SCIENTIFIC OPINION

Inability to assess the safety of chromium (III) and copper (II) ethanolamine phosphate added for nutritional purposes to food supplements based on the supporting dossier¹

Statement of the Panel on Food Additives and Nutrient Sources added to Food

(Question No EFSA-Q-2008-022, EFSA-Q-2008-023)

Adopted on 28 January 2009

PANEL MEMBERS


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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 chromium (III) ethanolamine phosphate and copper (II) ethanolamine phosphate 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 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 chromium (III) and copper (II) ethanolamine phosphate added for nutritional purposes in food supplements.

ACKNOWLEDGEMENTS


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ASSESSMENT

1. Introduction
The present statement deals only with the safety and bioavailability of chromium (III) ethanolamine phosphate and copper (II) ethanolamine phosphate as particular sources of chromium and copper, added in food supplements, and with the bioavailability of chromium and copper from the respective ethanolamine phosphate sources. The safety of chromium and copper themselves, in terms of amounts that may be consumed, is outside the remit of this Panel.

2. Chemistry

2.1. Chromium (III) ethanolamine phosphate
The CAS number for chromium (III) ethanolamine phosphate has not been provided.

Synonyms: chromium (III) 2-amino ethyl phosphoric acid, chromium (III) colamine phosphate, chromium (III) ethylamine phosphate, chromium EAP.

Molecular formula: \(Cr(\text{C}_2\text{H}_6\text{NPO}_4)_3\)

Molecular weight: 469.13 g/mol.

Solubility: No information provided.

2.2. Copper (II) ethanolamine phosphate
The CAS number for copper (II) ethanolamine phosphate has not been provided.

Synonyms: copper 2-amino ethyl phosphoric acid, copper colamine phosphate, copper ethylamine phosphate, copper EAP.

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

Molecular weight: 341.63 g/mol

Solubility: No information provided.

2.3. Case of need and proposed use levels
Chromium (III) ethanolamine phosphate is proposed to be included in food supplements to provide 20 – 500 µg chromium/day in adults. This use level would result in exposure to chromium (III) ethanolamine phosphate at 4.5 mg/day and to ethanolamine at 4.0 mg/day.

Copper (II) ethanolamine phosphate is proposed to be included in food supplements to provide up to 2 mg copper/day in adults. This use level would result in exposure to copper (II) ethanolamine phosphate at 10.8 mg/day and to ethanolamine at 8.8 mg/day.
2.4. Biological data

There are no data in the dossier on bioavailability of the cations from these nutrient sources. No toxicological data on chromium (III) and copper (II) 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 chromium (III) ethanolamine phosphate and copper (II) ethanolamine phosphate and the bioavailability of chromium and copper from the respective ethanolamine phosphate salts.

Therefore, the Panel concludes that due to the lack of an appropriate dossier supporting the use of chromium (III) and copper (II) ethanolamine phosphate in food supplements, the safety of chromium (III) and copper (II) ethanolamine phosphate and the bioavailability of chromium and copper from the respective ethanolamine phosphate salts cannot be assessed.

DOCUMENTATION PROVIDED TO EFSA


GLOSSARY / ABBREVIATIONS

CAS Chemical Abstract Service
EFSA European Food Safety Authority