


Safety Data Sheet

Product name: 5% Natural CBD+CBDA in MCT
Product code: CBD-OIL-5-NAT-MCT

SECTION 1: Identification of the substance/mixture and of the company/undertaking	
1.1.	Product identifier
	Trade name: NATURAL oil CBD+CBDA 5 % in MCT oil
	Main component: Cannabis sativa extract, MCT oil
	Constituent name: 2-[[1R,6R)-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol Cannabidiol, CBD
	Chemical name: /
1.2.	Relevant identified uses of the substance or mixture and uses advised against
	Uses: Industrial use; Intermediate
	Uses advised against: Bulk product
	Reason why uses advised against: None
1.3.	Details of the supplier of the safety data sheet
	Supplier: CBD Oil Europe
	Address: Voltaweg 11D, 4382 NG Vlissingen, the Netherlands
	Telephone number: +31 (0) 64 0690002
	e-mail of competent person: info@cbdoileurope.com
	Production: Croatia
	Brand: NATURAL oil
1.4.	Emergency telephone number
	National Protection and Rescue Directorate: (EU) 112
	Medical information: SZT (CRO) +385 98 405 636
	Other information:
SECTION 2. Hazards identification	
2.1.	Classification of the substance or mixture
2.1.1.	Classification according to Regulation (EC) No 1272/2008 (CLP)
	Hazard pictograms
	 GHS08
	Signal word: <i>Warning</i>
2.1.2.	Additional information
2.2.	Label elements/ Labelling according to Regulation (EC) No 1272/2008 [CLP]

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Product identification:	2-[(1R,6R)-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol Cannabidiol, CBD CAS:13956-29-1
Cosmetic Ingredients Database (EU)	Cannabidiol, CBD
CAS No. of the mixture:	Not assigned
EC No. of the mixture:	Not assigned
HS code of the mixture:	1302 19 (Vegetable saps and extracts)
Hazard statement:	
	H361 Suspected of damaging fertility or the unborn child.
Precautionary statement:	
	P201 Obtain special instructions before use.
	P202 Do not handle until all safety precautions have been read and understood
	P233 Keep container tightly closed
	P264 Wash skin thoroughly after handling
	P273 Avoid release to the environment
	P280 Wear protective gloves/ eye protection /face protection
	P370 In case of fire, use chemical foam, carbon dioxide

2.3. Other hazards
 The mixture does not meet the criteria for PBT or vPvB substances in accordance with Annex XIII of Regulation (EC) No 1907/2006 [REACH].

SECTION 3. Composition/information on ingredients

CAS No./EC No. Index number	REACH Registration No	Conc. % content (or range)	Identification name	Classification according to Regulation (EC) No 1272/2008 (CLP)
None	None	5,00-6,67	Cannabis sativa extract - Natural	Not classified
CAS: 73398-61-5/ 65381-09-1 EC: 277-452-2/ 265-724-3	None	93,33-96,00	MCT oil	Not classified

SECTION 4. First aid measures

4.1. Description of first aid measures

General notes: In case of any health problems after product contact (eyes, skin, aspiration, ingestion) consult a medical doctor and show this Safety Data Sheet.

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	Following inhalation:	If symptoms of overexposure are experienced, move to fresh air. Rinse mouth and throat with plenty of water. Provide medical treatment if irritation, dyspnoea/shortness of breath or other symptoms should persist.
	Following skin contact:	In case of exposure of clothes to product, remove contaminated clothes. Wash affected area with soap and water. If irritation or rash develops, seek medical attention.
	Following eye contact:	Rinse eyes with water. If irritation persists, seek medical attention.
	Following ingestion:	Rinse mouth and throat with plenty of water. Drink plenty of water. If person feels unwell seek medical advice immediately and provide this Safety Data Sheet.
	Self-protection of the first aider	In case larger amounts of product vapours should have produced protect yourself with a particle-filtering face mask. Take off contaminated clothes after first aid and wash with plenty of water and liquid soap.
4.2.	Most important symptoms and effects, both acute and delayed	
	Following inhalation:	Cough, shortness of breath.
	Following skin contact:	On long-term exposition there may be redness, itching, rash.
	Following eye contact:	There may be redness, discomfort, watering.
	Following ingestion:	Large amounts could cause nausea, vomiting, and irritation of the throat.
4.3.	Indication of any immediate medical attention and special treatment needed	
	The mixture and the Cannabidiol contained is lipophilic and nearly not soluble in water. To prevent extended absorption of CBD in the digestive tract after oral uptake, the affected person should refrain from eating any fats or oils for at least 24 hours after ingestion.	
	Quantities of up to 1500 mg of CBD per day are well tolerated by adults.	
	Acute toxicity is so low that it needs not to be classified accordingly.	
	If any treatment is needed, this should be symptomatic.	
SECTION 5. Firefighting measures		
5.1.	Extinguishing media	
	Suitable extinguishing media:	Small fire: Use fire extinguishing methods suitable to surrounding conditions CO ₂ , powder, or foam. Large fire: Use water spray or alcohol resistant foam. Treat as for vegetable oils.
	Unsuitable extinguishing media:	Water with full jet.
5.2.	Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Smoke is produced in a fire, with potential production of carbon monoxide and carbon dioxide (immediately toxic gases). Inhalation of hazardous degradation products (such as small soot particles from pyrolysis) may cause serious health damage (fume poisoning).

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5.3.	Advice for firefighters	
	Wear self-contained breathing apparatus for firefighting and full protective gear if necessary.	
5.4.	Additional information	
	No data available.	
SECTION 6. Accidental release measures		
6.1.	Personal precautions, protective equipment and emergency procedures	
6.1.1.	For non-emergency personnel	
	Protective equipment:	For personal protection see SECTION 8
	Accident prevention methods:	No special measures, spill area may be slippery.
	Emergency procedures:	Avoid inhaling vapours of the melt and provide adequate ventilation (e.g. local exhaust ventilation).
6.2.	Environmental precautions	
	See SECTION 12 for additional Ecological Information.	
6.3.	Methods and material for containment and cleaning up	
	Keep in suitable, closed containers for disposal	
6.3.1.	Bonding, covering of drains; capping procedures:	Prevent product run-off into the environment. Spilled product should be covered with suitable (non-flammable) absorption material (e.g. sand, diatomaceous earth or other).
6.3.2.	Cleaning up:	Collected material should be disposed of in accordance with locally valid regulations. After removal of the spilled product use plenty of water and soap for emulsification.
6.3.3.	Other information:	Upon escape of large amounts of product inform the Fire Department and the Environmental Department of the Municipal Authority.
6.4.	Reference to other sections	
	See SECTION 13 for Disposal.	
SECTION 7. Handling and storage		
7.1.	Precautions for safe handling	
7.1.1.	Protective measures	
	Provide appropriate exhaust ventilation at storage and at the workplace.	
	Avoid contact with eyes, skin and clothing, do not inhale. Wear appropriate protective equipment. During work do not eat, drink or smoke.	
	Normal measures for preventative fire protection.	
7.1.2.	Advice on general occupational hygiene	
	Handle in accordance with good industrial, hygiene and safety practice.	
7.2.	Conditions for safe storage, including any incompatibilities	

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	Technical measures and storage conditions:	Keep in original container tightly closed in dry and well-ventilated place. Recommended storage temperature not exceeding 30 °C. Protect the mixture against direct sun light and heat.
	Packaging materials:	Containers made of glass, high density polyethylene (HDPE), polypropylene (PP), polyamide (PA), polytetrafluoroethylene (PTFE), ceramics, stainless steel, or aluminium with wide opening and tight seals. Use compatible packaging materials throughout for the uses, also fulfils the requirements for packaging of cosmetic end products. To avoid migration of undesired substances from the (plastics) packaging into the mixture, food compatible packaging material should be chosen.
	Advices for storage equipment:	None
	Further information on storage conditions:	Keep away from heat/sparks/open flames/ hot surfaces – no smoking. Avoid contact with strong bases (alkaline substances) and with strong acids.
7.3.	Specific end use(s)	
	Recommendations:	Use in accordance with good manufacturing and industrial hygiene practices.
SECTION 8. Exposure controls/personal protection		
8.1.	Control parameters	
8.1.1.	Occupational exposure limits:	There are no established occupational exposure limits for the mixture or the main constituent Cannabidiol.
8.1.2.	DNEL/PNEC-values:	There are no established values for the products with Cannabidiol (CBD). A No Observed Effect Level (NOEL) for Cannabidiol could be derived as ≥ 0.32 mg CBD oral / kg body mass from a human preclinical study
8.2.	Exposure controls	
8.2.1.	Appropriate engineering controls	
		Avoid inhaling vapours of the melt and provide adequate ventilation (e.g. local exhaust ventilation).
8.2.2.	Personal protection equipment	
8.2.2.1.	Eye and face protection:	Wear standard safety glasses.
8.2.2.2.	Skin and hand protection:	In case of contact, wear suitable gloves. Change gloves in accordance with manufacturer's recommendations. If gloves are damaged during use, remove immediately and wash hands before replacing with new gloves. Laboratory coat or coverall should be worn to avoid skin contact.

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8.2.2.3.	Body protection:	The type of protective equipment must be selected according to the concentration and amount of the substance at the specific workplace.
8.2.2.3.	Respiratory protection:	Respiratory protection not required for handling of the mixture with efficient local exhaust ventilation. In a poorly ventilated environment wear respiratory mask for handling of the melt.
8.2.2.4.	Thermal hazards:	None
8.2.3.	Environmental exposure controls	
	Prevent product run-off to surface water or drains.	
	Control and change filters or absorption fluids of ventilation or absorption systems on a regular basis and provide for disposal of contents / containers to an authorised chemical waste disposal contractor only.	

SECTION 9. Physical and chemical properties

9.1.	Information on basic physical and chemical properties		
	Parameter	Value	Remark
	Appearance/form:	Thick, viscous liquid	
	Colour:	Dark yellow/ light brown liquid	
	Odour:	Flower odour / nutty, bitter taste	
	pH:	No data available	
	Melting point / freezing point;	No data available	
	Initial boiling point and boiling range:	Will degrade > 100 °C	experimental
	Flash point:	> 200 °C	experimental
	Evaporation rate:	No data available	
	Flammability (solid, gas):	No data available	
	Upper/lower flammability or explosive limits:	No data available	
	Vapour pressure:	< 0,1 mbar at 150 °C	experimental
	Vapour density:	No data available	
	Relative density	< 0.95 based on oil	experimental
	Bulk density:	No data available	
	Solubility(ies):	< 10 mg/l based on oil	estimated
	Partition coefficient: n-octanol/water (log Kow):	No data available	
	Auto-ignition temperature:	No data available	

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	Decomposition temperature:	> 200°C	estimated	
	Viscosity:	at 20 °C, 25 – 33 mPa s,	estimated	
	Explosive properties:	Not classified as explosive		
	Oxidising properties:	Not classified as oxidising		
9.2.	Other information			
	Practically insoluble in water, soluble in Ethanol, Methanol, vegetable fats.			
SECTION 10.: Stability and reactivity				
10.1.	Reactivity	In strongly basic media and the presence of air, Cannabidiol (CBD) is oxidized to a quinone. With strong acids it reacts to give a complex mixture of cannabinoids.		
10.2.	Chemical stability	Stable under recommended storage conditions.		
10.3.	Possibility of hazardous reactions	Hazardous polymerisation will not occur. Avoid contact with incompatible materials (see SECTION 10.5).		
10.4.	Conditions to avoid	Light, heat, moisture.		
10.5.	Incompatible materials	Strong oxidizing agents.		
		Strong reducing agents.		
		Strong base, strong acid.		
10.6.	Hazardous decomposition products	None known.		
SECTION 11. Toxicological information				
11.1.	Information on toxicological effects			
	<p>Studies in animals indicate that a large portion of the administered CBD is excreted intact or as its glucuronide. Due to extensive Phase I metabolism, the pharmacokinetics of CBD is complex, and the bioavailability of oral CBD is low across species.</p> <p>The most abundant metabolites are hydroxylated 7-COOH-derivatives of CBD that are excreted either intact or as glucuronide conjugates.</p>			
11.2.	Acute toxicity			
	There are no data available on acute oral toxicity for this mixture.			
	Data on acute oral toxicity for main constituent Cannabidiol (animal test):			
Study ID	Species	Use dose	Exposure time	Results

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GWTX150 3 BioA	CD1 Mice/12	0-300 mg/kg/day	13-week	The NOAEL was 400 mg/kg/day for male (Cmax AUC value of 6420 ng/mL and 37800 ng h/mL) and 550 mg/kg/day for female (Cmax AUC value of 8440 ng/mL and 41200 ng h/mL).
GWTX150 3 BioA	Wistar Rat/10	0-150 mg/kg/day	26-week + 4 weeks recovery	The NOAEL of 150 mg/kg/day for male (Cmax AUC value of 6160 ng/mL and 60000 ng /mL) and for female (Cmax AUC value of 7530 ng/mL and 67500 ng h/mL).
GWTX150 3 BioA	Beagle dogs/4- 6	0-100 mg/kg/day	39-week+ 4 weeks recovery	The NOAEL of 100 mg/kg/day for male (Cmax AUC value 20500 ng /mL) and for female (Cmax AUC value of 22400 ng h/mL).
EMA, Epidyolex, EMEA/H/C/004675/0000, 2019.				
11.2.1. Assessment/Classification				
The mixture does not meet the criteria for acute toxicity.				
11.3. Irritation and corrosion				
May give mild skin irritation, but not classified as irritant.				
11.3.1. Assessment/Classification				
Classification criteria are not met.				
11.4. Serious eye damage / irritation				
May be mildly irritant to the eye, but not classified as irritant.				
11.4.1. Assessment/Classification				
Based on available data, the classification criteria are not met.				
11.5. Respiratory or skin sensitisation				
Plant extract may produce an allergic reaction to the skin of some individuals.				
11.5.1. Assessment/Classification				
Based on available data, the classification criteria are not met.				
11.6. CMR effects (carcinogenicity; mutagenicity; reproductive toxicity)				
Summary of evaluation of the CMR properties;				
There is no data available on CMR effects of product.				

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	There is data available for a Cannabis sativa extract with a higher content in CBD (a biological drug substance containing 69% of Cannabidiol): with that substance four genotoxicity assays have been conducted: AMES test (bacterial mutation assay), mouse mammalian cell mutation assay (mouse lymphoma), the mouse micronucleus assay, and the unscheduled DNA synthesis assay, which all produced negative results. At the concentrations tested, there were no genotoxic effects.					
	<i>(Product Monograph Sativex®, GW Pharma Ltd., Cambridge, UK, Control N: 149598, date of Revision: March 31, 2015).</i>					
11.6.1.	Carcinogenicity					
	There are no reports on carcinogenic effects of the product. A biological substance (Cannabis sativa extract) containing 69% of Cannabidiol was evaluated in a 2-year carcinogenicity study in rats (GW Study No JJG003) with 15 and 50 mg/kg/d. There was no indication of carcinogenic potential.					
11.6.2.	Mutagenicity					
	Cannabidiol was evaluated in a range of in vitro and in vivo standard genotoxicity assays.					
In vitro mutagenicity / genotoxicity of Cannabidiol:						
	Cell type / Organism	Genetic Endpoint	Result / Evaluation	Remark		
	Fischer rat embryo (RLV/1706) cells	Cell transformation, viral enhanced (CTR-)	negative	Genetox Record No: 3129		
	Mammalian polychromatic erythrocytes	Micronucleus test, chromosome aberrations (MNT+)	positive	Genetox Record No: 3129		
	Human lymphocytes	Sister chromatid exchange (SCE) in vivo (SCY+)	positive	Genetox Record No: 3129		
In vivo mutagenicity / genotoxicity of Cannabidiol:						
	Effect dose/-concentration	Value	Cell type/ Organism	Genetic Endpoint	Result/ Evaluation	Remark
	n.a.	n.a.	Male mouse	Sperm morphology (SPI-)	negative	Genetox Record No: 3129
	The genotoxic potential of CBD has been evaluated in a standard test battery of in vitro and in vivo assays according to ICH S2(R1). All tests concluded CBD to be negative for genotoxic potential.					
11.6.3.	Reproductive toxicity					
	There is no data available on reproductive toxicity effects of this mixture.					
	Animal data on the main constituent Cannabidiol (CBD): Adverse effects of Cannabidiol on sexual function and fertility:					

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Study type/ Study ID	Species; number group	Route & dose	Dosing period	Major findings	NOAEL (mg/kg)
Male fertility GWTX1456/GLP	Wistar rat /20	75-250 mg/kg/day	2 weeks prior to pairing up to review of female pregnancy data	No effects on male reproductive organ weights	250 mg/kg/day
Female fertility GWTX1456/GLP	Wistar rat /20	75-250 mg/kg/day	2 weeks prior to pairing up to GD 6	No effect on female reproductive indices, female oestrus cycling or pregnancy parameters	250 mg/kg/day
Embryo-foetal development GWTX1455/non GLP	Wistar/6 DRF study	150-300 mg/kg/day	GD6 to 17	300 mg/kg/day: One dead rat, weight loss of 32% of controls. Increased preimplantation loss at 300 mg/kg/day. No adverse effects at lower doses	F0:250 mg/kg/day F1:250 mg/kg/day
Embryo-foetal development GWTX1454/GLP Bioanalysis & TK: non-GLP	Wistar /20	75-250 mg/kg/day	GD6 to 17	Complete litter loss of 2/20 dams at 250 mg/kg/day	F0:150 mg/kg/day F1:150 mg/kg/day
Embryo-foetal development DRF GWTX1453/ Non-GLP	Rabbit/6	50-125 mg/kg/day	GD7 to 19	Body weight loss compared to controls	DRF study NA
Embryo- foetal development DRF GWTX1452/ GLP	Rabbit /22	50-125 mg/kg/day	GD7 to 19	Unossified metacarpal, bulging eyes, and nonerupted incisors) were considered to be secondary to the reduced fatal weights at 125 mg/kg/day.	F0:80 mg/kg/day F1:80 mg/kg/day
Pre & postnatal development GWTX1532/GLP	Rat/22	75-250 mg/kg/day	GD6 to LD21	F1 males: Small testes F1 female: Reduced fertility indices	F0:250 mg/kg/day F1:75 mg/kg/day

EMA, Epidyolex, EMEA/H/C/004675/0000, 2019.

Assessment / Classification	
No human data on the effect of CBD on fertility are available. No effect on reproductive ability of male or female rats was noted with an oral dose of up to 150 mg/kg/day CBD	
11.6.4.	Specific target toxicity – single exposure (STOT SE1 and 2)
	CBD induces liver injury

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	Liver toxicity has been systematically monitored and may occur. These toxicity appear to be due to a direct hepatocellular effect of CBD-OS or its metabolites.	
	Committee on toxicity of chemicals in food, consumer products and the environment TOX/2020/02	
11.6.5.	Narcotic effects	
	CBD is not listed in the Single Convention on Narcotic Drugs, UN, 1961, as amended. CBD does not exert narcotic effects.	
	Assessment / Classification	
	The product does not have narcotic effects.	
11.6.6.	Aspiration hazard	
	Practical experience / human evidence: No data available	
	Assessment / Classification	
	Based on available data, the classification criteria are not met.	
11.2.	Practical experiences	
	Classification observations:	No information available
	Other observations:	
11.3.	General notes	
SECTION 12. Ecological information		
12.1.	Toxicity	
	Aquatic toxicity	
	There is no experimental data on short-term or long-term aquatic toxicity of the mixture.	
	The main constituent Cannabidiol is nearly insoluble in water, this also applies to the glycerides (fats) present in the mixture. Therefore, accumulation by dissolution in surface waters is not probable.	
	Assessment / Classification:	
	No classification no data available	
12.2.	Persistence and degradability	
	There is no experimental data on persistence or biodegradability.	

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	The product is composed of naturally occurring plant oils and is expected to be ultimately biodegradable.
12.3.	Bio accumulative potential
	There is no experimental data on bioaccumulative potential.
12.4.	Mobility in soil
	There are no experimental data on mobility in soil.
12.5.	Results of PBT and vPvB assessment
	Not required (for Chemical Safety Report only). This product does not meet the PBT/vPvB criteria of REACH, Annex XIII.
12.6.	Other adverse effects
	No data available

SECTION 13. Disposal considerations

13.1.	Waste treatment methods
	Recovery and recycling are not possible. Incinerate or dispose of in accordance with local regulations.
13.1.1.	Product/Packaging disposal
	Dispose of packaging material as low-hazard packaging waste within scope of local regulations.
13.1.2.	Other disposal recommendations
	Do not empty unused product into drainage systems.
	The product must not be disposed of with municipal waste.
	Empty containers must be used at waste incinerators (plastic) to produce energy or deposited in a dump with appropriate classification.
	Perfectly cleaned containers may be submitted for recycling.

SECTION 14. Transport information

	Transporting/shipment	
14.1	UN number:	
	AND	None
	ADR/RID	None

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	ICAO-TI/IATA-DGR	None
	IMDG	None
14.2	UN proper shipping name:	
	AND	Not dangerous goods
	ADR/RID	Not dangerous goods
	ICAO-TI/IATA-DGR	Not dangerous goods
	IMDG	Not dangerous goods
14.3	Transport hazard class(es):	
	AND	None
	ADR/RID	None
	ICAO-TI/IATA-DGR	None
	IMDG	None
14.4	Packing group:	
	AND	None
	ADR/RID	None
	ICAO-TI/IATA-DGR	None
	IMDG	None
14.5	Environmental hazards:	
	AND	None
	ADR/RID	None
	ICAO-TI/IATA-DGR	None
	IMDG	None
14.6	Special precautions for user:	
	Not dangerous goods in the meaning of transport regulation	
Further information:	Store, cooled, at dry and dark place.	
	Protect from direct light and heat.	
	Keep out of reach of young children.	
	The product should be transported in well closed containers or drums in closed and clean trucks.	
SECTION 15. Regulatory information		

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15.1.	Safety, health, and environmental regulations/legislation specific for the substance or mixture	
	Authorisations: Not required for professional use.	
	Restrictions on use: None under professional use	
	Restrictions of occupation: None	
15.2.	Chemical safety assessment	
	A Chemical Safety Assessment under the EU REACH Regulation is not required for this product.	
SECTION 16. Other information		
16.1	Indication of changes:	
	This safety data sheet is the original version 2.0, dated 01. April, 2021.	
16.2	Abbreviations and acronyms	
	ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
	CAS	Chemical Abstracts Service
	CLP	Classification, Labelling, Packaging
	DNEL	Derived No Effect Level
	EC	European Community
	EU	European Union
	IATA-DGR	International Air Transport Association - Dangerous Goods Regulations
	ICAO-TI	International Civil Aviation Organization - Technical Instructions
	IMDG	Code International Maritime Code for Dangerous Goods
	LC	Lethal concentration
	LD	Lethal dose
	log KOW	Octanol-water partition coefficient
	NOAEL No	Observed Adverse Effect Level
	PBT	Persistent, Bioaccumulative, and Toxic
	PNEC	Predicted No Effect Concentration
	REACH	Registration, Evaluation, and Authorisation of Chemicals
	vPvB	very Persistent and very Bioaccumulative
	STOT	Specific Target Organ Toxicity (SE = Single Exposure, RE = Repeated Exposure)

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UVCB	Substances of unknown or variable composition, complex reaction products or biological
VOC	Volatile Organic Compounds
ANNEX: Exposure scenario resulting to Chemical safety assessment	
<p>The information provided in this Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed as a guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information in this document are applicable to the product regarding appropriate safety precautions. It does not represent any guarantee of properties of the product.</p> <p>This information must be made available to those who may encounter the material or are responsible for the use of the material. This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006 and described in CLP Regulation (EC) No 1272/2008.</p>	
<p>*Further information: Copyright 2021. License granted to make unlimited paper copies for internal use only. CBD Oil Europe and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.</p>	