experimental evidence demonstrating the conversion of monomethylsilanetriol to orthosilicic acid.

CONCLUSIONS

The present opinion deals only with the safety of monomethylsilanetriol (potassium salt) and with the bioavailability of the nutrient silicon from this source. The safety of silicon itself, in terms of amounts that may be consumed, and the consideration of silicon as a nutrient are outside the remit of this Panel.

Given the absence of adequate data on the bioavailability of silicon from monomethylsilanetriol and the toxicity of monomethylsilanetriol, the Panel could not assess the safety of the source and the bioavailability of silicon from this source.

DOCUMENTATION PROVIDED TO EFSA

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2. Dossier on a stabilized, methylated form of silicic acid; the monomethylsilanetriol, Proposed for Addition to Annex I Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements. July 2005. Submitted by Dexsil laboratories, Belgium for AGZ Ltd, London, England.

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GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Foods
bw	body weight
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
EVM	Expert group on Vitamins and Minerals
FNB	Food and Nutrition Board
IARC	International Agency for Research on Cancer
IOM	Institute of Medicine
SCF	Scientific Committee on Food
UL	Tolerable Upper Intake Level