Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
On a request from the Commission related to

Magnesium Potassium Citrate as a source of magnesium and potassium in food for particular nutritional uses, food supplements and foods intended for the general population

Question n° EFSA-Q-2006-131

Adopted on 27 September 2006

SUMMARY

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) has been asked to evaluate the safety and bioavailability of magnesium potassium citrate as a source of magnesium and potassium when added for nutritional purposes in foods for particular uses in food supplements and in foods intended for the general population.

The present opinion deals only with the safety and bioavailability of a particular source of magnesium and potassium, magnesium potassium citrate. The safety of magnesium and potassium itself, in terms of the amounts that may be consumed, is outside the remit of this Panel.

The safety evaluation of magnesium potassium citrate as a source for magnesium and potassium in food supplements is based on the safety evaluations of the individual substances, citric acid, potassium citrate and magnesium citrate. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1973 and the EC Scientific Committee on Food (SCF) in 1990 evaluated the individual substances as food additives and established an ADI not specified for citrate and for the cations potassium and magnesium.

Citric acid has a well-established role as an intermediate metabolite in the tricarboxylic acid cycle. Citrates occur in many foods and are normal metabolites in the body and are therefore considered as of no safety concern.

The Panel concluded that the use of magnesium potassium citrate as a source for magnesium and potassium in food for particular nutritional uses, food supplements and foods intended for the general population is of no safety concern.

Regarding bioavailability, data in the literature show that potassium magnesium citrate provides an equivalent potassium bioavailability to that of potassium citrate and potassium chloride, and a comparable magnesium bioavailability to that of magnesium citrate.

The specifications of magnesium potassium citrate as commercialised should comply with the specifications for citric acid and its salts used as food additives.
KEY WORDS
Magnesium potassium citrate, 2-Hydroxy-1,2,3,-propane tricarboxylic acid Magnesium (2:1) Potassium(2:2) salt, Mg K Citrate, CAS Nr 137590-34-2, food supplements.

BACKGROUND
The European Community legislation lists substances that may be used for nutritional purposes in certain categories of foods as sources of certain nutrients. This application is a request for the inclusion of magnesium potassium citrate in Annex of:


In addition, there is a Commission proposal for a regulation on the addition of vitamins and minerals and certain other substances to foods.

TERMS OF REFERENCE
In accordance with Article 29 (1) (a) of 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 the substance magnesium potassium citrate when added for nutritional purposes in foods for particular uses and foods (including food supplements) intended for the general population.

ASSESSMENT
The present opinion deals only with the safety and bioavailability of magnesium potassium citrate as a source of magnesium and potassium intended for the general population, to be used in food supplements and in foods for particular nutritional uses. The safety of magnesium and potassium itself, in terms of the amounts that may be consumed, is outside the remit of this Panel.

Chemistry
Magnesium potassium citrate is a mixed salt of magnesium and potassium with citric acid, a substance with as chemical name [2-Hydroxy-1, 2, 3,-propane tricarboxylic acid Magnesium (2:1) Potassium (2:2) salt], chemical formula K₄ Mg (C₆H₅O₇)₂. The
percentage weight of magnesium, potassium and citrate in magnesium potassium
citrate are therefore respectively 4.3%, 28% and 67.7%.
Molecular mass: 568.66 g/mol; CAS registration number: 137590-34-2; White
crystalline powder, stable for several months at room temperature and at 40°C; Freely
soluble in water (gives a pH 5 – 7) and diluted HCl; insoluble in methanol.

Specifications

According to the petitioner magnesium potassium citrate contains, on a dried basis,
not less than 26% potassium and not less than 4% magnesium. The calculated citric
acid content is not less than 68%. The lead and arsenic contents are below 1 mg/kg.
In a sieve test, not less than 90% passes at 40 mesh and not less than 75% passes at 80
mesh. The loss on drying is not more than 6%.

Manufacturing process

According to the petitioner citric acid is added to demineralised water under stirring.
Then, calculated quantities of magnesium oxide are added followed by the addition of
calculated quantities of potassium carbonate to adjust the pH to 7.0 – 7.5. The
reaction mixture is further stirred and the resulting precipitate is removed and dried.

Methods of analysis in food

Not applicable.

Reaction and fate in foods

According to the petitioner no reactions are expected to occur under normal
processing conditions.
The petitioner provides data demonstrating that magnesium potassium citrate is stable
for up to six months at 40°C and 75% relative humidity and up to sixty months at
25°C and 60% relative humidity.

Exposure

No specific data were provided by the petitioner.

The potential exposure to citric acid was calculated based on the hypothesis that
addition of magnesium potassium citrate in food would be such as not to exceed either
250 mg per day of magnesium or 3 g per day of potassium. Based on the percentage
weight of magnesium (28%) in the substance, the intake of magnesium potassium
citrate should be less than 893 mg in order to limit the additional intake of magnesium
to less than 250 mg per day. In these conditions, based on the percentage weight of
potassium (4.3%), the additional intake of potassium would also be far less than its
safety limit of 3 g. The additional daily intake of citric acid deriving from the
addition of magnesium potassium citrate within the safety limits established for
potassium and magnesium may therefore be up to around 600 mg of citric acid,
considering that citric acid represents 67.7% of weight of the substance.
Existing authorisations and evaluations

In the EU, citric acid (E330) and its potassium salt (E332) are permitted food additives (EC, 2006). The magnesium salts of citric acid and potassium citrate are also permitted substances in all foods for particular nutritional uses (EC, 2001).

Biological and toxicological data

Bioavailability of magnesium and potassium from their Mg K citrate source

Data in the literature show that potassium magnesium citrate provides an equivalent potassium bioavailability to that of potassium citrate and potassium chloride, and a comparable magnesium bioavailability to that of magnesium citrate (Koenig et al., 1991).

Toxicological data

The JECFA evaluated citric acid and its salts as food additives in 1973 and concluded that due to the fact that these substances are natural constituents of the diet and that the intake from food additives is likely to be insignificant compared to the intake from natural sources there is no need for specific toxicity data. JECFA established an acceptable daily intake (ADI) not specified for citrate (JECFA, 1974).

The SCF evaluated citric acid and its potassium and magnesium salts in 1990 and established an ADI not specified for the cations potassium and magnesium. The SCF however, emphasized that no safety problems are likely to arise, provided the contributions from food intake do not disturb the homeostasis mechanisms controlling the electrolyte balance of the body. For magnesium, large single doses taken in bulk are known to produce diarrhoea particularly in children, and should be avoided (SCF, 1991).

In evaluating the acceptability of citrate the SCF emphasized that citrate has a well-established role as an intermediate metabolite in the citric acid cycle and as a natural component of food. The Committee agreed with the group ADI not specified established by JECFA (SCF, 1991).

CONCLUSION

From data in the literature it can be concluded that magnesium and potassium are bioavailable from magnesium potassium citrate. Their bioavailability is expected to be equivalent to their bioavailability from magnesium citrate and potassium citrate respectively.

The safety evaluation of magnesium potassium citrate as a source for magnesium and potassium in food for particular nutritional uses and foods (including, food supplements) intended for the general population is based on the safety evaluations of the individual substances, citric acid, potassium citrate and magnesium citrate. The JECFA in 1973 and the SCF in 1990 evaluated the individual substances as food
additives and established an ADI not specified for citrate and for the cations potassium and magnesium. If the addition of magnesium potassium citrate to food is such that the safety limits established for potassium and magnesium are not exceeded, the additional intake of citric would up to around 600 mg which is of no safety concern.

Citric acid has a well-established role as an intermediate metabolite in the tricarboxylic acid cycle. Citrates occur in many foods and are normal metabolites in the body and are therefore, considered as of no safety concern.

The Panel concluded that the use of magnesium potassium citrate as a source of magnesium and potassium in foods for particular nutritional uses and foods (including food supplements) intended for the general population is of no safety concern.

The Panel emphasises that the specifications of magnesium potassium citrate as commercialised should comply with the specifications for citric acid and its salts used as food additives.

DOCUMENTATION PROVIDED TO EFSA

Dossier on magnesium potassium citrate, Application for derogation submitted by Sami Labs Limited, Bangalore, India (July, 2005)

REFERENCES


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