

Summary of the application: Oil extract distillate from *Cannabis sativa* L.

Applicant: ARCO (Groupe ROBERTET), 37 avenue Sidi Brahim, 06130 Grasse, France.

The Novel Food (NF) application concerns a request for authorization to place on the market an oil extract distillate from *Cannabis sativa* L. (Broad Spectrum Hemp Extract (BSHE)).

This product corresponds to a liquid extract, obtained from aerial parts of the *Cannabis sativa* L., and titrated between 70 and 80% cannabidiol (CBD).

The product results of an extraction process providing a liquid extract. The product remains from the start to the end of the process on liquid form. The product is intended to be used as or in food supplement only, at the maximal daily dose providing 50 mg/d of CBD. Depending on the CBD content, the maximal daily dose for the product will be comprised between 62.5 and 71.4 mg/d. The product is intended to be used only by adults. Children under 18, pregnant and lactating women are excluded from the targeted population. Individuals under any medication should consult a physician before consuming the product.

The information provided on the identity, composition, specifications, and lack of batch-to-batch variability of BSHE 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 studies, performed with BSHE showed that the product is not associated with toxic effects in cellular models or animals at the proposed use levels. An Ames test substantiates the absence of mutagenic potential of the product, whereas a two repeated dose oral toxicity study defends the absence of systemic effects at the proposed dose. Based a 90-days repeated dose oral toxicity study performed according to OECD guideline 408, a no-observed adverse effect level (NOAEL) of 125 mg/kg bw/d of BSHE was considered. This, associated with the numerous clinical trials retrieved in per-reviewed published literature, substantiate the safety of the product under the proposed conditions of use.

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