

Proposed maximum levels for the addition of silicon to foods including food supplements

The accompanying main opinion "**Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods**" can be found here: <https://www.bfr.bund.de/cm/349/updated-recommended-maximum-levels-for-the-addition-of-vitamins-and-minerals-to-food-supplements-and-conventional-foods.pdf>

1 Results

The German Federal Institute for Risk Assessment (BfR) recommends maximum levels of 350 milligrams (mg) of silicon in the form of silicon dioxide, 100 mg of silicon in the form of silicic acid (silica gel) and 10 mg of silicon in the form of monomethylsilantriol and choline-stabilised orthosilicic acid per daily recommended dose of a food supplement (Table 1).

Silicon compounds have not yet been approved for the fortification of conventional foods and therefore no recommendation is made in this respect.

Table 1: Proposed maximum levels for silicon (per daily recommended dose of an individual food supplement)

Silicon compounds**	Maximum levels for silicon
Silicon dioxide	350 mg
Silicic acid (silica gel)	100 mg
Choline-stabilised orthosilicic acid	10 mg
Organic silicon (monomethylsilantriol)	10 mg***

** Only silicon compounds that are currently allowed to be used in food supplements according to EU Directive 2002/46/EC (consolidated version of 25 July 2017) are listed here.

*** Safe intake level for daily consumption authorised according to the Novel Food approval procedure.

2. Rationale

2.1 Tolerable Upper Intake Level¹ (UL) and Dietary Reference Value

The European Food Safety Authority (EFSA) in its risk assessment of silicon as a nutrient was unable to derive a Tolerable Upper Intake Level (UL) due to lack of data. However, total daily intakes corresponding to the amounts of silicon ingested with the usual diet (20–50 mg or 0.3–0.8 mg per kg body weight (bw) for persons with a body weight of 60 kg) were classified as not harmful to health (EFSA, 2004).

The US Food and Nutrition Board (FNB) was also unable to derive a UL due to a lack of data, but considered silicon ingested with conventional food to be harmless (FNB, 2002).

The British Expert Group on Vitamins and Minerals (EVM, 2003) derived a Safe Upper Level of 25 mg for silicon dioxide per kg bw for the additional intake of silicon via food supplements and fortified foods, corresponding to a daily intake of 700 mg silicon per day at 60 kg body weight. The Safe Upper Level for the total daily intake of silicon was estimated to be 760 mg per day (at 60 kg bw and supplemental silicon intake plus intake of silicon via usual food).

¹ Tolerable Upper Intake Level = Maximum level of total chronic daily intake of a nutrient (from all sources) considered to be unlikely to pose a risk of adverse health effects to humans.

The derivation was based on a *No Observed Adverse Effect Level* (highest experimental dose at which there was not an observed adverse effect on health; NOAEL) for silicon dioxide of 2.5 g per kg bw per day, derived from a long-term feeding study in rats with the application of an uncertainty factor of 100 (Takizawa et al., 1988). In the study, no substance-related toxic effects were observed after oral administration of silicon in the form of silicon dioxide (0–5 % in the feed) for 103 weeks, and accordingly the highest tested dose of 2.5 g silicon dioxide per kg bw per day (equivalent to 1.165 mg silicon per kg bw per day) was defined as the NOAEL (EVM, 2003; EFSA 2004).

In its 2009 opinion on the safety of calcium silicate, silicon dioxide and silica (silica gel) as sources of silicon in food supplements, the EFSA ANS Panel² referred to the safe upper level of 700 mg per day for adults derived by the UK EVM and did not see any safety concerns³ for intakes of up to 700 mg per day of silicon in the form of silicon dioxide and up to 200 mg per day of silicon in the form of silica (silica gel) from food supplements (EFSA 2009a⁴). With regard to the use of calcium silicate in food supplements at the requested level of up to 100 mg per day, EFSA had no safety concerns as long as the use would not conflict with the conditions for use as a food additive (EFSA 2009a).

In 2009, EFSA evaluated the use of choline-stabilised orthosilicic acid as a source of silicon in food supplements and did not raise any safety concerns for the requested use levels of up to 10 mg per day of silicon in the form of choline-stabilised orthosilicic acid (EFSA, 2009b⁴).

In its opinion on the assessment of organic silicon (monomethylsilanetriol, MMST) as a novel source of silicon in food supplements in the context of the authorisation of novel foods under the Novel Food Regulation (EFSA, 2016⁴), EFSA did not see any reason for safety concerns for the requested use levels of up to 10 mg per day of silicon in the form of monomethylsilanetriol.

In a 2018 opinion on the re-evaluation of silicon dioxide as a food additive, EFSA's ANS Panel concluded that there are no genotoxicity concerns related to the use of silicon dioxide as a food additive and that there is evidence for an overall low acute and chronic oral toxicity of silicon dioxide, as no adverse effects were observed in toxicological studies even with repeated intake of high doses (up to 9,000 mg per kg bw per day). However, the Panel was unable not derive an Acceptable Daily Intake (ADI) value due to limited data (EFSA, 2018a⁴).

In 2018, the EFSA ANS Panel published a scientific re-evaluation of calcium and magnesium silicates as food additives (EFSA, 2018b⁴). In its opinion, the Panel indicated that the absorption of silicates was very low and that there were no indications for genotoxicity or developmental toxicity of calcium and magnesium silicates. The Panel noted that in animal studies (2-year rat study), increased accumulation of silicon in the kidneys and liver was reported with ingestion of higher calcium silicate dosages (up to 5 g per kg bw per day). Calcium and magnesium silicates were also found to have low oral toxicity. A derivation of a group ADI for silicates was considered outdated or obsolete on mechanistic grounds. Due to the lack of reliable toxicological data (including for chronic toxicity, carcinogenicity and reproductive toxicity) for the individual silicates, the Panel was unable to derive ADI values for calcium silicate (E 552) and magnesium silicates (E 553a (i), E 553a (ii) and E 553b) (EFSA, 2018b).

² Scientific Panel on Food Additives and Nutrient Sources added to Food

³ "The Panel also concludes that the use of silicon dioxide up to 1500 mg SiO₂ /day (equal to 700 mg of silicon/day) and of silicic acid gel to supply up to 200 mg silicon/day added to food supplements is of no safety concern."

⁴ BfR points out that in these EFSA opinions only the safety of a requested use level was assessed and that the derivation of a Tolerable Upper Intake Level (UL) for silicon was not subject of these opinions.

Silicon has been classified by EFSA as a non-essential nutrient and no specific biochemical function in humans or animals has been identified (EFSA 2004). Recommended intakes are not given by EFSA (2004) or by the D-A-CH Societies⁵ (D-A-CH, 2019). Silicon deficiency symptoms have not been observed in humans.

2.2 Exposure

No silicon exposure data were determined in the second National Food Consumption Survey (NVS II).

In 2004, EFSA estimated that the daily intake of silicon naturally present in foods in the form of silicon dioxide and silicates is between 20 and 50 mg per day (EFSA, 2004).

In the 2018 EFSA opinion on the re-evaluation of silicon dioxide (EFSA, 2018a), estimates for intakes of silicon dioxide from use as a food additive were performed for different population groups. Depending on the exposure scenario, mean intakes of silicon dioxide for adults were estimated between 2.7 and 8.0 mg per kg bw per day, corresponding to silicon intakes of 88 to 262 mg per day (at 70 kg bw); P95⁶-estimates for intake of silicon dioxide ranged from 6.4 to 18.8 mg per kg bw per day, corresponding to daily silicon intakes between 209 and 1,316 mg. The highest silicon dioxide intakes were estimated for children aged three to nine years: Here, estimated mean silicon intakes ranged from 8.6 to 11.4 mg per kg bw per day, depending on the exposure scenario; P95 estimates ranged from 23.2 to 28.5 mg per kg bw per day. However, these exposure estimates were subject to several uncertainties and were considered as overall overestimated (EFSA 2018a).

Also in the EFSA opinion on the re-evaluation of calcium and magnesium silicates, exposure estimates were carried out on the intake of silicates from their use as food additives (EFSA, 2018b). These revealed daily silicate intakes of up to 46 mg per kg bw for adults and 31 mg per kg bw for children, depending on the exposure scenario (EFSA, 2018b). However, as EFSA considered these estimates to be "hampered by several uncertainties" and "overestimated", the BfR cannot use them to derive any reliable data for the assessment of additional silicon intake from silicates used as food additives.

2.3 Aspects considered in the derivation of maximum levels for silicon

Based on the EFSA assessment on silicon from 2004 and the dietary silicon intake of 20 to 50 mg per day estimated therein, the BfR had in 2016 had agreed to a maximum amount of 50 mg per daily recommended dose of a food supplement, as proposed by the German Federal Ministry of Food and Agriculture (BMEL) for silicon.

Taking into account the EFSA opinions from 2009 and 2018 on silicon compounds for addition to food supplements for nutritional purposes (EFSA, 2009a and b) and for use as food additives (EFSA, 2018a and b) and the much higher silicon exposures estimated therein due to use as food additives (EFSA 2018a; EFSA 2018b, see Section 2.2) and taking into account the authorisation of a novel silicon compound on the basis of an EFSA assessment from 2016 (EFSA, 2016), BfR has revised the maximum level recommended in 2016.

⁵ German-Austrian-Swiss Nutrition Societies

⁶ P95 = 95th percentile

In the earlier scientific literature, the isolated occurrence of siliceous kidney and bladder stones had been described in adults in relation with high, prolonged intakes of medicinal drugs (antacids) containing magnesium trisilicates (Haddad and Kouyoumdjian, 1986; Farrer and Rajfer, 1984; Levison et al, 1982; Joeques et al, 1973). For infants and young children, only case reports have been published showing that the incidence of siliceous kidney stones was associated with the consumption of mineral water or milk thickeners containing high levels of silicon dioxide (Daudon, 1999).

In the EFSA opinion on the re-evaluation of calcium and magnesium silicates as food additives, the Panel noted that despite many years of widespread use of high doses of magnesium trisilicates as antacids (daily doses up to 4 g magnesium trisilicate, equivalent to about 1,200 mg silicon), no adverse effects on the kidneys or urinary tract could be identified in the EudraVigilance database of the European Medicines Agency (EMA). The Panel noted that the association between the use of silicate antacid and kidney stones could also be incidental, but it could not conduct a conclusive risk assessment of silicates due to the lack of toxicological data (EFSA, 2018b).

Silicon is ubiquitously present in foods of plant and animal origin. There is no evidence that silicon naturally occurring in food and water and ingested with the diet is harmful to health (EFSA, 2004). In addition, various silicon compounds (silicon dioxide and silicates) are widely used as food additives (including as release agents, carriers or defoamers) in the food industry, which contributes to increasing silicon levels in foods. Reliable data about resulting silicon intakes are not available to the BfR.

2.3.1 Maximum levels for silicon in food supplements

In its assessment of silicon dioxide and silicic acid as sources of silicon in food supplements, EFSA did not indicate any safety concerns at intake levels of up to 700 mg per day of silicon in the form of silicon dioxide and up to 200 mg per day of silicon in the form of silicic acid (silica gel) (EFSA 2009a). In view of gaps in knowledge on the toxicological properties of various silicon compounds and uncertainties with regard to the level of exposure, the BfR applies in its derivation of maximum levels for food supplements an uncertainty factor of 2. This results in maximum amounts of 350 mg of silicon in the form of silicon dioxide and 100 mg of silicon in the form of silicic acid (silica gel), per recommended daily dose of an individual product of food supplements for persons aged 15 and over.

For the two silicon compounds also permitted in food supplements, choline-stabilised orthosilicic acid and organic silicon or monomethylsilantriol, reference is made to the use levels considered safe by EFSA, equivalent to 10 mg per day of silicon for each of them (EFSA, 2009b; EFSA, 2016).

2.3.2 Maximum levels for silicon in conventional foods

Silicon compounds have not yet been approved for the fortification of conventional foods and therefore no recommendation is made in this respect.

Further information on the BfR website on the subject of minerals

Topic page on the assessment of vitamins and minerals in foods:

https://www.bfr.bund.de/de/bewertung_von_vitaminen_und_mineralstoffen_in_lebensmitteln-54416.html



"Opinions-App" of the BfR

3 References

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About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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