

Executive Summary of Toxicology Studies

July 31, 2023

Background

Open Book Extracts (OBX), a cGMP and ISO9001:2105 certified manufacturer and distributor of the industry's most innovative and highest quality cannabinoid ingredients and finished products, announces the completion of phase two of the toxicology and safety results for their cannabinoid ingredients cannabigerol (CBG), cannabiniol (CBN), and cannabichromene (CBC). The investment in these toxicological assessments demonstrates OBX's commitment to furthering the science behind cannabinoid ingredients.

Previous Toxicology Studies

As previously announced, the phase one battery of tests included OECD 407 Repeated Dose 28-Day Oral Toxicity Study in Rodents, OECD 471 Bacterial Reverse Mutation Test, OECD 473 In Vitro Mammalian Chromosomal Aberration Test, and OECD 474 Mammalian Erythrocyte Micronucleus Test. The results were promising; no mortality events occurred and there were no abnormal findings in the clinical observations, body weight and weight gain, hematology, gross pathology, and histopathology. The Bacterial Reverse Mutation, or AMES, test results show CBC, CBG, and CBN Isolates do not demonstrate any mutagenic activity on the applied bacterium strains utilized in this assay. The in-vitro mammalian chromosomal aberration test resulted in CBC, CBG, and CBN Isolates to be non-clastogenic. The mammalian erythrocyte micronucleus test resulted in CBC, CBG, and CBN showing no signs of genotoxic activity.

Phase Two Summary

The OECD 408 Repeated Dose 90-day Oral Toxicity Study in Rodents with test substances CBC, CBG, and CBN Isolates have been completed. Factors evaluated during phase two included: mortality, food consumption, ophthalmoscopy, urinalysis, hematology, and histopathology. The OECD 408 study in CBC, CBG, and CBN Isolates resulted in No Observed Adverse Effect Levels (NOAEL) being noted at the 250 milligram / kilogram body weight / day. It is conclusive that the test substances do not have any subchronic and chronic toxicity characteristics at the 250 mg/kg bw/day dosing level.

Interpretation

The results of these toxicology and safety studies indicate CBC, CBG, and CBN Isolates should be safe to include in foods and dietary supplements.

Next Steps

These results are indicative of the overall safety profile of these minor cannabinoids. The data generated as a result of the phase one and phase two testing shall provide necessary information to enable regulatory submissions such as Generally Recognized as Safe (GRAS) Independent conclusion, New Dietary Ingredient (NDI) application, or submission to international regulators moderating the cannabinoid markets globally. The investment and commitment of OBX to understand the safety, efficacy, and toxicity of cannabinoids continues with its concurrent phase one evaluations of Cannabidiol (CBD) and a multi-cannabinoid, custom distillate blend.