

SCIENTIFIC OPINION

Ferrous phosphate added for nutritional purposes to food supplements¹

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food

(EFSA-Q-2006-197, EFSA-Q-2006-303)

Adopted on 29 January 2009

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SUMMARY

Following a request from the European Commission to the European Food Safety Authority, the Scientific Panel on Food Additives and Nutrient Sources added to Food was asked to provide a scientific opinion on ferrous phosphate as a source of iron added for nutritional purposes to food supplements.

The present opinion deals only with the safety of ferrous phosphate and the bioavailability of the iron from this source.

The Panel notes that the iron content of foods varies greatly. Foods rich in iron include liver and offal, game and beef, cereals, cereal products; pulses also contain moderate to high levels.

¹ For citation purposes: Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the European Commission on Ferrous phosphate added for nutritional purposes to food supplements. *The EFSA Journal* (2009) 951, 1-13.

² Editorial changes only: page 1 the interest declared by one member of the Panel had not been included in the footnote. The changes do not affect the overall conclusion of the opinion. To avoid confusion, the original version has been removed from the website.

* (conflict of interest) one member of the Panel did not participate in the discussion on the subject referred to above because of possible conflict of interest.

Poor sources of iron include milk and dairy products, whereas pork, poultry, and green vegetables contain intermediate concentrations.

The average and 97.5th percentile iron intakes from food from European countries vary from 10 to 17 mg/day and from 17 to 29 mg/day respectively. Iron intakes from food, food supplements included, produce high percentile values that range from 27 to 72 mg/day.

Phosphorus is found in a variety of food types; in particular, foods rich in protein generally have a high phosphorus content.

The average and 97.5th percentile phosphorus intakes from food from European countries vary from 1000 to 1600 mg/day and from 1700 to 2600 mg/day respectively. The contribution of dietary supplements to population average phosphorus intakes is estimated to be negligible for all age groups.

The petitioners indicated that the quantity of ferrous phosphate used in multivitamin-mineral tablets would normally supply 14 mg iron/day. This is equivalent to 42 mg ferrous phosphate/day and 5.2 mg phosphorus/day. This means that for a 60 kg adult the potential exposure to iron(II) would be 0.23 mg iron/kg bw/day and to phosphorus 0.09 mg phosphorus/kg bw/day respectively.

For guidance purposes only, the UK Expert Group on Vitamins and Minerals (EVM) indicated that a supplemental intake of approximately 17 mg iron/day (equivalent to 0.28 mg iron/kg bw/day for a 60 kg adult) would not be expected to produce adverse effects in the majority of people. The Panel notes that the quantity of 14 mg iron/day as proposed by the petitioners for use in multivitamin-mineral tablets is below this guidance value.

No specific data are available regarding the bioavailability of iron from ferrous phosphate as a mineral substance in food supplements. However, the Panel noted that iron salts are made soluble in the acidic environment of the stomach and that iron must be in the ferrous form for absorption. Therefore, the Panel considers that iron is bioavailable from the source considered in this opinion.

The Panel is further of the opinion that, given the previous evaluations of ferrous iron, phosphoric acid and phosphates as food additives and as nutrient sources by the Scientific Committee on Food (SCF), the European Food Safety Authority (EFSA) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) no additional toxicological studies on ferrous phosphate as source of iron are required.

The Panel therefore concludes that the use of ferrous phosphate in food supplements as a source of iron(II) is not of safety concern at the proposed use levels.

Key words:

Ferrous phosphate, CAS No. 10028-23-6; Iron(II) phosphate; [Phosphoric acid, iron(2+)salt(2:3), octahydrate]; [tri-iron bis(orthophosphate), anhydrous].

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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 ferrous 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 supplements³.

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 ferrous phosphate added for nutritional purposes to food supplements.

ACKNOWLEDGEMENTS

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³ OJ L 183, 12.7.2002, p.51.

ASSESSMENT

1. Introduction

The present opinion deals only with the safety of ferrous phosphate and the bioavailability of the iron from this source. The safety of the source in terms of the amounts of minerals that may be consumed is outside the remit of this Panel. Unless stated differently, in this opinion phosphorus levels are expressed in terms of phosphates.

This opinion is based on information provided by two petitioners.

2. Technical data

2.1. Chemistry

Ferrous phosphate is an inorganic compound with CAS Registry Number 10028-23-6. The molecular formula indicated by the petitioners corresponds to the octahydrate form $\text{Fe}_3(\text{PO}_4)_2 \cdot 8\text{H}_2\text{O}$ with a molecular weight of 501.66 g/mol.

Other synonyms proposed are [iron(II) phosphate]; [phosphoric acid, iron(2+)salt(2:3), octahydrate]; [tri-iron bis(orthophosphate), anhydrous]; The anhydrous form has a CAS Registry Number 14940-41-1).

2.2. Specification

Ferrous phosphate is described as a greyish-blue powder, practically insoluble in water but soluble in mineral acids. The chemical specifications as proposed by the petitioners are given in Table 1.

Table 1. Chemical specifications for ferrous phosphate as proposed by the petitioners.

	Submission EFSA-Q-2006-197	Submission EFSA-Q-2006-303
Assay $\text{Fe}_3(\text{PO}_4)_2 \cdot 8\text{H}_2\text{O}$	78.4 %	93.7 %-112 %*
Assay Fe(II)	26.2 %	31 %-37 %
Sulphate	Max 0.24 %	Max 0.24 %
Fe(III)	Not given	Max 13 %
Arsenic	max 0.0004 %	3 mg/kg
Cadmium	Not given	10 mg/kg
Mercury	Not given	1 mg/kg
Lead	max 0.005 %	1 mg/kg

* Calculated by the Panel

The Panel notes that according to Commission Regulation (EC) No 629/2008 the maximum levels of lead, mercury and cadmium in food supplements as sold should be 3.0 mg/kg and 0.1 mg/kg and 1 mg/kg respectively (EC, 2008).

2.3. Manufacturing process

No details on the manufacturing process of ferrous phosphate have been provided by the petitioners. One petitioner only provides a flow chart of the process. From this chart it can be deduced that ferrous phosphate is produced by mixing ferrous sulphate, sodium bicarbonate and sodium phosphate. After reaction, a precipitate is formed that is further purified and dried to obtain the commercial product. The petitioner claims that the final product undergoes a quality control assessment according to specifications or pharmacopoeias.

2.4. Methods of analysis in food

One petitioner indicates that the methods for analysing iron in food supplements are DS/EN 13805 and DS/ISO 11885 which are based on atomic absorption spectroscopy.

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

One petitioner indicates that the iron(II) ion may oxidise to iron(III).

2.6. Case of need and proposed use

The petitioners only state that the use is to provide a source of iron in food supplements.

2.6.1. Types of products in which the source is intended to be used.

The petitioners indicate that ferrous phosphate is intended to be used in tablets, capsules and other forms of food supplements.

2.6.2. Quantities to be added to these products

One petitioner indicates that the quantity of iron in multivitamin-mineral tablets is normally 14 mg iron/tablet. This petitioner also indicates that tablets with higher or lower iron content exist but no details are provided. The second petitioner states that its commercial product contains 41.2 mg ferrous phosphate/tablet/daily dose (equivalent to between 13 and 15 mg iron/day).

2.7. Information on existing authorisations and evaluations

The constituents of ferrous phosphate are iron, phosphate and water. Iron oxides as food colours have been evaluated by the Joint FAO/WHO Expert group on Food Additives (JECFA) (1983) and were allocated an Acceptable Daily Intake (ADI) of 0.5 mg/kg bw/day. In addition, ferrous gluconate has been evaluated as a food colour and stabiliser and was allocated an “ADI not specified” (JECFA, 1975).

Iron

For iron the Scientific Committee on Food (SCF) recommended daily intakes of 6 mg and 4 mg for infants aged 0.5-1 years and 1-3 years respectively, assuming 15% absorption of the daily intake. For adults, assuming 10% absorption of the daily intake, the recommended dietary iron intake has been estimated to be between 8 and 10 mg iron/day for adult males and to be between 15 and 20 mg/day for adult females of reproductive age (SCF, 1993; IOM, 2001; D-A-CH, 2000)

Regarding upper limits, the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) concluded in 2004 that the available data were insufficient to establish a tolerable upper intake level (UL) for iron. Based on estimates of current iron intakes in European countries, the risk of adverse effects from a high iron intake from food sources, including fortified foods in some countries, but excluding supplements, is considered to be low for the population as a whole, except for those homozygous for hereditary haemochromatosis (up to 0.5% of the population). However, intake of iron from food supplements in men and postmenopausal women may increase the proportion of the population likely to develop biochemical indicators of high iron stores. Some groups at special risk for poor iron status, such as menstruating women or children, could benefit from additional iron intake and/or an improved availability of dietary iron (EFSA, 2004).

The US Food and Nutrition Board established an UL of 45 mg/day for individuals aged 14 years and older and 40 mg/day for younger age groups (IOM, 2001).

The Expert Group on Vitamins and Minerals (EVM) concluded that there are insufficient appropriate data to establish a Safe Upper Level for iron (EVM, 2003). It was also stated that for guidance purposes only, a supplemental intake of approximately 17 mg iron/day (equivalent to 0.28 mg/kg bw/day for a 60 kg adult) would not be expected to produce adverse effects in the majority of people. Fortification of food with iron is common in developing countries where deficiency of the element is widespread. In the UK there is mandatory fortification of white and brown flour at a level not less than 16.5 mg iron/kg flour. Many breakfast cereals are fortified on a voluntary basis; levels vary but are typically within the range of 70 to 120 mg/kg (EVM, 2003).

Phosphorus (as phosphate)

Phosphorus is on the list of vitamin and mineral substances which may be used in the manufacture of food supplements in Annex I of Directive 2002/46/EC and a number of phosphorous salts are listed in Annex II of this Directive as approved mineral substances which may be used in the manufacture of food supplements (EC, 2002).

For phosphorus, the SCF established in 1993 Population Reference Intakes of 300 mg for children, 775 and 625 mg in males and females aged 11-17 years and 550 mg/day in adults (SCF, 1993). More recently higher recommendations were established by IOM (1997) and D-A-CH (2000) as follows: 700 mg/day for adults and up to 1250 mg/day for adolescents. For the younger age groups a factorial approach was used.

Regarding phosphorus, the NDA Panel could not derive a UL but indicated that normal healthy individuals can tolerate phosphorus intakes up to at least 3000 mg/day without adverse systemic effects (EFSA, 2005). However, in some individuals, mild gastrointestinal symptoms have been reported following exposure to supplemental intakes >750 mg phosphorus per day. However, the NDA Panel highlighted, that there is no evidence of adverse effects associated

adverse effects associated with the current dietary intakes of phosphorus in EU countries (EFSA, 2005).

The Institute of Medicine (IOM) established a UL of 4000 mg phosphorus/day for people aged 9 years and older and 3000 mg/day for younger children and the elderly (70+ years) (IOM, 1997).

The EVM (2003) could not establish a Safe Upper Level for phosphorus but concluded that for guidance purposes only, a supplemental intake of 250 mg/day would not be expected to produce adverse effects, including mild gastrointestinal upset.

2.8. Exposure

Iron

The iron content of food varies greatly, and factors such as the soil, climate conditions and processing can influence the iron content of similar foods. The amount of iron detected in food can also vary due to differences in analytical methods. Foods rich in iron include liver and offal, game and beef, cereals, cereal products and pulses also contain moderate to high levels. Poor sources of iron include milk and dairy products, whereas pork, poultry, and green vegetables contain intermediate concentrations (EFSA, 2004).

According to the NDA Panel, the average and 97.5th percentile iron intakes from food in European countries vary from 10 to 17 mg/day and from 17 to 29 mg/day, respectively. The intake of iron from food, food supplements included, produces high percentile values of 27 to 72 mg/day (EFSA, 2004).

Phosphorus (as phosphate)

Phosphorus is found in a variety of foods as phosphates. Foods rich in protein, in particular, are generally high in phosphorus, e.g. dairy products (100-900 mg/100g), meats (200 mg/100g), fish (200 mg/100g) and grain products (100-300 mg/100g) (EFSA, 2005).

According to NDA Panel, the average and 97.5th percentile phosphorus intakes from food in European countries are usually between 1000-1600 mg/day and 1700 to 2600 mg/day respectively (EFSA, 2005).

Phosphoric acid and phosphate salts are also added as food additives in processed foods and in soft drinks as regulators and stabilizers. No specific data on the contribution of phosphorus-containing food additives to the total intake of phosphorus in the EU have been identified (EFSA, 2005). In the US, the contribution of phosphorus from phosphorus-containing food additives is estimated to be 320 mg/day, i.e. 20-30% of the total adult phosphorus intake (Calvo and Park, 1996).

Ferrous phosphate

As stated in section 2.6.2, the quantity of iron in multivitamin-mineral tablets normally results in an intake of 14 mg iron/day. This is equivalent to 42 mg ferrous phosphate/day and to 5.6 mg phosphorus/day. Therefore, a 60 kg adult would be potentially exposed to 0.23 mg iron(II)/kg bw/day and 0.09 mg phosphorus/kg bw/day.

3. Biological and toxicological data

Bioavailability of the nutrient from its source following oral consumption

According to the petitioners no specific data are available on the bioavailability of iron from ferrous phosphate as a mineral substance in food supplements. According to the NDA Panel (EFSA, 2004) iron salts are made soluble in the acidic environment of the stomach and for absorption iron must be in the ferrous form. The absorption of iron is increased by the presence of ligands such as ascorbate, citrate and fumarate, as well as amino acids. In contrast, very stable complexes, e.g. with phytates, phosphates and oxalates, impair non-haem iron absorption. Depending on the concentration of supportive or inhibitory ligands in the intestinal lumen the absorption of non-haem iron can vary by a factor of 10 in single-meal studies, but the effects are less pronounced in more long-term studies (Hallberg and Rossander, 1984; Hunt and Roughead, 2000; Rossander, 1987, cited in EFSA, 2004).

3.1. Subsequent metabolic fate of the source and biological distribution.

Phosphates are normal constituents of the body. Phosphorus is a constituent of all major classes of biochemical compounds. Structurally, phosphorus occurs as phospholipids, which are a major constituent of most biological membranes, and as nucleotides and nucleic acids. Phosphorus plays an important role in carbohydrate, fat and protein metabolism and is essential for optimum bone health. The energy that is required for most metabolic processes is derived from the phosphate bonds of adenosine triphosphate and other high-energy phosphate compounds.

3.2. Any known interactions of the source with other components of the diet

According to the petitioners there are no known interactions of ferrous phosphate with other components of the diet.

3.3. Impact of the source on the intestinal milieu and on the absorption of other nutrients

The impact of phosphate on the intestinal milieu and on the absorption of other nutrients has been extensively reviewed (EVM, 2002). Phosphates may decrease the absorption of several mineral ions from the intestinal tract due to the formation of insoluble complexes. However, the relatively small amount ingested via the use of ferrous phosphate as a supplemental source of iron is considered insignificant compared to the natural content of phosphate in food.

3.4. Toxicological data

Given the previous evaluations of ferrous iron, phosphoric acid and phosphates as food additives and as nutrient sources by the SCF, EFSA and JECFA, as described in the sections above, the Panel accepts the statement of the petitioners that an additional thorough toxicological evaluation of ferrous phosphate is not required.

4. Discussion

In European countries, the average adult intake of iron and phosphorus is between 10 to 17 mg/day and 1000-1600 mg/day, respectively. High percentile intake values, intakes from food supplements included, are in the range from 27 to 72 mg/day for iron and 1700 to 2600 mg/day for phosphorus.

The petitioners indicated that the quantity of iron used in multivitamin-mineral tablets would normally supply 14 mg iron/day. This is equivalent to 42 mg ferrous phosphate/day and 5.2 mg phosphorus/day. Therefore, a 60 kg adult would be potentially exposed to 0.23 mg iron(II)/kg bw/day and 0.09 mg phosphorus/kg bw/day.

For guidance purposes only, the EVM (2003) indicated that a supplemental intake of approximately 17 mg iron/day (equivalent to 0.28 mg iron/kg bw/day for a 60 kg adult) would not be expected to produce adverse effects in the majority of people. The quantity of 14 mg iron/day as proposed by the petitioners for use in multivitamin-mineral tablets is below this guidance value.

The contribution of dietary supplements to population average phosphorus intakes is estimated to be negligible for all age groups.

Given the previous evaluations of ferrous iron, phosphoric acid and phosphates as food additives and as nutrient sources by the SCF, EFSA and JECFA, the Panel considers that no additional toxicological evaluation of ferrous phosphate as a source of iron in food supplements is required.

CONCLUSIONS

The present opinion deals only with the safety of ferrous phosphate and the bioavailability of the iron from this source. The safety of iron and phosphorus in terms of the amounts that may be consumed is outside the remit of this Panel.

Although no specific data are available on the bioavailability of iron from ferrous phosphate as a mineral substance in food supplements, the Panel noted that iron salts are soluble in the acidic environment of the stomach and that for absorption iron must be in the ferrous form as is the case for the source considered in this opinion.

The Panel is of the opinion that, given the previous evaluations of ferrous iron, phosphoric acid and phosphates as food additives and as nutrient sources by the SCF, EFSA and JECFA, no additional toxicological evaluation of ferrous phosphate is required.

Therefore the Panel concluded that the use of ferrous phosphate in food supplements as a source of iron is not of safety concern at the proposed use levels.

DOCUMENTATION PROVIDED TO EFSA

1. Technical dossier on Ferrous phosphate. June 2005a. Submitted by Cederroth International AB, Sweden.
2. Technical dossier on Ferrous phosphate. July 2005b. Submitted by The Danish Food and Veterinary Administration, Denmark.

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GLOSSARY / ABBREVIATIONS

ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
AFC	Scientific Panel on food additives, flavourings, processing aids and materials in contact with food.
bw	body weight
CAS	Chemical Abstract Service
EC	European Commission
EFSA	European Food Safety Authority
EVM	UK Expert Group on Vitamins and Minerals
FAO/WHO	Food and Agriculture Organization/World Health Organization
IOM	Institute of Medicine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NDA	Scientific Panel on Dietetic Products, Nutrition and Allergies
NOAEL	No-Observed-Adverse-Effect Level
SCF	Scientific Committee on Food
UL	Upper Limit