Title: CANNABIDIOL-ENRICHED CAPRYLIC ACID

Abstract: A chemical composition for human consumption includes a cannabinoid composition mixed in an oil-based delivery system. The cannabinoid composition may include cannabidiol (CBD) and the oil-based delivery system may include caprylic acid (C8). In a preferred embodiment, the chemical composition comprises CBD oil and caprylic acid. Another embodiment, directed to a method of producing a chemical composition for human consumption, includes the steps for mixing a cannabinoid composition into an oil-based delivery system.

FIG. 1
CANNABIDIOL-ENRICHED CAPRYLIC ACID

CROSS REFERENCE TO RELATED APPLICATIONS
This application claims the priority of Provisional Application No. 62/535,633 filed on July 21, 2017, inventor Annabelle Manalo, entitled "CANNABIDIOL-ENRICHED CAPRYLIC ACID".

The entire disclosure of this provisional patent application is hereby incorporated by reference thereto, in its entirety.

TECHNICAL FIELD
The present disclosure relates generally to cannabinoid-enriched caprylic acid for human consumption.

BACKGROUND
The present disclosure relates generally to cannabinoid-enriched caprylic acid for human consumption. More particularly, but not exclusively, the present disclosure pertains to a composition comprising cannabidiol (CBD) in caprylic acid (C8) and a method for mixing cannabidiol in caprylic acid.

Cannabinoids are chemical compounds that bind to chemical receptors in the human body.
Cannabinoids bind to specific cellular receptors called cannabinoid receptors. This system is known as the endocannabinoid system and results in the binding of both endogenous and exogenous compounds to cellular cannabinoid receptors. Cannabinoid compounds can be classified into three groups: endocannabinoids, phytocannabinoids, and synthetic cannabinoids. Phytocannabinoids are chemical compounds concentrated in the oily resin of plants such as cannabis and hemp. Over 100 phytocannabinoids have been identified, many of which show beneficial medical properties.

Cannabinoids can be administered to the human body through multiple routes including inhalation, oral ingestion, transdermal absorption, and sublingual absorption. Currently, common practice includes isolating phytocannabinoid compounds and diluting the isolates in an oily medium that can be consumed by sublingual absorption. The isolated phytocannabinoid compounds can either be either specifically isolated to obtain a single phytocannabinoid compound (single isolate) or be isolated to obtain a plurality of heterogeneous phytocannabinoid compounds (whole-plant extract). Single isolated cannabinoids are advantageous due to the elimination of unwanted compounds such as tetrahydrocannabinol (THC), a psychoactive compound that under current federal law cannot be present at concentrations above 0.03%. Nonpsychoactive cannabinoids, such as cannabidiol, have no psychoactive side effects and avoid toxicity often encountered with the high doses of THC useful in treating certain medical diseases.

The use of oils as a delivery method commonly includes oils such as coconut oil or MCT oil. MCT oil is made up of medium-chain triglycerides, or MCTs, and generally includes
triglycerides having chains of carbon molecules ranging from 6 to 12 carbons long. MCTs used for oil-based delivery systems are mostly extracted from coconuts and coconut oil. MCTs are converted to ketones and used as fuel in the body, however, they can commonly cause undesired side effects like digestive issues. Caprylic acid, an eight-carbon chain acid, is converted to ketones and is less susceptible to causing digestive issues. Caprylic acid is the rarest MCT but is also odorless and flavorless, making it ideal as a delivery system for human consumption.

Due to its low molecular weight, caprylic acid passes through the blood-brain barrier upon polymorphic transformation into beta-hydroxybutyrate (BHB) via interaction with an enzyme to modulate a ketone. Passage through the blood-brain barrier permits targeting to the central nervous system. Other MCTs such as capric acid (C10) must be cleaved at the methyl group before being converted into a ketone homologous to BHB, but this process must take place in the liver due to expression and location of necessary enzymes to carry out the reaction. Studies show a lower requirement for glucose to modulate this conversion, suggesting that the skeletal muscles benefit more from capric acid (C10) and the brain and CNS benefit more from caprylic acid (C8). This is further supported by caprylic acid having a suppressive effect on glycolysis and increasing neuronal metabolism. This activity has shown favorable results for treatment of cancers and seizures which use glucose as a nutrient source.

Ultra-refined caprylic acid provides a reliable energy source for the body through rapid absorption and conversion into ketones. Additionally, caprylic acid can pass through the blood-
brain barrier more quickly than other MCTs, which can suppress excessive glycolysis. Due to its molecular structure, caprylic acid is not stored as body fat and is metabolized more efficiently than sugar. The graph shown in FIG. 1, taken from Vandenberghhe, C. et al., *Acute plasma ketone response to coconut oil alone or in combination with different medium chain triglycerides*, ISSFAL Congress, Banf Canada (2016), demonstrates the differences between caprylic acid and other medium-chain triglycerides on the total plasma ketone levels over an eight-hour period. In this experiment, caprylic acid increased ketones by approximately three times more than capric acid (C10) alone.

Recent studies have demonstrated that ketone bodies provide the brain and central nervous system with energy and prevent the degradation of white matter in the brain to procure other energy sources. Caloric restriction studies have shown that during reduced caloric intake, a shift in energy sources, from glucose to ketones, occurs and supplies the brain with the necessary amount of energy. The reduced availability of glucose causes a switch to the use of ketones, which has shown preservation of white matter integrity as well as enhanced long-term memory due to caloric restriction.

Current commercial formulations of cannabinoid compounds mixed in oil-based delivery systems are limited in effectiveness due to a maximum concentration level based on the oil type used as the solvent, due to limited delivery of the cannabinoid into the body, and due to the side effects of both the cannabinoids and oil-based substrate.
SUMMARY OF INVENTION

Applicant identified a need for a CBD oil product containing a high concentration of CBD in an efficient delivery system. Applicant discovered that cannabinoid formulations within certain oil-based delivery systems, when properly paired, can overcome these limitations with increased concentrations, increased absorption rates, and decreased side effects. One aspect of the invention uses caprylic acid as the delivery system. Applicant found that use of single isolate caprylic acid as a CBD delivery system is highly effective and surprisingly delivers physiological results superior to currently available products. Applicant surprisingly found that use of caprylic acid as a CBD delivery system permits greater concentrations of CBD per volume, decreases delivery time to the body and central nervous system, decreases side effects, and decreases or even eliminates the need for flavoring agents.

From the foregoing, it is seen that it is a problem in the art to provide a compound, formulation, and method meeting the above requirements. According to the present invention, a compound or formulation and method is provided which meets the aforementioned requirements and needs in the prior art. Specifically, the present disclosure relates generally to cannabinoid-enriched caprylic acid for human consumption. More particularly, but not exclusively, the present disclosure pertains to a composition comprising cannabidiol (CBD) in caprylic acid (C8) and a method for mixing cannabidiol in caprylic acid.

The present disclosure relates, in one embodiment, to a chemical composition for human consumption. The chemical composition may include a cannabinoid composition mixed in an
oil-based delivery system. The cannabinoid composition may include cannabidiol (CBD) and
the oil-based delivery system may include caprylic acid. In a preferred embodiment, the
chemical composition comprises CBD oil and caprylic acid.

The present disclosure also relates, in another embodiment, to a method of producing a
chemical composition for human consumption. In a preferred embodiment, the method includes
the steps for mixing a cannabinoid composition into an oil-based delivery system. A further
aspect of the preferred embodiment comprises a method for mixing 3000 milligrams (mg) of
cannabinoid per one (1) ounce volume of the oil-based delivery system. In certain preferred
embodiments, the method comprises the steps for mixing 3000 mg of cannabidiol per one (1)
ounce caprylic acid.

Other objects and advantages of the present invention will be more readily apparent
from the following detailed description when read in conjunction with the accompanying
drawings.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is a graph whose source is identified above, which demonstrates the differences between
caprylic acid and other medium-chain triglycerides on the total plasma ketone levels over an
eight-hour period.
DESCRIPTION OF EMBODIMENTS

As used herein, "cannabinoid" includes any compound that interacts with a cannabinoid receptor and various cannabinoid mimetics, including naturally occurring compounds derived from plant extracts, and non-natural compounds which are semi-synthetically or synthetically produced. The cannabinoid may be included in its natural form, in the form of a pro-drug, or in the form of a pharmaceutically acceptable salt thereof. Additionally, the term "cannabinoid" is meant to include its natural form that has been isolated, purified, or modified, and synthetically derived cannabinoids that have been isolated, purified, or modified.

As used herein, "cannabidiol" refers to cannabidiol, cannabidiol prodrugs, pharmaceutically acceptable derivatives of cannabidiol, including pharmaceutically acceptable salts of cannabidiol, cannabidiol prodrugs, and cannabidiol derivatives.

In one embodiment the cannabinoid is substantially free from impurities. As used herein, "substantially free of impurities" shall mean that impurities, including any cannabinoid not intended to be administered in a therapeutically effective quantity, are present in an amount by weight of the composition of less than about 10%, less than about 5%, less than about 1%, less than about 0.1%, or less than about 0.01%.

In a further embodiment, the cannabidiol is substantially free from other cannabinoids. As used herein, "substantially free from other cannabinoids" shall mean that other cannabinoids, including any cannabinoid not intended to be administered in a therapeutically effective
quanti ty, are present in an amount by weight of the composition of less than about 1%, less than about 0.1%, or less than about 0.01%.

In a further embodiment, the cannabinoids are extracted from a "full-hemp extract" and include a plurality of cannabinoids together in a single extract. A full-hemp extract may comprise a high concentration of CBD, greater than 50% weight/weight. Another embodiment may comprise CBD greater than 75% weight/weight, greater than 80% weight/weight, greater than 90% weight/weight, or greater than 95% weight/weight. A preferred embodiment comprises CBD greater than 99% weight/weight.

As used herein, the term "oil" refers to a substance composed primarily of triglycerides of fatty-acids. Oils may include vegetable oils extracted from various parts of the plant, including the seeds, fruit, or leaves of plants. In some embodiments the oils are derived from canola, rapeseed, palm, palm kernel, coconut, tucum, sunflower, safflower, olive, macadamia, babassu, castor, peanut, cotton, flaxseed, linseed, cohune, and jatropha. In further embodiments, the oils may be derived from a genetically modified plant.

"Medium chain fatty acids" as used herein refers to fatty acids containing 6 to 14 carbons, preferably 8 carbons. In certain preferred embodiments, the oil-based delivery system comprises an 8 carbon medium chain fatty acid, caprylic acid. In certain embodiments, the caprylic acid is substantially free from impurities. As used herein, "substantially free of impurities" shall mean that impurities, including any other medium chain fatty acid not intended to be administered in a therapeutically effective quantity, are present in an amount by
weight of the composition of less than about 10%, less than about 5%, less than about 1%, less than about 0.1%, or less than about 0.01%. In some embodiments, impurities may comprise other medium chain fatty acids.

One embodiment described herein includes a chemical composition comprising a mixture of oil and a cannabinoid composition. In another embodiment, the oil comprises medium-chain triglycerides.

In another embodiment, the chemical composition comprises a mixture of oil, wherein the oil is a triglyceride having an eight-carbon chain backbone known as caprylic acid, and a cannabinoid composition. In yet another embodiment, the caprylic acid is substantially free from impurities such that the caprylic acid has less than about 10%, less than about 5%, less than about 1%, less than about 0.1%, or less than about 0.01% by weight of impurities. In certain embodiments, the impurities may comprise other medium-chain triglycerides.

In certain preferred embodiments, the chemical composition comprises cannabidiol. In another embodiment, the chemical composition comprises a full-hemp extract comprising cannabidiol. In yet another embodiment, the cannabidiol is isolated or purified from a plant source. In still another embodiment, the cannabidiol is substantially free from impurities and thus, the impurities are present in an amount by weight of the composition of less than about 1%, less than about 0.1%, or less than about 0.01%. In certain embodiments, the impurities may comprise other cannabinoids.
In certain preferred embodiments, the chemical composition comprises oil and cannabidiol wherein the cannabidiol is present at a concentration of at least 3000 mg per one (1) ounce volume of oil. In other embodiments, the chemical composition comprises caprylic acid and cannabidiol wherein the cannabidiol is present at a concentration of at least 3000 mg per one (1) ounce volume of caprylic acid.

In another embodiment, the chemical composition comprises oil and cannabidiol wherein the cannabidiol is present at a concentration of at least 2500 mg per one (1) ounce volume to 3000 mg per one (1) ounce volume of oil. In other embodiments, the cannabidiol is present at a concentration between 2500 mg per one (1) ounce volume to 3000 mg per one (1) ounce volume of caprylic acid.

In another embodiment, the chemical composition comprises oil and cannabidiol wherein the cannabidiol is present at a concentration of at least 1000 mg per one (1) ounce volume of caprylic acid. In another embodiment, the chemical composition comprises caprylic acid and cannabidiol wherein the cannabidiol is present at a concentration of at least 1000 mg per one (1) ounce volume of oil. In another embodiment, the chemical composition comprises oil and a cannabinoid compound present at a concentration of at least 1000 mg per one (1) ounce volume of oil.

In another embodiment, the method for making the chemical composition comprises providing
an oil-based substrate, heating the oil-based substrate to a specified temperature, and mixing a cannabinoid compound into the oil-based substrate. In yet another embodiment, the specified temperature is maintained for a specific time interval after initial mixing. In yet another embodiment, mixing of the heated oil-based substrate and cannabinoid compound mixture continues during the specific time interval at which the mixture is maintained at the specified temperature.

In another embodiment, the oil-based substrate comprises medium-chain triglycerides. In yet another embodiment, the oil-based substrate comprises caprylic acid. In another embodiment, the oil-based substrate comprises caprylic acid that is substantially free from impurities wherein the caprylic acid has less than about 10%, less than about 5%, less than about 1%, less than about 0.1%, or less than about 0.01% by weight of impurities. In certain embodiments, the impurities may comprise other medium-chain triglycerides.

In other embodiments, heating the oil-based substrate comprises applying a heat source to the oil-based substrate so that the substrate reaches at least 30 degrees Celsius. In other embodiments, heating the oil-based substrate comprises heating to a temperature of at least 40 degrees Celsius. In another embodiment, heating the oil-based substrate comprises heating to a temperature to at least 50 degrees Celsius.

In additional embodiments, the cannabinoid compound mixed with the oil-based substrate comprises a plurality of cannabinoid constituents. In other preferred embodiments, the
cannabinoid compound comprises a single cannabinoid constituent. In yet another preferred embodiment, the cannabinoid compound comprises cannabidiol. In yet another embodiment, the cannabinoid compound comprises cannabidiol that is substantially free from impurities and thus, the impurities are present in an amount by weight of the composition of less than about 1%, less than about 0.1%, or less than about 0.01%. In certain embodiments, the impurities may comprise other cannabinoids. In another embodiment, the cannabinoid compound is a full-hemp extract.

In other embodiments, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for at least fifteen minutes, at least twenty minutes, or at least twenty-five minutes. In certain embodiments, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for between seventeen and eighteen minutes. In one aspect, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for about 17.68 minutes. In certain embodiments, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for between twenty-one and twenty-two minutes. In one aspect, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for about 21.40 minutes. In certain embodiments, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for between twenty-five and twenty-six minutes. In one aspect, the mixture of the cannabinoid compound in the oil substrate is maintained at the specified temperature for about 25.22 minutes.
In another embodiment, the method comprises heating MCT oil (55% C8, 36% C10, 0.2 % Lauric Acid, 9% other fatty acids, total 14 g) to at least 50 degrees Celsius, mixing 500 mg of 99% CBD Isolate into 1.5 ounces (or 41.78 mL) MCT oil (55% C8, 36% C10, 0.2 % Lauric Acid, 9% other fatty acids, total 14 g), and maintaining the heat and mixture for at least 21.40 minutes. In another embodiment, the method comprises heating caprylic acid (99% C8, total 14g) to at least 50 degrees Celsius, mixing 500 mg of 99% CBD Isolate into 1.5 ounces (or 41.78 mL) caprylic acid (99% C8, total 14g) and maintaining the heat and mixture for at least 21.40 minutes.

In preferred further embodiment, the method comprises heating MCT oil (55% C8, 36% C10, 0.2 % Lauric Acid, 9% other fatty acids, total 14 g) to at least 50 degrees Celsius, mixing 3000 mg of 99% CBD isolate into 1 ounce (or 29.56 mL) MCT oil (55% C8, 36% C10, 0.2 % Lauric Acid, 9% other fatty acids, total 14 g), and maintaining the heat and mixture for at least 25.22 minutes. In another embodiment, the method comprises heating caprylic acid (99% C8, total 14g) to at least 50 degrees Celsius, mixing 3000 mg of 99% CBD Isolate into 1 ounce (or 29.56 mL) caprylic acid (99% C8, total 14g), and maintaining the heat and mixture for at least 17.68 minutes.

Sublingual administration of certain preferred embodiments of the invention yields faster absorption rates compared to current commercially available products. In one example, sublingual administration of a mixture of caprylic acid and cannabidiol with a concentration of approximately 3000 mg of cannabidiol per 1 ounce of caprylic acid demonstrated an
approximately three-fold increase over time in cannabidiol levels in the blood as measured in ng/ml.

The invention being thus described, it will be evident that the same may be varied in many ways by a routineer in the applicable arts. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications are intended to be included
CLAIMS

What is claimed is:

1. A chemical composition comprising:
   an oil-based delivery system, wherein the oil-based delivery system comprises caprylic acid, or pharmaceutically acceptable salts thereof; and
   cannabidiol, or pharmaceutically acceptable salts thereof, mixed in the oil-based delivery system.

2. A method for mixing cannabinoids, or pharmaceutically acceptable salts thereof, into an oil-based delivery system comprising the steps of:
   a) providing an oil-based substrate comprising caprylic acid;
   b) heating the oil-based substrate to a specified temperature;
   c) mixing a cannabinoid compound into the heated oil-based substrate; and
   d) maintaining the specified temperature for a time-interval.

3. A method for sublingual administration of a mixture of caprylic acid and cannabidiol with a concentration of approximately 3000 mg of cannabidiol per 1 ounce of caprylic acid, whereby there is an approximately three-fold increase over time in cannabidiol levels in the blood as measured in ng/ml.
**FIG. 1**

- **Control (CTL)**
- **CO** — Test product +
  - Breakfast (20 ml)
- **C8/C10** — Test product +
  - Alone (20 ml)
- **C8**

- * P<0.05: [C8 vs CTL, CO, C10];
  - [C8/C10 vs C8]

- $\$ P<0.05: [C8/C10 vs CTL, C10]

- $\Omega$ P<0.05: [C10 vs CTL]

- $\#$ P<0.05: [C10 vs CO]
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61K 31/352; C07C 39/23 (2018.01)
CPC - A61K 9/0053; A61K 31/352; C07C 39/23; C07C 229/12

According to International Patent Classification (IPC) or to both national classification and IPC.

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Relevant to claim No.</th>
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<td>US 2016/0367496 A1 (Insys Development Company, Inc.) 22 December 2016 (22.12.2016); entire document, but especially: para [0015], para [0090], para [0239], table 24 formulation #LF7</td>
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<td>US 2007/0104741 A1 (Munty et al.) 10 May 2007 (10.05.2007); entire document, but especially: para [0022], para [0036], para [0058], para [0064], para [0135], para [0136], para [0139].</td>
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
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Date of the actual completion of the international search: 01 October 2018
Date of mailing of the international search report: 27 OCT 2018

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<td>US 2010/0273895 A1 (Stinchcomb et al.) 28 October 2010 (28.10.2010); entire document, but especially: para [0002], claim 43</td>
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