Chanelle McCoy Health

Synthetic and Plant derived Cannabidiol (CBD) explained

Pureis® Ultra Pure Cannabidiol (CBD)



What is the difference?

Cannabis plant derived CBD

- CBD that is **derived directly from the** Cannabis plant
- Isolating pure CBD from a plant is difficult, and does require laboratory intervention
- To derive CBD from plant sources, the following extraction techniques are used:
 - Using liquid solvents such as alcohols
 - Supercritical fluid extraction
 - CO2 extraction
 - Oil extraction
 - CBD nano-delivery
 - Decarboxylation
- Relies heavily on agriculture and crop cultivation, which may lead to unnecessary product wastage
- CBD isolation from Cannabis is virtually impossible often other cannabinoids are present
- Has a distinct taste & smell- likely due to the presence of terpenes

Synthetically derived CBD

- With natural citrus starting sources; synthetic CBD is **designed to mimic the DNA of CBD** found in Cannabis; it is chemically identical and binds to the same receptors in the body
- There is **no reliance on agriculture**; minimal water usage and is potentially more sustainable and environmentally friendly
- Free from pollutants (environmental, insecticides or pesticides)
- Free from other cannabinoids including THC and terpenes that are practically impossible to remove from the plant; Ultra-pure CBD (selectivity and guaranteed purity)
- Guaranteed **no psychoactive properties**:
 - CBD is available in two common forms: (-)- CBD and +(-) CBD. (-)-CBD stimulates the CB2 receptor (primarily expressed on immune cells). (+)- CBD has affinity for both receptors and has the potential to display effects similar to THC (psychoactive response). With synthetic you can carefully design the correct negative enantiomer (-)- CBD compound therefore being CB2 selective to guarantee no psychoactive effects.
- **Odourless**; does not contain pungent smells from the plant; impacting taste and therefore patient compliance



Our Raw Material – Ultra Pure (Synthetic) CBD

- Our raw material is Ultra Pure CBD meaning it only contains CBD and nothing else, with 0% THC.
- Our raw material is FDA registered with a Drug Master File Number (DMF) from an FDA approved manufacturer in the US.

Why Synthetic CBD?

Reproducible & Scalable



Our raw material is synthetically produced; there is no concern about **crop failure**, **no reliance on land**, **weather or soil** conditions which affects yield. **No intra batch variability** meaning each batch is the exact same, this may differ in plant sources due to different harvest conditions. Synthetic **CBD is scalable to produce large batch sizes, which reduces cost and risk**; Plant raw material can have significant shortage issues

Sustainable



Our raw material utilises a citrus by product which otherwise would be wasted. No reliance on agriculture for our raw material means:

- X Not using gallons of water
- X Not using toxic pesticides/ insecticides
- X Not using up arable land on mass
- X No food wastage, due to product not meeting required legal and quality standards

Safe & Quality Guaranteed



Our Ultra Pure raw material is free from the following that the plant can contain; NO toxins and pollutants, NO traces of THC, NO other cannabinoids, NO terpenes, NO heavy metals, NO pesticides, NO insecticides, As the product is produced in a pharmaceutical company **under GMP conditions** and stringent security-controlled environment there is **no risk of contamination, theft or damage to product.**



Why is product Quality is so important?

Not all CBD products are created equally

- It is important when taking a CBD food supplement that the consumer is aware of what they are consuming!
- Some product found on the market can contain unwanted contaminants along with levels of THC and some may contain lower levels of CBD than claimed- all unknown to the average consumer
- According to a paper published April 2020 titled: An Analysis of Over-the-Counter Cannabidiol Products in the United Kingdom¹ 29 CBD food supplements available on the UK market were tested, the results were concerning:
 - 34% of products had 50% less of the CBD content advertised
 - 1 product had no CBD content
 - 55% of products had measurable levels of THC, above limit
 - CBN (which is another cannabinoid that is classed as a controlled substance therefore illegal) was present in products
 - One product had levels of ethanol (i.e. alcohol content)
 - Lead and arsenic were also detected
 - All products had other cannabinoids present such as CBDA/CBDV and CBVA. At present these cannabinoids do not fall scope of a CBD claiming food supplement. As these other cannabinoids that are active in some cases, they can exacerbate the effects of CBD itself, they have effects in their own right
- A national survey carried out by the FSAI (Food Standards Agency Ireland)² in February 2020 found that 84% of products they tested contained THC and 34% had THC levels significantly above what is consider safe and that 41% of products tested contained CBD levels which differed by greater than 50% compared to that declared.



CBD market concerns

Market study

- Having become aware of the concerns associated with the CBD market we conducted our own market study in 2021
- We had 3 off the shelf popular brands tested by an independent accredited laboratory, the results were worrying
- What is notable is that one of the products tested contained **significantly lower than advertised levels of CBD** (88% less than the advertised content of CBD) and **one product also contained levels of THC** (Tetrahydrocannabinol- the main psychoactive component of the cannabis plant)
- All products contained other undeclared cannabinoids
- Below is an overview of what we found:

Compound detected	Brand A (600mg in 30ml)	Brand B (500mg in 30ml)	Brand C (260mg in 10 ml)
Arsenic	0.004 mg/Kg	0.005 mg/kg	0.003 mg/Kg
Ethylbenzene	0.011 mg/kg	0.014 mg/kg	0.028 mg/kg
Styrene	0.011 mg/kg	-	0.20 mg/kg
Toluene	0.055 mg/kg	0.020 mg/kg	0.092 mg/kg
Pyrimethanil	-	0.73 mg/Kg	-
Ethyl- Chlorpyrifos	-	0.033 mg/kg	-
Benzene	-	0.017 mg/kg	-
Cannabinoids detected	Brand A (600mg in 30ml)	Brand B (500mg in 30ml)	Brand C (260mg in 10 ml)
CBD content	2.2565%	0.1928%	2.7347%
CBDA content	0.0082%	-	0.5020%
Total CBD (CBD+(CBDA X0.877))	2.2637%	0.1928%	2.7787%
Expected % CBD content	2%	1.60%	2.60%
CBDV (Cannabivarin)	0.0134%	-	0.1160%
CBC (Cannabichromene)	-	-	0.0059%
CBG (Cannabigerol)	-	0.0784%	-
THC (delta 9- Tetrahdryocannabinol)	-	-	0.0038%



Arsenic: FSA Ireland recommended safe intake of total arsenic stands at 1mg/Kg Ethylbenzene: TDI as set by WHO currently stands at 97.1g/kg b.w. Styrene TDI as set by WHO currently stands at 7.7g/kg b.w. Benzene: No TDI known carcinogen

CBD market concerns

Let's educate ourselves on what was found

<u>Arsenic</u>

- Highly toxic and a **confirmed carcinogen** (cancer causing agent)
- Associated with cardiovascular disease and diabetes.
- Exposure of Arsenic in early childhood has been linked to negative impacts on cognitive development.³

<u>Benzene</u>

- Known carcinogen which at high levels of exposure can cause our cells not to function properly.
- The link between Benzene and cancer is largely focused on leukaemia and blood cancers.⁴
- Benzene is found in gasoline and exhaust fumes and is used as a starting material in making plastics.

<u>Foluene</u>

- Commonly found in crude oil and is produced in the process of making gasoline and other fuels from crude oil
- Toluene may affect the nervous system ⁵
- Low to moderate levels can cause tiredness, confusion, weakness, memory loss, nausea and loss of appetite.

Pyrimethanil

•Fungicide used to control grey mould on crops

Ethyl-Chlorpyrifos

- Insecticide which is currently not approved for use in the EU.⁶
- Associated with cardiovascular disease and diabetes.
- Where identified levels were 30% higher than the current maximum residue levels by the European Food Safety Authority. ⁷

Styrene

- Found in tobacco smoke and is used widely to make plastics and rubber.
- It can be present in the air near industrial facilities or hazardous waste sites
- The national toxicology program in the US has listed Styrene as a reasonably **anticipated carcinogen** in 2011⁸

Ethylbenzene:

- Commonly found in gasoline, pesticides and plastics
- Acute (short-term) exposure to ethylbenzene can result in throat irritation, chest constriction, eye irritation of the eyes and dizziness ⁹



Tying it all together

Summarizing what we have learned

- Isolated CBD is difficult to obtain from a plant source; various laboratory extraction techniques are employed in order to attempt to do so
- Even when utilised these extraction techniques usually do not succeed in obtaining isolated CBD, other cannabinoids are often present along with pesticides and environmental pollutants.
- Synthetic CBD is manufactured from natural sources to mimic the DNA of plant derived CBD, it is molecularly identical and acts in the body by the same mechanisms.
- Synthetic CBD can guarantee selective pure CBD with no other cannabinoids present; and it can be synthetised to ensure no psychoactive effect occurs.
- Quality assurance in a CBD product is highly important; recent market studies have shown the products currently on the market can vary in Quality, consistency and safety.
- We at Pureis choose a synthetic raw material of the highest quality assuring Ultra-Pure CBD for the following reasons:
 - Quality and safety assured
 - Guaranteed to contain only (-)(-) CBD; causing no psychoactive properties
 - Odourless; does not have a pungent odour or unpleasant taste
 - No presence of unwanted contaminants; pesticides, insecticides or environmental pollutants
 - No reliance on agriculture and crop cultivation
 - More sustainable



References

- 1. An Analysis of Over-the Counter Cannabidiol products in the United Kingdom, Jonathan Paul Liebling et al
- 2. FSAI Survey: Regulatory Issues with Hemp-based food and food supplements on the Irish market; February 2020
- 3. WHO Arsenic fact sheet <https://www.who.int/news-room/fact-sheets/detail/arsenic> accessed 06-Aug-21
- 4. American Cancer society; Benzene and cancer risk <https://www.cancer.org/cancer/cancer-causes/benzene.html> accessed 06-Aug- 21
- 5. Christopher M. Filley et al, The Effects of Toluene on the Central Nervous System, Journal of Neuropathology & Experimental Neurology, Volume 63, Issue 1, January 2004, Pages 1–12,
- 6. EFSA renewal of approval Chlorpyrifos & Chlorpyrifos methyl < https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/chlorpyrifos-chlorpyrifos-methyl_en > accessed 06-Aug-21
- 7. EFSA maximum residue levels (mg/kg) <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/mrls/?event=details&pest_res_ids=56&product_ids=&v=1&e=search.pr> accessed 06-Aug-21
- 8. US National Institute of Environmental Health sciences; Styrene https://www.niehs.nih.gov/health/topics/agents/styrene/index.cfm accessed 06-Aug-21
- 9. US EPA Ethylbenzene hazard summary; updated January 2020



Thank You

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#NewScience

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