Summary of the application: Synthetic Cannabidiol (CBD)

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CBD and is manufactured by chemical synthesis from olivetol and menthadienol. It is proposed to be used in food supplements for healthy adults (excluding pregnant and breast-feeding women) at a dose of 30 mg/day.

The Cannabidiol (CBD) subject to this application is manufactured by chemical synthesis from two starting materials coupled with Lewis acid catalysed alkylation in a GMP-compliant facility. The final product is obtained through crystallisation. The data on the product composition, purity and stability do not raise safety concerns related to the product composition and manufacturing process. The potential toxicity of the synthetic CBD has been assessed through an extensive literature review and a package of genotoxicity studies. It was negative for mutagenicity and clastogenicity.

The literature provides no evidence of CBD converting to THC. A 104-week oral carcinogenicity rat study showed no evidence of CBD-related increase in tumour incidences. A NOAEL of 150 mg CBD/kg/day was derived from a 90-d oral subchronic rat study. The corresponding margin of safety is 1.5 mg CBD/kg/day (equivalent to 105 mg/day for a 70 kg adult) under which falls the proposed maximum recommended daily intake proposed by the applicant (30 mg/day and corresponding to 0.43 mg CBD/kg/day for a 70 kg adult). This is supported by the approvals of the medicines Epidiolex® (CBD) in the USA, Epidyolex in the EU and Sativex® (CBD:THC) in the EU. Overall, the information reviewed and provided in this application supports the safety of CBD as novel food under the proposed conditions of use and dose level.