

Summary of the application: Monosodium salt of L-5-methyltetrahydrofolic acid

Applicant: Merck & Cie, Im Laternenacker 5, 8200 Schaffhausen, Switzerland

The novel food application concerns the authorisation of monosodium salt of L-5-methyltetrahydrofolic acid (Arcofolin®) (CASRN 2246974-96-7) as a source of folate in the diet. Arcofolin® is intended to be used as an alternative to folic acid for addition to foodstuffs (under Regulation (EC) No 1925/2006), to food supplements (under Directive 2002/46/EC), and to foods for infants and young children, dietary foods for special medical purposes and total diet replacements for weight control (under Regulation (EU) 609/2013). The intended conditions of use of Arcofolin® correspond qualitatively and quantitatively to those of folic acid. Since Arcofolin® is intended to be used as a partial or complete substitute of folic acid and other sources of added folate, the authorisation of Arcofolin® as an alternative form of folate will, therefore, not increase the total intake of supplemental folates.

Arcofolin® and Metafolin® (calcium-L-methylfolate – which is authorised for used in foods and food supplements in the EU) are related compounds. Both are salts of L-5-MTHF (Arcofolin®: L-5-MTHF-Na; and Metafolin®: L-5-MTHF-Ca), produced in similar fashion, and have similar specifications. These salts completely dissociate in vivo and have comparable bioavailability. The comparable bioavailability of Arcofolin® and Metafolin® has been further corroborated by findings from studies undertaken by the applicant. As such, the safety data on Metafolin® that has previously been evaluated as part of the original application for its authorisation in food and food supplements in the EU can be utilised to support the evaluation of the safety of the proposed uses of Arcofolin® as an alternative source of folate in food.

Long term stability studies show that Arcofolin® is very stable under recommended storage conditions and is as stable as the related product Metafolin®. Results of the genotoxicity studies that have been completed on Arcofolin® show that it is non-mutagenic and did not significantly induce chromosomal aberrations under the experimental conditions. A modified 90-day toxicity test undertaken previously by the applicant on the related compound Metafolin® identified no treatment related effects at the highest dose tested. In addition, numerous clinical studies have been conducted with folic acid and folate derivatives as test articles and are available in the published literature.

Overall, it can be concluded that the proposed use of Arcofolin® as an alternative to folic acid in select food categories for which the addition of folic acid is approved does not raise any concern for human health.