

Botanical Extracts
Tinctures
Nutraceuticals
Cosmetic Intermediates
Phytochemicals
Spray Drying
Product Development



PRODUCT SPECIFICATION

Folistim-2

Code: 3993

PRODUCT DESCRIPTION: A blend of the botanical extracts in a base of Glycerin and Water.

INCI NAME:	CAS NUMBER:	EINECS NUMBER:
Glycerin	56-81-5	200-289-5 (I)
Water	7732-18-5	231-791-2 (I)
Mentha Piperita (Peppermint) Leaf Extract	84082-70-2	282-015-4 (I)
Heterotheca Inuloides Flower Extract	NA	NA
Urtica Dioica (Nettle) Leaf Extract	NA	NA
Centella Asiatica Extract	84696-21-9, 84776-24-9	283-640-5 (I)
Capsicum Frutescens Fruit Extract	NA	NA
Cochlearia Armoracia (Horseradish) Root Extract	84775-62-2	283-891-0 (I)

Test	Specification	Method / Reference
Physical:		
Appearance	Slightly viscous liquid	Visual
Color	Brown, compares to standard	Visual
Odor	Characteristic, aromatic	Olfactory
Solid Content	59.00 – 78.00 % (2 hrs @ 105° C)	TM 0006
pH	4.5 – 6.5	TM 0007/USP<791>
Refractive Index	1.42-1.46	TM 0008/USP<831>
Specific Gravity	1.18 – 1.24	TM 0009/USP<841>
Identification	Compares to Standard	FTIR or TLC
Analytical:		
Heavy Metals (as As, Cd, Pb, Hg)*	Less than 20 ppm	ICP-MS/USP<231>
Residual Solvents (Methanol)	Meets the USP requirements	USP <467>
Microbiological:		
Total Aerobic Plate Count	NMT 500 cfu/g	USP <2021>
Combined Yeast & Mold	NMT 200 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>

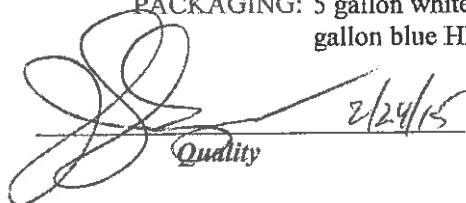
* Tested periodically.

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: 2/24/2015 Rev. 1



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BIO-BOTANICA, INC.

PHARMACEUTICALS
FOOD
COSMETICS

SAFETY DATA SHEET

(1 of 5)

IDENTITY: Folistim-2

CODE: # 3993

Rev 0

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: 01/18/2017

Section 2 – Hazards Identification:

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS): Not classified.

GHS Label elements: No labeling applicable.

OSHA Regulatory Status: This material is non-hazardous as defined by the American OSHA Hazard Communication Standard (29CFR 1910.1200)

Other Hazards: No additional information available.

Unknown Acute Toxicity (GHS-US): No data available.

Section 3 - Composition Information:

Definition/Botanical Origin: A blend of multiple botanical extracts in a base of Glycerin and Water.

INGREDIENT	INCI	CAS	EINECS
Glycerin	<i>Glycerin</i>	56-81-5	200-289-5 (I)
Water	<i>Water</i>	7732-18-5	231-791-2 (I)
Peppermint Leaves Extract	<i>Mentha Piperita Leaf Extract</i>	84082-70-2	181-015-4 (I)
Arnica Flower Extract	<i>Heterotheca Inuloides Flower Extract</i>	NA	NA
Nettle Leaves Extract	<i>Urtica Dioica Leaf Extract</i>	NA	NA
Gotu Kola Extract	<i>Centella Asiatica Extract</i>	84696-21-9, 84776-24-9	283-640-5
Decolorized Oleoresin Capsicum	<i>Capsicum Frutescens Fruit Extract</i>	NA	NA
Horseradish Extract	<i>Cochlearia Armoracia Root Extract</i>	84775-62-2	283-891-0 (I)

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SAFETY DATA SHEET

Folistim-2 #3993 (2 of 5)

Section 4 – First Aid Measures:

Inhalation: No vapors present at normal temperatures. If respiratory irritation occurs, remove individual to fresh air.

Eye Contact: Rinse immediately with plenty of water for at least 15 minutes. If irritation persists, seek medical advice.

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

Ingestion: Accidental ingestion of large quantities of product may necessitate medical attention. The product is intended for external use.

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

Section 5 – Fire Fighting Measures:

Flash Point: Not applicable

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: No applicable information has been found.

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.

Section 6 – Accidental Release Measures:

Personal Precautions: Avoid contact with eyes. Note that spillages, if wet, constitute a slipping hazard. Use individual protective equipment (safety glasses) in case of major spillages.

Environment Precautions: Keep away from drains, soils, surface and ground water.

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.

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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 practices & 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.

Fire Protection: The product is not flammable.

Section 8 – Exposure Controls / Personal Protection:

Control Parameters:

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

Respiratory Protection: No special measures under normal conditions.

Hand Protection: No special measures under normal conditions.

Eye Protection: Use safety glasses if there is a risk of splashing.

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

Section 9 - Physical & Chemical Properties:

Appearance: Slightly viscous liquid

Color: Brown, compares to standard

Odor: Characteristic, aromatic

Specific Gravity: 1.1800 - 1.2400

Solubility in water: Partially soluble in water

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.

Stability: Product is stable.

Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

Section 11 – Toxicological Information:

No known data

NTP: No

IARC: No

OSHA: No

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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.

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

Section 13 – Disposal Considerations:

Dispose to sanitary drainage systems. Non-Hazardous Industrial Waste, follow applicable local, state & federal regulations

Section 14 – Transport Regulations:

Consult applicable regulations for transport information.

Road (ADR/RID) non hazardous; not regulated under US DOT

Air (IATA) non hazardous

Sea (IMDG) non hazardous

Chip: See section 15

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.

Hazards n/a

Symbols n/a

Risk Phrases n/a

Safety Safety Phrases S3/ S16/ S15 / S25

TSCA: All chemical ingredients are listed on the TSCA inventory or are not regulated.

SARA 313 chemicals None

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

SAFETY DATA SHEET

Folistim-2 #3993 (5 of 5)

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			
			PA	RI	MN	MA
Glycerin	56-81-5	70-80				

Section 16 – Other Information:

References: Not available.

Other Special Considerations: Not available.

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, or for any damage to any property resulting from misuse of the product.

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ALLERGEN STATEMENT

January 18, 2017

Product: Folistim-2
Product Code #3993

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 **Folistim-2 #3993**.

Danielle Peters
Regulatory Associate
Bio-Botanica Inc.



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