HEMP LEXICON

May 2021 (Revised)

Prepared by the American Herbal Products Association

Disclaimer

The information contained herein is not and should not be considered legal advice. This AHPA publication is not a substitute for the actual laws and regulations that apply to the terms that are discussed herein. The information contained herein is not intended to replace or supersede federal laws or any state, tribal, or local laws, regulations or guidance.

This document is specifically relevant to addressing the current legal status of the ingredients identified herein. No other issues related to the manufacture, marketing, or sale of food, dietary ingredients, dietary supplements, cosmetics, or any other class of consumer goods are addressed herein.

While AHPA believes the information herein is accurate, AHPA advises all individuals and entities using this information to discuss all aspects of their application of this information with an attorney or qualified consultant, or with personnel at relevant regulatory agencies.

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Introduction

This lexicon was developed to support standardization of the terminology used in the cultivation, processing, manufacturing, and labeling of hemp and products derived from hemp as defined in U.S. federal law.[1] It is intended to be a reference tool used by the hemp industry and by the federal, state, tribal, and other jurisdictions that oversee the hemp industry to provide guidance and encourage clear, consistent communication. The definitions in the lexicon may provide consumers with a common understanding of the diverse terms used in the description, marketing, and labeling of hemp products as well.

Many of the terms in this lexicon have been long established in other AHPA documents, such as the AHPA *Guidance for Manufacture and Sale of Bulk Botanical Extracts* (2001),[2] *Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements* (2001),[3] *Standardization of botanical products: White paper* (2003),[4] and *Guidance for the Retail Labeling of Dietary Supplements Containing Soft or Powdered Botanical Extracts* (2000).[5] Many of these definitions were developed and implemented by AHPA in consultation with a group of global botanical experts, and are harmonized with or have been adopted by other national governments and regulatory bodies, such as the Therapeutic Goods Administration (TGA) in Australia.[6]

Where current hemp industry usage of specific terms for marketing purposes differs from the long-established botanical industry definitions, this lexicon acknowledges those differences and recommends alternate terminology that may be integrated by the industry as it matures. These alternate terms are provided with the long-term goals of achieving consistency within the industry and of establishing a common consumer understanding of hemp product labeling.

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[1] The term "hemp" refers to the definition established in 7 U.S.C. 1639o(a).

[2] This document is available on the AHPA website at http://www.ahpa.org/AHPAResources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/223/AHPAs-Guidance-Documents-for-the-Manufacture-and-Sale-of-Botanical-Extracts.aspx

[3] This document is available on the AHPA website at http://www.ahpa.org/AHPAResources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/223/AHPAs-Guidance-Documents-for-the-Manufacture-and-Sale-of-Botanical-Extracts.aspx.

[4] This document is available on the AHPA website at http://www.ahpa.org/AHPAResources/TechnicalGuidance/AHPAGuidanceDocuments/TabId/401/ArtMID/1244/ArticleID/225/White-Paper-Standardization.aspx.

[5] This guidance policy is available on the AHPA website at http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Retail_Labeling_DietarySupplements_ContainingSoftPowderedBotanicalExtracts.pdf.

[6] For example, see TGA's *Guidance on equivalence of herbal extracts in Complementary Medicines*.

AHPA strongly encourages the hemp industry to utilize terminology consistent with established botanical industry usage whenever possible.

In some cases, the definitions may indicate how a term is utilized in scientific literature as well as the common chemical or molecular structural definition of the term in the hemp industry. One example of this is the series of definitions for "cannabinoids," which may provide structural definitions of cannabinoid molecules as well as an acknowledgement of how cannabinoid terms are used from a pharmacological perspective in cannabinoid research.

This lexicon was developed by a working group of the AHPA Cannabis Committee. Comments on this lexicon and suggestions for additional terms to include, especially by hemp growers, manufacturers, processors, and product marketers who use the lexicon in their operations and communications, are welcome and should be submitted to AHPA at the email or physical address listed below. Revisions may be made to this lexicon as additional insights are gained through its practical use.

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Lexicon of terms

For the purposes of this lexicon, the following terms have the specific meanings provided.

"Activated cannabinoid" means a cannabinoid from which a carboxyl group has been removed, thus converting the precursor cannabinoid (such as CBDA) native in the plant into a decarboxylated form (such as CBD).

"**Active compound**" – See the entry for **Botanical compounds, types of**.

"**Adverse event**" means any health-related event associated with use of a product that is adverse.[7]

"**Batch**" means the following:

- with regard to plant material that has not been processed, a specific quantity of plant material harvested during a specified time period from a specified cultivation or harvest area;
- with regard to processed ingredients or finished products, a specific quantity of material or product that is uniform and that is intended to meet its established specifications, and that is produced during a specified time period during a single cycle of manufacture.

"**Batch number**," "**lot number**" or "**control number**" means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the cultivation, harvesting, and packing of a batch or lot of plant material, or the manufacturing/processing, packaging, labeling, and/or holding of a batch or lot of finished product, can be determined.

"**Biomass**" means botanical material from which an extract is made.

Botanical compounds, types of: The chemical constituents of botanicals and botanical preparations fall into several categories as described below.[8]

> **"Active compound"** means a compound, or a class of compounds, that has been shown to fully account for the intended biological activity of a botanical preparation by exhibiting the same magnitude and type of biological response when tested in isolation as when tested as part of a botanical preparation. Such compounds also exhibit a dose-dependent response.
>
> **"Co-Active compound"** means a compound, or a class of compounds, which has been shown to be biochemically active, either in vivo or in vitro, but which has been shown to

[7] Public Law 109-426 Sec. 761(a)(1).

[8] For a more complete discussion of these various types of compounds and their use in botanical products, see AHPA's "Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements."

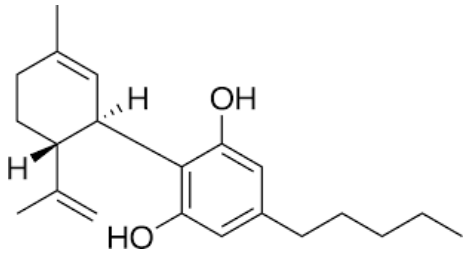
account only partially for the intended biological response of botanical preparations that contain it. In other words, if the compounds are tested both in isolation and as part of the corresponding botanical preparation, the isolated compounds exhibit less activity than those in their natural matrix. These compounds are known as “co-active” since two or more types of compounds work together to produce the observed activity.

“Marker compound” means a compound, or class of compounds, used for technical purposes in the manufacturing process such as to measure content uniformity, provide evidence of identity, evaluate stability, etc. Both biochemically active and inactive compounds may be used as markers.

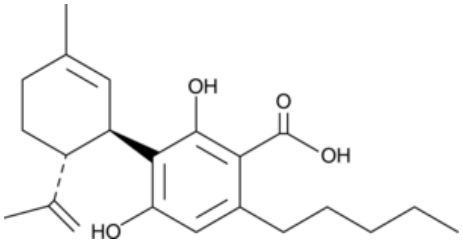
“**Broad spectrum extract**” – See the **Extracts** section.

“**Broad spectrum hemp extract**” – See the **Extracts** section.

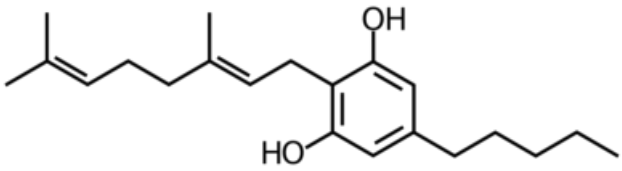
“**Cannabidiol (CBD)**” means the cannabinoid having the formula $C_{21}H_{30}O_2$ and chemical structure below.



“**Cannabidiolic acid (CBDA)**” means the cannabinoid having the formula $C_{22}H_{30}O_4$ and chemical structure below and that is the precursor to cannabidiol (CBD).



"Cannabigerol (CBG)" means a cannabinoid having the formula $C_{21}H_{32}O_2$ and the chemical structure below.



"**Cannabimimetic**" means a compound that is not structurally a cannabinoid, but which can elicit a biological response similar to those produced by structural cannabinoids by acting directly or indirectly on cannabinoid receptors in the body.

"**Cannabinoids**" are structurally defined as a diverse class of C_{21} or C_{22} terpenophenolic compounds found in cannabis, their carboxylic acids, analogs, and transformation products. The term is also used in the scientific literature to represent structurally unrelated cannabimimetic compounds.

> **NOTE: For purposes of consumer product labeling, AHPA recommends the term "cannabinoid" and variations such as "phytocannabinoid" be limited to structural cannabinoids produced by *Cannabis sativa* L. and their carboxylic acids, analogs, and transformation products.**
>
> **"Artificial cannabinoid"** means any cannabimimetic compound that interacts with cannabinoid receptors but whose molecular structure is not found in nature.[9] (These are often referred to as "synthetic cannabinoids," but AHPA discourages use of "synthetic cannabinoids" since it elides the distinction between the concepts of "artificial," "nature-identical," "synthesized," and "naturally occurring.")
>
> "**Endocannabinoid**" means a cannabimimetic compound produced endogenously in the bodies of humans or animals.
>
> **"Nature-identical cannabinoid"** means man-made structural cannabinoid compounds that are identical to those found in plants such as cannabis with respect to structure and stereochemistry. [10]

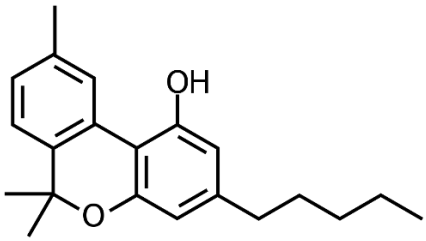
[9] Note that under current US laws and regulations, all artificial cannabinoids are illegal drugs.

[10] Note that FDA currently does not accept synthesized constituents of botanicals as dietary ingredients, even if nature-identical, except in a few grandfathered cases such as caffeine.

"**Phytocannabinoid**" means for the purpose of this document a structural cannabinoid compound produced by *Cannabis sativa* L.[11] The term may also be used in the scientific literature to refer to cannabimimetic compounds from other plants, such as non-C_{22} terpenes from hops.

"Synthesized cannabinoid" means a cannabinoid synthesized in a laboratory or by industry using directed synthetic or biosynthetic chemistry rather than traditional food preparation techniques such as heating or extracting. They may be nature-identical or artificial since this definition refers only to the process of their creation.

"Cannabinol (CBN)" means a cannabinoid having the formula $C_{21}H_{26}O_2$ and the chemical structure below.



"**Chemovar**" means a cultivated plant variety distinguishable by its chemical constituents.

"**Co-active compound**" – See the entry for **Botanical compounds, types of**.

"**Composition**" means the aggregate mixture which results from the manufacture of a product according to the formula and process defined in the product's manufacturing protocol.

"Cold press" means to obtain oils or other components from the plant material using mechanical pressure without adding heat.

"**Component**" means any substance intended for use in the manufacture of a product, including those that do not appear in the batch of the product. Components include hemp, hemp-derived products used as ingredients, other ingredients, and processing aids.

"**Crude extract**" – See the **Extracts** section.

"**Cultivar**" (or cultivated variety) means a plant variety intentionally selected for characteristics that are clearly distinct from other cultivated varieties of the same species, and that are uniform and stable such that these characteristics are retained when the cultivar is propagated.

"Dab" means a small quantity of pure (i.e., with no other ingredients added) hemp resin, rosin, or resinoid extract that is intended to be consumed or smoked. Depending on the texture,

[11] To date, no scientific reference has documented the presence of structural cannabinoids in a plant species other than *Cannabis*.

consistency, and/or physical form, dabs may be called “budder,” “crumble,” “crystals,” “pull-and-snap,” “shatter,” “wax,” or other evocative descriptors.

“Decarboxylation” means a process of treating a hemp material or product to remove carboxyl groups from the cannabinoids native in the plant, to form transformation products such as THC and CBD. Decarboxylation is commonly accomplished by application of heat either to the crude hemp material or during extraction.

“**Decoction**” – See the **Extracts** section.

“**Dietary ingredient**” is defined under U.S. law as an ingredient in a dietary supplement that is a vitamin; mineral; herb or other botanical; amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these.[12]

“**Dietary supplement**” is defined under U.S. law as a food product (other than tobacco) intended to supplement the diet that bears or contains one or more dietary ingredients; is intended for ingestion typically in tablet, capsule, powder, softgel, gelcap, or liquid form; is not represented for use as a conventional food or as a sole item of a meal or the diet; and is labeled as a dietary supplement.[13]

“Distillation” means a purification technique that uses heat and/or reduced pressure to vaporize botanical constituents from a liquid, followed by condensation and collection of the constituents. **“Distillate”** means a material prepared using this technique. (When applied to biomass using solvents such as steam or ethanol, distillation can also function as an extraction technique; see extract section below.)

> NOTE: In the hemp industry, CO_2 (carbon dioxide) extracts are sometimes called distillates, but this is not an accurate use of the term.

“**Essential oil**” means any of a class of volatile terpenoid chemical compounds derived from plants. Essential oils are also referred to as volatile oils.

“**Expressed oil**” – See the entry for **Pressed oil**.

[12] 21 U.S.C. § 321 (ff).

[13] The definition of “dietary supplement” under U.S. law contains additional details. For the complete definition see 21 U.S.C. § 321 (ff).

Extracts

"**Extract**" means a complex, multicomponent mixture obtained after using a solvent to dissolve components of the biomass. Extracts may be in dry, liquid, or semisolid form. Excipients may be added to extracts in order to adjust the concentration; enhance stability; limit microbial growth; and to improve drying, flow, or other manufacturing characteristics. Extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents.[14]

> NOTE: The choice of crude botanical material, solvent(s) and manufacturing processes used to produce an extract impacts the range and levels of the plant constituents present in the resulting extract.

> NOTE: The verb "extraction" can be used to describe any process that selectively removes part of the material native to the plant, either through use of solvents or physical processes. The resulting material is accurately described as an "extract" only if a solvent is employed such as water, ethanol, or CO_2. A material obtained using solely physical processes may be called a "pressed oil," "juice," "rosin," etc. as appropriate.

Extraction methods

Extracts can be described based on extraction method as follows:[15]

> **"Decoction"** means an extraction technique in which the herb is boiled in water, or an extract prepared using this technique.

> **"Distillation"** means an extraction technique in which solvent vapor (such as steam or ethanol vapor) is used to extract botanical constituents from the biomass, followed by cooling and condensation of the extracted constituents. **"Distillate"** means an extract prepared using this technique. (Distillation can also function as a purification technique for extracts made by other means; see "distillation" in the main list of definitions above, separate from the "Extracts" section.)

> > NOTE: In the hemp industry, CO_2 (carbon dioxide) extracts are sometimes called distillates, but this is not an accurate use of the term.

[14] However, it should be noted that some chemical modifications might occur as the natural consequence of the extraction process, for example transesterification, hydrolysis, decarboxylation, etc.

[15] This is not a complete list of extraction methods. For a more complete list, see AHPA's "Guidance for Manufacture and Sale of Bulk Botanical Extracts."

"Infusion" means an extraction technique by which an herb is steeped or soaked in water without boiling, or an extract prepared using this technique. Occasionally infusions are made by steeping in fixed oil, wine, vinegar, or honey as the extraction solvent.

"Maceration" means an extraction technique in which the botanical material is allowed to soak in the extraction solvent until the cellular structure of the herb is penetrated and the soluble portions are dissolved. **"Macerate"** when used as a noun means an extract prepared using this technique.

"Percolation" means an extraction technique in which the botanical material is exhaustively extracted with fresh solvent until no further soluble components remain.

"Percolate" when used as a noun means an extract prepared using this technique.

Chemical complexity of extracts

Extracts can be described based on their degree of chemical complexity as follows:

"Broad spectrum extract" means an extract comprising a wide range of the constituents native to the plant. Broad spectrum extracts are made using relatively non-selective solvents and manufacturing processes so that both relatively hydrophilic and relatively hydrophobic types of botanical constituents are captured.

> NOTE: In the hemp industry, the term "broad spectrum extract" is currently used in a different manner. See additional discussion below, in the subsection on extract terminology related to the hemp industry.

"Full spectrum extract" means an extract that is especially complete, either chemically or botanically. The term is variously applied to products made by repeatedly extracting the same biomass using different solvents ranging from hydrophilic to hydrophobic or polar to nonpolar (thereby obtaining the complete range of soluble constituents native to the plant); extracting multiple parts of the same plant (e.g., extracting root, aerial parts, and flowers); extracting multiple species from the same genus; or by inclusion of crude (i.e., un-extracted) botanical along with the extractives.

> NOTE: In the hemp industry, the term "full spectrum extract" is currently used in a different manner for most (but not all) hemp products. See additional discussion below, in the subsection on extract terminology related to the hemp industry.

"Selective extract" means an extract made using solvents that selectively extract only a narrow range of native constituents from the plant. Selective extracts are typically made using relatively hydrophobic or nonpolar solvents.

"Semi-purified extract" means an extract containing only a narrow range of the native constituents from the plant, which is made by partially purifying the desired components from an initially broader spectrum extract. [16]

Other extract-related terms

Other extract-related terms include:

"Crude extract" means an extract that has not been specially further processed to concentrate or remove botanical constituents after the initial extraction is made. (However, crude extracts may be further processed by filtration, pressing, partial or complete removal of solvent, milling, blending with excipients, and other physical processes that are not primarily intended to alter the botanical constituent composition of the extract.)

NOTE: For hemp that is extracted to obtain CBD, the crude extract will typically contain < 60% cannabinoids.

"Extract ratio" means a measure of the concentration or dilution level of an extract, expressed as a ratio in which the first number represents the amount of dried botanical starting material expressed in metric units, and the second number represents the amount of finished total extract expressed in metric units. Where fresh rather than dried starting material is used in determining the ratio, this fact must be disclosed. Where the ratio may vary from batch to batch, the ratio may be stated as a range (e.g., "4-5:1") or as the average.[17]

"Fortified extract" means an extract whose native content of specific constituents has been fortified through the addition of the same constituents obtained from exogenous sources of the same botanical, as by purchase from a vendor or by manufacturing a concentrate or isolate using an extraction process that targets the specified constituents.[18]

[16] If the purification is taken to completion then the resulting material can no longer be called an "extract," because an extract by definition is a complex multicomponent mixture.

[17] For further discussion see AHPA's "Guidance for the Retail Labeling of Dietary Supplements Containing Soft or Powdered Botanical Extracts" and "Standardization of Botanical Products: White Paper."

[18] Repeated extraction of the same biomass, then combining the fractions to produce one batch of extract, does not cause the resulting extract to be "fortified"; rather, this is the normal process by which most extracts are made. Similarly, combining separately-manufactured lots of extract into one batch in order to achieve a defined

NOTE: AHPA recommends (and for hemp some jurisdictions require) that fortification be disclosed in product labeling, at a minimum through disclosure of two separate ingredients in the "Ingredients" statement of the label (for example, "Ingredients: Hemp aerial parts extract, CBD isolate.") For dietary supplements, some jurisdictions require each such ingredient to be listed separately in the Supplement Facts box.

"Native extract" means the material present in an extract consisting only of components endogenous to the biomass or formed during extraction, excluding any excipients or other added substances. This term may refer to a concentrated liquid extract from which the solvent has been removed, or may refer to an extract or that portion of a finished extract that is comprised solely of native components.

"Resinoid extract" means an extract with a characteristic odor, obtained from biomass by extraction with a non-aqueous solvent.

"**Standardized extract**" means an extract produced through careful control of agricultural practices, raw material specifications, and manufacturing processes to optimize the batch to batch reproducibility of an extract, which may include controlling the level of one or more botanical constituents in the extract (i.e., marker, active, and/or co-active compounds). Where the levels of such constituents are to be controlled, the concentration may be adjusted by the addition of fillers or the mixing of extract lots of different strengths (where those extract lots are made using the same manufacturing process).[19] Standardized extracts may be full spectrum, broad spectrum, selective, or semi-purified; in other words, standardization refers to the controls used in manufacturing, not to the degree of chemical complexity or purification.[20]

"**Tincture**" means an alcoholic or hydroalcoholic liquid extract in which 1 part by weight of the original botanical material or extractives are extracted or dissolved in (typically) 2 or more parts by volume but (typically) not more than 10 parts by volume of the solvent, with all measurements in metric units. The use of fresh biomass in manufacturing and/or calculating the extract ratio is permissible but must be stated in

level of constituent(s), when all the lots are extracted using the same extraction process, does not cause the resulting extract to be "fortified"; rather, this is a common procedure for standardizing an extract.

[19] If an extract lot is combined with a concentrated source of one or more constituents made using a different manufacturing process, the resulting material is a "fortified extract" rather than a "standardized extract."

[20] For a more complete discussion of standardization, see AHPA's "Standardization of Botanical Products: White Paper" and "Use of Marker Compounds in Manufacturing and Labeling Botanically Derived Dietary Supplements."

the product labeling. The traditional preparation in the U.S. most commonly uses dried biomass and a dilution ratio of 1:5 or 1:10.

> NOTE: The term "tincture" has been sometimes used inappropriately in the hemp industry to describe hemp oils or diluted hemp oils.

Hemp-related extract terms

With respect to hemp products, extract-related terms include:

"Broad spectrum hemp extract" or "broad spectrum extract" as currently used in the hemp industry means a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, which has been processed to remove THC such that the THC has been found to be non-detectable by a compliant laboratory using a fit-for-purpose method with a limit of detection of less than 0.01%.[21] Broad spectrum hemp extracts may be fortified with components that have been separately concentrated or isolated from hemp. (See "fortified extract" above.)

> NOTE: This usage of the term "broad spectrum hemp extract" is inconsistent with long-established usage of "broad spectrum extract," and fails to clearly communicate the most salient feature of the preparation, namely that it is a selective or semi-purified extract from which the THC has been removed. AHPA recommends this term be replaced with alternate language such as "non-THC hemp CBD extract" as defined below. If a jurisdiction's regulations require use of "broad spectrum hemp extract" or "broad spectrum extract" to describe what is in fact a selective or semi-purified extract, the product labeling should include information that makes it clear to the consumer the true nature of the product, e.g., by prominently featuring the content of CBD or other cannabinoids or by using terms such as "resin" or "resinoid."

"Full spectrum hemp extract" or "full spectrum extract" as that term is currently most often used in the hemp industry means a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, including but not limited to any naturally-occurring THC, other cannabinoids, and terpenes, that has been processed without intentional removal of any compounds and has a final THC quantification of not greater than 0.3%.[22] Full spectrum hemp extracts may be fortified with components that have been separately concentrated or isolated from hemp. (See "fortified extract" above.)

[21] This portion of this definition aligns with the term "broad spectrum" in the US Hemp Authority® Certification Standard 3.0.

[22] This portion of this definition aligns with the term "full spectrum" in the US Hemp Authority® Certification Standard 3.0.

NOTE: This usage of the term "full spectrum hemp extract" is inconsistent with long-established usage of "full spectrum extract," and leaves the consumer no obvious way to distinguish "full spectrum" selective hemp extracts containing only a range of hydrophobic constituents from "full spectrum" hemp products that actually are an especially complete representation of the source botanical. AHPA recommends this term, when applied to products that in fact contain only a narrow selection of the plant's phytochemistry, be replaced with alternate language such as "full spectrum hemp CBD extract" as defined below. If a jurisdiction's regulations require use of "full spectrum hemp extract" or "full spectrum extract" to describe what is in fact a selective or semi-purified extract, the product labeling should include information that makes it clear to the consumer the true nature of the product, e.g., by prominently featuring the content of CBD or other cannabinoids or by using terms such as "resin" or "resinoid."

"Full spectrum hemp CBD extract" means a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, including but not limited to any naturally-occurring THC, other cannabinoids, and terpenes, that has been processed without intentional removal of any compounds and has a final THC quantification of not greater than 0.3%. The term "CBD" may be replaced with any accurate descriptor such as "cannabinoid," "resinoid," or a different cannabinoid such as CBN. Full spectrum hemp CBD extracts may be fortified with components that have been separately concentrated or isolated from hemp. (See "fortified extract" above.)

NOTE: AHPA suggests this term as a more accurate replacement for "full spectrum hemp extract" as currently used in the hemp industry to describe products that in fact contain only a narrow selection of the plant's phytochemistry.

"**Hemp [plant part] extract**" means an extract produced using biomass consisting of some or all of the parts of the hemp plant.[23] Hemp extracts of any type (e.g., full spectrum, standardized, non-THC, etc.) do not include (a) any added synthesized cannabinoid; or (b) any added components that were concentrated or isolated from a source other than hemp (e.g., terpenes from citrus oil). Hemp extracts may be fortified with components that have been separately concentrated or isolated from hemp. (See "fortified extract" above.)

[23] Dietary supplements consisting of or containing hemp extract must disclose the part(s) of the hemp plant utilized in making the extract (e.g., hemp flower, hemp leaf), as required by 21 CFR Part 101.36. For other products consisting of or containing hemp extract, marketers are encouraged to disclose the part(s) of the hemp plant utilized in making the extract (e.g., hemp flower, hemp leaf) in either the ingredients list or the nutritional panel of the product labeling.

NOTE: Hemp extract is sometimes identified in labeling as “hemp oil,” which is an imprecise use of the latter term.

“Hemp isolate” is not an extract, even though it is derived from hemp, because by definition an “extract” is a complex, multicomponent mixture. See definition below for “hemp isolate.”

“Hemp oil extract” (also known as **“hemp oil infusion”**) means a hemp extract produced using a fixed oil as the extraction solvent.

“Non-THC (or THC-free) hemp CBD extract” means a resinoid hemp extract comprising a wide range of relatively hydrophobic hemp constituents, which has been processed to remove THC such that the THC has been found to be non-detectable by a compliant laboratory using a fit-for-purpose method with a limit of detection of less than 0.01%. The term “CBD” may be replaced with any accurate descriptor such as “resinoid,” “cannabinoid,” or a different cannabinoid such as CBN. Non-THC hemp CBD extracts may be fortified with components that have been separately concentrated or isolated from hemp. (See “fortified extract” above.)

NOTE: AHPA suggests this term as a more accurate and straightforward replacement for “broad spectrum hemp extract” as currently used in the hemp industry.

NOTE: Certain jurisdictions may restrict use of descriptions such as “THC-free,” “non-THC,” or “reduced THC.”

“**Raw hemp extract**” means a hemp extract that has not undergone decarboxylation.

“**Extract ratio**” – See the **Extracts** section.

“**Fixed oil**” means a non-volatile lipid (glycerides of fatty acids) oil of animal or plant origin. Under atmospheric conditions and room temperature, fixed oils do not evaporate and typically have a low enough viscosity to flow readily.

“**Fortified extract**” – See the **Extracts** section.

“**Full spectrum extract**” – See the **Extracts** section.

“**Full spectrum hemp extract**” – See the **Extracts** section.

“**Hash**” (also known as “**hashish**”) means a resinoid substance derived from *Cannabis sativa* L. consisting of mechanically separated resin plus fragments of plant material, especially trichomes, obtained by techniques such as rubbing the plant between the hands or sieving dried plant material. When obtained using an ice water bath and/or frozen plant material it may be referred to as “**bubble hash**” or “**ice hash**.”

"**Hemp**" means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis[24].

"**Hemp-derived product**" means a product, other than hemp itself, which contains or is derived from hemp and is intended for inhalation, oral ingestion, or topical application.

"**Hemp food crop**" means a hemp crop that will be used as or in food, including dietary ingredients and dietary supplements.

"Hemp isolate" means a chemical constituent, such as cannabidiol (CBD), that has been isolated from hemp and contains THC as an impurity at levels below 0.3%. Isolates may contain trace amounts of other constituents, moisture, etc.

> NOTE: Some jurisdictions have established a quantitative threshold of 95% such that if a constituent from hemp is concentrated to at least 95% purity then it is considered an isolate.[25]

"**Hemp oil**" means a hemp extract or isolate dissolved in a fixed oil.[26] This term may also include a description of the type of hemp extract used, such as "broad spectrum hemp oil" or "CBD hemp oil."

> NOTE: This term has been used imprecisely to describe hemp extracts that may have an oily consistency.

"Hemp oil infusion" – see the entry for **Hemp Oil Extract** in the **Extracts** section.

"**Hemp operation**" means any firm engaged in the propagation, cultivation, post-harvest handling, manufacture/processing, packaging, labeling, packing, or holding of hemp or hemp-derived products.

"**Hemp planting material**" means hemp seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow hemp.

"**Hemp extract**" – See the **Extracts** section.

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[24] The term "hemp" is consistent with the definition established by the Agricultural Marketing Act of 1946, section 297A.

[25] Other authorities set the threshold lower, e.g., 70% or 80%. The most appropriate threshold above which a material should be considered an "isolate" is the subject of some controversy.

[26] For compliance with federal labeling laws, products should disclose the part(s) of the hemp plant utilized in making the extract in either the ingredients list or the nutritional panel of the product labeling. Federal law requires the disclosure of all ingredients in the order of predominance, including disclosure the fixed oil and the hemp extract as separate ingredients.

"**Hemp oil extract**" – See the **Extracts** section.

"**Hempseed oil**" means an edible fixed oil obtained by the pressing of hemp seeds or by extracting hemp seeds with a hydrophobic solvent.

> NOTE: Hempseed oil is not "hemp oil" since it consists of the oil naturally occurring the plant, rather than a preparation with exogenous oil added.

"**Identity**" means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of hemp and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling. In the case of hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

"**Infusion**" – See the **Extracts** section.

"**Ingredient**" means any substance that is used in the manufacture of a product and that is intended to be present in the finished product.

"**Isolate**" means a chemical constituent, such as hypericin or vanillin, that has been isolated from an herb or other organism.[27] Isolates may contain trace amounts of other constituents, moisture, etc.[28]

"Juice" means an aqueous liquid obtained by pressing botanical material without the addition of solvent, which may then be used as-is, concentrated by removal of water, or dried to a powder. The strength of a juice may be represented as the input quantity crude botanical to the output quantity of finished material expressed as a ratio, with all measurements in metric units.

"Live resin" means a resin obtained by extracting fresh (i.e., not dried), usually frozen hemp biomass with a hydrophobic solvent such as butane.

"Live rosin" means a rosin obtained by subjecting fresh (i.e., not dried), usually frozen hemp to heat and pressure.

"**Lot**" means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet its established specifications; or, in the case of a product produced by

[27] Where isolated constituents are added to a product where the same constituents may be present naturally as part of an herb or other organism (e.g., isolated CBD added to a hemp product to elevate the CBD level; isolated folate added to a yeast product to elevate the folate content; etc.), the presence of the exogenous constituent should be disclosed in product labeling.

[28] The most appropriate threshold above which a material should be considered an "isolate" is the subject of some controversy, but is generally considered to be in the range of 70-95%.

continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet its established specifications.

"**Maceration**" – See the **Extracts** section.

"**Marker compound**" – See the entry for **Botanical compounds, types of**.

"Microorganisms" means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

"**Mycotoxins**" means any of a group of naturally occurring toxins produced by fungi that can be found in certain crops and foods and that may have public health or sanitary concern.

"**Native extract**" – See the **Extracts** section.

"**Non-THC hemp extract**" – See the **Extracts** section.

"**Percolation**" – See the **Extracts** section.

"**Pesticide**" is defined under U.S. law as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and nitrogen stabilizers.[29] Pesticides include herbicides, fungicides, and insecticides as well as other substances.

"Pressed oil" (also known as **"expressed oil"**) means a fixed oil obtained from the plant material using mechanical pressure.

> NOTE: Some members of the hemp industry use the term "extract" to describe such preparations; this usage is inconsistent with the definition of "extract" accepted by regulators worldwide, so AHPA recommends such usage be replaced.

"**Processing aid**" means a component used in the manufacturing/processing, packing or packaging of a product which is not present as an ingredient in the finished product other than at trace levels. This may include, for example, food grade oil used to lubricate product-contact equipment parts, inert gas used to flush package headspace, or solvents used in extraction which are removed later in processing.

[29] The definition of "pesticide" under U.S. law contains additional details. For the complete definition see 7 U.S.C. § 136 (u).

"**Product complaint**" means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a product that could be related to its cultivation, harvesting, manufacture/processing, packaging/packing, labeling, holding, or related operations. Product complaints may include reports of adverse events or serious adverse events.

"Proprietary blend" means a blend of two or more dietary ingredients which are grouped together for purposes of dietary supplement labeling, and only the quantity of the whole group is disclosed on the product label. The individual components of the blend are not quantified on the label. The components of the proprietary blend are listed in the Supplement Facts box in descending order by weight. (Alternately for liquids, this may be in descending order by volume).

"**Purity**" means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.[30]

"**Quality**" means that the product consistently meets its established specifications (such as for identity, purity, strength, composition, packaging, packing, and/or labeling), and has been manufactured, processed, packaged, packed, labeled, and held under conditions to prevent adulteration.

"**Quality control**" means a system for verifying and assuring the quality of a product.

"**Raw hemp extract**" – See the **Extracts** section.

"Resin" means a solid or highly viscous, water-insoluble, chemically complex substance exuded by certain plants including *Cannabis sativa* L. Resins are often largely composed of esters and ethers of organic acids with complex alcohols; some are largely acids or acid anhydrides. In some instances they result from the oxidation of the terpene constituents of essential oils. Resins may be obtained from the plant by physical means (e.g., exudation) or by solvent extraction.

"**Resinoid extract**" – See the **Extracts** section.

"Rosin" means a resinoid substance obtained by subjecting resin to heat, or by using heat and pressure (e.g., heated pressure plates) to express the substance from the plant material.

"**Scientifically valid method**" means an analytical method that is based on scientifically legitimate principles and which is fit for purpose in the analysis of specific ingredients or products.

[30] In the context of dietary supplement GMPs (21 CFR Part 111), the term "purity" refers to the proportion that represents the intended material. For example, L-alanine containing 95% of the L isomer and 5% of the D isomer is "95% pure L-alanine" and has a purity of 95%.

"**Serious adverse event**" means an adverse event that results in any of the following outcomes:

- Death;
- Life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- Congenital anomaly or birth defect; or
- Medical intervention is necessary to prevent one of these outcomes.

"**Selective extract**" – See the **Extracts** section.

"**Semi-purified extract**" – See the **Extracts** section.

"**Standardized extract**" – See the **Extracts** section.

"**Strength**" means the measure of a product, expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of hemp present in a hemp-derived product; or (c), in the case of extracts, the input quantity of crude botanical to the output quantity of finished extract expressed as a ratio, with all measurements in metric units.[31,32]

> NOTE: In the hemp industry, the term "potency" is often equated to the concentration of a specific constituent such as CBD. The appropriate term to use is "strength" (or, in the context of dietary supplements, also "purity"), as "potency" is associated in U.S. federal regulations with drug products and certain vitamins because it refers to a measure of biological activity rather than simply chemical quantification.[33]

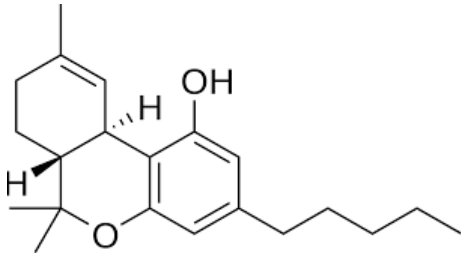
"**Terpenes**" means any of a class of hydrocarbons occurring widely in plants and animals and empirically regarded as built up from isoprene. The term encompasses the terpenoids, which are oxygenated derivatives of these hydrocarbons.

[31] Under dietary supplement regulations, the "strength" as defined in (a) will overlap with the "purity" specification, and the "strength" as defined in (b) may overlap with the "purity" and/or "composition" specifications.

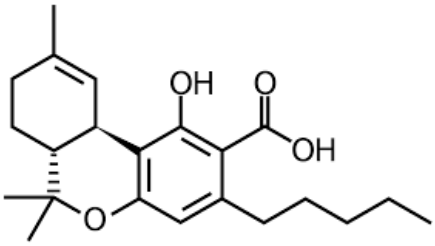
[32] This ratio is generally calculated on the dry weight basis; if on the fresh weight basis then this must be disclosed in labeling.

[33] To be precise, pharmacological potency refers to a measure of biological activity expressed as the amount of a chemical required to produce an effect of specified intensity.

"**Tetrahydrocannabinol (THC)**" means the cannabinoid having the formula $C_{21}H_{30}O_2$ and the chemical structure below. It is often referred to as Δ-9-tetrahydrocannabinol.



"**Tetrahydrocannabinolic acid (THCA)**" means the cannabinoid having the formula $C_{22}H_{30}O_4$ and the chemical structure below, and that is the precursor to tetrahydrocannabinol (THC).



"**THC-free hemp extract**" – See the **Extracts** section.

"**Tincture**" – See the **Extracts** section.