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Calcium l-methylfolate as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food

📌 calcium l-methylfolate, nutrient source, folate, folic acid, safety, bioavailability, infants, young children, extension of use

First published in the EFSA Journal:

📅 17 January 2020

Adopted: 📅 27 November 2019

Type: 📄 Scientific Opinion

Subject area



Foods for infants and other groups



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▼ Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver a scientific opinion on the extension of use of calcium l-methylfolate to be used as a source of folate added for nutritional purposes to infant and follow-on formula, baby food and processed cereal-based food pursuant to Regulation (EU) 609/2013. In 2004, EFSA assessed the use of calcium l-methylfolate as a source of folate in foods for particular nutritional uses, food supplements and foods intended for the general population. The new alternative synthetic step proposed to produce the nutrient source, using platinum as a catalyst, did not raise any safety concern and the production process was found to consistently yield a product in line with the proposed specifications. Based on the studies assessed in the previous evaluation, it was concluded that calcium l-methylfolate is non-genotoxic and that subchronic and

embryotoxicity/teratogenicity studies in rats did not reveal any adverse effects up to the highest doses tested. The Panel considered that no additional toxicological studies are required on the nutrient source. The intervention study in healthy infants provided by the applicant did not indicate differences in growth and tolerance parameters in infants who consumed either an infant formula supplemented with calcium L-methylfolate or with folic acid, and did not raise concerns regarding safety or tolerability of the infant formula with the proposed nutrient source. The study also provided further supporting evidence for the bioavailability of calcium L-methylfolate. The Panel considers that calcium L-methylfolate is a source from which folate is bioavailable and concludes that calcium L-methylfolate is safe under the proposed uses and use levels for infants and young children.

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› Panel members at the time of adoption

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Panel on Nutrition, Novel Foods and Food Allergens

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DOI: 10.2903/j.efsa.2020.5947

EFSA Journal 2020;18(1):5947

Question Number: [EFSA-Q-2018-00816](#)

On request from: European Commission