

SCIENTIFIC OPINION

Inability to assess the safety of iron glycerophosphate added for nutritional purposes as a source of iron in food supplements and the bioavailability of iron 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-2006-252)

Adopted on 30 April 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 iron glycerophosphate added for nutritional purposes to food supplements based on the supporting dossier following a request from the European Commission on iron glycerophosphate. *The EFSA Journal* (2009) 1078, 1-5.

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 iron glycerophosphate 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 iron glycerophosphate added for nutritional purposes in food supplements.

² OJ L 183, 12.7.2002, p.51.

ASSESSMENT

1. Introduction

The present opinion deals only with the safety of iron (III) glycerophosphate added for nutritional purposes as a source of iron in food supplements and with the bioavailability of iron from the source. The safety of iron in terms of amounts that may be consumed is outside the remit of this Panel.

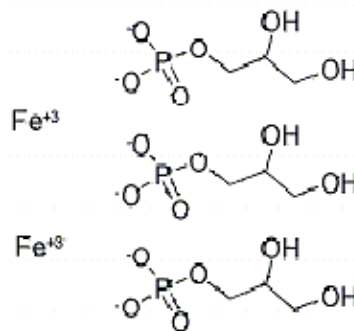
2. Chemistry

The CAS Registry Number of iron (III) glycerophosphate is 1301-70-8.

Synonyms: 1,2,3-propanetriol, mono(dihydrogenphosphate), iron(3+)salt(3:2) diiron tris(glycerophosphate), ferric glycerophosphate.

Molecular formula: $C_9H_{21}Fe_2O_{18}P_3$

Structural formula:



Molecular weight: 621.87 g/mol.

Iron (III) glycerophosphate is a yellow to green-yellow powder, odourless, soluble in water in the proportion 1:2, insoluble in ethanol. Impurities are arsenic < 4 mg/kg; lead < 50 mg/kg.

2.1. Case of need and proposed use levels

Iron (III) glycerophosphate is intended to be used as a source of iron in food supplements. No information was provided on the use levels of iron (III) glycerophosphate in food supplements.

2.2. Biological and toxicological data

Only data related to the biological and nutritional properties of iron as such were provided by the petitioner.

No data were provided on the bioavailability of iron from iron (III) glycerophosphate. However, given the solubility of iron (III) glycerophosphate in water, the Panel considered

that the bioavailability of iron from this source would be similar to that from other water soluble iron sources.

No toxicological data on iron (III) glycerophosphate or on other glycerophosphoric acid salts were provided by the petitioner.

CONCLUSIONS

The Panel concluded that the bioavailability of iron from this source would be similar to that from other water soluble iron sources.

In the absence of information on the intended use levels and on toxicity data supporting the use of iron (III) glycerophosphate as a source of iron in food supplements, the Panel concluded that, the safety of iron (III) glycerophosphate cannot be assessed.

Key words:

Food supplements, iron glycerophosphate, CAS Registry Number 1301-70-8, nutrient source, 1,2,3-propanetriol, mono(dihydrogenophosphate)iron (3^+)salts, diiron tris (glycerophosphate), iron (III) glycerophosphate.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier on Iron Glycerophosphate (Glycérophosphate de fer). August 2005. Submitted by Therabel Pharma, Belgium.

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GLOSSARY / ABBREVIATIONS

ANS	Panel on Food Additives and Nutrient Sources added to Foods
CAS	Chemical Abstracts Service
EC	European Commission
EFSA	European Food Safety Authority