

SCIENTIFIC OPINION

Inability to assess the safety of manganese ethanalamine phosphate added for nutritional purposes as a source of manganese to food supplements and the bioavailability of the manganese from this source, based on the supporting dossier¹

Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food (ANS)

(Question No EFSA-Q-2008-024)

Adopted on 5 June 2009

PANEL MEMBERS

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¹ For citation purposes: Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food on the inability to assess the safety of manganese ethanalamine phosphate added for nutritional purposes as a source of manganese to food supplements and the bioavailability of manganese from this source, based on the supporting dossier, following a request from the European Commission. *The EFSA Journal* (2009) 1115, 1-6

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 manganese ethanolamine phosphate 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 supplements².

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 manganese ethanolamine phosphate added for nutritional purposes in food supplements.

² OJ L 183, 12.7.2002, p.51.

ASSESSMENT

1. Introduction

Following a request from the European Commission, to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety of manganese ethanolamine phosphate added for nutritional purposes to food supplements and on the bioavailability of manganese from this source.

The present statement deals only with the safety of manganese ethanolamine phosphate as a source of manganese intended to be used in food supplements and with the bioavailability of the manganese from this source. The safety of manganese itself, in terms of amounts that may be consumed, is outside the remit of this Panel.

2. Technical data

2.1. Chemistry

CAS Registry Number: The CAS Registry Number for manganese ethanolamine phosphate was not provided.

Synonyms: manganese 2-aminoethyl phosphoric acid, manganese colamine phosphate, manganese ethylamine phosphate, manganese EAP.

Molecular formula: $\text{Mn}(\text{C}_2\text{H}_6\text{NPO}_4)_2$

Molecular weight: 333.03 g/mol

Solubility: No information provided.

2.2. Specifications

Manganese ethanolamine phosphate was described as a white powder and its purity is not less than 98.0%. The reported limits for impurities are as follows: arsenic not more than 3 mg/kg, lead not more than 5 mg/kg, and mercury not more than 1 mg/kg.

2.3. Manufacturing Process

The petitioner has provided only brief details of the manufacturing process. Manganese ethanolamine phosphate is synthesised from manganese(II) oxide and ethanolamine phosphate derived by the reaction of phosphoric acid with ethanolamine.

2.4. Methods of analysis in food

According to the petitioner, the analytical methods for analysis of manganese ethanolamine phosphate are based on determination of total manganese by Atomic Absorption Spectroscopy (AAS) or Inductively Coupled Plasma (ICP) spectrometry.

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

The petitioner reported that manganese ethanolamine phosphate is stable in foods, although no data were provided to support this statement.

2.6. Case of need and proposed use levels

The proposed use, according to the petitioner, is to provide a source of manganese supplied as a nutrient in food supplements. Manganese ethanolamine phosphate is used as an ingredient in tablets, caplets, capsules, chewable tablets, effervescent powders and liquids that are food supplements. The method of incorporation is determined by the individual manufacturers, as appropriate for the particular type of finished product.

The petitioner also proposes that manganese ethanolamine phosphate is to be included in food supplements to provide up to 4 mg manganese/day in adults. Assuming a manganese content of 16%, this proposed use level would result in exposure to manganese ethanolamine phosphate at approximately 24 mg/day and to ethanolamine phosphate at approximately 20 mg/day.

3. Biological and toxicological data

No specific information was provided on the bioavailability of manganese from manganese ethanolamine phosphate, other than a statement that the “metabolic fate and biological distribution of manganese ethanolamine phosphate is expected to be similar to that of inorganic sources of manganese in the diet”.

No toxicological data on manganese ethanolamine phosphate, as well as on ethanolamine phosphate were provided by the petitioner.

CONCLUSIONS

The Panel notes that the petitioner has not provided any data on the toxicity of manganese ethanolamine phosphate nor on the bioavailability of manganese from manganese ethanolamine phosphate.

Therefore, the Panel concludes that due to the lack of an appropriate dossier supporting the use of manganese ethanolamine phosphate in food supplements, the safety of manganese ethanolamine phosphate and the bioavailability of manganese from manganese ethanolamine phosphate cannot be assessed.

DOCUMENTATION PROVIDED TO EFSA

1. Biocare derogation registration. Manganese ethanolamine phosphate. BioCare Limited, Birmingham, UK
2. Additional Information on Manganese Ethanolamine Phosphate Proposed for Addition to Annex II of Directive 2002/46/EC of the European Parliament and of the Council Relating to Food Supplements to support the earlier Article 4(6) submission by BioCare Limited, Birmingham, UK

Key words:

Food supplements, manganese, manganese ethanolamine phosphate

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of Working Group A on Food Additives and Nutrient Sources of the ANS Panel for the preparation of this opinion: F. Aguilar, N Bemrah, P. Galtier, J. Gilbert, S. Grilli, R. Guertler, G.E.N. Kass, C. Lambré, J.C. Larsen, J-C. Leblanc, A. Mortensen, I. Pratt, I. Stankovic.

GLOSSARY / ABBREVIATIONS

AAS	Atomic Absorption Spectroscopy
ANS	Panel on Food Additives and Nutrient Sources added to Food
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority
ICP	Inductively Coupled Plasma