

Summary of the application (-)-Cannabidiol derived from chemical synthesis

Applicant: Cibdol AG, Oristalstrasse 68, 4410 Liestal, Switzerland

The application concerns a request for authorisation of (-)-Cannabidiol derived from chemical synthesis as a novel food.

Overall safety, toxicity and adverse effects

(-)-Cannabidiol is a single chemical entity, obtained through chemical synthesis, which is identical to the natural levo-rotary stereoisomer of cannabidiol from *Cannabis sativa* L. Already since the 1970s it was shown that oral cannabidiol, intravenous injections, and inhalation of cannabidiol did not lead to any adverse effects and showed an excellent safety profile.

In the overview of 2011, and the meta-analysis performed in 2019 covering over 1150 subjects in a total of 35 clinical studies, doses have been applied with an average of 600 – 1200 mg, up to 3000 mg per day. This equals 5 – 25 % of the proposed maximum daily dose (150 mg) for cannabidiol as a food supplement. Regarding safety, (-)-cannabidiol in the doses taken in the clinical studies is well tolerated. Only at doses from 1200 mg/day and above, a few isolated cases of diarrhea, vomiting, fatigue, decreased appetite, weight loss, dizziness, fever and elevated liver enzymes were reported. There is no evidence that any of the observed side effects needed further medical treatment.

The safe consumption of daily doses up to 150 mg without medical supervision by children above 6 years of age and the general adult population, with the exception of pregnant and breastfeeding woman is therefore supported by scientific literature evidence

Content Δ 9-tetrahydrocannabinol

(-)-Cannabidiol may contain a minute amount of Δ 9-tetrahydrocannabinol, whose psychoactive properties and effects may pose a health risk. From the batch to batch analysis performed for this application it can be concluded that at the proposed maximum daily intake of 150 mg cannabidiol this contains an absolute maximum of 0.075% Δ 9-tetrahydrocannabinol, which is below the maximum allowed daily intake of 0.083% conform EFSA. It is therefore unlikely that Δ 9-tetrahydrocannabinol levels present in the Novel Food pose a health concern.

Pregnancy and lactation

There are no adequate data on the developmental risks associated with the use of cannabidiol in pregnant women. From a literature review it became evident that cannabidiol has influence on reproduction in male and female animals, and has influences on plasma concentration of hormones involved. It is uncertain whether these effects will be predominant in man. It is however therefore recommended not to give cannabidiol during pregnancy and lactation.