

## 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 dossier<sup>1</sup>**

#### **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**

F. Aguilar, U. Charrondiere, B. Dusemund, P. Galtier, J. Gilbert, D.M. Gott, S. Grilli, R. Guertler, G.E.N. Kass, J. Koenig, C. Lambré, J-C. Larsen, J-C. Leblanc, A. Mortensen, D. Parent-Massin, I. Pratt, I.M.C.M. Rietjens, I. Stankovic, P. Tobback, T. Verguieva, R. Woutersen.

---

<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on chromium and copper ethanolamine phosphate. *The EFSA Journal* (2009) 953, 1-6.

## TABLE OF CONTENTS

Panel Members .....	1
Table of Contents .....	2
Background as provided by the Commission .....	3
Terms of reference as provided by the Commission .....	3
Acknowledgements .....	3
Assessment .....	4
1. Introduction .....	4
2. Chemistry.....	4
2.1. Chromium (III) ethanolamine phosphate .....	4
2.2. Copper (II) ethanolamine phosphate.....	4
2.3. Case of need and proposed use levels.....	4
2.4. Biological data .....	5
Conclusions .....	5
Documentation provided to EFSA .....	5

## **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:

- 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 supplements<sup>2</sup>

## **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**

The European Food Safety Authority wishes to thank the members of the Working Group B on Food Additives and Nutrient Sources for the preparation of this opinion: D. Boskou, R. Charrondiere, B. Dusemund, D. Gott, T. Hallas-Møller, K. F. A. M. Hulshof, J. König, D. Parent-Massin, I.M.C.M. Rietjens, G.J.A. Speijers, P. Tobbac, T. Verguieva, R. Woutersen.

---

<sup>2</sup> OJ L 183, 12.7.2002, p.51.

## 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:**  $\text{Cr}(\text{C}_2\text{H}_6\text{NPO}_4)_3$

**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**

1. Additional Information on Chromium (III) 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 Ltd.
2. Additional Information on Copper (II) 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 Ltd.

## GLOSSARY / ABBREVIATIONS

CAS	Chemical Abstract Service
EFSA	European Food Safety Authority