Summary of the application: Magnesium L-Threonate

Applicant: AIDP, 19535 East Walnut Drive South, City of Industry, CA 91748, USA

This novel food application concerns magnesium L-threonate monohydrate (Magtein®) which is composed of not less than 85% of L-threonic acid and of 7.2% to 8.3% of magnesium. Approval is sought under the novel food Regulation (EC) No 2283/2015 and following addition of magnesium L-threonate to the annex II of the Directive 2002/46/CE as source of magnesium is intended. The ingredient falls under the following category: “Chemical substances”.

The applicant request the authorization to use of the novel food in food supplements at dose up to 3 g/day (depending on the body weight). Children under 18 years, pregnant and lactating women, and people already consuming L-threonate via other food supplements are excluded from the target population.

The current novel food is intended to replace other sources of magnesium in food supplements, and not in association with other sources of magnesium or L-threonate. Magtein® does not mislead the consumers, and is not nutritionally disadvantageous.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.

All the specifications of the novel food are in accordance with European standard and regulations. Analyses have demonstrated the lack of various contaminants, including notably heavy metals, microbiological contaminants.

The safety of the novel food has been highlighted in accordance with the tiered approach proposed by EFSA, including three toxicity studies (GLP and OECD compliant studies): an in vitro bacterial reverse mutation test (OECD 471), an in vivo micronucleus test (OECD 474) and an in vivo 90-day repeated oral toxicity study (OECD 408); a NOAEL was set at the highest dose of 2000 mg/kg body weight/day for rats. In addition, a human clinical study showed the safety of a Magtein® supplementation at dose of proposed used i.e. 1500 mg and up to 2000 mg/day for 12 weeks in 50 adults aged 50 to 70 years. Regarding allergenicity, no safety concern can be highlighted due to the lack of protein in the product and an allergen statement indicates that no allergens are present in the product.

Therefore, Magtein® is well characterized and compliant with European regulations. The product is safe and devoid of significant allergic potential. The novel food does not present consequently any potential hazard to the European population in the conditions proposed by the applicant.