

Botanical Extracts
Tinctures
Nutraceuticals
Cosmetic Intermediates
Phytochemicals
Spray Drying
Product Development



TENTATIVE PRODUCT SPECIFICATION

Organic Burdock Root in Glycerin

Code: 3222ORG

PRODUCT DESCRIPTION: An organic fluid extract from the root of the botanical *Arctium lappa* in a base of water, glycerin and ethyl alcohol.

MATERIAL NAME	CAS #	EINECS
Organic Glycerin	56-81-5	200-289-5 (I)
Water	7732-18-5	231-791-2 (I)
Organic Burdock Root Extract	84012-13-5	281-658-8 (I)
Organic Ethyl Alcohol	64-17-5	200-578-6 (I)

Test	Specification	Method / Reference
Physical:		
Appearance	Transparent liquid	Visual
Color	Clear to yellow	Visual
Odor	Characteristic, slightly aromatic	Olfactory
pH	5.84 - 6.44	USP<791>
Specific Gravity	1.0800 – 1.3200	USP<841>
Microbiological:		
Total Aerobic Plate Count	NMT 100 cfu/g	USP <2021>
Combined Yeast & Mold	NMT 50 cfu/g	USP <2021>
<i>E. coli</i>	Absent in 10 g	USP <2022>
<i>Salmonella</i>	Absent in 10 g	USP <2022>
<i>Staph. Aureus</i>	Absent in 10 g	USP <2022>

NOTES: RETEST DATE: 24 Months Unopened
 STORAGE: Store in a well closed container in a dry place away from excessive heat. Do not freeze.
 SHIPPING: Do not exceed 120° F. Do not freeze.
 PACKAGING: 5 gallon white HDPE plastic pail with SBR gasket and HDPE locking lid or 55 gallon blue HDPE plastic drum with SBR gasket and HDPE locking lid.



 Quality

Effective Date: 02/02/2017 Rev. 0



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BIO-BOTANICA, INC.

PHARMACEUTICALS

FOOD

COSMETICS

SAFETY DATA SHEET

(1 of 6)

IDENTITY: Organic Burdock Root in Glycerin

CODE: #3222ORG

Version 1

Section 1 – Product and Company Identification

Bio-Botanica, Inc.
75 Commerce Drive
Hauppauge, New York 11788
Telephone: (631) 231-5522
Fax: (631) 231-7332
Date: 02/06/2017

Section 2 – Hazards Identification:

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS): Flammable liquids (Category 3), H226

Pictogram:



Signal Word(s): Warning

Hazard Statement: H226: Flammable liquid and vapor.

Flash Point: 43.10°C (109.58°F) (Closed Cup)

Precautionary Statements:

P210: Keep away from heat / sparks / open flames / hot surfaces – No smoking.

P381: Eliminate all ignition sources if safe to do so.

P410 + 403: Protect from sunlight. Store in a well-ventilated place.

Other Hazards:

Substance Meets the Criteria for PBT According to Regulation (EC) No. 1907/2006 Annex XIII:

PBT: This product does not contain any PBT substances.

Substance Meets the Criteria for vPvB According to Regulation (EC) No. 1907/2006 Annex XIII:

vPvB: This product does not contain any vPvB substances.

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SAFETY DATA SHEET

Organic Burdock Root in Glycerin #3222ORG (2 of 6)

Section 3 - Composition Information:

Definition/Botanical Origin: An organic fluid extract from the root of the botanical *Articum lappa* in a base of glycerin, water and ethyl alcohol.

INGREDIENT	INCI	CAS	EINECS
Organic Glycerin	<i>Glycerin</i>	56-81-5	200-289-5 (I)
Water	<i>Water</i>	7732-18-5	231-791-2 (I)
Organic Burdock Root Extract	<i>Arctium Lappa</i> Root Extract	84012-13-5	281-658-8 (I)
Organic Ethyl Alcohol	<i>Alcohol</i>	64-17-5	200-578-6 (I)

Section 4 - First Aid Measures:

Inhalation: Move the exposed person to fresh air at once. Perform artificial respiration if breathing has stopped. Keep the affected person warm and at rest. Seek prompt medical attention.

Eye Contact: Rinse immediately with plenty of water for at least 15 minutes. If irritation persists seek medical advice. Remove contact lenses if present and easy to do so.

Skin Contact: No negative effects expected. Wash thoroughly with soap & water. Apply cold compresses to affected areas to relieve any discomfort. If discomfort persists, contact a physician.

Ingestion: Never make an unconscious person vomit or drink fluids. Do not induce vomiting. If necessary, rinse mouth and provide fresh air. Get medical attention if any discomfort continues.

Other: When assessing action take Risk & Safety Phrases into account.

Section 5 - Fire Fighting Measures:

Extinguishing Media: Use Carbon Dioxide, dry powder or foam type extinguishers, spraying extinguishing media to base of flames. Do not use direct water jet on burning material. Avoid open flame and excessive temperatures.

Explosion Hazard: May explode when heated or when exposed to flames or sparks. May react with oxidizing materials.

Special Measures: Keep away from sources of ignition.

Extinguishing Procedures: Closed containers may build up pressure when exposed to heat and should be cooled with water spray.

Fire Fighting Instructions: Contact emergency personnel. Use self-contained breathing apparatus and full protective gear if large quantities of product are involved. Hazardous decomposition products may be released. Thermal degradation may produce oxides of carbon and/or nitrogen, hydrocarbons and/or derivatives.

SAFETY DATA SHEET

Organic Burdock Root in Glycerin #3222ORG (3 of 6)

Section 6 - Accidental Release Measures:

Personal Precautions: Avoid breathing vapors, mist or gas. Avoid contact with eyes. Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Environment Precautions: Do not flush large quantities into surface water or sanitary sewer system. Prevent large quantities of product from entering drains. For smaller quantities, drench with water making sure that washing enters drain only when very dilute.

Clean Up Methods: Contain spoiled material. Cover with an inert or non-combustible inorganic absorbent material, sweep up and remove to an approved disposal container. Clean with hot water & detergents. Observe state, federal & local disposal regulations.

For Household Settings: Absorb liquid and scrub the area with detergent. Dilute with water.

For Non-household Settings: Use safety glasses or safety goggles if splash hazard exists; use gloves and other protective clothing to prevent skin contact.

Section 7 - Handling & Storage:

For Household Settings: No applicable information has been found.

For Non-household Settings: No unusual handling or storage requirements. Storage in large quantities (as in warehouses) should be in a well-ventilated, cool area.

Precautions In Handling: Apply good manufacturing practice & industrial hygiene practices. Observe state, federal & local disposal regulations.

Storage Conditions: Store in tightly closed original container, in a cool & dry area away from heat sources & protected from light. Keep air contact to a minimum.

Section 8 - Exposure Controls / Personal Protection:

This is a dietary supplement or personal care product that is safe for consumers and other users under normal and reasonably foreseen use.

Chemical Name	ACGIH	NIOSH	OSHA - Final PELs
Ethyl alcohol (64-17-5)	1000 ppm TWA	1000 ppm TWA; 1900 mg/m ³ TWA 3300 ppm IDLH	1000 ppm TWA; 1900 mg/m ³ TWA

Glycerin (56-81-5)		
USA OSHA	OSHA PEL (TWA) (mg/ m ³)	5 mg/m ³

SAFETY DATA SHEET

Organic Burdock Root in Glycerin #3222ORG (4 of 6)

Ventilation System: A system of local and / or general exhaust is recommended. Please refer to the ACGIH document, Industrial Ventilation, A Manual of Recommended Practices, most recent edition, for details.

Personal Respirators (NIOSH Approved): For emergencies or instances where the exposure levels are not known, use a full face positive pressure, air supplied respirator. **WARNING:** Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection: Use suitable protective gloves if risk of skin contact.

Eye Protection: Use chemical safety goggles and / or a full face shield where splashing is possible. Maintain eye wash fountain and quick-drench facilities in work area.

Work/Hygiene Practices: Wash hands with soap & water after handling.

Section 9 - Physical & Chemical Properties:

Appearance: Transparent liquid

Color: Clear to yellow

Odor: Characteristic, slightly aromatic

pH: 5.84 – 6.44

Specific Gravity: 1.0800 - 1.3200

Solubility in water: Soluble in water

Flash Point: 43.10°C (109.58°F) - Based on Ethanol

Upper / Lower Flammability or Explosive Limits: Not determined

Section 10: Stability & Reactivity:

Reactivity: No significant reactivity hazards, by itself or in contact with water. Avoid contact with strong acids, alkali or oxidizing agents.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: May react with oxidizing materials.

Conditions to Avoid: Heat, flames and sparks.

Incompatible Materials: Iron, Aluminum, Zinc, Copper and their alloys.

Hazardous Decomposition Products: Carbon oxides, may produce hydrocarbon fumes.

Section 11: Toxicological Information:

No known data

NTP: No

IARC: No

OSHA: No

SAFETY DATA SHEET

Organic Burdock Root in Glycerin #3222ORG (5 of 6)

Section 12: Ecological Information:

The product ingredients are expected to be safe for the environment at concentrations predicted under normal use and accidental spills. Packaging components are compatible with the conventional solid waste management practices. Additional information is available from the supplier upon request.

Biodegradability: Readily biodegradable. No known ecological effect.

Bio-accumulative Potential: Low bioaccumulation potential (ethanol).

Precautions: Prevent surface contamination of soil, ground & surface waters.

Section 13: Disposal Considerations:

Waste Treatment Methods: Not a RCRA hazardous waste. Disposal of this material is not regulated under RCRA. Consult federal, state and local regulations to ensure that this material and its containers are disposed of in compliance with all regulatory requirements. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

Section 14: Transport Regulations:

Consult applicable regulations for transport information.

This product is not regulated under DOT.

Road/Rail (ADR/RID)	Not regulated
Air (IATA)	Not regulated
Sea (IMDG)	Not regulated

Section 15: Regulatory Information:

While the finished product is not considered hazardous as defined in 29 CFR 1910.1200 (d), this SDS contains valuable information critical to the safe handling and proper use of the product.

Risk Phrases	R10
Safety Phrases	S2, S16, S24/25
TSCA:	Compliant

SARA Codes:	CAS # 64-17-5: acute, chronic, flammable.
SARA 313 chemicals	None

OSHA:

None of the chemicals in this product are considered highly hazardous by OSHA.

SAFETY DATA SHEET

Organic Burdock Root in Glycerin #3222ORG (6 of 6)

US Federal

The product described in this SDS is regulated under the Federal Food, Drug, and Cosmetics Act and is safe to use as per directions on the container, box or accompanying literature (where applicable).

CERCLA reportable quantity (RQ): None

SARA 33/302/304/311/312 chemicals: None

Canada

All ingredients are CEPA approved for import to Canada. This product has been classified in accordance with the hazard criteria of the Canadian Controlled Products Regulation (CPR).

US States

State Right-To-Know:

The following ingredients are present in the finished product and are listed on the following state right-to-know lists:

Ingredient	CAS#	Level (%)	State			
Organic Glycerin	56-81-5	75-85%	PA	RI	MN	MA
Organic Ethyl Alcohol	64-17-5	<1%	PA	RI	NJ	MA

Section 16: Other Information:

References: Not available.

Other Special Considerations: Not available.

Hazardous Materials Identification System (HMIS) (U.S.A.):

Health Hazard: 1

Fire Hazard: 2

Reactivity: 0

Personal Protection: H

National Fire Protection Association (NFPA) (U.S.A.):

Health: 1

Flammability: 2

Reactivity: 0

Specific hazard: N/A

DISCLAIMER: This Safety Data Sheet is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered by Bio-Botanica to be dependable and is accurate to the best of the Company's knowledge as of the date specified in Section 1 of this Safety Data Sheet. It is not meant to be an all-inclusive document on worldwide hazard communication regulations.

This information is offered in good faith. Each user of this material should evaluate the conditions of use and design the appropriate protective mechanisms to prevent employee exposures, property damage or release to the environment. Bio-Botanica assumes no responsibility for injury to the recipient or third persons, of for any damage to any property resulting from misuse of the product.

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BIO-BOTANICA® INC


Compositional Breakdown

January 12, 2017

Product: Organic Burdock Root in Glycerin

Product Code # 3222ORG

MATERIAL NAME	INCI NAME	CAS #	EINECS	Amount (%)
Organic Glycerin	<i>Glycerin</i>	56-81-5	200-289-5 (I)	70-80%
Water	<i>Water</i>	7732-18-5	231-791-2 (I)	15-25%
Organic Burdock Root Extract	<i>Arctium Lappa</i> Root Extract	84012-13-5	281-658-8 (I)	<2%
Organic Ethyl Alcohol	<i>Alcohol</i>	64-17-5	200-578-6 (I)	<2%



Vanessa Deras
Regulatory Specialist
Bio-Botanica Inc.



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ALLERGEN STATEMENT

January 13, 2017

Product: Organic Burdock Root in Glycerin
Product Code # 3222ORG

Allergen	CAS	Source/ Yes/No
Amyl cinnamal	122-40-7	No
Benzyl alcohol	100-51-6	No
Cinnamyl alcohol	104-54-1	No
Citral	5392-40-5	No
Eugenol	97-53-0	No
Hydroxycitronellal	107-75-5	No
Isoeugenol	97-54-1	No
Amylcinnamyl alcohol	101-85-9	No
Benzyl salicylate	118-58-1	No
Cinnamal	104-55-2	No
Coumarin	91-64-5	No
Geraniol	106-24-1	No
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	31906-04-4	No
Anise alcohol	105-13-5	No
Benzyl cinnamate	103-41-3	No
Farnesol	4602-84-0	No
Butylphenyl methylpropional	80-54-6	No
Linalool	78-70-6	No
Benzyl benzoate	120-51-4	No
Citronellol	106-22-9	No
Hexyl cinnamal	101-86-0	No
Limonene (d-alpha)	5989-27-5	No
Methyl 2-octynoate	111-12-16	No
Alpha-isomethyl ionone	127-51-5	No
Evernia prunastri (oakmoss) extract	90028-68-5	No
Evernia furfuracea (treemoss) extract	90028-67-4	No

These representations are correct to the best of our knowledge, based on literature searches of the ingredients used in the formulation of **Organic Burdock Root #3222ORG**.

Danielle Peters
Regulatory Associate
Bio-Botanica Inc.



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