

Summary of the dossier: VOHO-AF IP HEMP OIL (HempFusion®)

Applicants:

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This novel food application consists in an organic hemp oil (VOHO-AF IP HEMP OIL), containing approximately 10-15% CBD and devoid of THC. The 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.

The ingredient falls under the following category: “Food consisting of, isolated from or produced from plants and their parts”. The applicant request the authorization to use of the novel food in food supplements with a maximum daily intake of 70 mg CBD. Children under 18 years, as pregnant and lactating women, and people under medications, are excluded from the target population.

The application presents the manufacturing process, including control points. Analyses have been performed on the organic hemp oil (VOHO-AF IP HEMP OIL).

The safety of the novel food have already been evaluated in several toxicological studies. These studies include a bacterial reverse mutation test, one *in vivo* micronucleus assay in mammalian cells, one maximum tolerated dose study in rats, one repeated dose 14-day oral toxicity study in rats, one repeated dose 90-day oral toxicity study with recovery period in rats, and one human study.