

Summary of the application: 95:5 D:L, Beta Hydroxybutyrate salts mix (59% BHB-Na, 27% BHB-Mg, 14% BHB-Ca)

Applicant: Pruvit Ventures Inc. , Melissa, Texas, USA

This novel food application consists in Beta Hydroxybutyrate (BHB) salts in a 95:5 ratio of D- to L-BHB, consisting of 59% BHB-Na (sodium), 27% BHB-Mg (magnesium), and 14% BHB-Ca (calcium). The applicant requests the possibility to use the novel food in food supplements (category 17) at the dose of 6 g per day.

The novel food 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.

An analysis of the novel food confirms its identity and demonstrates its compliance with EU regulations. Furthermore, the safety of consuming this novel food is substantiated by a significant volume of BHB salts mix sold in the United States, along with toxicity studies. A 90-day oral toxicity study conducted in accordance with OECD 408 guidelines resulted in a NOAEL (No Observed Adverse Effect Level) of 7750 mg/kg, the highest tested dose. Additionally, two human studies conducted on adults and adolescents showed no adverse effects when consuming BHB salts at doses of up to 25 grams per day.

In light of this information, this application seeks authorization for the use of the novel food in food supplements under category 17.