

**PRODUCT INFORMATION PACKET FOR
Broad Spectrum Hemp Oil Softgels**

Section 1. PRODUCT INFORMATION	
PRODUCT NAME & CODE:	Broad Spectrum Hemp Oil Softgels, 0.66g per softgel (10mg or 25mg CBD)
COMMON OR USUAL NAME OF PRODUCT:	Broad Spectrum Hemp Oil Softgels with phytocannabinoids; soft gelcaps
SCOPE OF DOCUMENT:	This document provides information specific to Broad Spectrum Hemp Oil Softgels
GENERAL PRODUCT INFORMATION:	Broad Spectrum Hemp Oil Softgels are gelatin encapsulating Broad Spectrum Hemp Oil (0.0% THC). The Broad Spectrum Hemp Oil (0.0% THC) is derived from the <i>Cannabis Sativa L.</i> plant, also known as Industrial Hemp.

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	Folium Biosciences, 615 Wooten Road Ste 110, Colorado Springs, CO 80915
AGRICULTURAL PROCESS:	Cultivated
MODE OF MANUFACTURING:	Formulation and Encapsulation
GMP COMPLIANCE:	Practicing GMP
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS:	Potential Sources: Microbial, Heavy Metals. No known sources.

Section 3. PHYSICAL/CHEMICAL INFORMATION				
INGREDIENT(S)				
COMMON OR USUAL NAME:	SYNONYM:	ORIGIN:	CAS NUMBER:	PERCENT:
POLYSORBATE 80	TWEEN 80	USA	9005-65-6	20-55%
POLYSORBATE 20	TWEEN 20	USA	9005-64-5	10-40%
FRACTIONATED COCONUT OIL/MCT Coconut Based USP/FCC	FCO/MCT	MALAYSIA	73398-61-5	2-30%
BROAD SPECTRUM HEMP OIL (0.0% THC)	CBD	USA	13956-29-1	4-14%
BETA-CARYOPHYLLENE	N/A	USA	87-44-5	0.1-10%
MELATONIN (OPTIONAL)	N/A	USA	73-31-4	0.1-5%
ROMAN CHAMOMILE OIL (OPTIONAL)	N/A	USA	8015-92-7	0.1-5%
CURCUMIN C3 COMPLEX (OPTIONAL)	CURCUMIN	INDIA	84775-52-0	0.2-10%
GELATIN SHELL: Bovine-derived Gelatin, Glycerin, Water, Artificial Coloring (Optional) which may contain Water, Sugar, U.S. Certified Blue 1, Yellow 5, Yellow 6, Blue 2, Red 40, Red 3, Modified Corn Starch, Vegetable Gum, Citric Acid, >1% Sodium Benzoate and Potassium Sorbate				
ASSAY METHOD:	UHPLC-DAD			

Section 4. LABELING INFORMATION	
RECOMMENDED RESTRICTIONS OF USE:	Not intended for children. Consult a physician if you have a pre-existing condition, are using any prescription medication, or if pregnant or nursing.
STORAGE:	Store in sealed container at room temperature, away from heat, light, or moisture at less than 50% relative humidity (RH). 18 months from date of manufacture under sealed conditions.

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915

Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com

Section 5. REGULATORY INFORMATION	
REGULATORY STATUS AND SUPPORTING DOCUMENTS:	USA: Broad Spectrum Hemp Oil Softgels are sold in USA under Federal Farm Bill 2018.
BBSE/TSE INFORMATION:	BSE/TSE questionnaire attached, Refer to Page 3
VEGAN OR VEGETARIAN STATUS:	Not Suitable for Vegan or Vegetarian
ALLERGENS/ HYPERSENSITIVITIES:	Allergen Statement is enclosed, Refer to Page 4
PRESERVATIVES (or PROCESSING AIDS):	Mineral Oil
KOSHER/HALAL/ORGANIC STATUS:	Kosher: No, Halal: No, Organic: No
GLUTEN and NON-GMO STATUS:	Gluten-Free: Yes, Non-GMO: No

Section 6. MISCELLANEOUS PRODUCT INFORMATION	
BATCH/LOT NUMBERING SYSTEM:	Product Code/Strength/Year/Sequential No.
BATCH DEFINITION:	GC2520-01: GC(C3/MEL): Product Code, mg of CBD (10 or 25): Strength, 20: Year, 01: Sequential Number
EXPIRATION DATING:	18 months from the date of manufacture under sealed conditions
PACKAGE SIZE(S):	Custom Bulk Amounts or Bottled
SDS ATTACHED:	Yes

Section 7. REVISIONS			
REVISION DATE:	31 MAR 2021	REVISION LEVEL:	QA-PIP-0004 REV2.0

Section 8. CONTACT INFORMATION			
COMPANY NAME:	Folium Biosciences		
CONTACT:	Quality Assurance Department		
CONTACT PHONE:	7195742159	EMAIL:	quality@foliumbiosciences.com

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915

Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com

BSE AND TSE QUESTIONNAIRE
Broad Spectrum Hemp Oil Softgels

1. Is the product partly or fully of animal origin? (i.e., tissue, tissue extract or fluid such as milk, serum, blood etc.)

Yes (Please specify): Limed bovine gelatin No

2. Are any materials of animal origin used as starting material or in the manufacturing process of the product?

Yes (Please specify): Gelatin No

3. Is the product derived from Microbiological or cell culture fermentations?

Yes (Please specify) No

If Yes, are any components used in the media culture derived from animal origin?

Yes (Please specify) No

4. Is the product purified using chromatography media (e.g., specific ligand columns) or buffers that contain components of animal origin?

Yes (Please specify) No

5. Is any of the equipment used for processing or storage of the product in contact at any time with other materials of animal origin?

Yes (Please specify) No

6. Is the product, for any other reason, at any time, in contact with materials of animal origin?

Yes (Please specify) No

This is to certify that our Broad Spectrum Hemp Oil Softgels are free from BSE (Bovine Spongiform Encephalopathy and TSE (Transpongiform Encephalopathy). The gelatin used in the Broad Spectrum Hemp Oil Softgels has a health certificate that meet all requirements to support this statement.

ALLERGENS AND INGREDIENTS LABELLING QUESTIONNAIRE

Broad Spectrum Hemp Oil Softgels

According to major food allergen specified in the US Federal law of Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and EU Directive 2003/89/CE amending Directive 2000/13/CE.

Allergen and/or Component	Present	Absent	If present, please specify ingredient(s)
Peanut or its derivatives, e.g., pieces, protein, oil, butter, flour, and such.		<input checked="" type="checkbox"/>	
Tree Nuts (almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, pistachios and walnuts or their derivatives, e.g., nut butters and oils, etc.		<input checked="" type="checkbox"/>	
Sesame or its derivatives, e.g., seeds, paste and oil etc.		<input checked="" type="checkbox"/>	
Milk or its derivatives, e.g., milk caseinate, whey, yogurt powder, etc.		<input checked="" type="checkbox"/>	
Egg or its derivatives, e.g., frozen yolk, egg white powder, egg protein isolates, etc.		<input checked="" type="checkbox"/>	
Fish or its derivatives, e.g., fish protein and extract, etc.		<input checked="" type="checkbox"/>	This product contains no allergens; processed in a facility that manufactures a product containing fish (cod)

Allergen and/or Comment	Present	Absent	If present, please specify ingredient(s)
Crustacean Shellfish (including crab, crayfish, lobster, prawn, and shrimp)		<input checked="" type="checkbox"/>	
Molluscan Shellfish (including snails, clams, mussels, oysters, cockle and scallops) or their derivatives, e.g., extracts, etc.		<input checked="" type="checkbox"/>	
Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates, etc.		<input checked="" type="checkbox"/>	
Cereals containing Gluten e.g., Wheat Barley, Rye, Oats, Spelt, Kamut, or their derivatives, e.g., flour, starches, etc		<input checked="" type="checkbox"/>	
Sulfur Dioxide and Sulfur concentrations of more than 10mg/kg or 10 mg/L expressed as SO ₂	<input checked="" type="checkbox"/>		This product contains sulfites
Celery or its derivatives		<input checked="" type="checkbox"/>	
Mustard or its derivatives		<input checked="" type="checkbox"/>	
Lupin (Lupinus Albus) and products thereof		<input checked="" type="checkbox"/>	

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915

Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com

SAFETY DATA SHEET
Broad Spectrum Hemp Oil Softgels

SECTION 1. PRODUCT NAME AND COMPANY IDENTIFICATION

Product Name: Broad Spectrum Hemp Oil Softgels
Product Use: Consumer Product
Company Name: Folium Biosciences
Company Address: 615 Wooten Road STE 110, Colorado Springs., CO 80915
Date Issued: 31Mar2021
Emergency Telephone Number: (719) 574-2159

SECTION 2. COMPOSITION/INGREDIENT INFORMATION

Ingredients: Polysorbate 80, Polysorbate 20, Fractionated Coconut Oil/MCT Coconut Based USP/FCC, Broad Spectrum Hemp Oil (0.0% THC), Beta-Caryophyllene, Melatonin and Roman Chamomile Oil, (Optional), Curcuminoids (Optional) Gelatin Shell: Bovine-derived Gelatin, Glycerin, Water, Artificial Coloring (Optional) which may contain Water, Sugar, U.S. Certified Blue 1, Yellow 5, Yellow 6, Blue 2, Red 40, Red 3, Modified Corn Starch, Vegetable Gum, Citric Acid, >1% Sodium Benzoate and Potassium Sorbate

Hazardous Components: None

CAS#: Polysorbate 80 9005-65-6
Polysorbate 20 9005-64-5
Fractionated Coconut Oil/MCT Coconut Based USP/FCC 73398-61-5
Broad Spectrum Hemp Oil (0.0% THC) 13956-29-1
Beta-Caryophyllene 87-44-5
Melatonin 73-31-4
Roman Chamomile Oil 8015-92-7
Curcuminoids 84775-52-0

SECTION 3. HAZARDS IDENTIFICATION

Routes of Entry: --
Eye Contact: Mild irritation may occur
Skin Contact: Mild irritation may occur
Ingestion: No known hazards
Inhalation: No known hazards

SECTION 4. FIRST AID MEASURES

Eyes: Flush with plenty of water or eyewash solution for 15 minutes. Get medical attention if irritation persists.

Skin: Wash with soap and water – get medical attention if irritation persists.

Ingestion: --
Inhalation: --
Medical Conditions: --
Generally Aggravated by Exposure: --

SECTION 5. FIRE FIGHTING MEASURES

Extinguishing Media:	Dry chemical, carbon dioxide, water fog, foam, water spray, water jet, sand/earth
Unsuitable Extinguishing Media:	N/A
Special Firefighting Procedures:	Wear proper protective equipment. Cool containers exposed to flame with water. Use air supplied equipment for fighting interior fires.
Unusual Fire & Explosion Hazards:	--
Special Hazards arising from the substance or its combustible products:	Combustible but no particular hazard. -- Hazardous decomposition products may be formed at extreme heat or if burned.
Resulting Gases:	Carbon oxides

SECTION 6. ACCIDENTAL RELEASE MEASURES (STEPS FOR SPILLS)

Personal precautions, protective equipment and emergency procedures: Equip clean crew with proper protection. Respiratory protection equipment may be necessary

Environmental precautions: Prevent entry to sewers and public waters.

Methods and materials for containment and cleaning up

Clean up any spills as soon as possible, using an inert, absorbent material to collect it. Use suitable disposable containers. Wash area with soap and water.

SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

Keep away from sources of ignition and open flame. No direct lighting. No smoking. Ensure prompt removal from eyes, skin and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and after handling. Handle in accordance with good industrial hygiene and safety procedures.

Storage Store in a cool, dry location, in a sealed container at room temperature.

Requirements for Storage container. Provide local exhaust or general room ventilation to minimize dust and/or vapor concentrations. Keep container closed when not in use.

SECTION 8. EXPOSURE CONTROL/PERSONAL PROTECTION

Eye:	Safety glasses should be worn.
Skin/Body:	Gloves should be worn.
Respiratory:	Not needed under normal conditions of use.
Other:	Evaluate need based on application. Slip proof shoes may be worn where spills may occur.
Work/Hygiene Practice:	Normal work and hygiene practices for handling non-hazardous liquid material.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Oval soft gelatin capsule
Color:	Various colors depending on type of soft gel
Phase:	Solid
Odor:	Characteristic
pH:	N/A
Vapor Pressure (mm Hg.):	N/A
Vapor Density (AIR = 1):	--

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915

Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com

Flash Point:	--
Specific Gravity (H ₂ O = 1):	--
Evaporation Rate:	--
Solubility in Water:	Soluble
Solubility in Oil:	Insoluble
Solubility in Alcohol:	Insoluble

SECTION 10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use
Incompatibility (Materials to Avoid):	Avoid strong oxidizers, store away from light
Conditions to Avoid:	--
Hazardous Decomposition or Byproducts:	None
Hazardous Polymerization:	Will Not Occur

SECTION 11. TOXICOLOGICAL INFORMATION

Oral:	Expected to possess a relatively low degree of oral toxicity
Dermal:	Expected to be practically non-toxic by dermal route
Inhalation:	N/A
Medical Conditions Generally Aggravated by Exposure:	--
Irritancy:	None
Skin:	Mild irritation may occur
Eyes:	Mild irritation may occur

SECTION 12. ECOLOGICAL INFORMATION

Biodegradation:	Ultimately Biodegradable
-----------------	--------------------------

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods:	Do not put into sewer lines. Dispose of according to local, state and federal regulations.
	--

SECTION 14. TRANSPORT INFORMATION

DOT Classification:	NA
Class/Division:	NA
Proper Shipping Name:	NA
Label:	None
Packing Group:	NA
ID Number:	NA
Hazard:	NA

SECTION 15. REGULATORY INFORMATION

Categorized as softgels produced from commercial hemp, under license from Colorado Department of Agriculture. Subject to Federal and State laws governing commercial or industrial hemp.

SECTION 16. ADDITIONAL INFORMATION

This information is provided for documentation purposes only. This product is not considered hazardous. The complete range of conditions or methods of use are beyond our control therefore we do not assume any responsibility and expressly disclaim any liability for any use of this product. Information contained herein is believed to be true and accurate however, all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.

This safety sheet cannot cover all possible situations, which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers.

DISCLAIMER

Any statements made in the document have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915


Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com

History of Change

Revision	Change	Reason for Change	Change Control #	Effective Date
1.7	Updated allergen statement; Updated ingredients and % ranges; storage, manufacturing and product information, remove information that does not apply to this document.	Allergen statement updated per FDA, EU and Canada regulations; Ingredients updated to reflect current formulation and % ranges used; storage manufacturing and product info updated to reflect an accurate representation of current product; legal information does not belong on this statement	CC12519	29Nov2019
1.8	Updated SDS, Folium heading, various formatting updates	Updates to match PIP of bulk ingredients for consistency	CC#05820	17Mar2020
1.9	Update contact information and changed document numbering	Contact listed is no longer with the company, document numbering updated to better control document revisions.	CC#11220	25Jun2020
2.0	Update Folium logo, Update Broad Spectrum Hemp Oil (0.0% THC) name throughout, Update Product Name, Revision Number, Revision Date	Consistency with other customer facing documents	CC#01321	31Mar2021

* Previous revisions of this document were not tracked as part of history of change

Required Signatures

QA Approved by: Ashley Orosco, Quality Assurance Coordinator	Date:
	26 Mar 2021

Folium Biosciences

615 Wooten Road STE 110, Colorado Springs, CO 80915
 Phone: 719-574-2159 Email: info@foliumbiosciences.com, www.foliumbiosciences.com