

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of iron compounds (E1) as feed additives for all species: Ferrous sulphate monohydrate based on a dossier submitted by Kronos International, Inc.¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

The full opinion will be published in accordance with Article 8(6) of Regulation (EC) No 1831/2003 once the decision on confidentiality, in line with Article 18(2) of the Regulation, will be received from the European Commission.

ABSTRACT

Ferrous sulphate monohydrate is safe when supplied up to a maximum iron content per kilogram complete feedingstuff of 450 mg for bovines and poultry, 500 mg for ovines, 600 mg for pets, and 750 mg for other species/categories, except horses and fish; for piglets up to one week before weaning a maximum of 250 mg Fe/day is considered safe. Because of insufficient data on horses and fish, as a provisional measure, the current value (750 mg Fe/kg) could be maintained. The values for total dietary iron for pigs, ovines, horses, fish and other species/categories (except poultry, bovines and pets) are in line with those currently authorised. Iron from ferrous sulphate monohydrate is unlikely to modify the iron concentration in edible tissues and products of animal origin. Consumer exposure in the EU is not associated with a risk of excess iron intake to the general population. Therefore, the FEEDAP Panel does not foresee any concern for consumer safety resulting from the use of ferrous sulphate monohydrate in animal nutrition, provided that the maximum iron content in complete feedingstuffs is respected. Ferrous sulphate monohydrate is irritant and corrosive to the skin, eyes and respiratory tract. The additive contains up to 109 mg Ni/kg. Nickel is a dermal and respiratory sensitiser, and inhalation may cause lung cancer. Thus, handling the additive poses a risk to the user/worker. Considering the high concentration of iron and sulphur in soil and water, the supplementation of feed with the additive is not expected to pose an environmental risk. Ferrous sulphate monohydrate is an effective iron source for all animal species and categories. The FEEDAP Panel recommends that the currently authorised maximum iron content in complete feed be reduced for bovines and poultry from 750 to 450 mg Fe/kg, and for pets from 1250 to 600 mg Fe/kg.

© European Food Safety Authority, 2014

KEY WORDS

nutritional additive, compounds of trace elements, iron, ferrous sulphate monohydrate, safety, environment, efficacy

¹ On request from the European Commission, Question No EFSA-Q-2012-00493, adopted on 5 March 2014.

² Panel members: Gabriele Aquilina, Vasileios Bampidis, Maria De Lourdes Bastos, Lucio Guido Costa, Gerhard Flachowsky, Mikolaj Antoni Gralak, Christer Hogstrand, Lubomir Leng, Secundino López-Puente, Giovanna Martelli, Baltasar Mayo, Fernando Ramos, Derek Renshaw, Guido Rychen, Maria Saarela, Kristen Sejrnsen, Patrick Van Beelen, Robert John Wallace and Johannes Westendorf. Correspondence: FEEDAP@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Trace Elements, including Noël Albert Dierick, Jürgen Gropp and Alberto Mantovani, for the preparatory work on this scientific opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014. Scientific Opinion on the safety and efficacy of iron compounds (E1) as feed additives for all species: Ferrous sulphate monohydrate based on a dossier submitted by Kronos International, Inc. EFSA Journal 2014;12(3):3607, 2 pp. doi:10.2903/j.efsa.2014.3607

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of ferrous sulphate monohydrate for all animal species.

Iron is an essential trace element. As a constituent of haemoglobin, it is involved in oxygen transport. Iron is an electron carrier and plays a functional role in proteins involved in oxidative phosphorylation.

Ferrous sulphate monohydrate is safe when supplied up to a maximum iron content per kilogram complete feedingstuff of 450 mg for bovines and poultry, 500 mg for ovines, 600 mg for pets, and 750 mg for other species/categories, except horses and fish; for piglets up to one week before weaning a daily maximum dose of 250 mg Fe is considered safe. Because of insufficient data, the FEEDAP Panel is not in a position to derive a maximum safe iron concentration in feed for horses or fish; as a provisional measure, the current value for other animal species (750 mg/kg) could be maintained. The values for total dietary iron for pigs, ovines, horses, fish and other species/categories (except poultry, bovines and pets) are in line with those currently authorised.

There is no evidence that the use of ferrous sulphate monohydrate would change the iron concentration in edible tissues and products of animal origin. Consumer exposure in the EU is not associated with a risk of excess iron intake to the general population. Therefore, the FEEDAP Panel does not see any concern for consumer safety resulting from the use of ferrous sulphate monohydrate in animal nutrition, provided that the maximum iron content in complete feedingstuffs is respected.

Ferrous sulphate monohydrate is irritant and corrosive to the skin, eyes and respiratory tract. The additive contains up to 109 mg Ni/kg. Nickel is a dermal and respiratory sensitiser, and inhalation may cause lung cancer. Thus, handling the additive poses a risk to the user/worker.

Considering the high background concentration of iron and sulphur in soil and water, the supplementation of feed with ferrous sulphate monohydrate is not expected to pose an environmental risk.

Ferrous sulphate monohydrate is an effective source of iron for all animal species and categories.

The FEEDAP Panel recommends that the currently authorised maximum iron content in complete feed be reduced for bovines and poultry from 750 to 450 mg Fe/kg, and for pets from 1250 to 600 mg Fe/kg.