## SCIENTIFIC OPINION

# Scientific Opinion on the use of potassium sulphate and sodium sulphate as sources of respectively potassium and sodium added for nutritional purposes to food supplements[1]

**EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)**[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

## ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food provides a scientific opinion on the safety of potassium sulphate and sodium sulphate as sources of potassium and sodium, respectively, and on their bioavailabilities from these sources. The safety of potassium and sodium in terms of the amounts that may be consumed is outside the remit of the Panel. Based on the available data and the fact that potassium sulphate and sodium sulphate are water-soluble, the Panel concluded that potassium and sodium from these sources are bioavailable. The petitioner indicates that potassium sulphate and sodium sulphate will be used in food supplements to provide maximum amounts of 100 mg potassium/day and 200 mg sodium/day for adults. The Panel calculated that these dose levels result in a supply of 0.123 g sulphate ion/day (equivalent to 2.1 mg sulphate ion/kg bw/day for a 60 kg person) from potassium sulphate and of 0.417 g sulphate ion/day (equivalent to 7 mg sulphate ion/kg bw/day) from sodium sulphate. This will result in a combined intake of 0.540 g sulphate ion/day (equivalent to 9.0 mg sulphate/kg bw/day for a 60 kg person). Previously the Panel concluded that a daily intake of sulphate ion up to 6 g/day (100 mg sulphate ion/kg bw/day) does not give rise to concern. The Panel noted that this intake of 100 mg potassium/day amounts to 2 to 4% of the average intake level of potassium from the diet and that the proposed level of sodium to be supplied via food supplements of 200 mg sodium/day would represent between 4-7% of the mean intake level of sodium from the diet. Therefore, the Panel concluded that the proposed use and use levels of potassium sulphate and sodium sulphate as sources of potassium and sodium are not of safety concern.



## KEY WORDS

Sulphuric acid, dipotassium salt, CAS No. 7778-80-5; bisodium sulphate anhydrous, CAS No. 7757-82-6; dibasic sodium sulphate; disodium monosulphate; disodium sulphate decahydrate, CAS No. 7727-73-3; Glauber's salt.

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1 On request from the European Commission, Question No EFSA-Q-2010-00818, adopted on 8 December 2010.

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3 Acknowledgement: The Panel wishes to thank the members of the Working Group B on Food Additives and Nutrient Sources added to Food: M. Bakker, D. Boskou, B. Dusemund, D. Gott, T. Hallas-Møller, A. Hearty, J. König, D. Marzin, D. Parent-Massin, I.M.C.M. Rietjens, G.J.A. Speijers, P. Tobback, T. Verguieva, R.A. Woutersen for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of potassium sulphate and sodium sulphate as sources of respectively potassium and sodium added for nutritional purposes to food supplements. EFSA Journal 2010;8(12):1940 [12 pp.]. doi:10.2903/j.efsa.2010.1940. Available online: www.efsa.europa.eu

## SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of potassium sulphate and of sodium sulphate when added for nutritional purposes in food supplements as sources of, respectively, potassium and sodium, and on the bioavailability of potassium and sodium from these sources.

The safety of potassium or sodium in terms of amounts that may be consumed is outside the remit of this Panel.

The Panel noted that potassium sulphate will be used in food supplements to provide a maximum of 100 mg potassium/day for adults and that sodium sulphate will be used in food supplements to provide a maximum of 200 mg sodium/day for adults.

No specific data on the bioavailability of potassium from potassium sulphate were provided by the petitioner. The Panel noted that data in the literature indicate that water-soluble potassium compounds, including potassium sulphate, are readily taken up through the gastrointestinal tract. Because potassium sulphate is water-soluble, the Panel concluded that potassium will be equally bioavailable from this source as from other water-soluble sources of potassium.

No specific data on the bioavailability of sodium from sodium sulphate were provided by the petitioner. The Panel noted that dietary sodium is virtually completely absorbed along the length of the intestine and that the active transport of sodium is closely linked to the wider ability of the small intestine to absorb other nutrients. Ionic sodium can also be absorbed actively from the lumen of the small intestine and colon. Because sodium sulphate is water-soluble, the Panel concluded that sodium will be equally bioavailable from this source as from other water-soluble sources of sodium.

In 2005, EFSA evaluated the safety of potassium and of sodium and concluded that the available data were insufficient to establish safe upper intake levels (UL) both for potassium and for sodium (EFSA, 2005a; EFSA, 2005b).

Potassium sulphate (E 515(i)) and sodium sulphate (E 514(i)) are approved in the EU as food additives in accordance with Directive 95/2/EEC[4] with an Acceptable Daily Intake (ADI) not specified.

The petitioner indicated that potassium sulphate will be used in food supplements to provide maximum 100 mg potassium/day for adults.

The petitioner indicated that sodium sulphate will be used in food supplements to provide maximum 200 mg sodium/day for adults.

The Panel calculated that a supply of 100 mg potassium/day from potassium sulphate as the source results in a supply of 0.123 g sulphate ion/day (equivalent to 2.1 mg sulphate ion/kg bw/day for a 60 kg person). Similarly, the supply of 200 mg sodium from sodium sulphate as the source results in a supply of 0.417 g sulphate ion/day (equivalent to 7 mg sulphate ion/kg bw/day). This will result in a combined intake, when both potassium and sodium are provided at the proposed levels in the form of their sulphate salt, of 0.540 g sulphate ion/day (equivalent to 9.0 mg sulphate/kg bw/day for a 60 kg person).

Previously the Panel concluded that a daily intake of sulphate ion up to 6 g/day (100 mg sulphate ion/kg bw/day) does not give rise to concern (EFSA, 2008). Therefore, the Panel concluded that the proposed use and use levels of potassium sulphate and sodium sulphate as sources of potassium and sodium are not of safety concern.

[4] European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. Official Journal L 061 , 18.03.1995, pp 1 – 40.

The Panel calculated that a supply of 100 mg potassium/day via food supplements for adults represents 2 to 4% of the average intake level of potassium from the diet. Similarly, a supply of 200 mg sodium/day for adults represents between 4-7% of the mean intake level of sodium from the diet.

Based on the available data, the Panel concluded that potassium and sodium from respectively potassium sulphate, sodium sulphate and sodium sulphate decahydrate, are bioavailable.

The Panel concluded that the proposed use and use levels of potassium sulphate, sodium sulphate and sodium sulphate decahydrate in food supplements as a source of potassium and sodium are not of safety concern.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN 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 sodium sulphate and potassium sulphate added for nutritional purposes to food supplements. The relevant Community legislative measure is:

- Directive 2002/46/EC[5] of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002[6], the European Commission asks the European Food Safety Authority to provide a scientific opinion, based on its consideration of the safety and bioavailability of sodium sulphate and potassium sulphate as a source of sodium and potassium, respectively, added for nutritional purposes in food supplements.

[5] 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.

[6] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p.1.

## ASSESSMENT

### 1. Introduction

The present opinion deals with the safety of potassium sulphate as a source of potassium and with the safety of sodium sulphate as a source of sodium intended to be added to food supplements for nutritional purposes and with the bioavailability of potassium and sodium from these sources. The safety of potassium and sodium themselves, in terms of the amounts that may be consumed, is outside the remit of this Panel.

### 2. Technical data

#### 2.1. Identity of the substances

*Potassium sulphate*

Potassium sulphate has the molecular formula $K_2SO_4$, a molecular weight of 174.258 g/mol, and the CAS Registry Number is 7778-80-5. Synonyms include sulphuric acid, dipotassium salt; potassium sulfate.

*Sodium sulphate*

Sodium sulphate (anhydrous form) has the molecular formula $Na_2SO_4$, a molecular weight of 142.0 g/mol and the CAS Registry number is 7757-82-6. Sodium sulphate (decahydrate form) has the molecular formula $Na_2SO_4.10H_2O$, a molecular weight of 322.2 g/mol, and the CAS Registry number is 7727-73-3.

Synonyms for the anhydrous form include sodium sulfate; bisodium sulphate, dibasic sodium sulphate, disodium monosulphate, disodium sulphate, disodium sulfate. Synonyms for the decahydrate form include disodium sulphate decahydrate, Glauber's salt, sodium sulphate decahydrate, sodium sulfate decahydrate.

#### 2.2. Specifications

*Potassium sulphate*

Potassium sulphate is described by the petitioner as either colourless or white crystals (rhombohedral structure) or white granules or powder. The substance is moderately soluble in water (12 g/100 ml at 25 °C; 24 g/100 ml at 100 °C). The substance is insoluble in alcohol. The melting point is at 1069 °C (the substance vaporises at 1689 °C).

The petitioner indicates that the purity is not less than 99.0% (as $K_2SO_4$).The limits for impurities set by the petitioner are as follows: arsenic not more than 3 mg/kg; lead not more than 5 mg/kg lead; mercury not more than 1 mg/kg; selenium not more than 30 mg/kg selenium.

The Panel notes that potassium sulphate is an approved food additive (E 515(i)) according to Directive 95/2/EEC[7], and that the specifications proposed by the petitioner comply with the purity criteria laid down in Directive 2008/84/EC[8] for potassium sulphate as a food additive.

[7] European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ L 61, 18.3.1995, p. 1-53.
[8] Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners. OJ L 253, 20.9.2008, p. 1-175.

*Sodium sulphate*

Sodium sulphate is described by the petitioner as colourless crystals or a fine, white, crystalline powder. The decahydrate form is efflorescent. The substance is freely soluble in water but insoluble in alcohol. Loss on drying at 130 °C is not more than 1.0 % (anhydrous form) or not more than 57 % (decahydrate form).

The petitioner indicates that the purity is not less than 99.0% ($Na_2SO_4$ as dried substance). The limits set by the petitioner for impurities are as follows: arsenic not more than 3 mg/kg; lead not more than 5 mg/kg; mercury not more than 1 mg/kg; selenium not more than 30 mg/kg.

The Panel notes that sodium sulphate is an approved food additive (E 514(i)) according to Directive 95/2/EEC, and that the specifications proposed by the petitioner comply with the purity criteria laid down in Directive 2008/84/EC for sodium sulphate as a food additive.

### 2.3. Manufacturing process

*Potassium sulphate*

According to the petitioner, potassium sulphate is produced by various methods, either by extraction and purification of the substance from the naturally occurring mineral, langbeinite ($K_2SO_4$•$2MgSO_4$ ) or by treatment of the mineral kieserite ($MgSO_4$•$H_2O$) with potassium chloride.

Potassium sulphate can also be produced by reacting potassium chloride with sulphuric acid (Mannheim method) or by heating a mixture of potassium chloride, sulphur dioxide, air and water (Hargreaves process).

The petitioner provided a short description of the different methods.

*Sodium sulphate*

According to the petitioner, sodium sulphate is mined from its natural mineral deposits and purified.

Sodium sulphate can also be synthesised by reacting sodium chloride with sulphuric acid (Mannheim process) or by reacting sodium chloride with sulphur dioxide in the presence of oxygen (Hargreaves process). Sodium sulphate is isolated from the solution by fractional crystallisation.

Sodium sulphate is also obtained as a by-product of the manufacturing process of phenol by caustic fusion.

The petitioner provided a short description of the different methods.

### 2.4. Methods of analysis in food

No specific methods for the analysis of potassium sulphate or sodium sulphate in foods are provided. The petitioner briefly described the tests for the determination of potassium ions, sodium ions and sulphate ions via gravimetrical methods (no references given).

### 2.5. Stability, reaction and fate in foods

The petitioner stated that potassium sulphate and sodium sulphate are stable and remain available in foods.

### 2.6. Case of need and proposed uses

The petitioner states that potassium sulphate and sodium sulphate are intended for use in dietary supplements as a stand-alone ingredient or in multi-ingredient formulas, as powders, tablets, two-piece hard gelatin capsules or soft gelatin capsules to provide a source of potassium and sodium cations.

Potassium sulphate will be used in food supplements to provide maximum 100 mg potassium/day for adults.

Sodium sulphate will be used in food supplements to provide maximum 200 mg sodium/day for adults.

### 2.7. Information on existing authorisations and evaluations

In 1990, the Scientific Committee on Food (SCF) evaluated the cations potassium, sodium, calcium, magnesium and ammonium, and the anions sulphate, chloride and carbonate. The SCF established a group Acceptable Daily Intake (ADI) 'not specified' for both these cations and anions based on the consideration that no safety problems were likely to arise provided that the contributions from food intake did not disturb the homeostatic mechanisms controlling the electrolyte balance in the body (SCF, 1990; SCF, 1993).

In 2005, EFSA evaluated the safety of potassium and of sodium and concluded that the available data were insufficient to establish safe upper intake levels (UL) both for potassium and for sodium (EFSA, 2005a; EFSA, 2005b).

In 2003, the Food Standards Agency's (FSA) Expert Group on Vitamins and Minerals (EVM) carried out a risk assessment on potassium and concluded that there were insufficient data to establish a Safe Upper Level (EVM, 2003).

The EVM also carried out a risk assessment on sodium chloride and concluded that it was not possible to establish a Safe Upper Level for sodium chloride. It was also concluded that sodium chloride is not ordinarily suitable for use in supplements (EVM, 2003).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated sodium sulphate in 2000 and again in 2002 and allocated a temporary ADI 'not specified' to the substance (JECFA, 1986, JECFA, 2000; 2002).

TemaNord evaluated sodium sulphate and potassium sulphate in 2000 and concluded that there is was no reason for a re-evaluation of sulphates, including potassium sulphate and sodium sulphate, as food additives (TemaNord, 2002).

Potassium sulphate (E 515(i)) and sodium sulphate (E 514(i)) are approved in the EU as food additives in accordance with Directive 95/2/EEC.

The Panel previously evaluated the safety of sulphate from calcium sulphate as the nutrient source and concluded that a daily intake of the sulphate ion up to a level of 6 g/day (100 mg sulphate ion/kg bw/day) does not raise a safety concern (EFSA, 2008).

### 2.8. Exposure

*Sulphate*

The Panel calculated that a supply of 100 mg potassium/day from potassium sulphate as the source results in a supply of 0.123 g sulphate ion/day (equivalent to 2.1 mg sulphate ion/kg bw/day for a 60 kg person). Similarly, the supply of 200 mg sodium from sodium sulphate as the source results in a supply of 0.417 g sulphate ion/day (equivalent to 7 mg sulphate ion/kg bw/day). This will result in a combined intake, when both potassium and sodium are provided at the proposed levels in the form of their sulphate salt, of 0.540 g sulphate ion/day (equivalent to 9.0 mg sulphate/kg bw/day for a 60 kg person).

Previously the Panel concluded that a daily intake of sulphate ion up to 6 g/day (100 mg sulphate ion/kg bw/day) does not give rise to concern (EFSA, 2008).

*Potassium*

The Panel noted that for adults the anticipated exposure to potassium from the proposed use of potassium sulphate in food supplements is 0.1 g/day, and that this intake represents 2-4% of the average intake level of potassium from the diet (2.7-4 g/day) (EFSA, 2005a).

*Sodium*

The Panel noted that for adults the anticipated exposure to sodium from the proposed use of sodium sulphate in food supplements is 0.2 g/day, and that this intake represents 4-7% of the mean intake level of sodium from the diet (3-5 g/day) (EFSA, 2005b).

## 3. Biological and toxicological data

### 3.1. Bioavailability

*Potassium sulphate*

No specific data on the bioavailability of potassium from potassium sulphate were provided by the petitioner.

The EVM (2003) stated that water-soluble potassium compounds (including potassium sulphate) are readily taken up through the gastrointestinal tract.

*Sodium sulphate*

No specific data on the bioavailability of sodium from sodium sulphate were provided by the petitioner.

EFSA (EFSA, 2005b) stated that dietary sodium is virtually completely absorbed along the length of the intestine and that the active transport of sodium is closely linked to the wider ability of the small intestine to absorb other nutrients. Ionic sodium can also be absorbed actively from the lumen of the small intestine and colon.

### 3.2. Toxicological data

No specific data on the toxicity of potassium sulphate or sodium sulphate have been provided by the petitioner.

The Panel noted that JECFA and SCF have previously evaluated potassium sulphate and sodium sulphate and set an ADI not specified as food additives.

No data on sulphate (ion) have been provided by the petitioner.

The Panel previously evaluated the safety of sulphate from calcium sulphate as the nutrient source and concluded that a daily intake of the sulphate ion up to a level of 6 g/day (100 mg sulphate ion/kg bw/day) does not raise a safety concern (EFSA, 2008).

## 4. Discussion

No specific data on the bioavailability of potassium from potassium sulphate were provided by the petitioner. The Panel noted that data in the literature indicate that water-soluble potassium compounds, including potassium sulphate, are readily taken up through the gastrointestinal tract and that the major excretory route of potassium is via the kidneys. Because potassium sulphate is water-soluble, the Panel concluded that potassium will be equally bioavailable from this source as from other water-soluble sources of potassium.

No specific data on the bioavailability of sodium from sodium sulphate were provided by the petitioner. The Panel noted that dietary sodium is virtually completely absorbed along the length of the intestine and that the active transport of sodium is closely linked to the wider ability of the small intestine to absorb other nutrients. Ionic sodium can also be absorbed actively from the lumen of the small intestine and colon. Because sodium sulphate is water-soluble, the Panel concluded that sodium will be equally bioavailable from this source as from other water-soluble sources of sodium.

Based on the available data, and the fact that potassium sulphate and sodium sulphate are water-soluble, the Panel concluded that potassium and sodium from, respectively, potassium sulphate and sodium sulphate are bioavailable.

Potassium sulphate (E 515(i)) and sodium sulphate (E 514(i)) are approved in the EU as food additives in accordance with Directive 95/2/EEC with an ADI not specified.

The petitioner indicates that potassium sulphate will be used in food supplements to provide maximum 100 mg potassium/day for adults. The Panel noted that this intake of 100 mg potassium/day amounts to 2 to 3% of the average intake level of potassium from the diet.

The petitioner indicated that sodium sulphate will be used in food supplements to provide maximum 200 mg sodium/day for adults. Considering that the mean daily sodium intakes of populations in Europe range from about 3000-5000 mg sodium/day, the proposed level of sodium to be supplied via food supplements of 200 mg sodium/day would represent between 4-7% of the mean intake level of sodium from the diet.

As regards sulphate (ion), the Panel calculated that a supply of 100 mg potassium/day from potassium sulphate as the source results in a supply of 0.123 g sulphate ion/day (equivalent to 2.1 mg sulphate ion/kg bw/day for a 60 kg person). Similarly, the supply of 200 mg sodium from sodium sulphate as the source results in a supply of 0.417 g sulphate ion/day (equivalent to 7 mg sulphate ion/kg bw/day). This will result in a combined intake, when both potassium and sodium are provided at the proposed levels in the form of their sulphate salt, of 0.540 g sulphate ion/day (equivalent to 9.0 mg sulphate/kg bw/day for a 60 kg person).

Previously the Panel concluded that a daily intake of sulphate ion up to 6 g/day (100 mg sulphate ion/kg bw/day) does not give rise to concern (EFSA, 2008). Therefore, the Panel concluded that the proposed use and use levels of potassium sulphate and sodium sulphate as sources of potassium and sodium are not of safety concern.

## CONCLUSIONS

Based on the available data, the Panel concluded that potassium and sodium from respectively potassium sulphate, sodium sulphate and sodium sulphate decahydrate are bioavailable.

The Panel noted that, at the proposed level of use in food supplements, the additional supply of potassium from the source amounts to a maximum of 4% of the average intake level of potassium from the diet.

The Panel also noted that at the proposed level of use in food supplements, the additional supply of sodium from the source amounts to a maximum of 7% of the mean intake level of sodium from the diet.

The Panel concluded that the proposed use and use levels of potassium sulphate, sodium sulphate and sodium sulphate decahydrate in food supplements as a source of potassium and sodium are not of safety concern.

## DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Sodium Sulphate Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements Under Article 4(5). November 2009. Submitted by Nutritech Consultancy UK.

2. Dossier on Potassium Sulphate Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements Under Article 4(5). November 2009. Submitted by Nutritech Consultancy UK.

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## GLOSSARY AND/OR ABBREVIATIONS

| | |
|---|---|
| ADI | Acceptable Daily Intake |
| ANS | Scientific Panel on Food Additives and Nutrient Sources added to Food |
| CAS | Chemical Abstracts Service |
| EC | European Commission |
| EFSA | European Food Safety Authority |
| EVM | Expert Group on Vitamins and Minerals |
| FSA | Food Standards Agency |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| SCF | Scientific Committee for Food |
| UL | Tolerable Upper Intake Level |