DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE (GRAS) NOTICE (Subpart E of Part 170)

Form Approved: OMB No. 0910-0342; Expiration Date: 09/30/2019
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER 000794	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

RECEIVED
JUN 7 2018
OFFICE OF FOOD ADDITIVE SAFETY

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration,5001 Campus Drive, College Park, MD 20740-3835.

SECTION A – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*
   ☒ New ☐ Amendment to GRN No._____ ☐ Supplement to GRN No. _____
2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*
3. Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: _____
4. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☒ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: 2018/04/13

SECTION B – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position or Title
Nicole K Berzins	Director of Regulatory and Quality Affairs

Organization *(if applicable)*: MycoTechnology Inc

Mailing Address *(number and street)*: 3155 North Chambers Road

City	State or Province	Zip Code/Postal Code	Country
Aurora	Colorado	80011	United States of America

Telephone Number	Fax Number	E-Mail Address
720-897-9306		nberzins@mycotechcorp.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position or Title

Organization *(if applicable)*:

Mailing Address *(number and street)*:

City	State or Province	Zip Code/Postal Code	Country

Telephone Number	Fax Number	E-Mail Address

SECTION C – GENERAL ADMINISTRATIVE INFORMATION

1. Name of notified substance, using an appropriately descriptive term

PureTaste Protein, Shiitake Fermented Vegetable Protein

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission Gateway

☐ Electronic files on physical media

☒ Paper

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes 1

Total number of pages 47

4. Does this submission incorporate any information in CFSAN's files? *(Check one)*

☐ Yes *(Proceed to Item 5)* ☒ No *(Proceed to Item 6)*

5. The submission incorporates information from a previous submission to FDA as indicated below *(Check all that apply)*

☐ a) GRAS Notice No. GRN _____

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

☐ e) Other or Additional *(describe or enter information as above)* _____

6. Statutory basis for conclusions of GRAS status *(Check one)*

☐ Scientific procedures *(21 CFR 170.30(a) and (b))* ☒ Experience based on common use in food *(21 CFR 170.30(a) and (c))*

7. Does the submission (including information that you are incorporating) contain information that you view as trade secret or as confidential commercial or financial information? (see 21 CFR 170.225(c)(8))

☐ Yes *(Proceed to Item 8*

☒ No *(Proceed to Section D)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☒ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☒ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

SECTION D – INTENDED USE

1. Describe the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance.

MycoTechnology, Inc. intends to use PureTaste75© as a food ingredient in multiple, specific food categories. The intended use levels and the food categories to which PureTaste75© will be added are summarized as Nutritional protein bars, Meal replacements (non milk based), Plant based, non meal replacement beverage, Ready to mix beverage powder, Soy/nut plant based beverages, Plant based frozen yogurt, Salad dressings, Fruit smoothie, Vegetable smoothie, Vegetable smoothie, Tomato juice, Chocolate, and Soup.

2. Does the intended use of the notified substance include any use in product(s) subject to regulation by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture?

(Check one)

☐ Yes ☒ No

3. If your submission contains trade secrets, do you authorize FDA to provide this information to the Food Safety and Inspection Service of the U.S. Department of Agriculture?

(Check one)

☐ Yes ☐ No , you ask us to exclude trade secrets from the information FDA will send to FSIS.

SECTION E – PARTS 2 -7 OF YOUR GRAS NOTICE

(check list to help ensure your submission is complete – PART 1 is addressed in other sections of this form)

☒ PART 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect (170.230).

☒ PART 3 of a GRAS notice: Dietary exposure (170.235).

☒ PART 4 of a GRAS notice: Self-limiting levels of use (170.240).

☒ PART 5 of a GRAS notice: Experience based on common use in foods before 1958 (170.245).

☒ PART 6 of a GRAS notice: Narrative (170.250).

☐ PART 7 of a GRAS notice: List of supporting data and information in your GRAS notice (170.255)

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

☐ Yes ☒ No

Did you include this other information in the list of attachments?

☐ Yes ☐ No

SECTION F – SIGNATURE AND CERTIFICATION STATEMENTS

1. The undersigned is informing FDA that Nicole K Berzins
(name of notifier)

has concluded that the intended use*(s)* of PureTaste Protein, Shiitake Fermented Vegetable Protein
(name of notified substance)

described on this form, as discussed in the attached notice, is (are) not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is generally recognized as safe recognized as safe under the conditions of its intended use in accordance with § 170.30.

2. Nicole Kay Berzins *(name of notifier)* agrees to make the data and information that are the basis for the conclusion of GRAS status available to FDA if FDA asks to see them; agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so; agrees to send these data and information to FDA if FDA asks to do so.

3155 North Chambers Road, Aurora, CO 80011
(address of notifier or other location)

The notifying party certifies that this GRAS notice is a complete, representative, and balanced submission that includes unfavorable, as well as favorable information, pertinent to the evaluation of the safety and GRAS status of the use of the substance.The notifying party certifies that the information provided herein is accurate and complete to the best or his/her knowledge. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
(b) (6)	Nicole Kay Berzins	05/05/2018

SECTION G – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Expert Panel Report Concerning the Generally Recognized as SAFE (GRAS) Status if the Proposed uses of Fermented Shiitake Pea and Brown Rice Protein as an Ingredient in Food and Beverage	6 pages
	GRAS Detemrination for the Use of Fermented Shiitake, Pea and Brown Rice Protein (PureTaste75 C) in Conventional Foods	41 Pages

OMB Statement: Public reporting burden for this collection of information is estimated to average 170 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,Food and Drug Administration, Office of Chief Information Officer, PRAStaff@fda.hhs.gov. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Generally Recognized as Safe (GRAS) Determination for the Use of Fermented Shiitake, Pea and Brown Rice Protein (PureTaste75©) In Conventional Foods

June 5, 2018

Prepared for:

Office of Food Additive Safety (FHS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD
20740

Prepared by:

dicentra LLC
and
MycoTechnology Inc.

Table of Contents

Part 1: 170.225 Signed Statements and Certification

In accordance with 21 CFR 170 Subpart E, MycoTechnology Inc. herby informs the U.S. Food and Drug Administration (FDA) that PureTaste75©, manufactured by ARD, is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) based on MycoTechnology's view that the notified substance is Generally Recognized as Safe (GRAS) under the conditions of its intended use described in Section 1.4, below. In addition, as the responsible official of MycoTechnology Inc., Ms. Nicole Berzins herby certifies that all data and information presented in this notice represents a complete, representative, and balanced submission, and which considered all unfavorable as well as favorable information known to MycoTechnology Inc. and pertinent to the evaluation of the safety and GRAS status of the intended use of Fermented Shiitake, Pea and Brown Rice Protein as an ingredient for addition to food.

Signed,

(b) (6)

X

Nicole Berzins

1.1 GRAS Notice Submission

MycoTechnology Inc submits this GRAS Notification through its agent Jacintha Roberts, Director of Regulatory Affairs in the company Dicentra LLC in accordance with the requirements of 21 CFR Part 170, Subpart E.

1.2 Name and Address of Notifier

MycoTechnology Inc.
3155 Chambers Rd Suite E
Aurora, CO USA 80011

1.3 Common or Usual Name of Notified Substance

The common name is Fermented Shiitake, Pea and Brown Rice Protein.

The trade name of this product is PureTaste75©.

1.4 Conditions of Use

Fermented Shiitake, Pea and Brown Rice Protein (PureTaste75©) containing approximately 75% protein is intended to be added as a food ingredient in foods where protein is used. The proposed ingredient will be used as a substitute for and/or in conjunction with soy protein and whey protein in conventional food products. Mycotechnology does not intend to add PureTaste75© to meat and poultry products that come under USDA jurisdiction, nor will it be added to infant formula or foods targeted to children. Intended food applications include, but are not limited to:

- Dry blend beverage bases (e.g. smoothies, protein powder mixes)
- Ready to drink beverages
- Baked goods and baking mixes
- Soups and soup mixes

Refer to Table 12 for a summary of inclusion levels of PureTaste75© by food category.

1.5 Statutory Basis for GRAS Status

Fermented Shiitake, Pea and Brown Rice Protein has been determined to be GRAS through scientific procedures pursuant to 21 CFR Part 170.30 (a) and (b) of the *Code of Federal Regulations* (CFR) for use as a food ingredient in certain specific categories of food where proteins are involved.

A comprehensive assessment of scientific (human and animal, quantitative and qualitative) literature and regulatory resources were consulted for this review. The safety of PureTaste75© is supported, based on its intended use. Data and information were gathered from a critical and comprehensive review of the scientific literature on the safety of fermented shitake, pea protein

and brown rice protein through searches of Pubmed, FDA dockets, internet searches, etc. In addition, the product was subjected to extensive physical and chemical analysis. Peas, brown rice and shiitake are an important part of the human diet in many countries and have been consumed since ancient times. Peas, brown rice and Shiitake are high in protein, fiber, vitamins, and minerals and are nutrient rich food products. Fermented foods have been safely consumed for hundreds of years. Based on a critical evaluation of the information presented below by qualified experts, it was concluded that the proposed use of Fermented Shiitake, Pea and Brown Rice Protein as a food ingredient is GRAS.

1.6 Premarket Exempt Status

Fermented Shiitake, Pea and Brown Rice Protein is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) based on the conclusion that the notified substance is GRAS under the conditions of intended use.

1.7 Availability of Information

The data and information that serve as the basis for the conclusion that Fermented Shiitake, Pea and Brown Rice Protein is GRAS for its intended use, will be made available to the United States (U.S.) Food and Drug Administration (FDA) upon request. At FDA's option, a complete copy of the information will be available for review and copying upon request during business hours at the offices of:

MycoTechnology Inc.
3155 Chambers Rd Suite E
Aurora, CO USA 80011

In addition, should the FDA have any questions or additional information requests regarding this notification during or after the Agency's review of the notice, MycoTechnology Inc. will supply these data and information.

1.8 Freedom of Information Act, 5 U.S.C 552

It is MycoTechnology's view that all data and information presented in Parts 2 through 7 of this notice do not contain any trade secret, commercial, or financial information that is privileged or confidential, and therefore all data and information presented herein are not exempt from the Freedom of Information Act, 5 U.S.C. 552.

1.9 FSIS Statement

Not applicable. Mycotechnology does not intend to add PureTaste75© to meat or poultry products or foods that come under USDA jurisdiction.

Part 2: 170.230 Identity, method of manufacture, specifications and physical or technical effect

2.1 Description of the product

PureTaste75© is a powdered protein concentrate that is comprised of three primary protein sources: Rice protein, Pea protein and fermented Shiitake mycelium. The relative percentages of these ingredients in the product composition are 45%, 45%, and 0.01%, respectively. Other ingredients include food grade excipients and processing aids. The PureTaste75© product provides a total of 75% protein on an "as is" (wet) basis.

2.2 Biological Identification Information

The biological identity of the three principle protein components are established as follows:

Rice Protein
- Proper Name: *Oryza sativa* Linn.
- Common name: Rice Seed Protein
- Source: Seed

Pea Protein
- Proper Name: *Pisum sativum*
- Common name: Pea Protein
- Source: Seed

Shiitake Mushroom
- Proper Name: *Lentinula edodes* (Berk.) Singer
- Common name: Shiitake
- Source: Cultured mycelia

2.3 Method of Manufacture

2.3.1 Manufacturing Site Information

PureTaste75© is manufactured consistent with current good manufacturing practices (cGMP) at a facility (ARD) located in France (FDA registration number 18812599800). PureTaste75© is manufactured in accordance with FDA section 409 of the Act, and FDA's implementing regulations 21 CFR 170.3 and 21 CFR 170.30 (c) and (f). ARD operates and manufactures this product under the following guidelines:

- Hazard Analysis and Critical Control Points (HACCP) and hygiene standards. ARD follows the codex alimentarius principles (CAC/RCP 1-1969, release 4 2003 for the French version).
- "Food Law" (Règlement 178/2002), the further regulations (Règlement (CE) n°853/2004, Règlement (CE) n°882/2004, Règlement (CE) n°852/2004, Règlement (CE) n°854/2004,

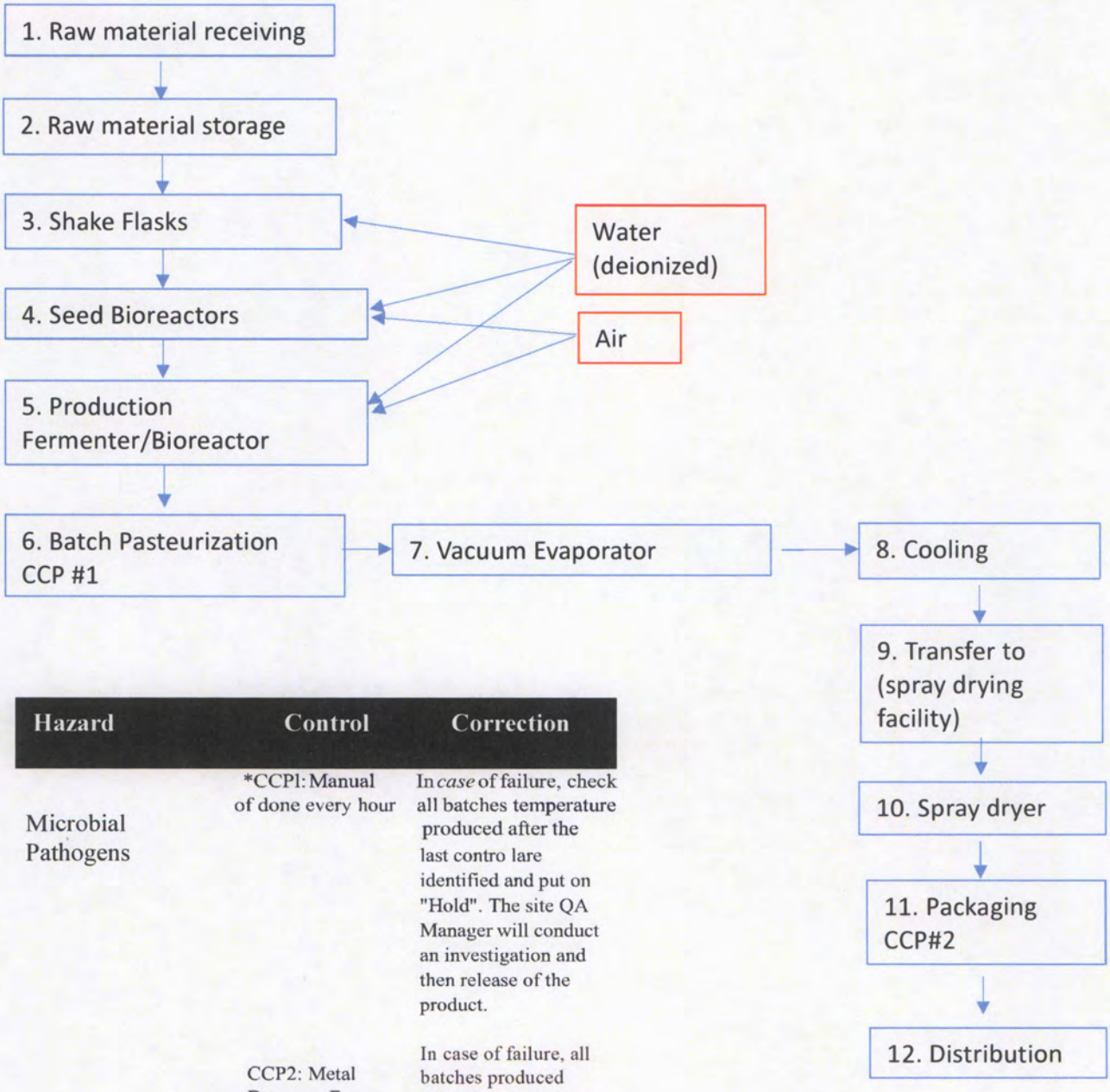
Règlement (CE) n°183/2005).

2.3.2 PureTaste75© Formula

Table 1 - Formula of PureTaste75©

Ingredient
Pea Protein
Rice Protein
Maltodextrin
Ammonium Phosphate
Carrot Powder
Antifoam
Citric Acid
Magnesium Sulfate
Inoculum - *Lentinula edodes*

2.3.3 *Flow Chart with Critical Control Points:*



Hazard	Control	Correction
Microbial Pathogens	*CCPl: Manual of done every hour	In *case* of failure, check all batches temperature produced after the last contro lare identified and put on "Hold". The site QA Manager will conduct an investigation and then release of the product.
Metal	CCP2: Metal Detector. Fe 2mm, S.S.: 2.5 mm, non- Fe: 2.5mm Metal detector check sheet every hour	In case of failure, all batches produced after the last control are identified and put on "Hold". The site QA Manager is in charge of the investigation and the release of product.

2.3.4 *Description of the Manufacturing Process*

Step 1. Raw materials are received from verified suppliers. All suppliers are approved in accordance with FSMA Foreign Supplier Verification Program protocols.

Step 2. Raw material are stored pending verification that specifications are met, whereupon they are released for manufacturing.

Step 3. *Lentinula edodes* mycelium is added from petri plate cultures then propagated into sterilized Erlenmeyer flasks containing media comprising an approximately 2% slurry of pea and rice protein concentrate supplemented with maltodextrin, magnesium sulfate, antifoam, citric acid, carrot powder and diammonium phosphate.

Steps 4 and 5. The flasks are propagated into a bioreactor seed train, wherein each bioreactor is approximately 8 - 25x the volume of the previous reactor, with the same media as the flask until the final bioreactor, holding an approximate 10% slurry of these ingredients, is inoculated.

Step 6. Bioreactor media concentrate heat treatment is carried out at 250^0 F for more than 30 minutes and cooled down using air and water circulation. Aeration is initiated before inoculation with *Lentinula edodes* culture depending on what step of the process is occurring. Fermentation occurs in a bioreactor and is checked for purity and growth of *Lentinula edodes* via microscopic examination.

Step 7. Harvested material is then concentrated to 20 - 25% slurry by an evaporator. No chemical solvents are utilized for manufacture of PureTaste75© protein.

Steps 8, 9, 10, 11. Concentrated material is then spray dried and packed into super sacks and analyzed for amino acid profile, heavy metals, aflatoxin, total sugars and fatty acid profile. PureTaste75© is also analyzed for solubility at various pHs (3 - 10). Other analyses include particle size distribution, emulsification, foaming characteristics, Digestible Indispensable Amino Acid Score (DIAAS) and Protein digestibility-corrected amino acid score (PDCAAS).

2.4 Specifications and Batch Analysis

2.4.1 *Raw Material Specifications:*

Brown Rice Protein 80%:

Description: The Brown Rice Protein is a free-flowing, off-white to light beige colored powder with characteristic Brown Rice Protein flavor and a minimal protein content of NLT 77%. Brown Rice Protein is made after concentrating and filtering hydrolyzed rice slurry which has undergone an all-natural enzymatic process.

MFG Confidential Commercial Information Noted (IP)

Table 2 - Brown Rice Protein 80% Specification

Parameter	Tolerance	Test Method
Appearance	Off white to light beige	Visual against standard
Odor	Odorless	Sensory
Protein (%)	80- 87 % (on dry basis)	AOAC 990.03
Aerobic Plate Count	≤ 10, 000 CFU /g	AOAC 966.23
Yeast	≤ 200 CFU / g	FDA-BAM, 7th ed.
Mold	≤ 100 CFU /g	FDA-BAM, 7th ed.
Listeria	Negative / 25 g	AOAC 2016.07
Coliforms	≤ 10 CFU / g	AOAC 966.24
Salmonella	Negative / 25 g	AOAC-R1I100201
E. Coli	≤ 10 CFU / g	AOAC 966.24
Mercury	< 1 ppm	ICP-MS, FDA EAM 4.7
Cadmium	< 0.5 ppm	ICP-MS, FDA EAM 4.7
Arsenic	< 1 ppm	ICP-MS, FDA EAM 4.7
Lead	< 1 ppm	ICP-MS, FDA EAM 4.7

Pea Protein 80%:

Description: The Pea Protein concentrate is a free-flowing, cream coloured powder with a protein content of NLT 80% (dry basis). A basic overview of the method of preparation of this ingredient is provided in the flow diagram below:

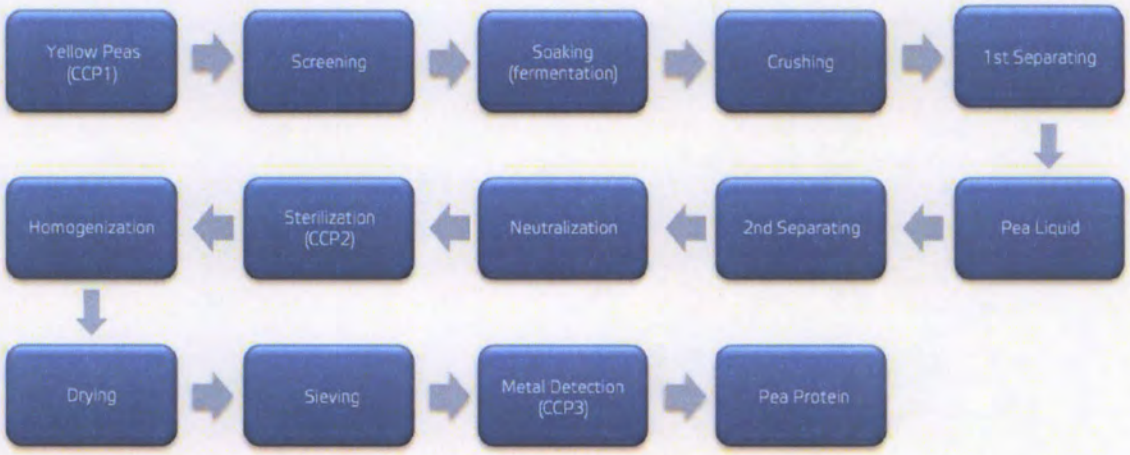


Table 3 – Pea Protein 80% Specification

Parameter	Tolerance	Test Method
Appearance	Off white	Visual against standard
Odor	Inherent Pea Odour	Sensory
Protein (%)	≥ 80 %	AOAC 990.03
Aerobic Plate Count	≤ 10, 000 CFU /g	AOAC 966.23
Yeast	≤ 200 CFU / g	FDA-BAM, 7th ed.
Mold	≤ 100 CFU /g	FDA-BAM, 7th ed.
Listeria	Negative / 25 g	AOAC 2016.07
Coliforms	≤ 10 CFU / g	AOAC 966.24
Salmonella	Negative / 25 g	AOAC-R1I100201
E. Coli	≤ 10 CFU / g	AOAC 966.24
Mercury	< 0.1 ppm	ICP-MS, FDA EAM 4.7
Cadmium	< 0.2 ppm	ICP-MS, FDA EAM 4.7
Arsenic	< 0.5 ppm	ICP-MS, FDA EAM 4.7
Lead	< 0.1 ppm	ICP-MS, FDA EAM 4.7

Remaining raw material and processing aids:

All the remaining raw materials and processing aids used in the manufacture of PureTaste75© , including the pea protein concentrate, and brown rice protein concentrate are food-grade materials and/or are used in accordance with applicable U.S. Federal Regulations for such uses. The Shiitake is obtained as a pure strain direct from Penn State and it's identify is verified via microscopy.

2.4.2 PureTaste75© Specifications

Table 4 - Physical Characteristics of PureTaste75©

Physical Description	Specification	Test Method
Particle Size	Mean Size <100um	PSA (Laser)
Color	Tan to Hunter	Visual/Color
Aroma	Cereal when concentrated	Sensory
Taste	Clean Taste slight cereal	Sensory /acidity

Table 5 - PureTaste©75Microbiological Characteristics

Test	Specification	Method
Aerobic plate Count	< 10,000/g	AOAC 966.23
Coliform MPN	<100 cfu/g	AOAC 966.24
Yeast and Mold	<100 cfu/g	FDA-BAM, 7th ed.
E. Coli	Negative/10 g*	AOAC 966.24
Salmonella	Negative/25g	AOAC-RI100201
Listeria	Negative/25g	AOAC 2016.07

* E. Coli: The standard procedure involves testing coliforms and if, and only if, coliform presence is detected, would a a specific analysis for E.Coli be conducted (Not Detected in 10g as per USP dietary supplement limits for powdered herbal botanicals).

Table 6 - PureTaste75© Nutritional/Chemical Data (Average Values for 100g of Commercial Product)

Chemical Analysis	Value	Tolerance	Unit of Measure	Method
Moisture	7	Max	g	AOAC 925.09
Protein (dry matter basis)	75.0 g (DW)	Min	g	AOAC 990.03
Total Fat	9.5	Average	g	AOAC 922.06
- Saturated Fat	2.6	Average	g	AOAC 996.06
- Mono-unsaturated	4.2	Average	g	AOAC 996.06
- Poly-unsaturated fat	2.7	Average	g	AOAC 996.06
- Cholesterol	0	Average	g	AOAC 996.06
- Trans Fatty Acids	0	Average	g	AOAC 996.06
Carbohydrates	13	Average	g	Calculated
- Sugars	6	Average	g	AOAC 980.13
- Dietary Fiber	6	Average	g	AOAC 991.43(Mod.)
Ash	4.8	Average	g	AOAC 925.51A
- Sodium	680	Average	mg	AOAC 984.27
- Phosphorus	0	Average	g	AOAC 984.27
- Potassium	36	Average	g	AOAC 984.27
- Calcium	350	Average	mg	AOAC 984.27
- Iron	105	Average	mg	AOAC 984.27
Calories	410	Average	Kcal	CFR 21-calcuation

Table 7 – Essential Amino Acid Profile of PureTaste75©

Essential Amino Acids	Average Values (% of protein)
Leucine	6.304
Lysine	3.828
Met. + Cyc.	2.514
Phe. +Tyr.	7.392
Thr.	2.74
Val	4.312

Table 8 - Specifications and Test Methodology for Heavy Metal Testing in PureTaste75©

Parameters	Tolerance	Methodology
Arsenic	<0.1 ppm	ICP-MS, FDA EAM 4.7
Cadmium	<0.1 ppm	ICP-MS, FDA EAM 4.7
Lead	<0.3 ppm	ICP-MS, FDA EAM 4.7
Mercury	<0.1 ppm	ICP-MS, FDA EAM 4.7

Table 9 - Specifications and Test Methodology for Aflatoxin Testing in PureTaste75©

Parameters	Tolerance	Methodology
Aflatoxin Bl	<5 ppb	HPLC AOAC 991.31(Mod.)
Aflatoxin B2	<5 ppb	HPLC AOAC 991.31(Mod.)
Aflatoxin Gl	<5 ppb	HPLC AOAC 991.31(Mod.)
Aflatoxin G2	<5 ppb	HPLC AOAC 991.31 (Mod.)
Aflatoxin Total	<5 ppb	HPLC AOAC 991.31(Mod.)

2.4.3 PureTaste75© Sample Batch Analysis:

Table 10 - Summary of Test Results of Five Batches of PureTaste75©

Parameter	Results					Tolerance
Dates of seed fermentation start (batch)	3/26/2017	4/10/2017	4/24/2017	4/1/2017	9/26/2017	-
Tests						-
Ash (%)	4.76	6.02	3.79	4.61	6.51	Report only
Microbial						-
E. coli	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	Negative/10 g
Coliforms	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<10 CFU/g	<100 cfu/g
Listeria spp	Negative /25g	Negative /25g	Negative /25g	Negative /25g	Negative /25g	Negative/25g
Mold	<100 CFU/g	<100 CFU/g	200 CFU/g	<100 CFU/g	<100 CFU/g	<100 cfu/g
Plate Count, Aerobic	<10 CFU/g	<10 CFU/g	10 CFU/g	<10 CFU/g	<10 CFU/g	< 10,000/g
Salmonella	Negative /25g	Negative /25g	Negative /25g	Negative /25g	Negative /25g	Negative/25g
Yeast	<100 CFU/g	<100 CFU/g	<100 CFU/g	<100 CFU/g	<100 CFU/g	<100 cfu/g
Moisture and Volatiles (%)	5.20	6	7.80	4.50	3.9	Max 7%
Total fat as Triglycerides (%)	9.89	9.51	9.76	10.84	10.56	Report only
Total fatty acids (%)	10.1	9.1	9.33	10.36		Report only
Crude fat (%)	10.11	10.32	10.62	11.05	11.27	Report only
Carbohydrates (%) Calculated (%)	3.48	3.28	5.51	7.59	3.30	Report only
Cadmium (ppm)	0.03	0.025	0.032	0.036	0.03	<0.1 ppm

Lead (ppm)	0.07	0.065	0.068	0.064	0.06	<0.3 ppm
Mercury (ppm)	0.014	0.012	0.012	0.025	0.02	<0.1 ppm
Arsenic (ppm)	0.032	0.04	0.039	0.039	0.03	<0.1 ppm
Fiber (%)	3.80	6.00	5.70	6.20	6.51	Report only
Protein (% as is)	76.67	75.19	73.14	72.46	75.02	Report only
Protein (% DW)	80.88	80.00	79.33	75.87	78.06	Min 75%
DIAAS (Digestible Indispensable Amino Acid Score)	104.3	103.3	105.7	101	98	Report only
Amino Acid (%)	76.01	74.03	71.86	70.01	75.64	Report only
Tryptophan (%)	0.9	0.87	0.83	0.77	0.92	Report only
Cystine (%)	1.04	0.96	0.99	0.71	0.81	Report only
Methionine (%)	1.8	1.63	1.64	1.48	1.51	Report only
Alanine (%)	3.71	3.59	3.44	3.41	3.89	Report only
Arginine (%)	6.19	6.07	5.85	5.76	6.09	Report only
Aspartic Acid (%)	7.78	7.54	7.38	7.14	7.78	Report only
Glutamic Acid (%)	13.14	12.91	12.45	12.67	13.53	Report only
Glycine (%)	3.21	3.13	3.01	2.98	3.21	Report only
Histidine (%)	1.75	1.76	1.67	1.6	1.76	Report only
Isoleucine (%)	3.62	3.51	3.33	3.29	3.67	Report only
Leucine (%)	6.61	6.34	6.19	6.02	6.36	Report only
Phenylalanine (%)	4.24	4.15	4.02	3.86	4.06	Report only
Proline (%)	3.48	3.52	3.45	3.39	3.54	Report only
Serine (%)	3.85	3.77	3.73	3.59	3.67	Report only
Threonine (%)	2.83	2.78	2.72	2.61	2.76	Report only
Lysine (%)	3.89	3.78	3.76	3.53	4.18	Report only
Tyrosine (%)	3.49	3.36	3.29	3.13	3.36	Report only
Valine (%)	4.48	4.36	4.11	4.07	4.54	Report only
Sucrose (%)	0.0036	0.0042	0.36	0.3	0.54	Report only
Total sugars (%)	0.0036	0.0042	0.36	<0.35	0.54	Report only
Aflatoxin B1 B2 G1 G2 (LC-MSMS) (Cont.)	< 5 ug/kg	< 5 ug/kg	< 5 ug/kg	< 5 ug/kg	< 5 ug/kg	<5 ppb
Vomitoxin	< 10ug/kg	< 10ug/kg*(batch 12)	< 10ug/kg	< 10ug/kg	< 50 ug/kg	Report only
Gluten	< 5.0 ppm	< 5.0 ppm	< 5.0 ppm	8.3 ppm	<3.0ppm	< 20 ppm

2.5 Allergens in PureTaste75©

MycoTechnology Inc. uses a control program in accordance with 21 CFR Part 301. The allergen control program ensures the facility has evaluated processes and the premises to mitigate with proper use, storage and labeling any risk of allergen related food safety incidents. This standard operating procedure (SOP) is for all employees to ensure adherence to the allergen awareness plan. MycoTechnology Inc. maintains a complete HACCP program including personnel training as it relates to allergens in its facility. The PureTaste75© product includes the use of a malt barley in less than 0.10g/L of malt extract in the inoculum used in the manufacturing process. This results in a minimal amount (< 5ppm) of gluten in the finished product. Internal quality testing analysis is conducted to ensure the FDA requirement of less than 20 ppm is present in the finished PureTaste75© product. Internal verification of gluten presence in the finished product shall be conducted annually, as well as internal validation of programs and tests around gluten presence in PureTaste75©. This finished product will not be labeled as a gluten free product.

Table 11 - Gluten Testing Results for PureTaste75© (Based on Limit of Detection (LOD))

Lot #	**3/26/17**	**4/10/17**	**4/24/17**
Gluten	< 5.0 ppm	< 5.0 ppm	< 5.0 ppm

The PureTaste75© product is dairy-free, peanut free, tree-nut free, soy free, and seafood free.

2.6 Technical Effect of PureTaste75©

The Fermented Shiitake Pea and Brown Rice Protein is intended for use as a food ingredient in foods where protein is used for nutritional purposes such as bakery products, smoothies, snack foods, beverages (including nutritional beverages), soups, dairy products, dry instant milk shake mixes and protein drinks, instant powdered nutritional beverages, vegetarian food products/meat analogues, and meal replacement/nutritional bars.

2.7 Labeling and Storage information

2.7.1 Label Declaration

The name to appear on the label will be:

Fermented Shiitake, Pea and Brown Rice Protein (PureTaste75©).

2.7.2 Lot Coding

Example Lot Number: 3/26/17 (Date of start of seed fermentation)

2.7.3 Non-GMO Declaration

PureTaste75© has been determined Non-GMO Project verified in compliance with version 14.2, ID Number SCS-703d-0061-02 with an effective date of 13 February 2018.

2.7.4 Packaging

Packaged in food grade 500kg PP uncoated conductive Type C 220gr/mg

2.7.5 Storage Conditions

Product should be stored in a cool, dry location, and in the original sealed package away from odorous material.

2.7.6 Shelf Life

The protein content of this product is stable under accelerated conditions

Part 3: 170.235 Dietary Exposure

MycoTechnology, Inc. intends to use PureTaste75© as a food ingredient in multiple, specific food categories. The intended use levels and the food categories to which PureTaste75© will be added are summarized in Section below. PureTaste75© will be added to the following list of food categories at levels ranging from 1% to 40%. The use levels provided are based on purity criteria of 75% protein concentrate. Mycotechnology also intends to market this protein as a supplemental protein to be used in protein/sports nutrition bars.

PureTaste75© is used but not limited to the finished conventional food products mentioned below:

- Nutritional protein bars
- Meal replacements (non milk based)
- Plant based, non meal replacement beverage
- Ready to mix beverage powder
- Soy/nut plant based beverages
- Plant based frozen yogurt
- Salad dressings
- Fruit smoothie
- Vegetable smoothie
- Tomato juice
- Chocolate
- Soup

3.1 Application Usage Estimates:

Table 12 - Application Usage Estimates

Food Category	Food-Uses	Proposed Use Level (%) of PureTaste75© as consumed per food category (Minimum 75 % protein)[X]
Baked Goods and Baking Mixes	Breads	4.8% - 7%
	Rolls	4.8%*
	Bagels	4.4%*
	English Muffins	4.4%*
Beverages and Beverage Bases	Non-Milk Based Meal Replacements	1.04 % - 11%
	Ready to Mix Beverage Powder	32.67g PureTaste75© / 35g serving (carbohydrate base)
	Plant Based Beverage, Non-Meal Replacement	1.04 % - 3 %
Breakfast Cereals	Ready-to-Eat Breakfast Cereals	4.4 – 16%*
Dairy Product Analogs	Soy/Nut Plant Based Beverages	1.04% -5.5%
	Cashew Product	5 % (4g PureTaste75© /79g serving of frozen dessert)
	Coconut Product	8 % (6.67g PureTaste75© /85g serving of frozen dessert)
Fats and Oils	Salad Dressings	~ 26 %
Grain Products and Pastas	Health Bars and Grain-Based Bars	20% - 33.3%
	Health Bars and Grain-Based Bars Containing Fruit and Vegetable	18-20 %*
	Pasta	4.6 – 17 %
Milk Products	Flavored Milk Drinks	1.04%*
	Milk-Based Meal Replacements	1.04% *
	Yogurt (Regular and Frozen)	1.1 - 7%

Plant Protein Products	Meat Alternatives	1 – 40%
Processed Fruits and Fruit Juices	Fruit Juice	1.04 %*
	Fruit Nectars	1.04 %*
	Fruit-Flavored Drinks	9-20%*
Processed Vegetables and Vegetable Juices	Tomato Juice	2.5 -20 %*
	Vegetable Smoothie	3.5 – 20 %*
Soups and Soup Mixes	Prepared Soups, Dry Soup Mixes, and Condensed Soups	0.96 – 3.3 %
Non Baked Goods (Bars)	Extruded Nutritional Protein Bars	36 %
Confectionary	Chocolate Dessert (Peanut Butter Cup)	7 %

*Values are consistent with the amount of pea protein concentrate to be added to the same product categories as supported by GRAS 608 (Pea Protein Concentrate), Table 3-1, based on minimum 80% protein. As PureTaste75© would be used as a substitute protein in these categories, the use level would be considered comparable.
X% PureTaste75© will vary due to the fact that most calculations are mass into volume assuming water. PureTaste75© use levels calculated based on purity of 75%

As indicated in GRAS 609 (Rice protein concentrate), the RDI for protein varies from 10 g / day (for infants) to 71 g / day (for pregnant and lactating women), with the RDI for adult males as 56 g/ day. Additionally, in GRAS 608 (Pea protein concentrate), the Reference Amount Customarily Consumed (RACC) for peas is 85 g / serving (21 CFR 101.12), with the reasonable daily intake estimated (90th percentile) to be ~ double the RACC which would equate to 170 g. Since peas contain ~24 % protein (Canadian Nutrient File, Peas, split, raw, Food Code (3394), it can be determined that the amount of protein that would be provided be peas to be 20.4 g protein per serving, and 40.8 g protein per day (90th percentile). Additionally, GRAS 608 (pea protein concentrate) further demonstrates that the maximum pea protein concentrate anticipated from use in sports nutrition would be 30 g/ person / day.

Since PureTaste75© is intended as source of protein that will substitute for other proteins in the diet, this ingredient will not result in an overall increase in the consumption of protein in the diet. Furthermore, as the 90th percentile of PureTaste75© based on the intended uses in each of the proposed food categories would by 17.3 g / per person / day, is lower than the 90th percentile of dietary pea protein consumption the recommended levels are safe for human consumption.

3.2 Daily Consumption Calculation:

PureTaste75© is intended to be used as a substitute for, and/or in conjunction with, pea protein, rice protein and other protein sources in conventional food products. Target product categories include food products needing protein-source properties such as promotion of ease of dry flow, masking of off-flavors, texturing of meat analogues, retention of oils and gelation, and increase of water-solubility.

As PureTaste75© is intended to be used an alternative product to those already available in a

similar inclusion manner, the estimated daily intake of PureTaste75© protein in the U.S. can be derived from the daily consumption estimates of other alternatives including rice, and pea protein.

3.2.1 *Protein as a Substitute from Rice and Peas*

FDA considers rice under a general food category that includes grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables. As such, exposure to rice protein can be considered from data on rice consumption/exposure and the known percentage of protein of rice (~ 8% protein) (Canadian Nutrient File, Food Code 4496). As the quantities of rice protein and pea protein of the present GRAS assessment are identical (each comprising 44.92% of PureTaste75©), the protein from rice and peas combined was considered, as the available information suggests that there is common exposure to rice and its protein

Based on the information provided in GRAS Notice 609 and GRAS Notice 608 (U.S. Food & Drug Administration, 2016) for Rice Protein, Table 13 is presented to be representative of the Estimated Daily Intake of Rice Protein Concentrate by Food Use in the U.S. Population based on 2011-2012 NHANES Data (Centers for Disease Control and Prevention, 2012).

Table 13 – Rice and Pea Protein Estimated Daily Intake

Population Group	**Age Group (Years)**	**All Person Consumption (g/day)**		**All-Users Consumption (g/day)**			
		Mean	**90th Percentile**	**% Users**	**N**	**Mean**	**90th percentile**
Infants and Young Children	Up to 3	5.9	12.4	83.2	683	7.1	13.4
Children	4 to 11	9.4	14.8	99.9	1347	9.4	14.8
Female Teenagers	12 to 19	10.5	16.5	98.8	526	10.6	16.5
Male Teenagers	12 to 19	11.8	18.7	98.5	508	12.0	19.7
Female Adults	20 and up	9.7	16.1	99.8	2204	9.7	16.1
Male Adults	20 and up	11.1	20.3	98.8	22067	11.2	20.5
Total Population	All Ages	10.1	17.2	98.4	7335	10.3	17.3

In summary, on an "all-user" consumption basis, the resulting mean and 90th percentile intakes of rice protein concentrate by the total U.S. population from all proposed food-uses in the U.S. is estimated to be 10.3 g/person/day (181 mg/kg body weight/day) and 17.3 g/person/day (388 mg/kg bodyweight/day), respectively as determined in GRAS notice 609 and GRAS notice 608. Male adults were identified as the individual sub-population group with the highest 90th

percentile consumption per day (20.5 g/ person/ day) and infants & young children had the lowest 90th percentile consumption per day (13.4 g / person/ day).

3.2.2 PureTaste75© Daily Intake

As PureTaste75© is to be used as an alternative/substitute to other protein products such as Rice, or Pea protein in similar applications and at similar inclusion levels, the mean adult daily consumption can be inferred for PureTaste75© from these products. In Table 14 the inclusion levels and estimated daily intake are presented for PureTaste75© based on the estimated levels for other, similar alternative protein sources. Consistent with the Nutrient Profile Comparison, Table 12, of GRAS 609 for Pea protein, the levels of PureTaste75© to be added to products like

Table 14 - Inclusion Rates and Estimated Daily Intake

	PureTaste75©	**Rice and Pea Protein**
Inclusion Range in Food Category	1.1 – 40%	0.96 – 34.3%
90th Percentile	17.3 g/day/person	17.3 g/day/person

Based on the above information, the conservative estimate of the daily mean consumption of PureTaste75© will be 17.3g/day/person.

3.3 Dietary Exposure Conclusions

The PureTaste75© product will be used in a number of food products. Most of the population's protein intake is derived from, and will continue to be derived from, unprocessed foods, including meat, poultry, fish, and legumes. PureTaste75© will be added to products as a competitive meat alternative ingredient on the market in a similar manner to other products on the market such as pea, and rice protein. Thus, the addition of PureTaste75© Protein ingredients will simply serve as a replacement for these other competitive protein sources and will not increase overall consumer exposure to protein.

Therefore, it is not realistically expected that the actual consumption of foods containing PureTaste75© will contribute to a significant portion of total protein intake in the general population. A conservative estimate of consumption of PureTaste75© products is 17.3 g/day/person. As the recommended dietary allowance (RDA) for protein is 50 g/day (based on a 2000 calorie diet), the conservative estimate of 17.3 g /day/ person is supported for safe use as this is below the RDA for protein.

Part 4: 170.240 Self Limiting Levels of Use

The use of the PureTaste75© as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability. The self-limiting level of use is independent of safety (toxicity, allergenic, etc.) concerns.

Part 5: 170.245 Experience Based on Common Use in Food Before 1958

The statutory basis for the GRAS conclusion for PureTaste75© is based on scientific procedures

Part 6: 170.250 Narrative and Safety Rationale

MycoTechnology Inc. developed the first Shiitake-fermented protein grown and manufactured, branded as PureTaste75©, which is known for its unique solubility characteristics and clean flavor.

PureTaste75© is composed of pea and brown rice protein fermented with *Lentinula edodes* mycelium. Based on the formulation of the product as indicated in Table 15 and the method of the manufacture, the safety of the product can be established through the safety of the ingredients used to produce PureTaste75©. The safety of PureTaste75© as a whole is compared to and discussed with regards to its comparability of its amino acid profile to amino acid profiles of other proteins (rice protein and pea protein) that are regarded as safe in other published GRAS notices as indicated in section 6.1.1 in further detail.

Table 15 - PureTaste75© Composition

Ingredient	**Percentage in PureTaste75©**
Pea Protein	44.92%
Rice Protein	44.92%
Maltodextrin	3.59%
Ammonium Phosphate	1.80%
Carrot Powder	1.80%
Antifoam	1.25%
Citric Acid	1.00%
Magnesium Sulfate	0.72%
Inoculum - *Lentinula edodes*	0.01%

6.1 Safety of Substances Used in the Manufacture of the PureTaste75© Products

6.1.1 Nutrition Information

The amino acid profiles of rice protein, pea protein and PureTaste75© are provided in Table 16 Some minor differences in a few amino acids are noted (such as tyrosine which is higher than the tyrosine in both the rice protein and pea protein, and glycine which is lower compared to the glycine content of rice protein and pea protein). However, the overall typical amino acid profile of PureTaste75© for most of the amino acids aligns with the protein values of rice protein and/or of pea protein indicating that the amino acid profile of PureTaste75© is comparable to the amino acid profiles of these two proteins that are regarded as safe for consumption as per GRAS notices 609 and 608, respectively and have not been substantially modified by the fermentation. The minor differences observed of the 2 amino acids tyrosine and glycine are not thought to be

attributed to the Shiitake mushroom in PureTaste75© as the quantity of this ingredient is minimal, at < 1%, in the finished product; however, may be associated with the differences in the sourcing of and/or cultivars of the peas and rice tested. Although PureTaste75© is a combination of the fermented ingredients: rice protein, pea protein and Shiitake, the amino acid profile of PureTaste75© is still in alignment with the typical amino acid profiles of rice protein and pea protein and thus, demonstrates the safety of this ingredient as a whole.

Table 16 - Amino Acid Profile Comparison of PureTaste75© with Rice Protein and Pea Protein

	% of total amino acids		
Amino acids	**Rice protein[1]**	**Pea protein[2]**	**PureTaste75 ©**
Phenyalanine	5.16	4.82	5.75
Valine	5.87	4.94	5.54
Threonine	3.67	3.72	3.64
Tryptophan	1.27	1.17	1.63
Methionine	2.25	1.07	2.36
Isoleucine	4.23	4.32	4.5
Leucine	8.28	7.50	8.6
Lysine	3.82	7.55	5.09
Histidine	2.54	2.54	2.3
Arginine	7.58	9.33	8.32
Cysteine	1.21	1.59[3]	1.41
Glycine	4.93	4.65	3.77
Proline	4.69	4.32	4.63
Tyrosine	3.75	3.03	4.92
Aspartic acid	9.36	12.34	10.31
Alanine	5.83	4.60	4.9
Glutamic	20.38	17.88	17.59
Serine	5.18	4.60	4.73
TOTAL	**100%**	**100%**	**100%**

[1] Source: Rice from GRAS Notice 609
[2] Source: Canadian Nutrient File, Food Code 3394, Health Canada
[3] Reported as Cystine in the Canadian Nutrient File

6.1.2 Pea Protein Safety

Pea Protein has been determined to be GRAS for use in applications similar to that of PureTaste75© at similar use rates ([GRAS Notice 608; U.S. Food & Drug Administration, 2016). Since PureTaste75© comprises ~ 45% Pea Protein (and ~45 rice protein), the exposure to pea protein from the proposed uses of PureTaste75© is expected to be determined to be safe as the rice and pea protein amounts are consistent with the amounts supported by GRAS Notice 608.

The mean and 90th percentile estimated daily intake of peas was reported to be 85 and 170 g/person/day (or 20.4 and 40.8 g pea protein/person/day), respectively (GRAS Notice 608). The estimated exposure to PureTaste75© from the proposed uses is 17.3 g/person/day resulting in ~ 7.8 g pea protein/person/day (where PureTaste75© contains ~45% pea protein, i.e. 0.45% *17.3

g PureTaste75©, yields ~7.8 g pea protein consumed), well below the current consumption of pea protein from the daily diet of peas.

Pea protein concentrate has been well characterized for its nutritional composition and characteristics and has been compared for its nutritional constituents and amino acid profile with other protein concentrates such as whey, casein and soy, and has been found to be substantially similar (Young, 1994). Pea protein concentrate is digested in the human gastrointestinal tract like all dietary proteins (Nicolas, 1996). Pea Protein is not a major allergen (Food Allergen Labeling and Consumer Protection Act of 2004.).

Pea protein has not been reported to be associated with adverse effects. For example, Abou-Samra et al. (2011) reported a study in which 32 healthy male volunteers (25 ± 4 years) consumed 20 g of pea protein dissolved in 250 ml of water. No adverse events were reported. Babault (2015) reported that the feeding of 25 g of pea protein dissolved in water to 161 males (18-35 years) healthy males twice daily for 6 weeks was well tolerated and no adverse events were reported.

In addition to the estimated exposure of PureTaste75©, the common food use information of peas and pea protein can be considered as relevant safety support for the pea protein in PureTaste75©. Peas are one of the oldest cultivated crops in the world and an important source of protein for humans and animals (Encyclopedia Britannica, 2017) and have been consumed as a food around the world since ancient times (Li, 2017). Peas are an excellent source of protein and the amino acid lysine (Vaclavik, V. 2013). The USDA Nutrient Database includes peas and its preparations as foods (United States Department of Agriculture). The Reference Amount Customarily Consumed (RACC) for peas is 85 g/serving (21 CFR 101.12). Based on data collected by the USDA, the mean and 90 percentile estimated daily intake of peas (and beans) is 85 and 170 g/person/day respectively. The available information demonstrates common human consumption of peas and pea protein.

6.1.3 Rice Protein

As with the pea protein above, PureTaste75© contains a combination of rice and pea protein in an amount that is equivalent to use rates in GRAS Notice 608. Since PureTaste75© comprises ~ 45% Pea Protein and ~45 rice protein), the exposure to pea and rice protein from the proposed uses of PureTaste75© is expected to be determined to be safe as the rice and pea protein amounts are consistent with the amounts supported by GRAS Notice 608. The Reference Amount Customarily Consumed (RACC) of prepared rice is 140 g (or 45 g dry rice) as per 21 CFR 101.12(b). Rice contains approximately 8% protein (so dry rice would contain 3.6 g rice protein), and the intake of protein from consumption of rice at the mean and 90th percentile in the US is estimated to be 12.3 and 25.0 g/person/day, respectively.

Bran and germ from the brown rice are concentrated sources of vitamins, minerals, flavones, and other phytonutrients. Brown rice is used in the preparation of various foods including breakfast cereals, baked goods, rice cakes, tea, pasta, and noodles. The consumption of rice in developing countries is approximately 68.5 kg/person/year (188 g/person/day) and 12.8 kg/person/year (35 g/person/day) in developed countries (Kahlon, 2009).

In addition to the estimated exposure of PureTaste75©, the common food use information of rice protein can be considered as relevant safety support for the rice protein in PureTaste75©. Rice, brown rice, and their derivatives have a long history of human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Rost, 1997). Among the cereals, rice and wheat share equal importance as leading food sources for humankind (Chang, 2000). Rice is produced on most continents and serves as a dietary staple for a majority of populations across the world (FAO, n.d.). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and hydrolyzed rice protein (Sun Rice, n.d.).

Based on its history of common use, rice is generally regarded as safe current levels of consumption. The USDA Nutrient Database list includes rice and its preparations as foods. The USDA National Nutrient Database has listed 3528 (USDA ND, November 20, 2017) food products that contain rice suggesting common exposure to rice.

6.1.4 Maltodextrin

Maltodextrin ($(C_6H_{10}O_5)n$, CAS Reg. No. 9050-36-6) is a non-sweet nutritive saccharide polymer that consists of D-glucose units linked primarily by [alpha]-1-4 bonds and a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes, meeting Food Chemicals Codex, 3d ed., 3d supp. (1992), p. 125. Maltodextrin as used in PureTaste75© is listed in 21 CFR 184.1444 as affirmed as GRAS. This ingredient is used in PureTaste75© consistent with current good manufacturing practice (cGMP, 21 CFR 184.1444)

6.1.5 Ammonium Phosphate, dibasic

Ammonium phosphate, dibasic ($(NH_4)2HPO_4$, CAS Reg. No. 7783-28-0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8. This ingredient used in PureTaste75© meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p.21. As per 21 CFR 184.1141b Ammonium phosphate, dibasic is for use in food as a processing aid.

6.1.6 Carrot Powder

The carrot powder used in PureTaste75© is composed of 100% organic carrots. There is common knowledge of a long history of human consumption of carrot, both fresh and cooked. Traces of carrot have been discovered at archeological sites (pre-historic lake dwellings in Switzerland), and carrot was included in the listing of vegetables in the Babylonian royal gardens (8th century B.C.) (Davidson, 1999). Carrots were also among the vegetables eaten by early Mediterranean civilizations in Sumer and Egypt (around 3000 B.C.) (McGee, 1984). These early references likely refer to carrot's use as an aromatic herb rather than root vegetable (Davidson, 1999).

The first description of the modern carrot was in the early 12th century in Andalusia. Carrots reached Western Europe in the 14th century and Britain in the 14th. The violet/purple carrot was

grown in Italy by the early 1300s (Schneider, 2001). The early descriptions of carrots were of two types, purple/red and pale yellow/white. The orange carrot first appeared in the 17th century and soon dominated carrot production. Cultivated carrots were brought to the New World before 1565, likely by the Spanish and were then adopted by Native Americans (Davidson, 1999).

Based on the long history of use of Carrots as a food product and the minimal amount present in PureTaste75© this ingredient is not expected to pose a safety risk from consumption of PureTaste75©.

6.1.7 Magnesium Sulfate

Magnesium sulfate ($MgSO_4.7H_2O$, CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization. The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p.183 and is listed in 21 CFR 184.1443 as direct food substance affirmed as GRAS by the FDA. In accordance with 184.1(b)(1), The ingredient is used in PureTaste75© consistent with current good manufacturing practice (cGMP) as a processing aid.

6.1.8 Citric Acid

The Citric Acid used in PureTaste75© is affirmed GRAS for use as (21 CFR 184.1033). Citric acid ($C_6H_8O_7$, CAS Reg. No. 77-92-9) is also known as 2-hydroxy-1,2,3-propanetric carboxylic acid. It is a naturally occurring constituent of plant and animal tissues. It occurs as colorless crystals or a white powder and may be anhydrous or contain one mole of water per mole of citric acid. Citric acid may be produced by recovery from sources such as lemon or pineapple juice; by mycological fermentation using Candida spp. and by the solvent extraction process for the recovery of citric acid from *Aspergillus niger* fermentation liquor.

The citric acid used in PureTaste75© meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 86-87. Citric Acid is used in the production of PureTaste75© consistent with cGMP (21 CFR 184.1(b) (1))

6.1.9 Antifoam

The antifoam (TRANS-4062) used in the production of PureTaste75© is made from vegetable oil, which is a food safe processing aid. TRANS-4062 is considered a secondary direct food additive according to the Code of Federal Regulations, Title 21, and is compliant with 21 CFR 173.340(a)(2). It is degraded during the production process and residues are not expected in the final food PureTaste75© product.

6.1.10 Lentinula edodes

The fruiting bodies of *Lentinula edodes*, also known as shiitake, are a common food particularly in Asia. As a source of diverse secondary metabolites, fungi have a long history of use in both culinary and medicinal applications (Karen M. VanderMolen J. G.-E., 2017). It is the second

most popular edible mushroom in the global market (Bisen PS, 2010). Mushrooms have a great nutritional value since they are quite rich in protein, with an important content of essential amino acids and fiber (Tiane Cristine Finimundy, 2014). The world mushroom industry markets more than 2 million tons of mushrooms per year and is still expanding (Nakamura, 1992). Shiitake mushrooms are the second most produced edible mushrooms worldwide (Nakamura, 1992).

Mushrooms have nutritional value since they are rich in protein (~2.26 %protein), with an important content of essential amino acids and fiber (Finimundy, 2014). Edible mushrooms are a high nutritional quality food and have been used as an alternative to dietary protein in countries with high malnutrition rate (Finimundy, 2014, Canadian Nutrient File for Shiitake Mushroom, Food code 6904). The chemical and nutritional characteristics of mushrooms vary in function after harvest, and processing (Finimundy, 2014).

In a review of the nutritional compounds found in *Lentinus edodes* Finimundy (2014) it was reported that the dietary fiber present in *L. edodes* consists of soluble and insoluble fractions. Water-soluble β-glucans and proteins are found in the soluble fraction. In the non-soluble fraction, polyuronide (acidic polysaccharide), hemicellulose, β-glucan chains with heterosaccharide, lignin, and chitin are found. *L. edodes* provides a nutritionally significant content of vitamins B1, B2, B12, C, D, and E. The aroma components include alcohols, ketones, sulfides, alkanes, and fatty acids . The main constituents which are volatile include matsutakeol (1-octen-3-ol) ethyl, n- amyl ketone. The characteristic aroma of shiitake was identified as 1,2,3,5,6-Pentathiepane (Finimundy, 2014). *L. edodes* mycelium are composed of glycoproteins containing glucose, galactose, xylose, arabinose, mannose, and fructose (Coates, 2010)

In order to identify the effect of oral intake of fermented shiitake powder or fermented shiitake protein powder, a comprehensive search of the scientific literature through 2017 was conducted using PubMed and Science Direct. Safety and tolerability of cooked and/or processed (extract) shiitake mushrooms were well established in human studies, with numerous toxicological, clinical and observational studies covering the common endpoints for *L. edodes*. Specifically, mutagenicity and genotoxicity assays have all reported negative results and minimal toxicity has been reported in systemic and Developmental and Reproductive Toxicity (DART) studies for the oral administration with only mild, transient gastrointestinal symptoms being reported (VanderMolen, 2017) which typically disappear after a short period of time(Wasser, 2004).

Levy (1998) reported some adverse effects from chronic consumption of 4g daily of raw shiitake powder including eosinophilia and abdominal cramping. This trial involved feeding ten healthy adults 4 g of dried shiitake mushroom powder to assess the changes in eosinophil-active cytokines and eosinophil proteins in blood and stool. The estimated daily consumption of 10.9 g of PureTaste75© comprising <1% Shiitake will result in an expected exposure of 1.09 mg Shiitake /day This is much less than the 4g daily dose reported by Levy (1998). PureTaste75© undergoes a heat-treatment step. Levy (1998) fed the raw material and this study is not considered relevant to the safety of PureTaste75© (EFSA, 2010). Clinical Studies on the safety of Shiitake are summarized in Table 17.

To confirm the final PureTaste75©product content met product specifications, samples were sent to two independent laboratories. The results of these analyses were consistent and there were no

protein matches present in MS/MS data that were unaccounted for from either the media or known ingredients. The proteins that were present in the ingredients prior to fermentation vary very little with respect to the final product after fermentation. This is consistent with the raw material amino acid specifications in comparison to the amino acid specifications of PureTaste75©.

Table 17 - Shiitake Mushroom, Safety Evidence from Human Studies

Study Title (reference)	**Study Design**	**Outcome Measures/Endpoint**	**Results**
Shiitake *(Lentinus edodes)* dermatitis (Nakamura, 1992).	Retrospective study (from 1974 to 1991) to examine 51 patients with shiitake dermatitis due to the intake of half-baked raw shiitake.	Shiitake dermatitis in 41 men and 10 women (15-76 years) was analyzed retrospectively. Dosage: varies and not reported.	All patients (n=51) had truncal involvement of Shiitake dermatitis. Extremities, neck, face and head were involved in decreasing order of frequency. No patients had digestive or nervous system symptoms, nor were the mucous membranes affected. Conclusion: Shiitake dermatitis can be avoided by eating sufficiently boiled raw shiitake.
Flagellate dermatitis after consumption of Shiitake Mushrooms. (Czarnecka et al, 2014).	Case report, investigated Flagellate dermatitis occurrence in patients who had eaten Shiitake mushrooms.	A 55-year-old German patient (male) was diagnosed with Flagellate dermatitis after eating Shiitake mushroom at a restaurant. Dosage: not reported.	Examination revealed severely-itching parallel, striped whiplash-like infiltrated erythema with severe itching on the trunk and upper extremities. In addition, there were papulovesicles on urticarial erythemas on the shoulders. Conclusion: Flagellate dermatitis could be avoided by eating adequately cooked shiitake mushrooms.

Flagellate mushroom (Shiitake) dermatitis and photosensitivity. (Hanada, 1998).	Case report, investigated Flagellate skin lesions in a patient after eating the mushroom *Lentinus edodes.*	A 44-year-old man was diagnosed with Flagellate dermatitis after eating Shiitake mushroom.	This patient was diagnosed with flagellate skin lesions on his trunk after eating *L. edodes*. The patient also developed photosensitive lesions on skin exposed to sunlight . Analysis of the case histories of 94 Japanese patients with shiitake dermatitis revealed that 44 (47%) cases developed dermatitis on the skin exposed to sunlight. Conclusion: Despite the high consumption of Shiitake mushrooms, the incidence of severe allergic reactions appears to be very low.
Systemic allergic contact dermatitis due to consumption of raw shiitake mushroom. (Kopp, 2009).	Case report, investigated the effect of raw Shiitake mushroom (*Lentinus edodes*) on contact dermatitis.	A 52-year-old man who developed a generalized pruritic papulovesicular eruption 2 weeks after daily consumption of uncooked shiitake mushrooms. Prick-to-prick and scratch tests with uncooked mushrooms resulted in an eczematous reaction at 24 h that peaked at 72 h and persisted for 1 week.	This patient had systemic allergic contact dermatitis due to consumption of raw shiitake mushroom. Conclusion: Shiitake dermatitis could be avoided by eating adequately cooked or processed shiitake mushrooms.
Eosinophilia and gastrointestinal symptoms after ingestion of shiitake mushrooms. (Levy, 1998)	An open label, observational study; investigated whether ingestion of shiitake mushroom powder (freeze dried powder) induces eosinophilia or symptoms.	Dosage: Each capsule contained 250 mg of Shiitake mushroom powder (freeze dried). 10 Subjects (9 men and 1 woman*, with an average age of 40.6 years, range of 31 – 63 years) ingested 4 grams (16 capsules = 4 medium sized mushrooms) of freeze dried shiitake powder daily for up to 10 weeks (trial 1) or 3 to 6 months (trial 2). *The woman was of child-bearing age and she was requested to use contraception to prevent pregnancy during the study.	Conclusion: At 4g per day of raw shiitake mushrooms some abdominal cramping and eosinophilia were reported.
Consuming *Lentinula edodes* (Shiitake) Mushrooms Daily Improves Human Immunity	A randomized dietary intervention study; to determine whether consumption of whole, dried *Lentinula edodes* (shiitake) mushrooms	Fifty-two healthy males and females (21-41 years), participated in a 4 weeks parallel group study, consuming either 5 or 10 g of shiitake mushrooms daily.	Conclusion: Dosage was well tolerated. Safety and adverse events were not reported in the study.

(Dai, 2015)	could improve human immune function.		
Safety of orally administered *Lentinula edodes* mycelia extract for patients undergoing cancer chemotherapy: a pilot study. (Yamaguchi, 2011)	Observational study to investigate safety of *Lentinula edodes* on quality of life (QOL) and the immune response in patients undergoing cancer chemotherapy.	Seven patients were studied in total. The patients were undergoing post-operative adjuvant chemotherapy for breast cancer (n = 3) or gastrointestinal cancer (n = 2), or were receiving chemotherapy to prevent recurrence of gastrointestinal cancer (n = 2). The first course of treatment was chemotherapy alone and the second was chemotherapy plus concomitant administration of *Lentinula edodes* extract. Outcome measures: Adverse events and changes in the QOL score were evaluated during the study period.	Conclusion: Treatment with *Lentinula edodes* extract with chemotherapy is safe and no adverse events were attributable to *Lentinula edodes* extract.
Oral Administration of *Lentinula edodes* Mycelia Extract for Breast Cancer Patients Undergoing Postoperative Hormone Therapy. (Suzuki, 2013)	This was a 12-week, single-arm, open-label study. All subjects first entered a 4-week observation period, followed by an 8-week period of oral *Lentinula edodes* extract ingestion at 1800 mg daily. Preparation: *Lentinula edodes* mycelia were cultivated in a solid medium composed of sugar-cane bagasse and defatted rice bran. Medium containing the mycelia was incubated in hot water, and then the soluble fraction was dried and used as *Lentinula edodes* extract.	This study investigated the influence of *Lentinula edodes* on the quality of life (QOL) and immune response in breast cancer patients undergoing postoperative adjuvant hormone therapy. Twenty patients* were studied in total. They received only hormone therapy in the first 4 weeks followed by hormone therapy and *Lentinula edodes* (1800 mg/day) during the next 8 weeks. *As subjects are breast cancer patients, this suggests strongly that all subjects are female.	Conclusion: No subjects reported any serious adverse events. Safety of oral administration of *Lentinula eododes* Mycelia Extract was supported by this study.
Efficacy of Orally Administered *Lentinula edodes* Mycelia Extract for	This study was conducted as an 8-week single-group open label study.	This study investigated the influence of *Lentinula edodes* mycelia extract (LEM), an oral immunomodulator, on	Conclusion: Concomitant use of *Lentinula edodes* Mycelia Extract with chemotherapy

Advanced Gastrointestinal Cancer Patients Undergoing Cancer Chemotherapy: a Pilot Study. (Okuno, 2011).	During the study period, each subject took two courses of chemotherapy. *Lentinula edodes* extract was orally ingested during the second course at a dose of 1800 mg/day for 4 weeks. Preparation: Lentinula edodes mycelia were cultivated in a solid medium composed of sugar-cane bagasse and defatted rice bran. Medium containing the mycelia was incubated in hot water, and then the soluble fraction was dried and used as LEM	immune function and adverse events from chemotherapy. Subjects comprised 1 gastric (male) and 7 colorectal (5 females, 2 males) cancer patients. Ages ranged from 52 to 71. The first course of treatment was chemotherapy alone and the second was chemotherapy plus concomitant administration of LEM. Adverse events and interferon (IFN)-γ production by CD4+ T, CD8+ T and CD56+ NK/NKT cells were evaluated at the end of each course.	can decrease the incidence of adverse effects from cancer chemotherapy among patients with advanced cancer. Safety of *Lentinula edodes* is supported by this study.
Dietary supplementation with rice bran fermented with *Lentinus edodes* increases interferon-γ activity without causing adverse effects: a randomized, double-blind, placebo-controlled, parallel-group study. (Choi, 2014)	A randomized, double-blind, placebo-controlled, and parallel-group investigated the hypothesis that dietary supplementation with rice bran fermented with *Lentinus edodes* (rice bran exo-biopolymer, RBEP), a substance known to contain arabinoxylan, enhances natural killer (NK) cell activity and modulates cytokine production in healthy adults.	Dosage: 80 healthy (non-pregnant/lactating adults, aged 25-70 years old comprised of 31 females and 49 males) participants were randomly assigned to take six capsules per day of either 3g RBEP or 3g placebo for 8 weeks.	Conclusion: This well designed RCT demonstrates the safety of fermented *Lentinus edodes* with rice bran. No adverse events were reported.

6.2 Allergenicity to PureTaste75© Protein

Although at least 170 foods have been reported to cause allergic reactions, there are only eight major food allergens – milk, egg, peanut, tree nuts, wheat, soy, fish and crustacean shellfish are responsible for most of the serious food allergy reactions in the US (Facts and Statistics, n.d.). It is estimated that up to 15 million Americans have food allergies, including 5.9 million children under the age of 18 (Facts and Statistics, n.d.). Each year in the U.S., it is estimated that anaphylaxis to food results in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths (Consumers - Food Allergies: What You Need to Know, 2017).

PureTaste75© is primarily composed of rice and pea protein. The following discussion is limited to the potential allergenicity of rice and pea protein.

Cereal grains have been reported to be a cause of food allergies. Rice specifically has been reported as an inhalant or contact allergen, rather than a food allergen (GRAS 609). In Japan, the prevalence of IgE- mediated rice allergy is approximately 10% in atopic subjects ; however it is much lower in Europe and the US, <1% (Besler, M, 2001). As indicated in GRAS notice 609, allergy to rice is rate and the frequency may differ among varying populations. Furthermore, the GRAS notice 609 speaks to the use of rice as one of the earliest solid foods given to babies due to its instrinsic hypoallergenic nature.

Peas are part of a family of plants called legumes, which also include alfalfa, clover, beans, lentils, mesquite, carob, soybeans, peanuts, tamarind, and wisteria (Grains & Legumes Nutrition Council, 2017). Allergenic response to legumes may range from mild skin reactions to life-threatening anaphylactic reactions (Verma, 2013). Legumes have been reported to be a cause of food allergies, especially peanut allergy (Sicherer, 1999). Peanuts and soybeans are the major legume allergies in the United States, United Kingdom, and Japan, while lentils, chickpeas and pea allergies are more common in the Mediterranean area and India (Sanchez-Monge, 2004). Peanut and/or Tree Nut allergy affects approximately 1.1% of the general population, or about 3 million Americans (Sicherer, 1999). Legume cross-reactivity varies by region - while extensive cross-reactivity among lentil, chickpea and pea were reported in the Mediterranean area, only minimal cross-reactivity among legumes (mainly reported between peanut and soy) have been reported in North America (Abrams, 2015). As indicated in GRAS notice 608 for pea protein, the available information for allergenicity of pea proteins indicates that persons with peanut allergies may be sensitive to peas; however, allergic reactions to peas appear to be rare and may fluctuate among different populations.

The low anticipated allergenicity concern with the rice and pea proteins in PureTaste75© can be mitigated by the listing of the common name of this product on a label, which is Fermented Shiitake, Pea and Brown Rice Protein. As such, appropriate labelling by use of the common name of PureTaste 75© does not hinder the safety and GRAS status that is the subject of this notification.

MycoTechnology, Inc. acknowledges that PureTaste75© does not contain any of the eight foods (milk, egg, fish, crustacean shellfish, tree nuts, peanuts, soybeans, wheat) considered to be major food allergens under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). For a more extensive review of potential allergens which may be present in PureTaste75© please refer to Table 18.

Table 18 - Allergens Present in PureTaste75©

Component	Present in the product	Present in other products produced on the same line	Present in the same plant
1. Barley, Rye, Oats	YES	NO	YES
2. Celery (not including seeds)	NO	NO	NO
3. Corn	NO	NO	NO
4. Egg or egg product	NO	NO	NO
5. Fish	NO	NO	NO
6. Mille & Mille by-product	NO	NO	NO
7. Monosodium Glutamate (MSG)	NO	NO	NO
8. Peanuts or peanut products	NO	NO	NO
9. Seeds (Poppy, Sunflower, Cottonseed)	NO	NO	NO
10. Sesame Seeds	NO	NO	NO
11. Shell Fish & Crustaceans	NO	NO	NO
12. Soybean Oil (excluding refined soy oil)	NO	NO	NO
13. Soybean (not including oil)	NO	NO	NO
14. Sulphites (enter maximum ppm)	NO	NO	NO
15. Tree Nuts	NO	NO	NO
16. Wheat or wheat products	NO	NO	NO
17. Gluten <l O ppm	NO	NO	NO
18. Yellow 5 (Tartrazine)	NO	NO	NO
19. Animal Fat	NO	NO	NO
20. Grains containing gluten	NO	NO	NO
21. Mustard	NO	NO	NO
22. Lupin	NO	NO	NO
23. Lactose	NO	NO	NO

6.3 Safety Narrative Summary

PureTaste75© is a product manufactured with fermentation technology comprising of proven safe food ingredients with a long history of common use in the worldwide food supply.

MycoTechnology Inc. has determined the Generally Recognized as Safe (GRAS) status of PureTaste75© based on the following:

- The published toxicological studies using the same test materials as those included in PureTaste75© included pea, brown rice and Shiitake proteins were reviewed and no adverse events were reported at levels which are proposed for PureTaste75©.
- Both pea and rice proteins, the main constituents of PureTaste75©, have been consumed for centuries through the consumption of peas and rice and through the consumption of the protein products as affirmed GRAS (GRAS Notice 609 and 581)
- All ingredients included in PureTaste75© are safe for use in food at levels and uses proposed for PureTaste75©.
- The PureTaste75© Protein is manufactured under good manufacturing practices (GMPs) and meets appropriate food grade specifications and within a BRC inspected facility.
- PureTaste75© Protein raw materials are not listed as major allergens (Food Allergen Labeling and Consumer Protection Act of 2004).
- Consumption data and information pertaining to the individual proposed food uses of rice protein, pea protein, and soy protein were used to estimate the all-person and all-user intakes of PureTaste75© for the U.S. population. In summary, the mean intake or PureTaste75© for "all users" is estimated to be 10.3 g/person/day (mean) and 17.3 g /person/day (90^{th} percentile).
- PureTaste75© will substitute for other protein sources in the diet, and thus will not increase the overall increase of consumption of protein in the diet.

6.4 Conclusion of the Expert Panel

At the request of MycoTechnology, Inc., we, the undersigned expert panel members, Michael W. Pariza, Madhu Soni, Ph.D., and Joseph Borzelleca, Ph.D., independently and collectively critically evaluated the information summarized in this GRAS report on the safety of Shiitake Fermented Pea and Brown Rice Protein We also considered other information deemed appropriate.

Following this critical evaluation, we, unanimously concluded that Shiitake Fermented Pea and Brown Rice Protein, produced consistent with current Good Manufacturing Practices (cGMP) and meeting the food ingredient specifications described herein, is safe under its intended conditions of use as a nutritional food ingredient.

We unanimously concluded that that Shiitake Fermented Pea and Brown Rice Protein, produced consistent with current Good Manufacturing Practices (cGMP) and meeting the food ingredient specifications described herein, is GRAS based on a long history of safe use and on scientific procedures.

Part 7: 170.255 List of Supporting Data and Information in your GRAS Notice

All the references used in this GRAS including animal and human studies are generally available and listed below.

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Bonnette, Richard

Subject: FW: GRAS notice - procedure and format

From: Nicole Berzins [mailto:nberzins@mycotechcorp.com]
Sent: Monday, July 09, 2018 11:17 AM
To: Bonnette, Richard <Richard.Bonnette@fda.hhs.gov>
Subject: RE: GRAS notice - procedure and format

Richard,

Good Morning. I had not received a receipt of my previous response so I am sending this note again.

Thank you kindly for the review notes and interpretation requests.

As noted in questions 1, The note of item 8 was a copy from the previous submission, which was corrected and an oversight in the resubmission. There shall be not traded secret details noted in this submission.

The Expert Panelists indicated that the submission I based on the use in common foods. This analysis was interpreted via a bridging and gap analysis of the materials used which did indicate scientific procedure. So by default, this would result in the information of use in common foods.

Please reach out to me to confirm anything further during your evaluation.

Kindly,
Nicole Berzins

Nicole K. Berzins *Director of Regulatory & Quality Affairs, MycoTechnology*
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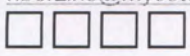

From: Bonnette, Richard <Richard.Bonnette@fda.hhs.gov>
Sent: Friday, June 22, 2018 6:38 AM
To: Nicole Berzins <nberzins@mycotechcorp.com>
Subject: RE: GRAS notice - procedure and format

Nicole,
We've completed the prefiling evaluation of your most recent submission for fermented shitake, pea, and rice protein, received on June 7, 2018. There are a few points that we need to clarify to file this submission as a GRAS notice continue forward with an evaluation. You can reply to this email with your responses and this exchange will become part of the record, and part of the original GRAS notice that is uploaded to the web if the responses clarify our questions such that we can file the submission as a GRAS notice.

1. There are inconsistencies about confidential or trade secret information in the submission that needs clarification. Form 3667 item 7 notes that there is no such information, but item 8 notes that trade secret information has been designated in the submission. Similarly, in Part 1 of the GRAS notice (page 5), we note that item 1.8 indicates that there is no trade secret, commercial, or financial information present in the notice. We note that page 9 of the manufacturing process at the bottom contains the statement "MFG Confidential Commercial Information Noted (IP)." Please clarify if this is an oversight, or if you intend for information in this section to be held as confidential. Please note that is you do intend for information to be confidential, there are other regulations that come into play (170.250 (d) and (e)) that will require explanation about this information held as confidential.
2. We noted some minor discrepancies between the Form 3667 and Part 1 of the GRAS notice, particularly in the basis for the GRAS conclusion. The form notes that the basis is "Experience based on common use in foods," while Part 1 of the notice indicates "Scientific procedures." The content of the notice suggests that scientific procedures is the basis. Can you confirm this?

Please let me know if you have any questions.
Regards,
Richard

Professor Emeritus
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Expert Panel Report Concerning the Generally Recognized as Safe (GRAS) Status of the Proposed Uses of Fermented Shiitake Pea and Brown Rice Protein as an Ingredient in Food and Beverages

24 March 2018

INTRODUCTION

MycoTechnology, Inc. proposes to market Fermented Shiitake Pea and Brown Rice Protein (PureTaste75©) as an ingredient in foods and beverages. MycoTechology convened a panel of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients ("Expert Panel") to conduct a critical and comprehensive evaluation of the publicly available data and information concerning the safety (" there is a reasonable certainty of no harm under the intended conditions of use") and the GRAS status of the proposed uses of Fermented Shiitake Pea and Brown Rice Protein.

The Expert Panel consisted of Professors Joseph F. Borzelleca, Ph.D. (Virginia Commonwealth University School of Medicine), Michael W. Pariza, Ph.D. (University of Wisconsin) and Madhusudan Soni, Ph.D. (President, Soni & Associates, Inc.). The Food and Drug Administration's guidance for industry on *Best Practices for Convening a GRAS Panel* (U.S., FDA 2017b) were considered. The Expert Panel is balanced and there are no conflicts of interest. The Expert Panel was compensated for its deliberations and compensation was not dependent on the conclusions of the Expert Panel.

The Expert Panel, independently and collectively, critically evaluated a GRASN submitted by MycoTchnology, Inc. supporting the Generally Recognized as Safe (GRAS) Status of Pea and Brown Rice Shitake Fermented Protein, PureTaste© when used as an ingredient in food and beverages. The Expert Panel also considered other information considered appropriate.

Following an independent and collective critical evaluation of the GRASN and other information deemed appropriate, the Expert Panel conferred with representatives of MycoTechnology, Inc. by teleconference on 01 March 2018. The Expert Panel reviewed its findings and, following discussion, unanimously concluded that the intended uses (described in the GRASN) as an ingredient in food and beverages of Fermented Shiitake Pea and Brown Rice Protein (PureTaste©) meeting appropriate food-grade specifications and manufactured consistent with current Good Manufacturing Practices (cGMP), are safe and suitable, and GRAS based on scientific procedures.

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SUMMARY AND BASIS FOR GRAS

PureTaste75© is a powdered blended protein concentrate that is comprised of three primary protein sources: rice protein, pea protein and shiitake mycelium (fermented). The relative percentages of these ingredients in the product composition are 45%, 45%, and less than 1%, respectively. Other ingredients include food grade excipients and processing aids. The product provides a total of 75% protein on a dry weight basis.

PureTaste75© is the fermentation product manufactured by reacting *Lentinula edodes* mycelia with a slurry of pea and brown rice protein concentrate supplemented with maltodextrin, magnesium sulfate, antifoam, citric acid, carrot powder and diammonium phosphate in a bioreactor. All components of the media and processing aids used in the production of PureTaste75© are food grade and meet FCC and USP specifications and are approved by the USFDA. No chemical solvents are utilized in the manufacture of PureTaste75© protein.

PureTaste75© is manufactured consistent with current good manufacturing practices (cGMP) at a facility (ARD) located in France (FDA registration number 18812599800). PureTaste75© is manufactured consistent with FDA section 409 of the Act, and FDA's implementing regulations 21 CFR 170.3 and 21 CFR 170.30 (c) and (f). ARD operates and manufactures this product under the following guidelines:

- Hazard Analysis and Critical Control Points (HACCP) and hygiene standards. ARD follows the codex alimentarius principles (CAC/RCP 1-1969, release 4 2003 for the French version).
- "Food Law" (Règlement 178/2002), the further regulations (Règlement (CE) n°853/2004, Règlement (CE) n°882/2004, Règlement (CE) n°852/2004, Règlement (CE) n°854/2004, Règlement (CE) n°183/2005).

Analytical data on five non-sequential batches of PureTaste75© reviewed by the Expert Panel demonstrated that the production process consistently resulted in a product that met the established specifications. Analytical data demonstrate that there are no viable mycelia in the finished product.

PureTaste75© is stable for a minimum of 24 months under ambient conditions.

MycoTechnology, Inc. intends to use PureTaste75© as a food ingredient in multiple specific food categories. The intended use levels range from 1% to 40% and the use levels are based on purity criteria of 75% protein concentrate. On an all-user consumption basis, the mean and 90th percentile intake of PureTaste75© from all proposed food-uses in the U.S. is estimated to be 10.3 and 17.3 g/person/day, respectively. The addition of PureTaste75© Protein ingredients will serve as a replacement for other competitive protein sources and will not increase overall consumer exposure to protein.

There are no known self-limiting levels of use for PureTaste75©.

PureTaste75© is composed of pea and brown rice protein fermented with *Lentinula edodes mycelium*. Based on the formulation of the product and the manufacturing process, the safety of the product is established through the safety of the ingredients used to produce PureTaste75©.

Peas are one of the oldest cultivated crops in the world and an important source of protein for humans and animals (Encyclopedia Britannica, 2017) and have been consumed as a food around the world since ancient times (Li, 2017). Peas are an excellent source of the amino acid lysine. The available information demonstrates safe common human consumption of peas and pea protein. Pea Protein has been determined to be GRAS for use in applications similar to that of PureTaste75© at similar use rates ([GRASN 608; U.S. Food & Drug Administration, 2016). Since PureTaste75© comprises ~ 45% Pea Protein, the exposure to pea protein from the proposed uses of PureTaste75© is expected to be less than half what was determined to be safe in this GRAS notice.

The mean and 90 percentile estimated daily intake of peas was reported to be 96 and 197 g/person/day (or 23.57 and 48.36 g pea protein/person/day), respectively (GRAS Notice 608). The 90th percentile estimated exposure to PureTaste75© from the proposed uses is 10.9 g/person/day resulting in ~ 4.5 g pea protein/person/day, well below the current consumption of pea protein from the daily diet of peas.

Rice, brown rice, and their derivatives have a long history of safe human consumption, with rice cultivation documented back to prehistoric times, starting in Asia and eventually spreading across Europe around the sixth century (Rost, 1997). Among the cereals, rice and wheat share equal importance as leading food sources for humankind (Chang, 2000). Rice is produced on most continents and serves as a dietary staple for a majority of populations across the world (FAO, n.d.). Once harvested, the rice is hulled and the resulting brown rice can be further processed to generate derivatives such as rice bran oil, rice bran extract, and rice protein

Bran and germ from the brown rice are concentrated sources of vitamins, minerals, flavones, and other phytonutrient. Brown rice is used in the preparation of various foods including breakfast cereals, baked goods, rice cakes, tea, pasta, and noodles. The consumption of rice in developing countries is approximately 68.5 kg/person/year (188 g/person/day) and 12.8 kg/person/year (35 g/person/day) in developed countries (Kahlon, 2009).

Based on its history of common use, rice is generally regarded as safe at current levels of consumption. The USDA Nutrient Database list includes rice and its preparations as foods. The USDA National Nutrient Database has listed 3528 (November 20, 2017) food products that contain rice suggesting common exposure to rice. The Reference Amount Customarily Consumed (RACC)] of prepared rice is 140 g (45 g dry rice) 21 CFR §101.12(b). Rice contains approximately 8% protein, and the intake of protein from consumption of rice at the mean and 90th percentile in the US is estimated to be 12.3 and 25.0 g/person/day, respectively.

Rice protein has been determined GRAS for use in applications similar to that of PureTaste75© and at similar use rates. As PureTaste75© comprises ~ 45% rice protein, exposure to rice protein from the proposed uses of PureTaste75© is expected to be well below the current consumption of rice and is safe.

The following approved processing aids used in the manufacture of PureTaste75© are safe and do not present any health risk to consumers of PureTaste75©: maltodextrin, ammonium phosphate dibasic, carrot powder, magnesium sulfate, citric acid, antifoam [to be named

Maltodextrin $(C_6H_{10}O_5)n$, CAS Reg. No. 9050-36-6) is a non-sweet nutritive saccharide polymer that consists of D-glucose units linked primarily by [alpha]-1-4 bonds and a dextrose equivalent (D.E.) of less than 20. It is prepared as a white powder or concentrated solution by partial hydrolysis of cornstarch, potato starch, or rice starch with safe and suitable acids and enzymes. Maltodextrin as used in PureTaste75© is listed in 21 CFR 184.1444 and affirmed as GRAS. This ingredient is used in PureTaste75© consistent with current good manufacturing practice (cGMP, 21 CFR 184.1444) and meets the specifications of the Food Chemicals Codex, 10th edition, 2016-2017.

Ammonium phosphate, dibasic ($(NH_4)2HPO_4$, CAS Reg. No. 7783-28-0) is manufactured by reacting ammonia with phosphoric acid at a pH above 5.8. This ingredient used in PureTaste75© meets the specifications of the Food Chemicals Codex, 10th Ed. (2016- 2017).

Ammonium phosphate, dibasic is GRAS for use in food as a processing aid as defined in 21 CFR 170.3(o)(24).

The carrot powder used in PureTaste75© is composed of 100% organic carrots. There is common knowledge of a long history of safe human consumption of carrot, both fresh and cooked. Traces of carrot have been discovered at archeological sites (pre-historic lake dwellings in Switzerland), and carrot was included in the listing of vegetables in the Babylonian royal gardens (8* century B.C.) (Davidson, 1999). Carrots were among the vegetables eaten by early Mediterranean civilizations in Sumer and Egypt (around 3000 B.C.) (McGee, 1984). These early references likely refer to carrot's use as an aromatic herb rather than root vegetable (Davidson, 1999). Based on the long history of use of carrots as a food and the minimal amount present in PureTaste75©, this ingredient is not expected to pose a safety risk from consumption of PureTaste75©.

Magnesium sulfate ($MgSO_4.7H_2O$, CAS Reg. No. 10034-99-8) occurs naturally as the mineral epsomite. It is prepared by neutralization of magnesium oxide, hydroxide, or carbonate with sulfuric acid and evaporating the solution to crystallization. The ingredient used in the production of PureTaste75© meets the specifications of the Food Chemicals Codex, 10th Ed. (2016) and is listed in 21 CFR 184.1443 as direct food substance affirmed as GRAS by the FDA. This ingredient is used in PureTaste75© consistent with current good manufacturing practice (cGMP) as a processing aid.

Citric acid ($C_6H_8O_7$, CAS Reg. No. 77-92-9), also known as 2-hydroxy-1,2,3-propanetric carboxylic acid, is a naturally occurring constituent of plant and animal tissues and is affirmed GRAS for use as a processing aid (21 CFR 184.1033). The citric acid used in the production of PureTaste75© meets the specifications of the Food Chemicals Codex, 10th ed. (2016) and is used consistent with cGMP (21 CFR 184.1033(b)).

The antifoam TRANS 4062 used in the production of PureTaste75© is an approved safe food processing aid. It is degraded during the production process and residues are not expected in the final PureTaste75© product.

Shiitake mushrooms have been consumed for more than 3000 years As a source of diverse secondary metabolites, fungi have a long history of use in both culinary and medicinal applications (VanderMolen, 2017). The world mushroom industry markets more than 2 million tons of mushrooms per year and is still expanding (Nakamura, 1992). Shiitake mushrooms are the second most produced edible mushrooms worldwide (Nakamura, 1992; Bison, PS, 2010).

The fruiting bodies of *Lentinula edodes*, also known as shiitake, are a common food particularly in Asia (VanderMolen K., 2017). *Lentinus edodes* is the first medicinal macrofungus to enter the realm of modern biotechnology. It is the second most popular edible mushroom in the global market (Bisen PS, 2010).

In a review of the nutritional compounds found in *Lentinus edodes* (Finimundy, 2014), it was reported that the dietary fiber present in *L. edodes* consists of soluble and insoluble fractions. Water-soluble β-glucans and proteins are found in the soluble fraction. In the non-soluble fraction, polyuronide (acidic polysaccharide), hemicellulose, β-glucan chains with heterosaccharide, lignin, and chitin are found. *L. edodes* provides nutritionally significant amounts of vitamins B1, B2, B12, C, D, and E. The aroma components include alcohols, ketones, sulfides, alkanes, and fatty acids . The main constituents, which are volatile, include matsutakeol (1-octen-3-ol) ethyl, n- amyl ketone. The characteristic aroma of shiitake

was identified as 1,2,3,5,6-Pentathiepane (Finimundy, 2014). *L. edodes* mycelium are composed of glycoproteins containing glucose, galactose, xylose, arabinose, mannose, and fructose (Coates, 2010)

In order to identify the effect of oral intake of fermented shiitake powder or fermented shiitake protein powder, a comprehensive search of the scientific literature through 2017 was conducted using PubMed and Science Direct. The following medical subject headings (MeSH) search terms were used to identify relevant studies; e.g., "shiitake", "lentinus edodes", "Fermented shiitake", "shiitake protein", "lentinus edodes protein", "fermented shiitake protein", "animal study", "human study", "lentinan", 'adverse events" and "safety". Safety and tolerability of cooked and/or processed (extract) shiitake mushrooms were well established in human studies. Numerous toxicological, clinical and observational studies covering the common endpoints are available for *L. edodes*. Mutagenicity and genotoxicity assays have all reported negative results and minimal toxicity has been reported in systemic and DART studies via the oral route with only mild, transient gastrointestinal symptoms being reported (VanderMolen, 2017), which typically disappear after a short period (Wasser, 2004).

The European Food Safety Authority (EFSA) provided a Scientific Opinion on the safety of an aqueous mycelial extract from *Lentinus edodes* to be used in dietary supplements, yoghurts, soft drinks, cooked and processed foods, and baked goods. EFSA concluded that the product was safe for use (EFSA, 2010).

No new proteins are formed during the fermentation process.

PureTaste75© does not contain any of the eight foods (milk, egg, fish, crustacean shellfish, tree nuts, peanuts, soybeans, wheat) considered to be major food allergens under the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and does not present an allergicity concern.

CONCLUSION

We, members of the Expert Panel, have independently and collectively critically evaluated the publicly available data and information on the safety of the intended uses as an ingredient in food and beverages of PureTaste75©, manufactured consistent with current Good Manufacturing Practices (cGMP) and meeting appropriate food grade specifications, and we unanimously conclude that the proposed uses are safe and suitable and Generally Recognized as Safe (GRAS) based on scientific procedures.

It is our opinion that other qualified experts would concur with this conclusion.

(b) (6)

24 March 2018

Professor Joseph F. Borzelleca, Ph.D.
Virginia Commonwealth University School of Medicine

Date

(b) (6)

27 March 2018

Professor Michael W. Pariza Ph.D.
University of Wisconsin

Date

(b) (6)

28 March 2018

Madhusudan Soni, Ph.D.
President, Soni & Associates Inc.

Date