

SUBSTANTIAL EQUIVALENCE OPINION

Magnesium Citrate Malate

Introduction

The Food Safety Authority of Ireland (FSAI) received an application in January of 2015 from Dr. Paul Lohmann GmbH KG in Germany for an opinion on the substantial equivalence of magnesium citrate malate to magnesium citrate and magnesium malate under *Article 3.4* of the novel food Regulation (EC) No 258/97. Both magnesium citrate and magnesium malate are authorised sources of magnesium for use in food supplements in the EU (Regulation (EC) No 1170/2009 – amending Directive 2002/46/EC). However, magnesium citrate malate is not authorised as a source of magnesium for food supplements in the EU. In 2008, the AFC panel of EFSA concluded that due to insufficient information the safety of magnesium citrate malate as a source of magnesium for use in food supplements had not been established.

Magnesium citrate malate is produced in a one step process in which defined proportions of food grade citric acid and malic acid (authorised additives) are dissolved in purified demineralised water, to which is added food grade alkaline magnesium salts (MgO , $\text{Mg}(\text{OH})_2$ or MgCO_3) which are also authorised food additives. The solution is filtered and spray-dried to yield an amorphous powdered form of magnesium citrate malate.

The applicant considers magnesium citrate malate as an example of a “mixed salt”. Mixed salts are not necessarily a simple mixture of individual salts, but can be considered as compounds in their own right with characteristic physico-chemical properties and in some cases their own CAS number and E-number. Stoichiometrically, magnesium citrate malate could be viewed as being composed of one mole of tri-magnesium di-citrate and two moles of magnesium malate. The final mixed salt does not have the bitter taste characteristic of tri-magnesium di-citrate and is highly water soluble relative to both the individual salts. For these reasons, the applicant considers magnesium citrate malate to be novel according to the novel food Regulation (EC) No 258/97. Therefore, in addition to the process for its inclusion in the list of permitted magnesium sources for use in food supplement in the EU as set

out in Directive 2002/46/EC, the novel food status of magnesium citrate malate must be addressed.

Composition

The novel ingredient is anhydrous magnesium citrate malate which is a mixed salt containing magnesium cations as well as citrate and malate anions in a 5:2:2 molar ratio. In terms of the overall chemical composition of magnesium, malate and citrate, the novel ingredient is not different to a simple mixture of magnesium citrate and magnesium malate. In the solid form, it is colourless to yellowish/white with a magnesium content of 12 – 15%. The raw materials used in the production of the novel ingredient are food grade and comply with the purity criteria that apply to their existing use as food additives. The novel ingredient is sufficiently defined in the specifications, including its own CAS number. Production controls include pH checks as well as monitoring the proportion of citric acid to malic acid prior to spray drying. The stability of the novel ingredient in solid form was established at three months under various temperature and relative humidity conditions, while it remained completely dissolved in a 20% aqueous solution for six days.

Nutritional Value and Metabolism

Similar to existing food supplement sources of magnesium (magnesium citrate and magnesium malate, among others), the nutritional value of the novel ingredient lies in the magnesium content, while malate and citrate absorption and metabolism proceed along established pathways. The applicant claims that the bioavailability of metal cations like magnesium is linked to the solubility of the metal salt in water or gastric juice. For this reason, they consider the bioavailability of magnesium from magnesium citrate malate to be equivalent if not higher than that of magnesium from magnesium citrate or magnesium malate.

Intended Uses

The novel ingredient is intended only for use in food supplements on the EU market.

Level of Undesirable Substances

The raw materials used in the production of magnesium citrate malate include purified demineralised water as well as food grade citrate, malate and magnesium salts, all of

which are currently authorised as food additives in the EU. Breakdown products of citrate or malate were not detected. The applicant provides batch test results on heavy metal and microbial contaminant analyses, while each 900 kg batch of the final novel ingredient is tested against the specifications.

Conclusions

Having reviewed the information provided by the applicant, the FSAI is satisfied that magnesium citrate malate is substantially equivalent to the authorised magnesium sources for food supplement (magnesium citrate & magnesium malate) in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. This opinion is provided in line with *Article 3.4* of the novel food Regulation (EC) No 258/97 and is without prejudice to the requirements set out in Directive 2002/46/EC as amended, with regard to vitamins minerals and their sources that may be used in food supplements within the EU.