SCIENTIFIC OPINION

Calcium sulphate for use as a source of calcium in food supplements¹

Scientific Panel on Food Additives and Nutrient Sources added to food

(Question No EFSA-Q-2005-075)

Adopted on 24 September 2008

PANEL MEMBERS


SUMMARY

Following a request from the Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) has been asked to evaluate the safety and bioavailability of calcium sulphate for use as a source of calcium in food supplements.

The present opinion deals only with the safety and bioavailability of a particular source of calcium, calcium sulphate, to be used as a nutritional substance in food supplements. The safety of calcium itself, in terms of the amounts that may be consumed, is outside the remit of this Panel.

The Panel noted that the safety of calcium sulphate when used as a food additive has been evaluated by the Scientific Committee on Food (SCF) and the FAO/WHO Joint Expert Committee on Food Additives (JECFA) who allocated an Acceptable Daily Intake (ADI) not specified for the respective calcium and sulphate ions. The SCF also allocated a tolerable upper intake level of 2500 mg calcium/day. Calcium sulphate as a source of calcium in food for particular nutritional uses and in foods intended for the general population was evaluated by the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC). This present opinion is predominately based on these previous opinions.

Calcium sulphate (gypsum, CaSO₄) exists in an anhydrous form and as a dihydrate. It is only slightly soluble in water. It is permitted as a food additive in most foods with no other restriction other than good manufacturing practice. It is intended to be used in food supplements as an alternative source of calcium and the petitioner estimates that the daily dose is unlikely to exceed 800 mg calcium (equivalent to 2.7 g calcium sulphate/day), which is the Recommended Daily Allowance defined in Directive 90/496/EEC on nutritional labelling.

A single feeding study in rats indicated no difference in calcium bioavailability from a diet with added calcium sulphate or calcium from other sources. Human studies indicate that the bioavailability of calcium from calcium sulphate in mineral waters is comparable to that from milk and that the sulphate anion does not affect the urinary excretion of calcium. Although human studies were not available for food, the AFC Panel concluded in 2004 that the bioavailability of calcium from calcium sulphate in other foods is not expected to differ from that of already permitted calcium sources in foods for particular nutritional uses.

If calcium sulphate as a “worst case” scenario would be assumed to be consumed up to the tolerable upper intake level of 2500 mg calcium per day this would correspond to an intake of 8.5 g calcium sulphate (anhydrous) per day. This would amount to a daily intake of 6 g sulphate ion. JECFA states that the few available studies in experimental animals do not raise concern about the toxicity of the sulphate ion in sodium sulphate. Sodium sulphate is used clinically as a laxative. In clinical trials using 2-4 oral doses of up to 4.5 g sodium sulphate decahydrate per person (9 – 18 g per person) only occasional loose stools were reported. These doses correspond to 2.7 – 5.4 g sulphate ion. Because of the low solubility of calcium sulphate compared with sodium sulphate it can be expected that the sulphate ion would not be present as a bolus dose after ingestion of calcium sulphate, but would rather dissociate at a lower rate.

On the basis of available studies the ANS Panel considers that the bioavailability of calcium from calcium sulphate is comparable to other inorganic calcium salts and that the use of calcium sulphate as a source of calcium in food supplements is of no safety concern assuming the total dietary exposure to calcium remains within the defined tolerable upper intake level and that the commercially available calcium sulphate will comply to the existing specifications as laid down in Directive 2000/63/EC.

Key words:
Calcium sulphate, CAS Number 7778-18-9 (anhydride), CAS Number 10101-41-4 (dihydrate), food supplement.
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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 calcium sulphate added for nutritional purposes to food supplements. The relevant Community legislative measure is:


TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with article 29 (1) (a) of the Regulation (EC) No. 178/2002, the European Commission asks the European Food Safety Authority (EFSA) to provide a scientific opinion, based on its considerations of the safety and bioavailability of calcium sulphate added for nutritional purposes to food supplements.

ACKNOWLEDGEMENTS


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2 OJ L183, 12.7.2002, p51
ASSESSMENT

The present opinion deals only with the safety and bioavailability of a particular source of calcium, calcium sulphate, to be used as a nutritional substance in food supplements. The safety of calcium itself, in terms of the amounts that may be consumed, is outside the remit of this Panel.

1. Introduction

The ANS Panel noted that the safety of calcium sulphate as a food additive has been evaluated by the Scientific Committee on Food (SCF) when an ADI not specified was allocated for the respective calcium and sulphate ions (SCF, 1990). Calcium sulphate as a source of calcium in food for particular nutritional uses and in foods intended for the general population has been evaluated by the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) (EFSA, 2003; EFSA, 2004). This present opinion is predominantly based on these previous opinions.

2. Technical data

2.1. Chemistry

Calcium sulphate, CaSO₄·2H₂O, gypsum, E 516

The CAS number for calcium sulphate: Anhydrous 7778-18-9
Dihydrate 10101-41-4

EINECS number: 231-900-3

Molecular weight (anhydrous form): 136.14 g/mol

Calcium sulphate is a fine, white to slightly yellowish-white odourless powder. It is slightly soluble in water (2g/l at 20°C).

2.2. Specifications

The petitioner indicates that the product in question complies with the present specification for calcium sulphate as a food additive (EC, 2000).

The percentage of sulphate in calcium sulphate anhydrous is 71% on a weight basis.

2.3. Case of need and proposed uses

Calcium sulphate is to be used as a source of calcium in food supplements. According to the petitioner the quantity of calcium (as calcium sulphate) to be added to food supplements will be determined by individual formulators but is normally the quantity necessary to supply up to 800 mg/day of calcium.
2.4. Exposure

According to the petitioner, the anticipated exposure of the population to calcium in food supplements is by self-selection of products containing Multivitamins & Multiminerals or of more specific combinations providing calcium. The petitioner states that typical levels of calcium included in Multivitamin and Mineral Tablets is often only 10-30% of the RDA of 800 mg (80 – 240 mg calcium).

Food supplement products containing calcium at levels of up to 800 mg/day have been on free sale in EU Member States for at least 20 years. This level is often achieved in calcium or calcium and vitamin D products by inclusion of 400 mg calcium/chewable tablet with a dose of 2 tablets/day.

2.5. Existing authorisations and evaluations

Calcium sulphate is authorised as food additive permitted quantum satis (q.s.) to all foods, which may contain food additives according to the Directive on food additives other than colours and sweeteners (EC, 1995).

Calcium sulphate was evaluated by the Scientific Committee on Food (SCF), which allocated an ADI not specified for the respective ions calcium and sulphate (SCF, 1990) when used as food additive (E 516). The FAO/WHO Joint Expert Committee on Food Additives (JECFA) similarly allocated ADI not specified for the calcium and sulphate ions (JECFA, 1986). SCF also allocated a tolerable upper intake level of 2500 mg calcium/day as a nutrient (SCF 2003)

According to the petitioner, calcium sulphate is an approved additive on the Food and Drug Administration GRAS (Generally Recognized As Safe) list of food additives. Approvals for the use of calcium sulphate in specific food products for nutritional and functional uses are listed in FDA Regulations, Title 21, Food and Drugs, Parts 1 to 199, Revised April 1, 1985.

3. Biological and toxicological data

3.1. Bioavailability of calcium from the source

A single feeding study in rats indicated no difference in calcium bioavailability from a diet with added calcium sulphate or other calcium sources (carbonate, chloride, hydroxide, sulphate, oxide, lactate, acetate, propionate or yeast) (EFSA, 2004).

The human studies indicated that the bioavailability of calcium from calcium sulphate in mineral water is comparable to that from milk and that the sulphate anion does not affect the urinary excretion of calcium. The AFC Panel concluded that the bioavailability of calcium from calcium sulphate in other foods is not expected to differ from that of other already permitted calcium sources in foods for particular nutritional uses (EFSA, 2004).

3.2. Toxicological data on calcium sulphate

No data on toxicological aspects were submitted by the petitioner.
4. Discussion

If calcium sulphate as a “worst case” scenario would be assumed to be consumed up to the tolerable upper intake level of 2500 mg calcium per day this would correspond to an intake of 8.5 g calcium sulphate (anhydrous) per day. This would amount to a daily intake of 6 g sulphate ion per person. For sodium sulphate JECFA states that the few available studies in experimental animals do not raise concern about the toxicity of the sulphate ion. Sodium sulphate is used clinically as a laxative. In clinical trials using 2-4 oral doses of up to 4.5 g sodium sulphate decahydrate per person (9 – 18 g per person) only occasional loose stools were reported. These doses correspond to 2.7 – 5.4 g sulphate ion (EFSA, 2004). Because of the low solubility of calcium sulphate compared with sodium sulphate it can be expected that the sulphate ion would not be present as a bolus dose after ingestion of calcium sulphate, but would rather dissociate at a lower rate. Therefore the ANS Panel concludes that the studies with dose levels up to 5.4 g sulphate ion from sodium sulphate per person provide sufficient reassurance over the safety of a “worst case” exposure scenario to the 6 g of sulphate ion from calcium sulphate.

Given the previous evaluations of the calcium and sulphate ions and calcium sulphate as a food additive (JECFA, 1986; SCF, 1990), the ANS Panel considered that a new toxicological evaluation of calcium sulphate was not needed for this present opinion.

CONCLUSION

On the basis of the available information, the ANS Panel concludes that the bioavailability of calcium from calcium sulphate is comparable to other inorganic calcium salts and that the use of calcium sulphate as a source of calcium in food supplements is of no safety concern assuming that the total dietary exposure to calcium remains within the defined tolerable upper intake level and that the calcium sulphate will comply with the existing specifications as laid down in Directive 2000/63/EC.

DOCUMENTATION PROVIDED TO EFSA


REFERENCES


GLOSSARY / ABBREVIATIONS

ADI  Acceptable Daily Intake
ADI not specified  It is a term used when, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and/or its present use in food at the levels necessary to achieve the desired technological effect, will not represent a hazard to health
AFC  Scientific Panel on food additives, flavourings, processing aids and materials in contact with food
EC  European Commission
EFSA  European Food Safety Authority
JECFA  FAO/WHO Joint Expert Committee on Food Additives
GRAS  Generally Recognized As Safe
RDA  Recommended Daily Allowance
SCF  Scientific Committee for Food