



PRODUCT REGULATORY INFORMATION DATASHEET Botanical Dietary Ingredients

Section 1. BOTANICAL PRODUCT INFORMATION

PRODUCT NAME & CODE:	Shi-Gen powder: LEP
COMMON OR USUAL NAME OF PRODUCT:	Powdered Shiitake Mushroom Mycelial Biomass
SCOPE OF DOCUMENT:	To describe the relevant processing and identity information for the above listed product.
GENERAL PRODUCT INFORMATION:	Beige fine powder at 60 mesh particle size. Mildly soluble material.

Section 2. BOTANICAL MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURING SITE:	Gourmet Mushrooms, Inc. PO Box 180 Sebastopol, CA 95473
MODE OF MANUFACTURING:	Mushroom mycelial biomass powder production
AGRICULTURAL PROCESS*:	Mushroom varieties aseptically cultivated from a single parent strain. After incubation, material is processed for drying and grinding.
MANUFACTURING PROCESS:	Material is dried and ground, no further manufacturing occurs.
GMP COMPLIANCE:	Yes
STERILIZATION OR FUMIGATION METHOD(S):	Low temperature pressure sterilization on an as needed basis
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS (including solvents) :	None

* Include method(s) of cultivation (Ex: sustainably-wildcrafted, or cultivation method), identification, harvest, handling, & post-harvest processing.

Section 3. PHYSICAL/CHEMICAL PROPERTIES

INGREDIENT LIST (include excipients and non-botanical ingredients*):						
COMMON or USUAL NAME (per current Herbs of Commerce):	LATIN BINOMIAL:	PLANT PART USED:	ORIGIN*:	HARVEST AGE/ SEASON:	CAS #:	WEIGHT PERCENT:
Shiitake Mushroom Mycelial Biomass	<i>Lentinula edodes</i>	Mycelium	USA	Year round	N/A	100%
NON-BOTANICAL INGREDIENTS:						
COMMON or USUAL NAME	ORIGIN*					
N/A	N/A					
CURRENT PRODUCT SPECIFICATION SHEET ATTACHED:				Yes		
BIOASSAY METHOD:				Material is aseptically cultivated from a master parent strain. Post processing material is organoleptically assayed.		

*For botanicals specify country-of-origin; for excipients and non-botanical ingredients specify source information (synthetic, animal, vegetable, mineral, fermentation, etc.).

**GOURMET MUSHROOMS, INC.**PO Box 180
Sebastopol, CA 95473Phone: 707-823-1743
Fax: 707-823-1507**Section 4. LABELING INFORMATION**

REQUIRED FINISHED PRODUCT LABEL STATEMENTS	Include: Batch #, Customer ID #, Strain ID, batch #, and net weight.
RECOMMENDED RESTRICTIONS OF USE:	None
NUTRITIONAL/SUPPLEMENT FACTS LABELING	N/A
OTHER:	

Section 5. REGULATORY INFORMATION

PATENT COVERAGE:	N/A
COMPENDIAL GRADE:	N/A
REGULATORY STATUS AND SUPPORTING DOCUMENTS:	N/A
PRODUCT MASTER FILE(S):	N/A
BSE/ TSE INFORMATION:	Not animal derived, therefore, free of BSE and TSE
VEGAN OR VEGETARIAN STATUS:	Vegan
ALLERGENS/ HYPERSENSITIVITIES:	Non-Allergenic, no known allergens present
PRESERVATIVES (or PROCESSING AIDS):	No preservatives or processing aids
KOSHER/ HALAL/ORGANIC STATUS*:	Certified Kosher by OK Kosher Certified Organic by Quality Assurance International
GM STATUS (for each dietary ingredient):	All ingredients are non-GM
TARIFF CODE for IMPORT/EXPORT:	0712390000

* Include certifying agency/authority

Section 6. MISCELLANEOUS PRODUCT INFORMATION

BATCH/ LOT NUMBERING SYSTEM:	Batches are defined by mushroom strain, seed lot ID, and production date
BATCH DEFINITION:	See above
EXPIRATION DATING:	3 years from date of production
RECOMMENDED STORAGE CONDITIONS:	Dry and cool conditions out of direct sunlight
OTHER OPTIONAL INFORMATION:	
PACKAGE SIZE(S):	15 kg food grade white drum with one time safety strip air tight lid
RECYCLED PACKAGING MATERIALS:	N/A
SUGGESTED PRODUCT CLAIMS, SUPPORTING DOCUMENTATION INCLUDED:	None
MSDS ATTACHED:	Yes
OTHER PRODUCT SAFETY INFORMATION:	None

Section 7. REVISIONS

REVISION DATE:	04/15/2010	REVISION LEVEL:	1
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Section 8. CONTACT INFORMATION

COMPANY NAME:	Gourmet Mushrooms, Inc.		
CONTACT NAME:	Mikayla Zumwalt	TITLE:	Nutraceutical Product Manager
CONTACT PHONE:	(707) 823-1743	EMAIL:	Mikayla@mycopia.com