

CBD-Oils from Industrial Hemp (*Cannabis sativa* L.)

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(EIHA)



Cannabis* (plant) is the genus in the family *Cannabaceae



Hemp in different European countries

THC content less than

0.2 % (EU)

0.3 % (Austria, Czechia, other)

1.0 % (Switzerland)

depending the **country's regulatory framework.**

UNODC testing protocol

$$\frac{[\text{THC}] + [\text{CBN}]}{[\text{CBD}]} = X$$



Medicinal Cannabis

$X < 1$ ✓ **Fiber type**

$X > 1$ ✗ **Drug type**

[THC] Area of THC in the chromatogram



What is a CBD-Oil and what should it be ?

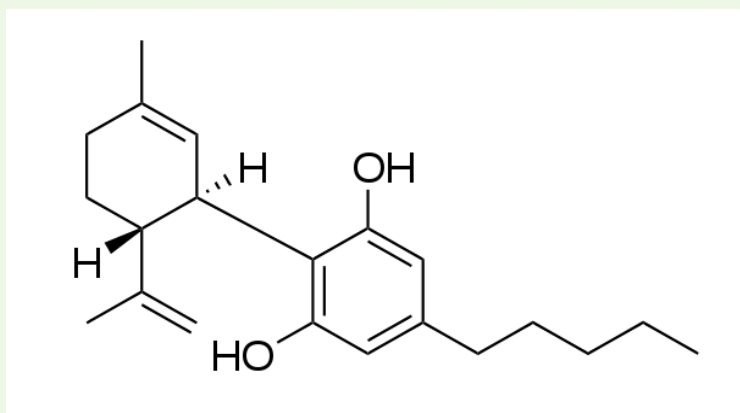
General definition:

An extract from industrial hemp (EU-listed varieties) of the aerial parts of the *Cannabis sativa* plant, either further processed or not, diluted in a vegetable oil and standardised to a certain CBD-content.

Intended use:

e.g. as/in a food supplement; as a flavouring preparation.

(-)-trans-Cannabidiol:



CAS Reg-No.:

13956-29-1

Chemical formula:

$C_{21}H_{30}O_2$

Molar mass 314.5 g/mol

What is a CBD-Oil and what should it be ?

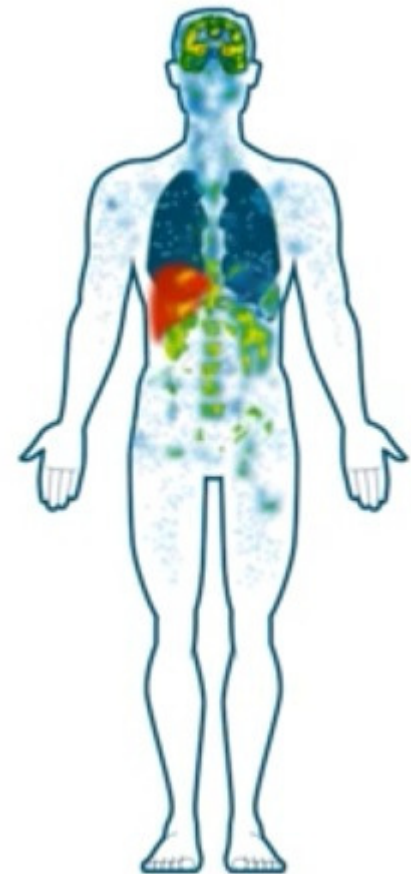
General manufacturing procedure (example):

1. **Growing** of industrial hemp (EU-certified varieties, THC max. 0.2 %);
2. **Harvesting:** fibre, seeds, remainder (“green matter”) => triple use;
3. **Drying** of green matter (best not exceeding 40°C);
4. **Extraction** of green matter (with CO₂ or other solvents acc. to Dir. 2009/32/EC)
=> product of extraction is a “primary extract”
containing as cannabinoids CBDA and CBD, THCA and THC in concentrations depending on extract ratio and work-up after extraction;
adjustment to desired concentration.
product example: 5 % CBD/CBDA-tincture (alcoholic).
5. Removal of solvent if necessary
6. Decarboxylation by heating (> 100°C)
=> product of complete decarboxylation is a thick dry extract;
7. Dilution with vegetable oil for adjustment to desired concentration
product example: 3 % CBD in vegetable oil (preferred: hemp seed oil),
THC-content max. 0.2 %.
8. Quality control for compliance with EU food laws (e.g. contaminants).

Why are Hemp CBD Extracts Beneficial to Health ?

- ☐ Cannabidiol or CBD was first isolated by a team of chemists at the University of Illinois back in 1940 (Adams).
- ☐ Its structure was elucidated in 1963 (Mechoulam et al.).
- ☐ CBD is the most abundant cannabinoid present in industrial hemp and is non-psychoactive and non-intoxicating, neither is CBDA.
- ☐ Hemp CBD extracts provide important substances* with physiological effects to our body, they could be assigned health claims (to be applied for):
 - ☐ contribute to the protection of cells from oxidative stress (as for example, Vitamin C , Vitamin E or Olive Oil Polyphenols)
(see Hampson et al. Proc. Natl. Acad. Sci. USA, 95, 8268-73, 1988)
 - ☐ contribute to the normal functioning of the nervous system
 - ☐ contributes to the normal function of the immune system

*Cannabinoids, (poly)unsaturated fatty acids (as triglycerides), terpenes, bioflavonoids, phytosterols, chlorophyll (depending on process of preparation, inter alia).



What is a CBD-Oil and what should it be ?

Product quality and composition:

1. Extracts vary widely in their composition

2. Composition depends on **many factors**:

- hemp variety used, and climate,
- parts of the plant used (i.e. whole aerial plant, upper 1/3, or leaves only)
- manufacturing method (e.g. type of extraction, its selectivity, further processing by decarboxylation,...)
- dilution (standardisation to a certain concentration of CBD)

3. **Most important factor is heat treatment during processing:**

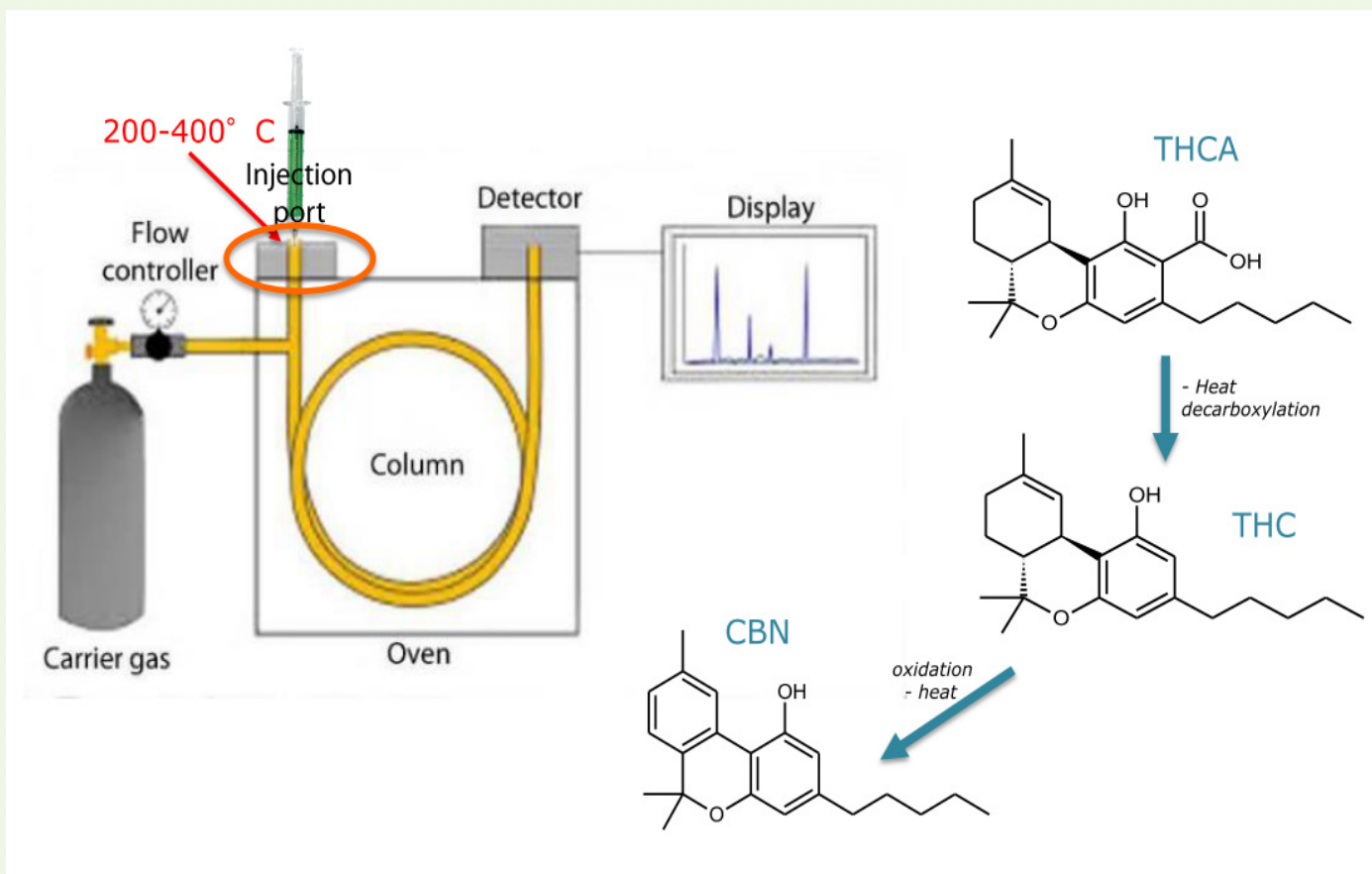
Remember: fresh plant contains up to 90% of the main cannabinoids in the form of their corresponding acids (CBDA, THCA)

=> primary extracts (no heat treatment) have very low Δ 9-THC levels, i.e. the remainder of total THC is present as THCA (to be analysed by HPLC).

$$[\text{measured total THC} = \Delta\text{9-THC} + 0.877 * \text{THCA}]$$

What is a CBD-Oil and what should it be ?

- ❑ **Decarboxylation** occurs on heating of the green matter or of any processed material, hence also in gas chromatographic analysis (GC).
- ❑ There is no enzymatic (biochemical) pathway from THCA to THC.
- ❑ **THCA is not converted to THC in the human body.**
- ❑ **THCA is not psychotropic !**



What is a CBD-Oil and what should it be ?

How much CBD and THC does a CBD-Oil contain ?

Total-CBD-content in raw biomass of EU-registered varieties is between **1 and 5 %** depending the variety and climate.
This is the **naturally occurring level** of total CBD.

In hemp extracts which have not been enriched by addition of pure CBD, the **ratio of concentrations of CBD and THC vary within a certain range.**

Reason:

- ➔ the EU listed hemp varieties which are suitable for triple use, have a ratio of CBD/THC in between 15 and 60, i.e.
- ➔ total CBD-content is between 15 and 60 fold the content of total THC (the ratio may be spread up to 70 without adding pure CBD).

What is a CBD-Oil and what should it be ?

How much CBD and THC does a natural CBD-Oil contain ?

Case No.	Bottle size [ml]	Bottle size [mg]	CBD:THC (total) ratio	Substance	Concentration	In Bottle [mg]	Daily [mg]	CBD-Oil mg/d
1	10	9.200,00	20	CBD	3,00%	276	8	267
				Delta9-THC	0,15%	13,8	0,4	
				THCA	0,00%	0	0	
2	10	9.200,00	55	CBD	2,75%	253	20	727
				Delta9-THC	0,05%	4,6	0,36	
				THCA	0,00%	0	0	
3	10	9.200,00	50	CBD	5,00%	460	20	400
				Delta9-THC	0,05%	4,6	0,2	
				THCA	0,05%	4,6	0,2	

PART 2

Proposal on Regulatory Framework for CBD-containing Extracts

What is a CBD-Oil and what should it be ?

How much THC should be admissible in food supplements ?

Regulatory proposal for food supplements*:

- 1) maximum level of $\Delta 9$ -THC
in food supplements from industrial hemp: 0.2 weight-%**
- 2) Maximum daily intake must not exceed the Acute Reference Dose
of 7 μg of $\Delta 9$ -THC per kg of body weight.**
For the average adult (70 kg b.w.) this is max. 490 μg of $\Delta 9$ -THC per day.**

Prerequisites:

- ☐ *Clear directions for use (maximum daily intake) on label.*
- ☐ *Do not exceed recommended daily dose.*
- ☐ *Not recommended for pregnant or nursing women, and women intending to become pregnant, or organ transplant recipients.*
- ☐ *For adults only over age of 18.*
- ☐ *Store in a cool and dry place.*

* Regulatory proposal for general foods: see EIHA's THC Position Paper

** For comparison: EFSA(2015) derived an ARfD of 1 μg $\Delta 9$ -THC /kg b.w., and Geiwitz (Canada, 2001) derived a TDI of 14 μg $\Delta 9$ -THC /kg b.w..

What is a CBD-Oil and what should it be ?

How to fit EIHA's proposal into a legal framework:

1) maximum level of Δ 9-THC*

in food supplements from industrial hemp: 0.2 weight-%

Could be implemented into Commission Regulation (EC) No 1881/2006

(setting maximum levels for certain contaminants in foodstuffs),

Annex, Section 8: Inherent plant toxins (as e.g., Erucic acid, and Tropane alkaloids)

2) Maximum daily intake must not exceed 7 μ g of Δ 9-THC per kg of body weight.

For the average adult (70 kg b.w.) this is max. 490 μ g of Δ 9-THC per day.

=> Guidance.

- * setting a limit for Δ 9-THC (not total-THC) we follow the logic of EFSA deriving an ARfD for Δ 9-THC only, and the Commission Recommendation (EU) 2016/2115 on the monitoring of the presence of Δ 9-THC, its precursors (e.g. THCA), and other cannabinoids in food.

EIHA's Three-tier Regulatory Proposal for CBD

Scientific literature shows that pharmacological activity for a wide variety of effects of CBD in clinical studies is not observed under approx. 200 mg oral/d for an average adult.

(Devinsky et al., 2014; dos Santos et al., 2014; Food Standards Australia P1042; Friedman et al., 2015; Hill et al., 2012, Iffland et al., 2016; Schubart et al., 2013)

Proposed use of *Cannabidiol* and/or CBD-rich hemp extracts based on **daily oral dose of CBD equivalent** for an average adult.

Daily dose per average adult	Proposed use
Over 200 mg	As active ingredient in medicinal products with or without prescription.
Between 20 – 160 mg	Should be freely available as food supplements (such as valerian or hop pills, silymarin, glucosamine or Ginkgo Biloba). Extract to be standardised to CBD content.
Less than 20 mg	Should be allowed in food products without any restrictions.

Thank you !

Questions & Answers

European Industrial Hemp Association