

Summary of the application: Dihydroberberine

Applicant: Nanjing Nutrabuilding Bio-tech Co., Ltd (NNB Nutrition), Room 1805, Building E6, No. 270 Jiqingmen Street, Nanjing, China

The novel food application concerns request for authorization to place on the market Dihydroberberine (DHB), a hydrogenated derivative of berberine (BBR). The product results of a chemical synthesis involving berberine and other reactants. The product is intended to be used only as or in food supplement at the maximal daily dose of 100 mg/d. The product is intended to be used only by adults, excluding pregnant and lactating women and individuals under medication.

The information provided on the identity, composition, specifications, and lack of batch-to-batch variability of DHB 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. An AMES assay, an in vitro gene mutation in mammalian cells assay and an in vitro micronucleus assay showed that DHB is not associated with mutagenic nor genotoxic potential. A 90-day toxicological studies in rats administrated orally DHB establishes a NOAEL of 100 mg/kg of body weight/d. Clinical studies from literature substantiated the absence of adverse effects of DHB at dose up to 200 mg/d after oral supplementation.

The applicant has applied for data protection in accordance with Article 26 of the novel food regulation.