Meeting

Magnesium L-Threonate (Magtein®) Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/162/06

Advisory Committee For Novel Foods and Processes.

Application for Authorisation as a Novel Food for Magnesium L-Threonate (Magtein®).

Additional Information from Applicant for review.

Application number RP956.

Issue

The Committee reviewed this application for the first time at the September 2022 Further reviews were conducted at the November 2022 and April 2023 meetings. Members requested further information on which to base their assessment of the novel food. The Committee are invited to consider the response from the applicant and whether it addresses the requests for information satisfactorily or if further information is required.

Background

1. On the 7th April 2021, the FSA received the submission for magnesium L-threonate monohydrate (Magtein®) from AIDP. The novel food is made by the chemical reaction of ascorbic acid and calcium carbonate to form calcium L-threonate which is then converted by a further reaction to magnesium L-threonate monohydrate. The applicant proposes to use the novel food as magnesium source in food supplements only.

2. The Committee conducted a review of the application at the September and November 2022 meetings. At the April 2023 meeting. Members assessed the applicant’s response to further information.

3. The Committee suggested additional information was needed from the applicant on which to base their assessment. Information was requested on:

- Identity
- Production Process
- Composition

4. The FSA’s request for further information and the applicant’s response are included as Annexes A and B, respectively.

Applicant’s response to request for further information

Identification

5. The Committee sought further information to clarify which form of magnesium L-threonate, the anhydrous form or monohydrate form, or a mixture of these two forms, is the novel food seeking authorisation. Analytical data for three or more independent batches of the novel food which quantified the magnesium, L-threonate and the water/moisture content was requested. This data was sought to confirm that the mass balance for the magnesium L-threonate meets the proposed specification.

6. The applicant states that the novel food is magnesium L-threonate monohydrate only and the molecular formula (C8H16MgO11) has been confirmed by elemental analysis (Annex B – Annex 77).

7. The applicant has provided certificates of analysis for three independent batches of the novel food (Annex B – Annex 78). he loss on drying does not include water molecule in the monohydrate (Annex B – p1 response to RFI letter). These results are summarised below.

Sample	Magnesium (%)	L-Threonate (%)	Water (%)	Assay (%)
SM-202211316	7.8	86.2	0.2	100

SM-202211318	7.8	85.3	0.2	99
SM-202211319	7.7	85.4	0.2	99

8. The applicant states that the assay for magnesium L-threonate monohydrate is determined by using the following equation:

$$= [\ (\%\ \text{magnesium} + \%\ \text{threonate})\ \times \frac{\text{molecular weight of } Mg(C_4H_7O_5)_2.H_2O}{\text{molecular weight of } Mg(C_4H_7O_5)_2}\ ] + \%\ \text{water}$$

= [(% magnesium + % threonate) x (312.51 / 294.50)] + % water

Production Process

9. The Committee commented that there was a need for more detailed description of the food safety management plan (HACCP plan) for the novel food production process. Members were seeking to understand how the potential allergenic, biological, chemical and/or physical hazards were monitored and controlled.

10. The applicant has provided an updated version of the hazard risk assessment document concerning the novel food production process (Annex B – Annex 79).

Composition

11. The Committee pointed out that the certificates of analysis for the magnesium carbonate were translated and highlighted the need for reassurance that the translations provided were accurate. This request was in response to comments from the applicant that inaccurate translations had been provided previously.

12. The applicant has provided copies of the ISO 9001:2015 certification (Annex B – Annex 80) and the ISO 17100 certification (Annex B – Annex 81) for the Beijing Yibao International Translation Company Limited.

13. The applicant has also provided a copy of a certificate from the Ministry of Human Resources and Social Security of the People’s Republic of China for the translator and interpreter (Annex B – Annex 82). A copy of the translation for the certificate of analysis for heavy magnesium carbonate can be found in Annex B – Annex 83.

14. Evidence was requested to demonstrate that the method of analysis used to assay the magnesium L-threonate has been validated. Further documentation demonstrating the laboratory is proficient in utilising this methodology was considered necessary.

15. The applicant states that the assay for the novel food, magnesium L-threonate monohydrate, is determined by calculation (Annex B – p4 response to RFI letter and point 8 in this document).

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to address the data gaps discussed at the last meeting.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.

ACNFP Secretariat

August 2023

Annexes

Annex A – RFI Letter

Annex B – Applicant’s Response to RFI Letter