PUBLIC SUMMARY

Summary of the application: DAG/MAG-BHB.
Applicant: Unichem Estense S.r.l., Via Borsari, 46, 44121, Ferrara, Italy

The novel food application concerns request for authorization to place on the market a modified β-hydroxybutyrate (BHB) with the name of DAG/MAG-BHB that consists of a mixture of the mono- and diesters 2,3-dihydroxypropyl (R)-3-hydroxybutyrate (MAG-BHB) and 2-hydroxy-1,3-propanediyl (R)-3-hydroxybutyrate (DAG-BHB) and trace amount of the reactants methyl (R)-3-hydroxybutyrate and glycerol. The product is produced through a patented controlled supply chain consisting in a fully enzymatic synthesis. The product is intended to be used only as or in food supplement at the maximal daily dose of 30 mg/d and is intended to be consumed only by healthy adults, excluding pregnant women and lactating women, as well as children under 18. The information provided on the identity, composition, specifications and lack of batch-to-batch variability of DAG/MAG-BHB demonstrates control of the production process and that the product is compliant with EU regulations and neither nutritionally disadvantageous substance nor toxic contaminant is present. Moreover, preclinical, and clinical studies performed showed that the product wasn't associated with toxic effects in cellular models or animals at the proposed use levels. AMES assay and an *in vitro* micronucleus assay, performed according to OECD guidelines and GLP standard, showed that DAG/MAG-BHB is not associated with mutagenic nor genotoxic potential. A 90-day toxicological study in mice administrated orally DAG/MAG-BHB establishes a NOAEL of 2000 mg/kg of body weight/d. Clinical studies from literature substantiated the absence of adverse effects of ketones mono- and diesters after oral supplementation at the dose of the product. The applicant has applied for data protection in accordance with Article 26 of the novel food regulation.