

SAFETY DATA SHEET

Cannabidiol Oral Solution (Epidiolex) –100 mg/ml in
Sesame Oil

This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This information must be made available to those who may come into contact with 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.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1 Product identifier**
Cannabidiol Oral Solution –100 mg/ml in Sesame Oil
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Pharmaceutical product
- 1.3 Details of the supplier of the safety data sheet**
GW Pharmaceuticals,
Sovereign House, Vision
Park, Histon,
Cambridge CB24 9BZ, UK
- 1.4 Emergency telephone number**
Tel: +44 (0) 1795 431650 Hours: 0900h to 1730h Monday to Friday
ehss@g-pharm.com

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Flammable Liquid Category 2 H225 Highly flammable liquid and vapour

2.2 Label elements



Danger

- H225 Highly flammable liquid and vapour
P202 Do not handle until all safety precautions have been read and understood
P210 Keep away from heat/sparks/open flames/ hot surfaces – no smoking
P233 Keep contain tightly closed
P243 Take precautionary measures against static discharge
P370 In case of fire, use chemical foam, carbon dioxide P403
Store in a well ventilated place
P501 Dispose of contents / container as flammable laboratory waste in accordance with local/national regulations.

2.3 Other hazards

Possible narcotic effects in case of over exposure

Section 3 COMPOSITION**3.1 Substances**

Not applicable, the product is a mixture.

3.2 Mixtures

Concentrated cannabis extract (CBD) in mixture with vegetable oil, ethanol with sweetening and flavour

Name		Conc	Classification
2-[3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-Benzenediol [Cannabidiol]	EC not assigned CAS 13956-29-1	10%	Acute Toxic 4, H302 Aquatic Chronic 4, H413
Ethanol	CAS 64-17-5 EC 200-578-6 Index 603-002-00-5	7.9%	Flam Liq 2 H225 Eye Irrit. 2 H319
Sesame oil	CAS 8008-74-0 EC 232-370-6	82%	Not considered hazardous
Sucralose and flavour		< 0.1%	Not considered hazardous

Full H Statements are given in Section 16

SECTION 4: First Aid Measures**4.1 Description of first aid measures**

EYE CONTACT: Rinse eyes with water. If irritation persists, seek medical attention.

INHALATION: If symptoms of overexposure are experienced, move to fresh air and keep still.

SKIN CONTACT: Wash affected area with soap and water. If irritation or rash develops, seek medical attention.

INGESTION: Seek medical attention immediately. Vomiting may be induced under medical supervision.

4.2 Most important symptoms and effects, both acute and delayed

INGESTION: Nausea, narcotic activity

INHALATION: Dizziness

EYES: Redness, discomfort, watering

SKIN: Redness, itching, rash

4.3 Indication of any immediate medical attention and special treatments needed

Treat as for cannabis overdose.

SECTION 5: Firefighting Measures**5.1 Extinguishing media**

Use chemical foam, carbon dioxide. Treat as for vegetable oils.

5.2 Special hazards arising from the substance or mixture

Forms acrid fumes, carbon monoxide and carbon dioxide in a fire. May give off narcotic fumes.

5.3 Advice for fire fighters

Avoid inhalation of fumes. If feeling unwell, remove to fresh air and treat as for cannabis effects.

SECTION 6: Accidental Release Measures**6.1 Personal precautions, protective equipment and emergency procedures**

For cleaning spillage, gloves resistant to ethanol required. Spill area may be slippery.

6.2 Environmental precautions

Prevent run-off to surface water or drains.

6.3 Methods and materials for containment and clearing up

SMALL SPILLS (under 1 litre): Absorb onto cloth or mop and place contaminated materials in a suitable container for disposal. Wash area with water and if no risk for environmental contamination, use detergents.

LARGE SPILLS: (more than 1 litre) : Use absorbent materials suitable for oils products and place in suitable container for disposal as chemical waste. Coveralls and gloves resistant to oil products required.

6.4 References to other sections

See section 8 for further advice on protective equipment and section 13 for further advice on disposal.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Do not allow this material to come in contact with eyes. Avoid prolonged contact with skin. Use in well-ventilated areas with at least 3 air exchanges per hour. For laboratory use, handle under fume extraction hoods or in areas of laminar ventilation.

Take precautionary measures against static discharge

Do not store > 30°C

Employees should thoroughly wash hands with soap and water after handling this material.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed when not in use, and in a cool, dry place away from direct sunlight.

Keep away from heat/sparks/open flames/ hot surfaces – no smoking.

7.3 Specific end uses(s)

Only for use as research product or for medicinal uses

SECTION 8. Exposure Controls/Personal Protection

8.1 Control parameters

Component	CAS No	Value Form of Exposure	Control Parameters (WEL)	Basis
Cannabidiol	CAS 13956-29-1	TWA 8 Hour	500 µg/m ³	Safebridge Inc.
Ethanol	CAS 64-17-5	TWA 8 Hour	1000 ppm 1920 mg/m ³	EH40

8.2 Exposure controls

Engineering controls

Normal room ventilation is usually adequate (> 3 air exchanges per hour). For laboratory use, handle under fume extraction hoods or in areas of laminar ventilation.

Respiratory protection

Not normally required when handling in small quantities. If working in areas where spray can be formed or if handling at > 40°C, respiratory protective equipment is required suitable for the working conditions.

Hand Protection

In case of contact, wear gloves suitable for handling ethanol (nitrile or neoprene) or fat soluble materials. Change gloves in accordance with manufacturer's recommendations. If gloves are damaged during use, remove immediately and wash hands before replacing with new gloves.

Eye protection

Not normally required when handling in small quantities < 100 ml, but considered good practice.

When handling > 100 ml quantities, eye protection is recommended.

Skin protection

Laboratory coat or coverall should be worn to avoid skin contact.

General Hygiene Considerations

Wash hands thoroughly after handling. Launder protective clothing on regular basis and after contamination.

Environmental exposure controls

Precautions should be taken to avoid accidental release to water courses

SECTION 9: Physical and Chemical Properties**Information on basic physical and chemical properties Appearance: Yellow vegetable oil solution**

Odour:	Slight alcoholic smell
Odour threshold:	No data
pH:	Not applicable
Melting point:	Liquid at 0°C
Boiling point:	Will degrade > 100° C
Flashpoint:	Measured 18.5°C. Will support combustion
Evaporation rate:	No data
Flammability (solid, gas):	Liquid
Upper/lower flammability limits:	No data
Vapour pressure:	Ethanol component volatile
Vapour density	No data
Relative density	No data. Estimated < 0.95 based on oil
Solubility in water:	Estimated < 10 mg/l based on oil, but ethanol fraction soluble
Solubility in other solvents:	Miscible in a wide range of polar and hydrocarbon solvents
Partition coefficient (log Kow)	Estimated Log Kow > 3 for oil and CBC
Autoignition temperature	No data
Decomposition temperature	Considered > 100°C
Viscosity	More viscous than water
Explosive properties	Not classified as explosive
Oxidising properties	Not classified as oxidising

9.1 Other information

None

SECTION 10: Stability and Reactivity**10.1 Reactivity**

Not known to be dangerously reactive.

10.2 Chemical stability

Stable under normal 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

No specific conditions.

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological Information**11.1 Information on toxicological effects**

This product has not been tested. The active component is subject to medical research and is known to be biologically active at low concentrations.

(a) acute toxicity

Active CBD tolerated by humans orally 1500 mg/day
 Active CBD tolerated in mice 500 mg/kg/day over 14 days, dietary
 Cannabidiol oral solution 100 mg/ml not considered to be sufficiently harmful to require classification for supply.

(b) skin corrosion/irritation

May give mild skin irritation, but not classified as irritant.

(c) serious eye damage/irritation

May be mildly irritant to the eye, but not classified as irritant.

(d) respiratory/skin sensitisation	Plant extracts may produce an allergic reaction to the skin of some individuals Cannabidiol oral solution 100 mg/ml has given no indications of sensitising reactions during handling or use
(e) germ cell mutagenicity	The active component is not considered to be mutagenic from pre-clinical in-vitro testing.
(f) carcinogenicity	The components are not classified as a carcinogen by IARC There was no evidence that administration of CBD as CBD Botanical Drug Substance (BDS) influenced tumour formation at up to 50 mg CBD/kg/day in a 2 year rat dietary carcinogenicity study.
(g) reproductive toxicity	No indication of reproductive or teratogenic effects from data derived for pre-clinical testing of active component.
(h) STOT-single exposure	Not expected to cause systemic effects to organs on single exposure.
(i) STOT-repeated exposure	Not expected to cause systemic effects to organs on repeated exposure.
(j) aspiration hazard	Not applicable. Non-hydrocarbon.

Further information

This is an active form of a medicinal product that is known to have biological effects at low concentrations. Exposure must be avoided where possible.

SECTION 12: Ecological Information

This product has not been tested. Evaluation using EPISuite model has suggested that aquatic toxicity is unlikely within the limits of water solubility.

12.1 Toxicity

Active CBD not considered hazardous to aquatic organisms at the limit of solubility in water.
Oil and ethanol not considered harmful to aquatic organisms

12.2 Persistence and degradability

The product is composed of naturally occurring plant oils with ethanol and is expected to be ultimately biodegradable.
It is not considered readily biodegradable within the definition of meeting the 10-day window for 60%.

12.3 Bioaccumulative potential

Not expected to be bioaccumulative as this class of substance will metabolise.

12.4 Mobility in soil

Predicted to be of low mobility in soil, but will biodegrade

12.5 Results of PBT and vPvB assessment

There are no indications that this product contains substances likely to be classified as PBT/vPvB.

12.6 Other adverse effects

None

SECTION 13: Disposal Considerations**13.1 Waste treatment methods**

Recovery and recycling are not possible. Incinerate or dispose of in accordance with local regulations.

Dispose of packaging material as low-hazard laboratory or medical packaging waste within scope of local regulations.

SECTION 14: Transport Information

Not classified as dangerous goods, no labelling for transport is required when carried in accordance with Special Provision 601 (ADR).

	ADR	IMDG	ICAO
14.1 UN Number	1170	1170	1170
14.2 UN Proper shipping name	ETHANOL SOLUTION	ETHANOL SOLUTION	ETHANOL SOLUTION
14.3 Transport hazard class(es)	Class 3	Class 3	Class 3
14.4 Packing group	II	II	II
14.5 Environmental hazards	None	None	None
14.6 Special precautions for user	None	None	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	Not shipped in bulk	Not applicable

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product is considered to be a controlled substance as defined by the UK Controlled Drugs (Supervision of management and use) Regulations 2013

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product.

SECTION 16: Other Information

Revision information:

This is revision of previous SDS, formatted to meet Regulation (EU) No 2015/830

List of Abbreviations used in this SDS:

CAS Chemical Abstracts Service
 CBD Canabidiol
 CLP Classification, Labelling and Packaging Regulation (EC) no 1272/2008
 DSD Dangerous Substances Directive 67/548/EEC
 DPD Dangerous Preparations Directive 1999/45/EC
 EC European Community/Commission
 PBT Persistent, Bioaccumulative and Toxic
 REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
 UVCB Unknown, Variable Chemical or of Biological origin
 vPvB very Persistent, very Bioaccumulative

References:

EPISuite – US Environmental Protection Agency environmental modelling

Method used for classification of mixtures:

Ingredient based approach

H Statements used in Section 2 and/or 3

H225 Highly flammable liquid and vapour
 H302 Harmful if swallowed
 H319 Causes serious eye irritation
 H413 May cause long lasting harmful effects to aquatic life

Training requirements for workers

Those handling this material need to be fully aware of potential biological effects and symptoms of over-exposure