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April 20, 2022

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Dr.
College Park, MD 20740

Attention: Dr. Susan Carlson
Re: GRAS Notification – Lemnature™ Fiber (LF)

Dear Dr. Carlson:

GRAS Associates, LLC, acting as the Agent for Lemnature Aquafarms USA, Inc. (Vero Beach, FL), is submitting for FDA review Form 3667 and the enclosed CD, free of viruses, containing a GRAS Notification for Lemnature™ Fiber (LF) - *Lemnacea* (water lentil) fiber powder. Along with Lemnature Aquafarms USA, Inc.'s determination of safety, an Expert Panel of qualified persons was assembled to assess the composite safety information of the subject substance iintended to be used as an ingredient in human food products and a component of the human diet as a dietary fiber source and to be used as a multipurpose food ingredient (e.g., anticaking agent, water binding aid, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, or purge reduction aid) at inclusion levels ranging from 0.5-10% in the food categories listed in Part III of the GRAS Assessment. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email.

We look forward to your feedback.

Sincerely,

William J. Rowe

President
Agent for Lemnature Aquafarms USA, Inc.
GRAS Associates, LLC
1810 Grand Park Ave, Suite 500
North Bethesda, MD 20852
wrowe@nutrasource.ca
Enclosure: GRAS Notification for Lemnature Aquafarms USA, Inc. – Lemnature™ Fiber (LF)

GRAS ASSESSMENT

Lemnature™ Fiber (LF) – *Lemnaceae* (water lentil) fiber powder

Food Usage Conditions for General Recognition of Safety

For

Lemnature AquaFarms USA, Inc.
Vero Beach, FL

April 20, 2022

TABLE OF CONTENTS

LIST OF ACRONYMS AND ABBREVIATIONS

Abbreviation	Definition
%MNPCE	Percent micronucleated polychromatic erythrocytes
ADME	Absorption, distribution, metabolism and excretion
AH	Acid hydrolysis
AI	Adequate intake
ANF	Antinutritional factor(s)
AOAC	Association of Official Agricultural Chemists
AOCS	American Oil Chemists' Society
AOM	Azoxymethane
APC	Aerobic plate count
AW	Water activity
BAM	Bacteriological Analytical Method
BAs	Biogenic amines
BHA	Butylated hydroxyanisole
BHT	Butylated hydroxytoluene
BW	Body weight
CFR	Code of Federal Regulations
cfu	Colony forming unit
cGMP	Current good manufacturing process
COA	Certificate of analysis
CP	Crude protein
CSFII	Continuing survey of food intakes by individuals
dmb	Dry matter basis
DMBA	7,12-dimethylbenz-alpha-anthracene
DMSO	Dimethyl sulfoxide
DNA	Deoxyribonucleic acid
EAA	Essential amino acid
EDI	Estimated daily intake
EFSA	European Food Safety Authority
Est.	Estimate
EU	European Union
FAO	Food and Agriculture Organization
FDA	United States Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSIS	Food Safety and Inspection Service
g	Gram
GA	GRAS Associates, LLC

GAE	Gallic acid equivalents
GHS	Globally Harmonized Classification System
GLP	Good Laboratory Practice
GRAS	Generally recognized as safe
GRN	GRAS notification
HARPC	Hazard Analysis and Risk Based Preventive Controls
IARC	International Agency for Research on Cancer
IOM	Institute of Medicine
ISCDRA	The International Steering Committee on Duckweed Research and Application
ISO	International Organization for Standardization
kg	kilogram
LC	LENTEIN® Complete
LC/MS/MS	Liquid Chromatography/Mass Spectrometry/Mass Spectrometry
LD_{50}	Lethal Dose (50%)
LF	Lemnature™ Fiber
LOQ	Limit of quantification
µg	microgram
mg	milligram
MPN	Most probable number
N/A	Not applicable
NHANES	National Health and Nutrition Examination Survey
NOAEL	No observed adverse effect level
NR	Not reported
NRC	National Research Council
OECD	Organization for Economic Cooperation and Development
PPM	Parts per million
RNA	Ribonucleic acid
SCFA	Short chain fatty acid
sp.	Species
TI	Trypsin inhibitors
TIU	Trypsin inhibitor units
UL	Tolerable upper intake level
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
w/w	Weight to weight
WHO	World Health Organization

FOREWORD

Lemnature AquaFarms USA, Inc. ("Lemnature") based our Generally Recognized as Safe (GRAS) assessment of the Lemnature™ Fiber, primarily on the composite safety information, i.e., scientific procedures with corroboration from history of use. The safety/toxicity of Lemnature™ Fiber, history of use of water lentil, and compositional details, specifications, and method of preparation of the subject ingredient were reviewed. In addition, a search of the scientific and regulatory literature was conducted through January 2022, with particular attention paid to adverse reports, as well as those that supported conclusions of safety. Those references that were deemed pertinent to this review are listed in Part 7. The composite safety/toxicity studies, in concert with dietary exposure information, ultimately provide the specific scientific foundation for the GRAS conclusion.

At Lemnature's request, GRAS Associates, LLC ("GA") convened an Expert Panel to complete an independent safety evaluation of Lemnature™ Fiber. The purpose of the evaluation is to ascertain whether Lemnature™ Fiber is generally recognized as safe, i.e., GRAS, under the intended conditions of use. In addition, Lemnature has asked GA to act as Agent for the submission of this GRAS notification.

Note: In March 2022, *Lemnature Aquafarms USA, Inc.* became the legal name of the company previously known as *Parabel USA, Inc.* See Appendix A for Certificates of Amendment.

I. SIGNED STATEMENTS AND CERTIFICATION

Lemnature has concluded that its Lemnature™ Fiber, also referred to as "LF" and *Lemnaceae* (water lentil) fiber powder, and which meets the specifications described below, is GRAS in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Lemnature is hereby submitting a GRAS Notice in accordance with Title 21 of the Code of Federal Regulations part 170, subpart E. Lemnature asserts that the notified substance, *Lemnaceae* (water lentil) fiber powder, as manufactured by Lemnature, is not subject to the premarket approval requirements of the FD&C Act based on Lemnature's conclusion that the notified substance is GRAS under the conditions of intended use. In addition, Lemnature certifies that, to the best of our knowledge, this GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to Lemnature and pertinent to the evaluation of the safety and GRAS status of the use of the substance *Lemnaceae* (water lentil) fiber powder as a food ingredient for addition to food products, as described herein. This determination was made in concert with an appropriately convened panel of experts who are qualified by scientific training and experience. The GRAS determination is based on scientific procedures as described in the following sections. The evaluation accurately reflects the intended conditions of food use for Lemnature™ Fiber.

This signed statement and certification has been prepared in accordance with the requirements of 21 CFR 170.225.

(a) This certification is signed by a responsible official of GRAS Associates, LLC acting as agent for Lemnature.

(b) This Part 1 of the GRAS dossier does not include any confidential information.

(c) (1) This Independent GRAS Assessment was conducted in accordance with Subpart E of 21 CFR Part 170.

(c) (2) Names and addresses of organizations;
Sponsoring Party:
Lemnature AquaFarms USA, Inc.
1991 74th Ave., Suite B
Vero Beach, FL 32966, USA
+1 772-207-4794

As the Responsible Party, Lemnature accepts responsibility for the GRAS conclusion that has been made for Lemnature™ Fiber as described in the subject safety evaluation.

Agent:
GRAS Associates, LLC
11810 Grand Park Avenue
Suite 500
North Bethesda, MD 20852, USA

(c) (3) The name of the ingredient is Lemnature™ Fiber or Lemnature™ Flour. The common name for the ingredient in food labeling is considered *Lemnaceae* (water lentil) fiber powder or *Lemnaceae* (water lentil) flour. The term "flour" will be used for USDA regulated foods and "fiber" will be used for FDA regulated foods.

Lemnature asserts it would be reasonable to propose "water lentil" as *Lemnaceae*'s common or usual name. Health Canada (2021) has approved "Water lentil protein concentrate" as an extract from *Lemna minor* and *Wolffia globosa*. Water lentil might not be commonly used in the scientific literature; however, Lemnature asserts it is a consumer centric approach to distinguish "water lentil" as a food grade ingredient from "duckweed" which is a term commonly used in wastewater remediation. Duckweed is often referred to as "pond scum" and typically grows in polluted waters containing high levels of heavy metals and toxins. In contrast, Lemnature's water lentil crop is cultivated in controlled growth and above-ground contained systems.

(c) (4) The ingredient to be used as an ingredient in Lemnature™ Fiber is a naturally derived water lentil fiber intended to be used as an ingredient in human food products and a component of the human diet as a dietary fiber source. Lemnature™ Fiber is also intended to be used as a multipurpose food ingredient (e.g., anticaking agent, water binding aid, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, or purge reduction aid) at inclusion levels ranging from 0.5-10% in the food categories listed in Part III. The foods in which the substance will be used include baked goods, beverages, breakfast cereals, cheese, spreads and condiments, confections and frostings, dairy product analogs, salad dressings, frozen dairy desserts, puddings and pie fillings, grain products and pasta, gravies and sauces, hard candy and cough drops, herbs and seasoning blends, jam and jellies, meal replacements and nutritional bars, plant protein products, protein products (processed meat and poultry products, processed fruit and vegetable juices, snack foods, soups and soup mixes (commercially prepared), and sweet sauces and

toppings. Infant formula is excluded from the intended uses. A full list of the potential food applications and levels of intended use for Lemnature™ Fiber are discussed further in Part III.

(c) (5) The statutory basis for our conclusion of GRAS status is through scientific procedures in accordance with § 170.30(a) and (b).

(c) (6) It is Lemnature's view that the ingredient is not subject to the premarket approval requirements of the FD&C Act based on the conclusion that the notified substance is GRAS under the conditions of its intended use.

(c) (7) If the United States Food and Drug Administration (FDA) were to ask to see the data and information that are the basis for Lemnature's conclusion of GRAS status, either during or after the FDA evaluation of this notice, Lemnature agrees to:

(i) make the data and information available to FDA; and

(ii) agree to both of the following procedures for making the data and information available to the FDA:

(A) Upon the FDA's request, we will allow the FDA to review and copy the data and information during customary business hours at our address specified where these data and information will be available; and

(B) Upon request by the FDA, we will provide the FDA with a complete copy of the data and information either in an electronic format that is accessible for their evaluation or on paper.

(c) (8) None of the data and information in Parts 2 through 7 of this GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552, with the exception of Appendix C, which includes trade secret information that is privileged and confidential.

(c) (9) Lemnature certifies that, to the best of its knowledge, this GRAS Assessment is a complete, representative, and balanced review that includes unfavorable information, as well as favorable information, known by Lemnature and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

(c) (10) Lemnature intends to add *Lemnaceae* Flour to meat and poultry products that come under FSIS/USDA jurisdiction and authorizes a copy of this notification, including any materials marked as business confidential/trade secret, to be shared with the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA).

(c) (11) Signature

Agent for Lemnature AquaFarms USA, Inc.
William J. Rowe Date:
President
GRAS Associates, LLC
11810 Grand Park Ave

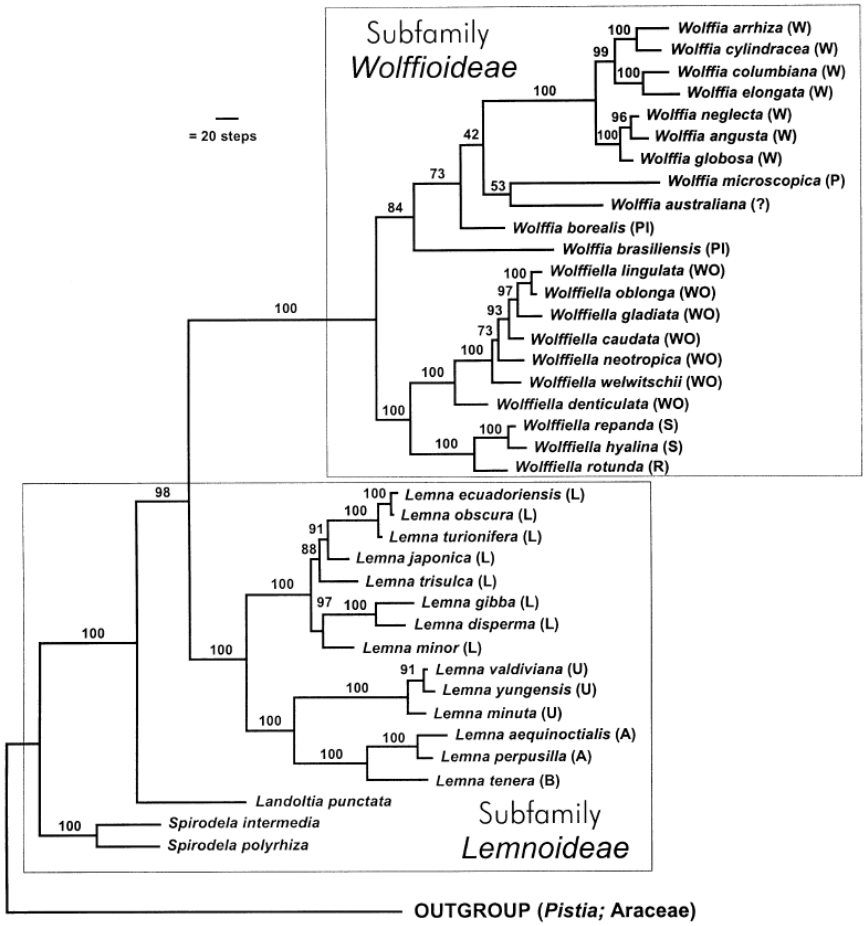
Suite 500
North Bethesda, MD 20852, USA

II. IDENTITY, METHOD OF MANUFACTURE, SPECIFICATIONS, AND PHYSICAL OR TECHNICAL EFFECT

II.A. Background

The family *Lemnaceae* Dumort (Appenroth et al., 2013; 2015; Landolt and Kandeler, 1987; Sree et al., 2016), or *Araceae* subfamily *Lemnoideae* (Nauheimer et al., 2012), consists of several species of small, free floating aquatic plants that are capable of rapid reproduction. The plant *Lemnaceae* is globally commonly called water lentils, water lens, watermeal, *lemna* and/or *wolffia*. The *Lemnaceae* family includes the subfamilies *Wolffioideae* and *Lemnoideae*. Phylogenetic analysis has shown that the *Wolffioideae* subfamily is comprised of two genera, *Wolffia* and *Wolffiella*, whereas the *Lemnoideae* subfamily is comprised of three genera *Lemna, Landoltia*, and *Spirodela* (Les et al., 2002). A phylogenetic cladogram of the *Lemnaceae* family is shown in Figure 1; while Figure 2 summarizes the species categorization. Water lentils are tiny free-floating vascular plants with worldwide distribution. *Lemnaceae* grow best in tropical and temperate zones but are found in all but arctic zones (Goopy and Murray, 2003) .

Figure 1. *Lemnaceae* Family Cladogram [a]



[a] Adapted from (Les et al., 2002)

In the environment, water lentils grow in still or slow-moving fresh water, flourishing ponds or in areas rich in organic matter, where they can double every 1-2 days under favorable growth conditions. Water lentils are tolerant of both full sun and low light conditions and can grow in layers up to 1 cm thick. Optimal growth temperatures range from 20 – 30 ºC, although they will grow in water temperatures ranging from 6 – 33 ºC (Hillman, 1961; Leng, 1999). In addition, water lentils are well suited for hydroponic cultivation.

Water lentils are monocotyledons and of relatively simple morphology with no stems or true leaves. The plant usually consists of a single or a few flat, oval shaped, leaf-like fronds, with a single thread-like root attached, seldom exceeding 5 mm long (Goopy and Murray, 2003; Hillman, 1961; Leng, 1999; Les et al., 2002; Van der Spiegel et al., 2013). According to Wang et al. (2010), water lentils "exhibit tiny, closely-related and often morphologically similar features".

As shown in Figure 2, water lentils are represented by 37 species which are categorized into five genera: *Spirodela* (2 species), *Landoltia* (1), *Lemna* (13), *Wolffiella* (10) and *Wolffia* (11) (Appenroth et al., 2013; Sree et al., 2016). Lemnature's water lentil crop includes a mono or polyculture of the *Lemnaceae* family, generally consisting of plants in the *Lemna* genus (20%-100%), *Wolffia* genus (0 - 80%), *Wolffiella* (0 – 30% of the–crop) and *Landoltia* (0 - 30% of the crop). A selected list of *Lemnaceae* that Lemnature actively grows, as well as identifying features is shown in Table 1. Any mono or polyculture of these water lentils may comprise the raw material from which LF is made.

Figure 2. *Lemnaceae* Dumort species categorization [a]

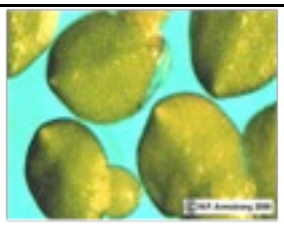
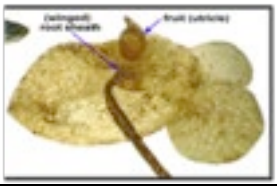
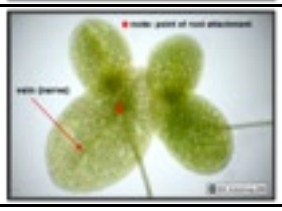
Subfamily	Genera	Species
Lemnoideae Engl.	*Spirodela* Schleid.	*S. polyrhiza* (L.) Schleid.
		S. intermedia W.Koch
	Landoltia Les & Crawford	*L. punctata* (G.Mey.) Les & D.J.Crawford
	Lemna L.	*L. disperma* Hegelm.
		L. gibba L.
		L. japonica Landolt
		L. minor L.
		L. obscura (Austin) Daubs
		L. turionifera Landolt
		L. trisulca L.
		L. aequinoctialis Welw.
		L. perpusilla Torr.
		L. tenera Kurz
		L. minuta Kunth
		L. valdiviana Phil.
		L. yungensis Landolt

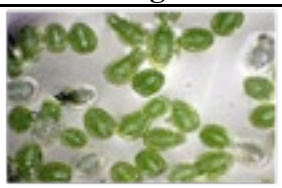
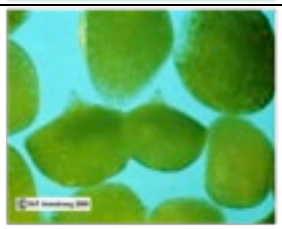
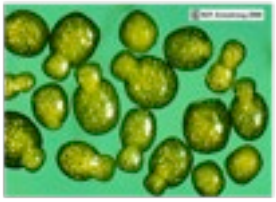
Wolffioideae Engl.	*Wolffiella* Hegelm.	*W. caudata* Landolt
		W. denticulata (Hegelm.) Hegelm.
		W. gladiata (Hegelm.) Hegelm.
		W. lingulata (Hegelm.) Hegelm.
		W. neotropica Landolt
		W. oblonga (Phil.) Hegelm.
		W. welwitschii (Hegelm.) Monod
		W. rotunda Landolt
		W. hyalina (Delile) Monod
		W. repanda (Hegelm.) Monod
	Wolffia Horkel ex Schleid.	*W. angusta* Landolt
		W. arrhiza (L.) Horkel ex Wimm.
		W. columbiana H.Karst.
		W. cylindracea Hegelm.
		W. elongata Landolt
		W. globosa (Roxb.) Hartog & Plas
		W. neglecta Landolt
		W. australiana (Benth.) Hartog & Plas
		W. borealis (Engelm. ex Hegelm.) Landolt
		W. brasiliensis Wedd.
		W. microscopica (Griff.) Kurz

a Reference: Sree et al. (2016)

Table 1. Selected *Lemnaceae* and *Wolffia* species grown by Lemnature

Strain	Defining features	Images
Lemna minor	1 root, not reddish on lower surface, can be red on upper. 3 veins.	
Lemna gibba	1 root, gibbous on bottom	

Strain	Defining features	Images
Lemna japonica	Hybrid of *L. minor and L. turionifera*. 1 root, row of dorsal papillae	
Lemna obscura	Prominent apical papule on smooth dorsal surface	
Lemna turionifera	Shiny, red blotches on ventral side, and occasionally dorsal. Typically has dorsal papule row. Turions often present (seasonal)	
Lemna valdiviana	Plant bodies connected in 4-8 colonies, thin transparent with single vein extending more than 3/4 from root node to apex	
Lemna aequinoctialis	2-3.5 mm, no red color, rounded at base, very distinct papillae near apex and root node, base of root has sheath with 2 wing-like appendages	
Lemna minuta	Frond 1-2mm, one vein extending less than 2/3 from node to apex	
Wolfiella gladiata	Fronds are usually connected to form star like colonies. The fronds are 5-10 mm long; the flowers are extremely small and difficult to see. *Wolfiella* floats just beneath the surface of the water	

Strain	Defining features	Images
Wolffia globosa	Plant body 0.4-0.8 mm, longer than wide (ovoid-cylindrical), upper surface barely rounded (flattened along top)	
Wolffia arrhiza	Plant body 0.8-1.3 mm, ovoid to nearly spherical. Distinctly flattened dark green dorsal. No brown pigment cells.	
Wolffia brasilensis	Plant body 0.7-1.2 mm, ovoid-ellipsoid, upper surface flattened with a minute-prominent papule in the center; dead plants dotted with brown pigment cells	
Wolffia columbiana	Plant body 0.8-1.2 mm, almost spherical, most of upper surface clearly rounded, the uppermost top area flat	
Spirodela polyrhiza	2-4 roots per frond. Red/Purple ventral common	

Lemnature recognizes the controversy involving the taxonomic position of the family *Lemnaceae*, or *Araceae* (as subfamily *Lemnoideae*). Nevertheless, Lemnature agrees with the opinion from The International Steering Committee on Duckweed Research and Application (ISCDRA) members (Appenroth et al., 2013; Bog et al., 2019; Sree et al., 2016) that *Lemnaceae* is more appropriate and more frequently adopted in the literature. As summarized by Bog et al. (2019):

> "[Water lentils] constitute the family *Lemnaceae* Dumort. Although, it has been shown convincingly that *Lemnaceae* are very closely related to *Araceae* (Choi et al., 2017; Cusimano et al., 2011; Nauheimer et al., 2012), it has been further discussed that it is not necessary to integrate *Lemnaceae* into the family of *Araceae* (as subfamily *Lemnoideae*) and that this group can be treated in accordance with taxonomic rules as plant family, i.e., *Lemnaceae* Dumort (Appenroth et al., 2013; 2015; Bog et al., 2018)"

Moreover, regarding the taxonomic position of the family *Lemnaceae,* Sree et al. (2016) reviews experts opinions and summarizes the arguments presented by Appenroth et al. (2013, 2015) in favor of designating *Lemnaceae* as the family name for water lentils as follows :

a) Although water lentils are monophyletic with those of the *Araceae*, the branching is estimated to have started in the Early Cretaceous when the breakup of Pangea was in its final stage (Nauheimer et al., 2012).
b) The notion to unify *Araceae* and *Lemnaceae* originated from a certain similarity between *Pistia* spp. and some water lentils, especially *Spirodela polyrhiza* L. (Schleid.) (Hooker and Brown, in Smith, 1824). On the basis of more recent morphological and molecular investigations (Cusimano et al., 2011), it is now clear that this similarity is only superficial.
c) The characteristics of the members of *Lemnaceae* which are similar to those of *Araceae* at the morphological, anatomical or biochemical levels are not only restricted to *Araceae* but are similar in all Alismatales.
d) All species belonging to *Lemnaceae* together form a well-defined unit on morphological, biochemical and habitat bases.

II.A.1. *Chemical composition of Lemnaceae as reported in the scientific literature*

Publication by Appenroth et al. (2017) analyzed the chemical composition of six species of water lentils "representing all five genera Spirodela polyrhiza, Landoltia punctata, Lemna gibba, Lemna minor, Wolffiella hyalina, and […] Wolffia microscopica (Sree et al., 2015a)." The derived compositional results indicate the six-species' dry weight content range from 4 to 8%, the protein content ranging from 20 to 35% on a dry matter basis (dmb), the fat content 4 to 7% (dmb), and the starch 4 to 10% (dmb). In addition, water lentils contain micronutrients including minerals and phytonutrients (Appenroth et al., 2017). Hu et al. (2022) investigated the nutritional value of *Wolffia arrhizal* 7678a grown under controlled culture conditions and found approximate values on dry weight basis as follows: crude protein 50%, carbohydrate 31%, ash 11% and fat 6%. While over 20 fatty acids were detected, the three dominant fatty acids were palmitic acid, linoleic acid, and α-linolenic acid. Pagliuso (2022) reports that the overall nutritional composition of duckweed as a plant-based source of protein, starch and dietary fibers is adequate for human consumption, that they can accumulate essential minerals, have a low fatty acid content variability among genera and species and that the amino acid composition is similar to other plants.

Table 1 represents the definitive list of species (and strains) that Lemnature has identified and analyzed over years of extensive research that produce a safe product. As indicated in GRAS Notice (GRN) 742 (FDA, 2018b), variation in the composition of *Lemna* and *Wolffia* species is driven by water quality and chemistry, not by the subtle morphological and genetic differences that are used to speciate them. Thus, depending on the location of a future commercial site and the local environmental conditions, Lemnature will select a subset of one or more species from this list for cultivation. Refer to dossier GRN 742 for additional information concerning *Lemnaceae*'s chemical composition (uploaded in the GRAS Notices as GRN 742-part 1, under section 2.B, pages 19-29, FDA (2018b)).

Once a species or species mix is selected for cultivation, the compositional integrity of the crop is carefully monitored to ensure only the target species is grown. For example, in its current farm, Lemnature grows two strains; one is a *Lemna* species, and the other is a *Wolffia* species, and the specific strains are proprietary. As part of our quality assurance and quality control standards, the compositional purity and integrity of the crop is tracked. As previously mentioned, among the species in Lemnature's list, the quality and composition of the plant tissue is driven by water culture, as opposed to subtle differences in phylogenetic relationships between species. Since Lemnature's water lentils are cultivated under identical nutrient water media, the chemical composition of the strains is highly similar.

In summary, and as it relates to food safety, exact species assignments (which can change as the taxonomic understanding of the water lentil group evolves) are far less relevant than water chemistry conditions that support the crop. As with most agricultural products, cultivation parameters can have impacts on the quality and safety of the crop (the raw material for LF). Therefore, similar to other agricultural operations, Lemnature's extensive testing program monitors crop composition to both ensure quality and safety of all input materials.
Finally, the strong similarity between species is supported by the level of difficulty in differentiating between them. As recently stated by a leading water lentil researcher (Appenroth, 2018), even *Lemna gibba* and *Lemna minor* are very difficult to differentiate:

> "I collected [100] clones of [water lentils] in many countries, […] and Elias Landolt investigated them on a morphological basis and gave them a clone ID […] However, I should mention that even [Dr, Landolt] made some mistakes in typing [water lentils] samples because this is really difficult on a morphological basis on multiple species. To describe one example: Beside the famous *L. gibba* clone G3 (very popular for Phyto toxicological investigations even today) there was a clone, *L. gibba* G1, which was collected by Prof. Riklef Kandeler from Vienna. It had some contrasting properties concerning the photoperiodic regulation of flowering. I lost the clone in my collection. Even asking all members of the German Botanical Society I could not get this clone again and I decided to collect a clone from the same place near Berlin as Riklef Kandeler described the place very precisely to me. Elias Landolt confirmed that the two samples I collected are *L. gibba* (termed by us G1A and G1B) but our molecular analysis by AFLP showed that these clones are very different from the original G1 clone. Finally, Jiaming Zhang of Hainan, China, found using molecular approaches that these clones are in fact not *L. gibba* but *L. minor*. I am telling this story to explain why I decided as a physiologist to enter the field of [water lentil] taxonomy. Thus, we decided to carry out molecular taxonomy of [water lentils] because there will be few who could duplicate the experience of Elias Landolt and even then, mistakes in identification based on morphology alone will be possible."

II.B. Identity of notified substance

The specific substance subject of this safety evaluation is identified as Lemnature™ Fiber from *Lemnaceae* poly-genus, including *Wolffia, Lemna, Landoltia*, and *Spirodela*, as grown, harvested, processed, and intended to be sold by Lemnature. The proposed common name for this substance is "*Lemnaceae* (water lentil) fiber powder".

II.C. Chemical and physical properties

Lemnature™ Fiber is a fine powder produced from the vegetable source water lentils and is composed of water lentils' cell wall non-digestible carbohydrates, cellulose, hemicellulose, as well as lignin. LF is a free-flowing powder that functions as a multipurpose food ingredient and dietary fiber source in various conventional foods.

The nondigestible carbohydrates within LF are naturally inherent in water lentils, thus no synthetic or isolated non-digestible carbohydrates are added in the manufacturing of LF. For the purposes of food labeling, cellulose, hemicellulose, and lignin meet FDA's definition of dietary fiber (FDA, 2018a). Moreover, LF is minimally processed, thus Lemnature's manufacturing process does not modify the dietary fiber composition inherent in the crop (including both dietary soluble and insoluble fibers).

Moreover, LF contains no sulfites, added flavors, components from an animal source, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), genetically altered plant material, or irradiated material.

Lemnature™ Fiber has a high content of total dietary fiber (typically 60% dmb) and protein (typically 20% dmb) as shown in Table 2 and is a suitable fiber and protein source in American diets. The essential amino acid profile of LF is found in Table 4.

Table 2. Typical Composition of Lemnature™ Fiber

Nutrient	Limit values (dmb)	Values (as-is)	Lab. Methodology
Protein (N x 6.25), %	16-27	16- 25	AOAC 990.03
Total carbohydrate (%)	47-58	52-68	By difference
Dietary fiber, %	50-72	48-66	AOAC 991.43
Total fat, %	< 6	3.1- 4.7	AOAC 922.06
Ash, %	< 10	7.1 - 8.6	AOAC 923.03
Moisture, % max	< 10	5.4 – 9.2	AOCS Ba 2a-38

* Calculated as 100 – (moisture+protein+ash+fat); AOAC – Association of Official Agricultural Chemists; AOCS – American Oil Chemists' Society; dmb – dry matter basis
Range of values from five separate production lots (LF-210630-D3-RW, LF-210709-D3-RW, LF-210902-D3, LF-210915-D3, and LF-210923-D3); Range of values for total dietary fiber content taken from 41 data points from 2021.

Table 3 compares the typical dietary fiber composition of LF with other types of dietary fibers. The compositional analysis shows that LF consists of approximately 23% cellulose, 12% hemicelluloses, and 5% lignin (typically >90% insoluble fibers). As shown in Table 3, the composition of LF is comparable to dietary fibers which are recognized as GRAS ingredients. These insoluble fibers are expected to have similar metabolism in humans. As described in the

absorption, distribution, metabolism and excretion (ADME) discussion within Part VI.B herein, insoluble fibers act as a bulking agent in the colon to improve fecal bulk and laxation and some are fermented to short chain fatty acids (SCFA) and some gases although their degree of fermentation is less than that of soluble fibers (Institute of Medicine, 2005).

Table 3. Comparison of Lemnature™ Fiber to Other GRAS Fiber Sources

Parameter (%, as-is)	LF[1]	Carrot fiber GRN 116	Oat hull fiber GRN 261	Oat hull fiber GRN 342	Rice bran fiber GRN 373	Corn hull fiber GRN 427	Sugar beet fiber GRN 430	Rice hull GRN 478	Pea fiber GRN 525	Pecan shell fiber GRN 646	Citrus fiber GRN 943
Cellulose	23	12.8	NR	70	30	49-52	28	49	NR	65-78	40-45
Hemicellulose	12	7.7	NR	25	20	22.5-37	42	34	NR		
Lignin	5	11.4	NR	5	20-27	<0.2	3	17	NR		
Total dietary fiber	48-66	85[2]	85	87	>40	87-92	NLT 62	>91	>60	80-85	>80
Soluble fiber	6	27	0.5	3	<10	3.6	NLT 20	<3	<1	NR	41.9-45.5
Insoluble fiber	52	58	84.5	84	>90	88	40	>97	>99	78-83	39.8-42.2
Sugar	<0.4	NR	0	0	NR	<0.25	5	<0.1	25-30	NR	<0.1
Starch	<5	NR	NR	NR	<25	4.9-6.9	NR	<0.1	NR	NR	NR

1 - Average value from various seasonal samples; 2 – Values from report of analysis; GRN- GRAS notification; NLT – Not less than; NR – Not reported

Table 4. Percent Essential Amino Acid Composition of Lemnature™ Fiber

Essential amino acid	% in **LF (**as-is)[1]
Threonine	0.7825
Methionine	0.325
Cysteine	0.1925
Isoleucine	0.785
Leucine	1.5075
Valine	1.0425
Tryptophan	0.3625
Tyrosine	0.5125
Phenylalanine	0.905
Histidine	0.345
Lysine	1.1225
Total EAA	7.8825

[1] Results are the average value from four separate production lots (LF-210630-D3-RW, LF-210709-D3-RW, LF-210902-D3, and LF-210915-D3); EAA – essential amino acids

Moreover, LF provides significant contributions to essential minerals. LF contains calcium (980-1520 mg/100 g), iron (28-66 mg/100 g), potassium (600-1590 mg/100 g), magnesium (280-360 mg/100 g), and zinc (1.1-10 mg/100 g).[1] The estimated exposure to these minerals from the intake of LF is discussed in section III.G.

II.D. Manufacturing process

As described in GRN 742 (FDA, 2018b), Lemnature's proprietary aquafarming crop growth areas are above the soil and plastic-lined to prevent any lixiviation or contamination of the environment. The plastic liner is impervious and therefore non-leaching. It also provides the unique ability for Lemnature to 'fertilize' water lentils without the run-off due to rain or leaching into ground water systems. Moreover, the growth system is comprised of computerized controls for managing the optimum nutrition of the plant and its growth conditions through optimum use of nutrients and water. Lemnature's ponds are not located near industrial facilities or roads and no pesticides, herbicides, or algaecides are used or stored at the aquatic farm, processing facility, warehousing areas, or surrounding areas.

For the hydroponic culturing of water lentils, groundwater with the addition of soluble mineral fertilizer is used. These include nitrogen, phosphorus, potassium, and other micronutrients. While we consider information related to our fertilizer formula as highly proprietary and sensitive, we can confirm that our fertilizer and nutrient formula does contain metal-sulphate salts and nitrogen compounds, including nitrates. Also, no animal wastes or human treated "biosolids" are used in our fertilizers.

[1] Data ranges from 7 different lots produced in 2021.

Lemnature carefully monitors the fertilizers in the growth media, in order to maintain maximum product yields, crop quality, and ensure they meet established specifications for heavy metals and/or potential contaminants. Moreover, we source fertilizers from reputable vendors that provide COAs of the product, including heavy metal specifications. We further ensure that our fertilizer sources are free of heavy metals via third party testing as a preventative measure. Finally, we test the source water at the commercial production site to ensure it does not contain levels of metals that pose a risk for bioaccumulation.

From the growth systems, the *Lemnaceae* are harvested daily to provide the processing system a fresh supply of material. A typical Lemnature facility ranges from one hundred to several hundred hectares of growth systems.

After harvesting and entering the processing facility, the water lentils are initially pre-screened for removal of any foreign materials, washed with food grade detergent, and rinsed with clean potable water.

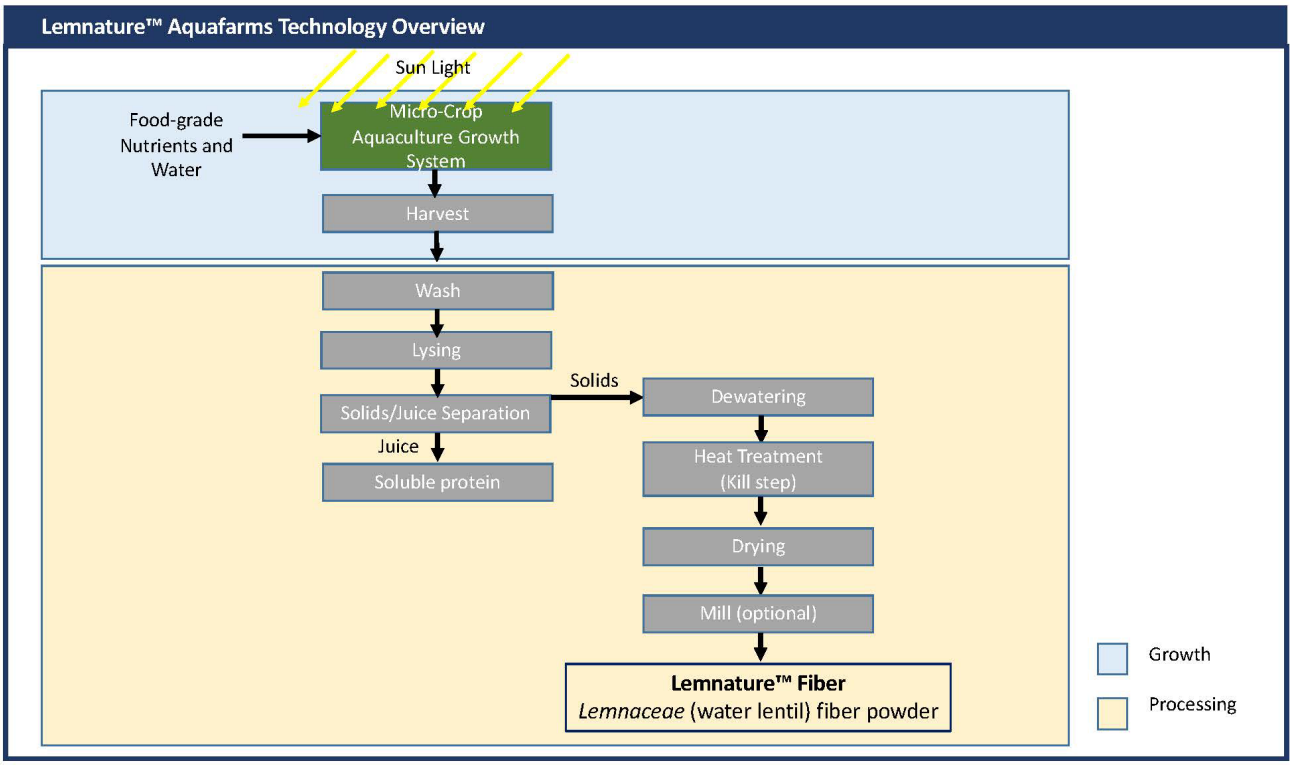
The *Lemnaceae* are then mechanically lysed by a high-shear mixer to release their nutritional components. The supernatant is separated from the in-soluble fiber components by centrifugal separation. This fiber component is then dewatered to reduce the amount of available moisture as measured using water activity (<0.50) which is followed by a thermal pasteurization step. The FDA recognizes that low-moisture foods (i.e., foods with a water activity below 0.60) have an extended shelf life, even without refrigeration (FDA, 2014). The dried material may be kept in its coarse form or further milled to a desired particle size and passed through a magnet and metal detector prior to packaging in a controlled environment. This product is identified as Lemnature™ Fiber (*Lemnaceae* (water lentil) fiber powder). The finished material is packaged in 5.0 mil. mylar foil bags that are food grade and approved for food contact.

Meanwhile, the supernatant-containing soluble protein is further processed to produce Lemnature™ protein concentrate. This protein concentrate is not a topic of this GRAS document. Refer to Figure 3 for LF's manufacturing diagram.

The wash-water is recycled either into the manufacturing system or recycled to the crop growth area.

All processing steps are performed in food-grade facility that meets the requirements set forth in 21 CFR 117 subpart B. LF is manufactured under 21 CFR parts 110 and 117 for Current Good Manufacturing Practices (cGMPs) and Hazard Analysis and Risk Based Preventive Controls (HARPC).

Figure 3. Lemnature™ Fiber General Manufacturing Diagram



II.E. Product specifications

Lemnature™ Fiber is a food ingredient mainly composed of water lentil fiber (cellulose, hemicellulose, and lignin) and protein as shown in Table 2. LF is a free-flowing, tan powder that functions as a fiber source as well various technical functions in food. Table 5 provides the product specifications and Table 6 compares five commercial-representative lots against LF product specifications. The results of the comparison confirm that LF is consistently produced under controlled manufacturing yielding product that meets specifications. The contents of arsenic, cadmium, mercury, and lead in LF are below <0.05 mg/kg.

Moreover, even though water lentils are aquatic plants, there are no concerns regarding the microbiological safety of water lentils grown in Lemnature's controlled system, as pathogens including *E. coli*, *Listeria*, and *Salmonella sp.* are monitored for every lot processed. In addition, the production process of LF involves a thorough washing step to wash the crop and remove any undesirable contaminants and debris off the harvested material. In addition, Lemnature's manufacturing process involves a kill step prior to drying to further reduce the risk of microbial contamination. Ultimately, the water activity of LF powder is <0.5 aw which limits the potential for microbial growth. Microbiological data as reported in Table 6 for LF indicates that there were no pathogenic organisms detected and the total viable counts were low, meeting the food ingredient product specifications.

Table 5. Specifications of Lemnature™ Fiber

PARAMETER	UNIT	LAB. METHOD	LIMIT VALUES	BASIS
Physical and Chemical				
Form	N/A	Organoleptic / Visual	Fine powder	N/A
Odor	N/A	Organoleptic / Smell	Natural leafy aroma, no off-odors	N/A
Moisture	%	AOCS Ba 2a-38 AOAC 925.09	<10	as is
Water activity	aw	Internal method	<0.5	as is
Protein (N x 6.25)	%	AOAC 990.03	16-26	as-is
Dietary fiber	%	AOAC 991.43	48-66	as-is
Total fat	%	AOAC 922.06	<6	as-is
Ash	%	AOAC 923.03	<10	as-is
Heavy Metals				
Cadmium	mg/kg	AOAC 2013.06	≤0.05	as is
Lead	mg/kg		≤0.05	as is
Mercury	mg/kg		≤0.01	as is
Arsenic	mg/kg		≤0.05	as is
Microbiological				
Total Plate Count	cfu/g	AOAC 966.23	<30,000	as is
Yeast	cfu/g	FDA-BAM, 7th ed. AOAC 966.23	≤100	as is
Mold	cfu/g	FDA-BAM, 7th ed. AOAC 966.23	≤100	as is
Coliform	cfu/g MPN/g	AOAC 991.14 ISO-7251:2005	≤100	as is
Salmonella	per 25g	AOAC- RI 100201	Negative	as is
Escherichia. coli	MPN/g	AOAC 996.24 ISO-7251:2005	<3	as is
	cfu/g	AOAC 991.14	<10	
Listeria sp.	per 25g	AOAC- RI 030502	Negative	as is

AOAC– Association of Official Agricultural Chemists; AOCS–American Oil Chemists Society; aw – water activity; BAM – Bacteriological Analytical Manual; cfu– colony forming units; FDA- Food and Drug Administration; g– gram; kg– kilogram; mg–milligram; MPN– most probable number; N/A– Not applicable

Table 6. Specifications of Lemnature™ Fiber Against Production Lot Results

PARAMETER	Specifications	Lot# LF-210630-D3-RW	Lot# LF-210709-D3-RW	Lot# LF-201005-COMP	Lot# LF-210915-D3	Lot# LF-210923-D3
Moisture (%)	<10	7.60	5.44	9.1	8.4	8.85
Water activity	<0.5	0.100	0.346	0.411	0.344	0.344
Protein (%) (N x 6.25)	16-26	16.11	17.60	23.68	19.76	24.63
Dietary fiber (%)	48-66	60.4	60.8	59.3	48.5	48.9
Total fat (%, AH)	<6	3.11	3.55	4.85	3.48	4.68
Ash (%)	<10	7.09	7.70	6.99	8.16	8.58
Cadmium (mg/kg)	≤0.05	<0.01	<0.01	<0.01	<0.01	<0.01
Lead (mg/kg)	≤0.05	0.04	0.02	<0.03	<0.02	<0.02
Mercury (mg/kg)	≤0.01	<0.01	<0.01	<0.01	<0.01	<0.01
Arsenic (mg/kg)	≤0.05	<0.02	<0.02	0.02	0.05	0.04
Total Plate Count (cfu/g)	<30,000	1600	2400	1300	380	400 est.
Yeast (cfu/g)	≤100	<10	<10	<10	<10	100 est.
Mold (cfu/g)	≤100	<10	<10	50	80 (est.)	100 est.
Coliform	≤100 (cfu/g)	<10	<10	<10	<10	<100
	≤100 (MPN/g)	N/R	N/R	N/R	3.0[#]	3.6[#]
Salmonella (per 25g)	Negative	Negative	Negative	Negative	Negative	Negative
E. coli	<10cfu/g	NR	NR	N/R	<10 cfu/g*	<100 cfu/g**
	<10 MPN/g	<3	<3	<3	<0.3--	<0.3
Listeria sp. (per 25g)	Negative	Negative	Negative	NR	NR	NR

*Per AOAC 991.14 Method, by Eurofins Scientific Lab; **Enumeration utilized Petrifilm method (required a 1:100 dilution due to LF color) while other results utilized AOAC 966.24 method. These samples were re-tested per AOAC 996.24 method and values reported as MPN.
AH- Acid hydrolysis; cfu – colony forming units; est. - estimate; g – grams; kg – kilograms; mg – milligrams; MPN – most probable number; NR – Not reported.

II.F. Secondary metabolites

Lemnature monitors its LF for secondary metabolites including nucleotides, biogenic amines, mycotoxins, microcystins, nitrates, and antinutritional factors such as oxalic acid, phytic acid, and trypsin inhibitor. Lemnature also monitors its *Lemnaceae* polyculture and its derived fiber for pesticide residues, annually or as requested by customers. The results for the essential secondary metabolites and undesirable components, monitored in LF are provided below in Table 7. Results indicate that the water lentil fiber does not contain any of these contaminants at levels of concern. Additional information is provided within Part VI narrative herein.

Table 7. Secondary Metabolite Data

Parameter	Results [1]	Lab. Methodology
3' Nucleotides	7018 µg/g	Eurofin's internal method
Adenosine-3-monophosphate	1113 µg/g	
Cytidine-3-monophosphate	1938 µg/g	
Guanosine-3- monophosphate	2700 µg/g	
Uridine-3- monophosphate	1268 µg/g	
Biogenic Amines		Czech J. Food Sci. Vol. 21
2-Phenylethylamine [2]	2.14 mg/kg	
Cadaverine	5.90 mg/kg	
Histamine [3]	1.55 mg/kg	
Putrescine	142 mg/kg	
Spermidine	3.04 mg/kg	
Spermine	<1 (LOQ) mg/kg	
Tryptamine	7.43 mg/kg	
Tyramine	5.80 mg/kg	
Nitrates	59 ppm	
Microcystin data	Not detected	LC-MS/MS
Mycotoxins [4]		
Aflatoxin total (B1, B2, G1, G2)	<4 µg/kg	AOAC 999.07 Modified
Fumonisin total	<30 µg/kg	LC-MSMS
Ochratoxin A	<1.0 µg/kg	AOAC 999.07 Modified
Vomitoxin	<50 µ g/kg	LC-MSMS
T-2 Toxin	< 1 µg/kg	LC-MSMS
HT-2 Toxin	<10.0 µg/kg	LC-MSMS
Zearalenone	<5 µg/kg	LC-MSMS
Pancreatic Protease [5]	<60 USP per g	UPS-DS, USP
Phytic Acid	<0.14 %	Analytical Biochemistry Vol. 77:536-539
Oxalic Acid [6]	0.1%	AOAC 986.13 mod.
Trypsin Inhibitor	3977 TIU/g	AOCS Ba 12-75
Quantitative multi pesticide screening[7]	Not detected	LC-MSMS and GC-MSMS Eurofin's internal method

[1] Results are on an as-is basis and are the average value from four separate production lots (LF-210630-D3-RW, LF-210709-D3-RW, LF-210902-D3, and LF-210915-D3) unless otherwise noted; [2] Includes one value below the LOQ.
[3] Includes two values below the LOQ; [4] Values from report on lot LF-210630-D3-RW; [5] Value derived from Lot#

LF-200624C also known as LM2020ESUMMER COMP; [6] Average value from lots LF-210630-D3-RW, LF-210709-D3-RW, LF-210902-D3; [7] As reported for one lot (LF-210709-D3-RW)
GC-MSMS - Gas chromatography with tandem mass spectrometry; g – grams; kg – kilograms; LC-MSMS - Liquid chromatography with tandem mass spectrometry; LOQ- Limit of quantification; µg – micrograms; mg – milligrams; TIU – trypsin inhibitor unit; USP – United States Pharmacopeia

II.G. Product Stability Data

The recommended storage conditions for the Lemnature™ Fiber will be the same as those recommended for Lentein Complete (LC): "Recommended storage is cool temperature (below 25°C/75°F) with low relative humidity (<60%). Maintain the product in the provided packaging, air-tight sealed bags, and store away from direct light." Under these storage conditions, LF is expected to have similar shelf-life to LC. The packaging for the LF is the same as that used for the LC (food grade 0.5 mil mylar foil bags as described in Appendix D of GRN 742). Lemnature described the accelerated test conditions in GRN 742 (FDA, 2018b) and similar studies are in process for LF; however no data is available at this time.

Updated stability data for LC supports a 3-year shelf-life and includes a six-month and 12-month accelerated shelf-life studies along with 36-months of real time data, in which samples packaged in aluminum foil bags were stored at 20°C and 50% relative humidity for 36 months (Appendix B). Samples for the real-time study were pulled at 0, 6, 12, 18, 24 and 36 months and results show that the LC remained stable and within product specifications for nutritional and microbial quality parameters during the 36-month storage period. Protein quality was not significantly altered during storage and omega 3 and 6 fatty acids remained stable.

III. DIETARY EXPOSURE

III.A. Intended use

Lemnature™ Fiber, manufactured in accordance with cGMP as specified in 21 CFR 110 and 117, is intended for use as a multipurpose food ingredient at inclusion levels ranging 0.5-10% in the food categories listed in Table 8, as defined in 21 CFR 170.3(n) and USDA's What We Eat in America Food Categories: 2017-2018 (USDA, 2020) . LF will be used as a substitute for, and/or in conjunction with, other dietary fiber sources (such as citrus fiber, oat fiber, rice bran, among others). Besides LF's nutritional contribution to the listed food categories, LF's intended use is attributed to its functional capabilities (e.g., anticaking agent, water binding, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, purge reduction).

Intended use includes use in processed meat and poultry products. The use levels of LF in processed meat and poultry products was determined based on evaluations on cooked yield, purge, texture profile and color. Results of evaluations performed on the use of LF as a functional ingredient in comminuted and whole muscle meat products confirm that LF is a functional ingredient that increases cook yield, reduces purge, and improves texture without significantly changing the quality attributes of various processed meat and poultry products. A copy of the technical report is included in Appendix C.

A list of the proposed food uses and use-levels for LF is provided in Table 8. Furthermore, LF is not intended for use in foods subject to a standard of identity or as a coloring agent.

Table 8. List of proposed food uses and use-levels for Lemnature™ Fiber

INTENDED USE	MAXIMUM USE LEVEL (%)
FOOD CATEGORY	**LF**
Baked goods and baking mixes	0.5-5%
Bars- Meal replacement/nutritional bars, cereal, and granola bars	0.5-2%
Beverages and bases-Protein and nutritional drinks	1-10%
Breakfast cereals	1-5%
Candy- soft candy	0.5-2%
Cheese-vegetarian/imitation cheese and cheese dip	0.5-4%
Condiments and spreads	0.5-4%
Confections and frostings	0.5-2%
Dairy product analogs	1-3%
Fats and oils- salad dressing	0.5-3%
Fish products	1-7%
Frozen dairy desserts (ice cream)	0.5-4%
Gelatins, puddings, pie fillings	0.5-4%
Gravies and sauces	0.5-1%
Hard candy	0.5-2%
Jams and jellies	0.5%
Pasta	1-2%
Protein foods -processed meat/poultry products	1-3%
Protein foods - plant protein products (meat analogs)	1-10%
Processed fruit and vegetable juice	0.5-2%
Snack foods/chips	1-5%
Soups and soup mixes	0.5-2%
Spices, seasonings, and blends	1-5%
Sweet sauces, toppings, and syrups	0.5-2%

III.B. Estimate of dietary exposure

The estimated daily intake (EDI) is based on proposed intended uses in all food categories shown in Table 8 (except for seasoning blends) and the mean and 90th percentile (high user) consumption estimates of these foods as reported by the National Health and Nutrition Examination Survey (NHANES) 2017 – 2018 survey. Calculations for the mean and 90th percentile per capita and consumer-only intakes were performed for all proposed food uses however only the consumer-only intakes are reported here. The summaries of the EDI for individual food categories as well as the food codes used in the calculation can be found in the intake report in Appendix D. The food codes selected for the intake analysis are based on uses that would be similar to the intended use for the ingredient.

"Per capita" intake refers to the estimated intake averaged over all individuals surveyed, regardless of whether they consumed food products to which LF is intended to be added. Individuals were considered "consumers" if they reported consumption of one or more food products on either Day 1 or Day 2 of the survey. Mean and 90th percentile intake estimates based on sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size.

Children under 1 year of age (infants) had low numbers reporting in most of the categories resulting in data that may not be statistically reliable, as infants do not normally consume significant amounts of conventional/processed foods not targeted to their age group. Therefore, infants are not reported for the estimated daily intake. As many of the foods selected are specialty items (*e.g.*, vegetable based pastas, meat analogs and vegetarian cheese) the percentage of the survey participants reporting consumption was low in many categories. The foods selected for addition of LF are not products targeted to children so similarly, numbers reporting intake in the non-adult age groups were also low. The "all ages" group had statistically reliable data for the mean and 90th percentile for most of the food categories to which LF will be added and this population serves as the mot statistically reliable data for the intake estimate.

Table 9 provides a summary of the estimated daily intake from the consumer only group on a grams per day basis, while Table 10 provides the EDI on a g/kg body weight basis.

Table 9. Summary of estimated daily mean and 90th percentile intake of LF from all intended food uses based on consumer-only population (Based on NHANES 2017–2018 Survey)

POPULATION GROUP	AGE (YEARS)	ESTIMATED CONSUMER ONLY INTAKE (GRAMS/DAY)	
		MEAN	90TH PERCENTILE
Children, Male	1-5	31.0	53.4
Children, Female	1-5	35.7	55.6
Children, Male	6-11	51.8	79.8
Children, Female	6-11	41.2	66.0
Teenagers, Male	12-18	44.8	80.6
Teenagers, Female	12-18	42.3	75.8
Adults, Male	>19	75.1	138.3
Adults, Female	>19	61.2	118.0
All Ages (Male and Female)		63.4	125.3

Table 10. Summary of estimated daily mean and 90th percentile intake of LF on a g/kg body weight basis from all intended food uses based on consumer-only population (Based on NHANES 2017–2018 Survey)

POPULATION GROUP	AGE (YEARS)	ESTIMATED CONSUMER ONLY INTAKE (GRAMS/KG BODY WEIGHT/DAY)	
		MEAN	90TH PERCENTILE
Children, Male	1-5	2.1	3.7
Children, Female	1-5	2.3	3.7
Children, Male	6-11	1.6	2.5
Children, Female	6-11	1.1	1.7
Teenagers, Male	12-18	0.7	1.3
Teenagers, Female	12-18	0.7	1.2
Adults, Male	>19	0.8	1.5
Adults, Female	>19	0.8	1.7
All Ages (Male and Female)		0.9	1.7

Little data exists regarding actual dietary intake of culinary herbs and spices and NHANES data does not include spices and seasonings as individual servings in their data. Carlsen et al. (2011) developed a food frequency questionnaire for the assessment of habitual diet, with focus on phytochemical rich food, including herbs and spices. They estimated the consumer-only intake of 3 commonly consumed seasoning blends (barbeque, curry, and taco) to be 1.6 g, 1.6 g, and 1.9 g (respectively) per eating occasion (average 1.7 g/day). Assuming one eating occasion per day of meat products containing a seasoning made up of 5% of LF, the total estimated intake of all uses in all populations found in Table 9 and Table 10 will be increased by a negligible amount of 0.0085 g/day for the mean and 0.017 g/day for the 90th percentile.

Intake of fruits and vegetables account for 28% of dietary fiber intake for the US population, breads, grain-based mixed dishes and cereals account for 33%, plant-based protein foods account for 8% while processed foods account for 10% (Hoy and Goldman, 2014). As a result, the consumer will have dietary fiber intake in the form of unprocessed food plus LF product. Moreover, as noted above, for the processed foods to which the fiber ingredient will be added, there are competitive fiber products already in the market (such as citrus fiber, oat fiber, rice bran, among others) which LF will be used as a substitute for, and/or in conjunction with.

The Institute of Medicine (IOM) recommended intake (i.e., Adequate Intake) for dietary fiber is 25 g/day for adult women and 38 g/day for adult men (Institute of Medicine, 2005). It is not realistic to expect that the actual consumption of foods containing LF would result in a daily

consumption greater than the Adequate Intake (AI) for dietary fiber. Furthermore, a Tolerable Upper Intake Level was not established for total dietary fiber or individual dietary fibers (IOM, 2002). Despite the proposed use of LF in a broad range of applications, it is extremely unlikely that any consumer will be exposed to maximum amounts as calculated using the NHANES dataset (1.7 g/day at the 90^{th} percentile, which would be 119 g/day for an adult). The intake calculations based on the NHANES data is an overestimation because it assumes a food from all food categories containing the LF ingredient are eaten in one day and all of those foods contain the LF ingredient. According to USDA Nutrition Insights (a publication of the USDA Center for Nutrition Policy and Promotion), males, aged 51 years or older, consume the greatest number of servings of food per day, estimated as 18.2 servings of food/day, from the following categories: grains, fruits, vegetables, milk, meat and other (fats, oils, sweets) (Basiotis et al., 2000). Estimating daily intake of LF using a cumulative intake from all food categories would likely exceed 18 servings per day. Additionally, consumers are not likely to consume only foods containing LF ingredient.

Additionally, recent reports from the National Health and Nutrition Examination Survey (NHANES) assessing dietary intakes of fiber for the US population, for years 1999-2010; indicate the mean adult (aged 20 years and older) dietary fiber intake ranged from 15.7-17.0 g/day. Hoy and Goldman (2014) analyzed the 2009-2010 NHANES data and estimated that the mean dietary fiber intake of all individuals 2 years and older was 16 g/day. Nevertheless, more recently, the IOM calculated that less than 10% of any population group had dietary fiber intakes greater than the AI (McGill et al., 2016). Other reports of dietary fiber intake by the American population estimate an average of 19.2 and 14.4 g/day for adult men and women, respectively (King et al., 2012; Thompson et al., 2005). For the purposes of food labeling, the Daily Value for dietary fiber for individuals greater than 4 years of age is 28 g (FDA, 2016a).

Based on more current estimates, the American population continues to consume fiber below the adequate intake, with only 7.4% of adults meeting the AI for fiber (Miketinas et al., 2021). The LF will be added to food products as a fiber ingredient substitute, thus LF will not contribute to any additional exposure to fiber for consumers, meaning the fundamental intake of fiber would not likely be impacted. Considering the totality of information and considering that LF contains 48-66% fiber (typically 60% fiber dmb) and that the Daily Value of dietary fiber is 28 g/day, the consumption of LF from the intended uses is not expected to exceed 29 g of LF/day (an amount that would provide half of the Daily Value of dietary fiber (14g) assuming LF consists of 48% dietary fiber).

SELF-LIMITING LEVELS OF USE

The use of Lemnature™ Fiber as a food ingredient is limited by the inclusion levels at which it can technically be added to a given food without jeopardizing the final food product's quality and overall consumer acceptability.

While it is not expected that the intake of LF from the proposed use will exceed the AI for dietary fiber, it is important to note that the IOM did not to set a Tolerable Upper Intake Level (UL) for dietary fiber stating that, due to the bulky nature of dietary fibers, excess consumption is likely to be self-limiting (Institute of Medicine, 2005). Furthermore, no ULs were set for individual dietary fibers, such as cellulose, hemicellulose or lignin.

EXPERIENCE BASED ON COMMON USE IN FOOD BEFORE 1958

The statutory basis for the conclusion of GRAS status of LF in this document is not based on common use in foods before 1958. The GRAS determination is based on scientific procedures.

Lemnature acknowledges water lentils were not recognized as a human food source until the 1970's. The earliest scientific publication discussing the use of *Lemnaceae* as human food appeared in August 1971 (Appenroth et al., 2017; Bhanthumnavin and McGarry, 1971) stating that water lentils have been consumed for many generations in parts of Asia. Since that time, water lentils have been investigated as a dietary source of protein for many animal species including aquaculture species, poultry, ruminants, and swine (Pagliuso et al., 2020; Baek et al., 2021).

NARRATIVE

Pursuant to 21 CFR 170.30 (a) and 21 CFR 170.30(b), the intended use of LF has been determined to be GRAS based on scientific procedures. A comprehensive literature search conducted through January 2022 was used for this safety evaluation. The safety determination of LF is based on the totality of the available qualitative and quantitative scientific evidence including LF's composition analysis; product data on plant toxins, antinutritional factors, heavy metals and other secondary metabolites; widespread use of water lentils as a food source and history of safe consumption by humans in Southeast Asia; animal data from published studies of various water lentil preparations; analysis on the ADME of macronutrient constituents (fiber and protein); and toxicity studies on Lemnature's water lentil-derived product, LENTEIN® Complete.

A number of animal toxicity studies have been completed on Lemnature's LENTEIN® Complete and no significant adverse events were reported (FDA, 2018b).

III.C. Current regulatory status

Currently, LF is not included in the list of approved food additives or GRAS substances in the U.S. However, Lemnature's whole water lentil powder "LENTEIN® Complete" and its degreened version are both recognized as GRAS by the FDA, under GRN 742 (FDA, 2018b), for use as a source of protein in food at levels ranging from 3-20%. Lemnature's LENTEIN® Complete (LC) is also a product derived 100% from Lemnature's *Lemnaceae*, meaning LF's chemical composition is composed of similar macronutrients, elements, and secondary metabolites to LC, except at different concentration levels due to their differences in the manufacturing process. LC is derived from a simple process where whole water lentils are blanched or heat treated, dewatered and milled into a fine powder. LF follows a similar process except the starting material is lysed and separated to capture only the insoluble material of the plant (fiber or pulp from water lentils), this material is then dewatered, heat treated, and milled into a fine powder. Therefore, LF is concentrating the dietary fiber from water lentils by removing or separating the soluble macronutrients within water lentils (i.e., protein, most fatty acids, and phytonutrients). Table 11 represents the similarities between both products' chemical composition, indicating that the main differences, as expected, fall in the total crude protein and dietary fiber content.

Table 11. Typical chemical composition of Lemnature's LC and LF[a]

Component (as-is)	LF	LC
Moisture (%, as-is)	5-9.5	1-8
Crude Protein (%)	16-25	40-50
Total Fat (%)	3-5	6-10
Dietary Fiber (%)	48-66	30-45
Sugars (%)	<0.35-0.47	<0.35
Starch (%)	8-12	<12

Ash/Minerals (%)	7-9	4-8
Calcium, mg/100g	980-1520	1,100-1,500
Iron, mg/100g	28-66	24-53
Potassium, mg/100g	600-1590	350-490
Magnesium, mg/100g	280-360	300-390
Zinc, mg/100g	1.1-10	5-10
Manganese (ppm)	140-192	NR
Arsenic, ppm	<0.02-0.05	<0.02
Cadmium, ppm	<0.01	<0.02
Lead, ppm	<0.02-0.04	<0.05
Mercury, ppm	<0.01	<0.01

[a] Typical composition per product. COA for LC available in GRN 742, under Appendix A.
g- grams; mg- milligrams; ppm – parts per million

Moreover, cellulose, a major component of LF, has been recognized as a GRAS substance since 1973 (SCOGS, 1973b). In addition, the FDA had no questions on the safety of other fiber ingredients including oat hull fibers (GRN 261 (FDA, 2016b) and 342 (FDA, 2010b)), citrus fiber (GRN 599 (FDA, 2016c)), rice bran fiber (GRN 373 (FDA, 2011)), carrot fiber (GRN 116 (FDA, 2003a)), barley fiber (GRN 207 (FDA, 2006)), ground rice hull (GRN 478 (FDA, 2015)), corn husk (GRN 427 (FDA, 2012c)), and potato fiber (GRN 310 (FDA, 2010a)). These plant-based fibers total fiber composition is similar to that of LF, as they mostly consist of cellulose, hemicelluloses (arabinoxylans), and lignin.

III.D. ADME analysis

Lemnature™ Fiber's physiologically relevant constituents are macronutrients, which are generally considered to be the major components in plant-based flours/fibers, including protein and dietary fiber. These macronutrients are normal constituents of a healthy human diet.

LF is composed primarily of protein (average is 22% on dry matter basis) and total dietary fiber (average is 60% on dry matter basis) with the remaining composition consisting of fat and ash. With respect to the metabolic fate of LF, the digestion and subsequent absorption, distribution, metabolism, and excretion of the ingredient is relevant to the metabolic fate of their macronutrient constituents, protein, and dietary fiber, described as follows.

1. **Dietary Fiber components**

Dietary fibers in LF are typically composed of naturally occurring water-insoluble hemicelluloses (9% as-is), cellulose (24% as-is), and lignin (1.5% as-is) as indicated by values for neutral detergent fiber (approximately 33% as-is). In addition, LF is composed of non-fibrous carbohydrate or Neutral Detergent Soluble Carbohydrates as well as some sugar and starch. In general, and according to the typical dietary fiber composition data provided in Table 3, the cellulose fraction of LF fully resembles that of other fiber sources. According to the literature, the majority of plant cellulose is recovered in the feces as it remains largely undigested in the upper gastrointestinal tract and is not highly fermented in the colon

(Spiller et al., 1980; Stephen, 1989),although natural plant celluloses and some water-soluble cellulose derivatives, such as hydroxypropyl cellulose are fermentable. Therefore, the metabolism of cellulose derived from LF does not raise safety concerns, and no systemic toxicity is expected following ingestion of cellulose from LF.

As shown in Table 3, the composition of LF is comparable to many other plant-based fibers such as wheat bran, and sugar-beet pulp, which are already recognized as safe feed and food ingredients. These insoluble fibers function as a bulking agent in the colon to relieve constipation and are fermented to SCFA and some gases, although their degree of fermentation is less than that of soluble fibers. Thus, considering the similarities among LF and other plant-based fibers, the metabolic fate of the hemicellulose and lignin moieties of LF are expected to resemble that of other lignans and hemicelluloses including rice bran, oat hull and wheat bran. These insoluble fibers remain largely undigested in the upper gastrointestinal tract and are fermented, to a varying extent, in the colon leading to production of gases and SCFA that lowers the pH of the colon (Lattimer and Haub, 2010; Scheppach et al., 2001; Tomlin and Read, 1988). Any plant-derived fiber that comprises sources of fermentable fiber , such as some hemicelluloses, lead to generation, absorption, and excretion of the same metabolites (hydrogen, carbon dioxide and SCFA) as those produced upon consumption of LF. The metabolism of lignin and hemicelluloses derived from LF do not raise safety concerns, and no systemic toxicity is expected following ingestion hemicellulose and lignin from LF.

2. Protein components

Lemnature™ Fiber is typically composed of 22% (range 16 - 25%) protein (dmb). This macronutrient and protein content is expected to undergo normal metabolism. Following consumption, the protein components of LF are expected to be denatured in the stomach by acid and/or cleaved by enzymes to release individual amino acids. These amino acids, which are listed in Table 4, will be absorbed in the small intestine. Therefore, the metabolism of protein derived from LF do not raise safety concerns, and no systemic toxicity is expected following ingestion of protein from LF.

The initial step in protein digestion is its denaturation at acidic pH (2.0) and hydrolyzation by the action of several pepsins in the stomach. Negligible amounts of free amino acids are released, and large polypeptides enter the duodenum. The products of luminal proteolysis are free amino acid and small peptides. The bulk of ingested protein appears to be absorbed in the proximal jejunum while the colon is the major site that absorbs the digested protein (Silk et al., 1985). Amino acids are required for the synthesis of body protein and other important nitrogen-containing compounds, such as creatin, peptide hormones, and some neurotransmitter. Metabolic products of amino acids (urea, creatinine, uric acid, and other nitrogenous products) are excreted in the urine; while nitrogen is also lost in faces, sweat, or other body secretions and in sloughed skin, hair, and nails (NRC, 1989).

Amino acids consumed at levels more than the amount needed for the synthesis of nitrogenous tissue constituents are not stored but degraded; the nitrogen is excreted as urea, and the keto acids left after removal of amino groups are either utilized directly as sources of energy or are converted to carbohydrate and fat (NRC, 1989). Because the disposal system of excess nitrogen is efficient, protein intakes moderately above requirement are believed to be safe.

Moreover, protein metabolism is influenced by a variety of factors, including age, gender, diet, as well as exercise type, duration, and intensity. To maintain nitrogen balance, individuals who are physically active require more dietary protein than sedentary counterparts (Kreider and Campbell, 2009). Inadequate protein consumption results in negative nitrogen balance, losses in lean body mass, and may even delay recovery after exercise. To optimize skeletal muscle recovery after prolonged exercise through increased protein synthesis and myofiber repair (Kreider and Campbell, 2009; Phillips et al., 2007), protein consumption of 1.1 g/kg/day is recommended for low to moderate intensity endurance athletes and 1.4-2.0 g/kg/day for competitive or elite endurance athletes. These levels are 50-150% higher than those recommended for sedentary adults. Similarly, habitual intakes of protein in the United States are substantially above the requirement, and although there is no firm evidence that these intake levels are harmful, it has been deemed prudent to maintain an upper bound of no more than twice the recommended dietary allowance for protein (NRC, 1989).

Therefore, the absorption, distribution, metabolism, and excretion of the protein components in LF are expected to undergo normal metabolic processes and do not raise safety concerns. Thus, no systemic toxicity from the amount of protein ingested from LF is expected.

III.E. Antinutritional Factors (ANF) in water lentils and Lemnature™ Fiber

Several secondary metabolites have been identified in water lentils across the literature which may be detrimental to human health at elevated concentrations. Among those identified include condensed tannins, trypsin inhibitors, oxalates and phytates (Natesh et al., 2017; Hill, 2003; Gilani et al., 2012). Some of these secondary metabolites are recognized as undesirable chemical substances and referred to as anti-nutritional factors (ANF) as they are considered counteractive to optimum nutrition. These ANF are abundant in both cultivated and wild plant species yet their recognition as ANFs depends on the digestive process of the ingesting animal (Natesh et al., 2017).

Maznah (1998) analyzed anti-nutritional factors tannins, trypsin inhibitor, nitrate and nitrite in water lentil species *Spirodela polyrrhiza* and *Lemna perpusilla*, and their protein concentrates. Results indicated that there is not a significant variation in the levels of these anti-nutritionals among the different water lentil species and concluded that “the low content of these anti-nutritional factors enable the plant to be used safely as a protein source for domestic animals as well as for human consumption.”

Over the years, Lemnature has recognized these undesirable substances and analyzed their concentrations in Lemnature’s water lentil derived products, including LF. This section will discuss the safety of the ANFs identified by the scientific literature and compare levels of these antinutrients in LF to other common food sources and food ingredients. To determine the concentrations of these ANFs in LF, a daily fiber intake of 14 g is used which is 50% of the daily AI for dietary fiber. The use of 14 g of fiber intake per day is still likely to be an overestimation in that is assumes that, in addition to the high fiber intake, all of this fiber is from LF product. To evaluate the intake of LF product from the 14 g dietary fiber consumption, the LF fiber content

of 48% was used as this represents the highest possible amount of LF required to provide the entire daily 14 g fiber intake as LF. The daily intake of LF used in the following sections is 29 g.

1. Oxalic acid

Oxalic acid is an organic acid, which forms oxalates when in combination with its salts and minerals, and is the ANF generally associated with water lentils as it is a compound present in the cell sap of many green leafy vegetables (Natesh et al., 2017). It is a chelating agent for metal cations, meaning it can bind to essential minerals such as calcium, magnesium, and iron, making these minerals insoluble and lower their bioavailability.

Many plant species contain oxalic acid including beets, asparagus, celery, and parsley (Santamaria et al., 1999). Oxalate in spinach was measured at a mean of 0.54%, with results ranging from 0.23 to 1.0% (Santamaria et al., 1999); soybeans were measured to contain oxalic acid ranging from 0.67 to 3.5% (Massey et al., 2001).

Upon consumption, insoluble oxalates (calcium oxalate, magnesium oxalate and iron oxalate) are not absorbed in the digestive system and pass harmlessly in the feces. (Natesh et al., 2017). However, soluble oxalates can be freely converted into insoluble oxalates in the gut or in the bloodstream. Thus, insoluble calcium oxalate, in crystal form, is then stored in the kidney leading to the formation of kidney stones which can cause serious health concerns (Natesh et al., 2017).

Water lentils grown in the wild are known to contain oxalic acid, often in the form of calcium oxalate raphides (Goopy and Murray, 2003; Leng, 1999). Lemnature's growth and production process is monitored for oxalic acid; the resulting LF typically results below laboratory method's level of detection of oxalic acid (<0.001%). Table 12 provides oxalic acid values for a variety of plant species, including *Lemna minor* and LF.

Table 12. Oxalic acid and oxalate content of selected edible plant and plant products

Plant/Product	Oxalic Acid (%, as-is)	Reference
Beetroot	0.0404 0.07[a]	Duke (2014) Santamaria et al. (1999)
Beet leaf	0.32-0.92[a]	Noonan (1999)
Swiss chard	0.21[a]	Santamaria et al. (1999)
Spinach	0.5-9.39 0.32-1.26[a]	Duke (2014) Noonan (1999)
Soybean	0.077	Duke (2014)
Lemna minor	3.5	Kalita et al. (2007)
Lemnaceae Fiber	0.063[b]	Mean value from representative composite samples

[a] As oxalate
[b]mean from lots LF-210630-D3RW; LF-210709-D3-RW, LF-210902-D3, LF210831-D3 and LM2020SummerComp as free oxalic acid

Although oxalic acid has been reported in the literature to be a constituent of water lentils, most of the oxalic acid is removed in the manufacturing process of LF. As shown in Table 12,

vegetables have higher levels of oxalic acid than LF. Using the estimated daily intake of LF (29 g), the highest estimated intake of oxalic acid from LF consumption would be 0.0183 g/day or 18.3 mg/day. The estimated intake of oxalate from the diet is 70 – 150 mg/ day (Noonan, 1999). No safety concern should be expected regarding the oxalic acid content in LF.

2. Tannins

Tannins are water soluble phenolics commonly available in the plant kingdom. Tannins are specifically high molecular weight polyphenols (up to 20,000 Da) that can form complexes with carbohydrates and proteins in aqueous solutions (Natesh et al., 2017). They interfere with digestion by binding proteins, minerals, or digestive enzymes, limit vitamin B12 absorption (Francis et al., 2001) and can produce undesirable effects in foods when present at elevated concentrations.

Tannins are nutritionally undesirable because of their ability to form complexes with protein, starches, and enzymes to reduce the nutritional quality of foods. They have been shown to precipitate proteins, inhibit digestive enzymes, and affect the utilization of vitamins and minerals (Chung et al., 1998). Tannins have been implicated in high levels of cheek and esophageal cancers in the far East, where Betel nuts containing 11-26% tannins are often consumed after dinner (Chung et al., 1998). The incidence of esophageal cancer in Caribbean islanders has been correlated to the consumption of tea and other tannin-rich food items such as sorghum(Chung et al., 1998). Moreover, tannins were found to cause tumors in experimental animals when applied to burns or injected subcutaneously (Chung et al., 1998). The carcinogenicity of tannins may be more related to their ability to cause cellular damage rather than DNA mutation. A study conducted to evaluate the carcinogenicity of tannic acid in male and female F344 rats, however, showed that tannic acid at 0.25% and 0.5% in distilled water did not increase the incidence of tumors (Onodera et al., 1994). In this study, rats were given the tannic acid *ad libitum* in the drinking water for up to 2 years. Similarly, the International Agency for Research on Cancer (IARC)'s evaluation on tannic acid and tannins reports that tannic acid is carcinogenic in rats and mice following its subcutaneous injection, producing liver tumors. However, pertaining to human carcinogenicity data, no case reports, no adequate published studies, nor epidemiological studies involving oral administration of tannins in animals were available to the Working Group (IARC, 1998).

In addition, even though the Food and Agriculture Organization's (FAO) report on Sorghum and Millets in Human Nutrition (FAO, 1995) states that while tannins may adversely affect the grain's nutritional quality, and several studies in rats, chickens and livestock have shown that high tannin in the diet adversely affects digestibility of protein and carbohydrates reducing growth, feeding efficiency, metabolizable energy and bioavailability of amino acids; there is no direct evidence regarding the anti-nutritional effects of dietary tannins in human subjects.

Considering the mentioned health effects and palatability issues concerning tannins, Lemnature evaluated the tannin content for plants as reported in the literature compared to Lemnature's LC product. Kalita et al. (2007) reported 0.9% tannins in *Lemna minor*; this represents a lower concentration than other plant products such as chickpea and peas. Tannin content of LF has not been assessed; however, tannin content has been evaluated in the LC product (FDA, 2018b). As

summarized in Table 13, the typical concentration of tannins in LC is 0.20 %, significantly lower than commonly consumed foods such as barley (0.5-1.2%) or kidney beans (0.5-1.8%). In a recent article by Pagliuso (2022) in which the tannin levels were evaluated in numerous *Lemnoideae* and *Wolffioideae* spp, the tannin levels were found to be 19.5 and 20.0 mg/mg dry weight basis, respectively. The total polyphenols in as reported in GRN 742 for the LC product is 3,244 mg gallic acid equivalents (GAE)/kg. One lot of LF (LF-210915-D3) was tested for total polyphenols and the result was 21.7 mg GAE/kg. This implies that the tannin content of the LF would also be lower in the LF as compared to the LC product that received a no questions letter from FDA. No safety concern should be expected regarding the tannins in LF.

Table 13. Tannin content of select edible plant and plant products

Plant	Tannins (%)	Reference
Chickpea	0.6-2.7	Jansman & Longstaff (1993)
Cowpea	1.4-10.2	
Pea	0.6-10.5	
Kidney beans	5.3-17.55	
Barley	5.5-12.3	
LENTEIN® Complete	<0.20 %	Internal Report

3. Trypsin inhibitors

Trypsin inhibitors (TI) prevent protein digestion by inhibiting the enzymes trypsin and chymotrypsin. They are found in common foods such as lima beans, peas, peanuts, wheat, barley, and potatoes (Hill, 2003).

TI cause pancreatic heterotrophy and poor growth in animals (Liener, 1979). However, the human pancreas is likely insensitive to TI due to the relative size of the human pancreas. Also, cooking or heat processing of soybeans reduces the amount of TI compared to the raw soybean (Liener, 1979).

According to (Kalita et al., 2007), the concentration of TI in *Lemna minor* is 1.47%. This represents a lower concentration than soybeans. Soybeans are considered the richest source of dietary TI among common food and feed products with contents in raw soybean varying from 8.6-48.2 mg/g (0.86-4.8%) or 20.3-122.6 mg/g protein (Gilani et al., 2012). Soy products contain between 3.29 Trypsin inhibitor units (TIU)/mg (cooked soy beans) to 45.89 TIU/mg (raw soy beans) (Shi et al., 2017). LF was reported to contain on average 1.7 TIU/mg. Therefore, no safety concern should be expected regarding the trypsin inhibitor content of LF.

4. Phytic Acid (Phytates)

Phytic acid is a natural substance that acts as a major storage depot of phosphorus in leafy vegetables, such as water lentils (Natesh et al., 2017). It is a simple sugar that occurs naturally in bran and germ of many plant seeds, and in nuts, legumes, and grains. When phytic acid is bound to the mineral in the crop it is referred to as phytate. Phytate can also chelate essential minerals in the human body (i.e., calcium, magnesium, copper, iron, etc.). These phytate-mineral

complexes are insoluble in the intestinal tract (Dolan et al., 2010) and inhibit the bioavailability of iron and zinc, playing an important role in their deficiencies (Ma, 2005). Moreover, phytates can form complexes with proteins, limiting protein digestibility (Francis et al., 2001). As a result, vegetarians who consume large amounts of tofu and bean curd are susceptible to mineral deficiencies or decreased protein and starch digestibility because of phytate consumption (Dolan et al., 2010).

Table 14 summarizes the phytic acid values of foods as reported in the literature. Phytate percentage can range from 0.1% in rice to 1.8% in rice bran. Phytate ranges from 0.06 to 6% in cereal, cereal products, and cereal-based products (Reddy, 2002). In a study conducted on traditional Kuwaiti foods, phytate content ranged from 32.6 mg/100 g in labneh (strained yoghurt) to 2835 mg/100 g in rahash (Dashti et al., 2001). In different varieties of bread, phytate content ranged from 0 to 0.2% (Mameesh and Tomar, 1993), and in different varieties of uncooked rice, phytate content was between 0.05 and 0.22% (Mameesh and Tomar, 1993). A study conducted on tropical foods reported phytic acid contents were highest for gingelly (3-87%), gingelly meal (3-76%), and rice bran (3-65%) (Ravindran et al., 1994). In addition, when analyzing foods commonly consumed in China, the phytate content of 60 foods ranged from 0 to 1878 mg/100 g (Ma, 2005); resulting in a phytate intake between 648 and 1433 mg/day, with urban residents consuming much less phytate than their rural counterparts (781 vs 1342 mg/day) (Ma, 2005).

As reported in Table 14, and as noted by (Kalita et al., 2007), phytic acid content of water lentils is reported to be a very small constituent of the crop. LF typically contains undectable levels of phytic acid, which is much lower than the phytic acid reported in commonly consumed foods including white rice, soybeans, cashews, wheat, and corn. Therefore, no safety concern is expected regarding the phytic acid content of LF.

Table 14. Phytic Acid content of select edible plant and plant products [a]

Plant	Phytic Acid (%)
Rice, Polished, White	0.3
Rice, Wild	2.2
Wheat	0.6
Corn	0.7
Soybean	2.6
Cashew	2.0
Lemnature™ Fiber [b]	**<0.14**

[a] Data taken from Gilani et al., 2012. [b] Four separate production lots (LF-210630-D3-RW, LF-210709-D3-RW, LF-210902-D3, and LF-210915-D3)

III.F. Safety of secondary metabolites within Lemnature™ Fiber

1. Biogenic amines

Biogenic amines (BAs) are molecules generally produced by microbial decarboxylation of amino acids which may cause adverse reactions upon consumption due to their toxicity (Gardini et al., 2016). The most common biogenic amines found in foods are histamine, tyramine, cadaverine,

2- phenylethylamine, spermine, spermidine, putrescine, tryptamine, and agmatine (Naila et al., 2010). BAs have been found in a variety of commonly consumed foods. Although generally considered as more prominent in animal products (e.g., fish and cheese) and fermented plant foods, BAs are also ubiquitous in non-fermented foods of plant origin (Muñoz-Esparza et al., 2019; Sánchez-Pérez et al., 2018). Considering this, the presence of BAs at some levels in the water lentil-derived products is expected.

Certainly BAs, especially histamine, can represent a toxicological hazard if present at elevated levels; at lower levels BAs can play important and positive roles in human health given their antioxidant and anti-inflammatory properties (Muñoz-Esparza et al., 2019). BAs can also result in allergic reactions manifesting as difficulty in breathing, itching, rash, vomiting, fever or hypertension (Naila et al., 2010). As shown in Table 7, an analysis of biogenic amines in a commercially representative batch of LF showed low levels of histamine (1.05 ppm).

Özogul and Özogul (2019) state that toxic levels of BAs are very difficult to set but that a maximum total BA level in human food of 750 to 900 mg/kg has been proposed. Wojcik et al. (2021) also states that there are large differences and discrepancies in the BA content of foods and setting a recommended daily limit is difficult. In an older reference, an intake of greater than 40 mg BAs per meal has been considered potentially toxic; while levels of 50-100 ppm of histamine, 100-800 ppm of tyramine, and 30 ppm of β-phenethylamine, or a total of 100-200 ppm in foods are regarded as acceptable (Shalaby, 1996). In a 6-week repeat dose study in rats, the no observed adverse effect level (NOAEL)s for tyramine, putrescine and cadaverine were determined to be 180 mg/kg bw/day, 83 mg/kg bw/day for spermidine and 19 mg/kg bw/day for spermine (Til, 1997).

While there are no reports of BAs found in water lentils in the literature, LF's BA results (see Table 7) indicate a total of ~169 mg total BA/kg LF (~169 ppm) and therefore a total of approximately 4.9 mg total BAs per 29 g maximum estimated daily intake; results are significantly lower than the 40 mg/meal proposed toxicity levels. Moreover, when compared to other commonly consumed foods, LF BA levels are significantly lower than the BA levels in cheese (5 - 4500 ppm) and sauerkraut (110-300 ppm) (Karovicova and Kohajdova, 2005).

Ultimately, none of the common biogenic amines are present in LF at levels of concern and are lower than the highest levels found in common foods. Thus, no food safety risk is expected regarding the biogenic amine values present in LF under the conditions of intended use.

2. Mycotoxins and Microcystin

Regarding mycotoxins, a representative lot of LF was analyzed for aflatoxin B1, B2, G1, and G2, as well as Fumonisin, HT-2 Toxin, Ochratoxin A, T-2 Toxin, Vomitoxin, and Zearalenone. The results as reported in Table 7, indicate no mycotoxins were reported above the laboratory's limits of quantification.

Similarly, Lemnature recognizes that aquatically grown foods can be impacted by algae toxins, thus Lemnature has contracted third party GreenWater Laboratories to evaluate a sample of its LF using the most sensitive, accurate and advanced methods for detecting and quantifying microcystins (Liquid Chromatography/Mass Spectrometry/Mass Spectrometry; LC/MS/MS). As

a result, the total microcystin levels were found to be very low and not detected above the laboratory's limits of detection (10 µg/kg dry weight).[2] Moreover, the resulting total microcystins values do not exceed the World Health Organization (WHO) 0.04 µg/ kg bw tolerable daily intake for chronic exposure (WHO, 2020). The report of analysis for microcystin is provided in Appendix E.

Therefore, no health and safety implications are expected from the consumption of mycotoxins and microcystin from ingestion of LF under the conditions of intended use.

3. Nucleotides

Nucleic acids are naturally occurring macromolecules including deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). They are ubiquitous cellular components in all animals and plants, including water lentils. Rusoff et al. (1980) reported nucleic acid compositions for four water lentils species. The nucleic acid content was found to be 6.0% for *Lemna gibba*, 6.2% for *Spirodela punctata*, 6.3% for *Spirodela polyrhiza*, and 6.4% for *Wolffia columbiana*. Based on the data summarized in Table 7, LF has a total of 0.7% nucleotides. As reported in *Spirulina platensis*'s GRN 127(FDA, 2003b), the nucleic acid content in LF is much lower than those of Spirulina (4%), Chlorella (6%), other microalgae, yeast, and fungi (6-11%). Hence, the nucleic acid content of LF is below recognized levels in other water lentil and edible algae species.

High intake of nucleic acids (DNA and RNA) may be associated with increased blood concentration of uric acid. The FDA had no questions about the intended use of 3 g/serving of *Spirulina platensis,* which contains 4% nucleic acids (GRNs 127, 394, and 417(FDA, 2003b; FDA, 2012a; FDA, 2012b)). The maximum estimated intake was 2 servings (6 g) of *Spirulina platensis* per day – amounting to 0.24 g/day of nucleic acids. The estimated intake of LF is 29 g, and at this intake, the total nucleic acid amount would be 0.20 g/day. Since the intake of nucleic acids is very similar, no adverse effects related to nucleic acids are expected after ingestion of LF under recommended conditions of use.

4. Nitrates

Nitrate is a relevant natural compound present in vegetables as it is responsible for characterizing its quality (Natesh et al., 2017), and is involved in the growth of the plant.

The WHO established the acceptable daily intake of nitrate at 3.7 mg/kg body weight and nitrite at 0.06 mg/ kg body weight. Similarly, the European Commission Regulation number 1881/2006 (EC, 2006) established the maximum nitrate levels for various leafy vegetables including in spinach at 2500-3500 mg/kg (as-is), lettuce at 3000-5000 mg/kg (as-is), and 'Iceberg' lettuce at 2000-2500 mg/kg (as-is) (Devlamynck et al., 2020; EC, 2006).

As indicated in Table 7, LF contains 59 mg/kg nitrate based on an average of four lots. Considering the recognized dietary limitations set by expert bodies for nitrate, LF values are considered significantly below the safety limits for leafy vegetables. Nitrate is highly water-

[2] 10 µg/kg LF x 0.029 kg/day LF divided by 70 kg bw =0.004 µg/kg bw

soluble and can be easily reduced or removed in the food production process. Therefore, no health and safety implications are expected from the consumption of LF as it concerns nitrates under LF's conditions of intended use.

5. Pesticides

Lemnature produces LF from Lemnature's cultivated water lentils in modern aquafarming ponds in which pesticides are not used and pathogens and environmental contaminants are closely monitored. LF was analyzed using a full FDA pesticide screen conducted by a third-party Eurofins laboratory and none were detected; refer to Appendix F for certificate of analysis of one lot of LF analyzed for various parameters, including pesticides.

III.G. Safety of trace elements content

The content and concentration of trace elements present in *Lemnaceae* depend largely on the aqueous growing environment (Appenroth et al., 2017; Haustein et al., 1990; Van der Spiegel et al., 2013). Lemnature's aquafarming crop system is completely contained in order to prevent leaching or contamination by sewage or heavy metals. As noted by Appenroth et al. (2017), the trace element content can be adjusted by cultivation conditions. This was also reported in a recent article by Pagliuso (2022) where the ash and mineral content was evaluated in multiple species of duckweed and reported that duckweed can accumulate minerals by up to several hundred fold as compared to the concentrations of those minerals in the growth water. Hence, Lemnature carefully controls the composition of the growth media and closely monitors plant tissue and water data, in addition to evaluating the concentration of various metals in the final product.

The European Food Safety Authority (EFSA) reported a concern with the estimated manganese intake based on the information provided by Lemnature on their LENTEIN® Complete (EFSA Panel on Nutrition Novel Foods and Food Allergens et al., 2021). Lemnature has adjusted their growing methods to reduce the manganese in their LF and the expected maximum level of manganese in LF is 200 ppm as reported in Table 15. The amount of manganese in 29 grams of the LF is equal to the amount of manganese in 3 ounces of cooked blue mussels (NIH ODS, 2021).

Table 15 shows quantities of trace elements detected in LF, the estimated amount that would be consumed at the estimated maximum daily intake of 29 g, and the Tolerable Upper Intake Level (UL) for adults in the U.S. as determined by the National Institutes of Health. Each element falls below the recognized benchmark level; therefore, no health and safety implications from trace elements are expected from the consumption of LF. Element data is representative of the products' typical composition, based on analytical results from analysis of seven (7) different lots of material produced in 2021.

Table 15. Trace elements in LF and Tolerable Upper Intake Levels

Element	Expected Maximum Level	Amount of element in 29 g LF (mg)	Tolerable Upper Intake Levels for Adults (mg/day)

	in LF as-is (ppm)		
Aluminium	12	0.35	Not established
Calcium	16,400	476	2500
Copper	0.5	0.015	10
Iron	700	20.3	45
Magnesium	3,000	87	Not established for food sources
Manganese	200	5.8	11
Potassium	16,000	464	Not established
Selenium	<0.02	0.0006	0.4
Sodium	4,100	119	2,300
Zinc	105	3.05	40

Tolerable upper intake level information cited from Institute of Medicine and National Academies of Sciences (Institute of Medicine, 1997; Institute of Medicine, 2000; Institute of Medicine, 2001; Institute of Medicine, 2005; National Academies of Sciences, 2019). mg – milligrams; ppm – parts per million.

III.H. Widespread use of water lentils as a food source

Water lentils have been identified as a core dietary component for a variety of animals in the wild, including muskrats, ducks, and other waterfowl (Hillman, 1961; Leng, 1999). For decades, water lentils have also been investigated as a feed ingredient for poultry, ruminants, and swine (Gwaze and Mwale, 2015; Leng, 1999; Roman et al., 2021; Rusoff et al., 1980; Sońta et al., 2018), with results from these studies indicating that they are a safe and nutritious option.

The benefits of water lentils for humans were first described in the 17th century. The Cruydt Book (Dodonaeus, 1644), a Dutch medicinal plant guide published in 1644, stated that they could be used as a nutritive food source or applied topically to treat illnesses, including inflammations and fractures. In certain parts of the world, *Lemnaceae* have been consumed for generations, long recognized as a highly nourishing food source (Bhanthumnavin and McGarry, 1971; Van der Spiegel et al., 2013). While they are a familiar dietary staple in Thailand and other neighboring countries in Southeast Asia, water lentils have recently received attention around the world due to their impressive nutritional profile, rapid growth rate, and ability to be sustainably cultivated (Appenroth et al., 2018; de Beukelaar et al., 2019; Sree et al., 2015b; Ziegler et al., 2015).

In Thailand, the *Wolffia* genus of *Lemnaceae* is seasonally available for purchase by the public in vegetable markets throughout the country, gathered from ponds and swamp areas (Appenroth et al., 2018; Shirai and Rambo, 2014). Water lentils are often used in traditional local dishes, such as soups and salads, but are also incorporated into a variety of contemporary food products, such as pork balls and sausages, cookies, breads, noodles, and muffins (Armstrong, 2001; Siripahanakul et al., 2013). Examples of available recipes for *Lemnaceae* are provided in Appendix G.

As early as 1971, water lentils were suggested as an inexpensive source of protein for human consumption (Bhanthumnavin and McGarry, 1971), but the high content of dietary fiber is another valuable aspect of the plant's nutrition profile. Studies have reported that dietary fiber comprises 26-28% of the dry weight of the *Wolffia* genus of water lentils (Appenroth et al., 2017; Appenroth et al., 2018). Defined as "non-digestible carbohydrates and lignin that are intrinsic and intact in plants" by the Institute of Medicine Food Nutrition Board defines (Institute of Medicine, 2005), the protective effects of fiber against cardiovascular disease, type 2 diabetes, and certain cancers are well-established (Aune et al., 2016; Dahl and Stewart, 2015; Reynolds et al., 2019; Threapleton et al., 2013; Yao et al., 2014). Based on a 2,000 calorie diet, the Daily Value for dietary fiber is 28g for adults and children age 4 years and older (*Code of Federal Regulations (21CFR101.9) - Nutrition Labeling of Food*, 2020). However, a large analysis of NHANES data revealed that the mean intake among Americans is approximately 16 g/day (Grooms et al., 2013). Incorporated into a variety of food products, dietary fiber derived from water lentils may help increase average fiber consumption in the U.S.

III.I. Safety studies with Lemnature's LENTEIN® Complete (LC)

The similarity in the composition of Lemnature's LF and LC was previously outlined in Table 11. Based on the similarity between the LF and LC products, no additional toxicity studies were conducted. Both published animal studies and unpublished research conducted by Lemnature suggest there are no safety or toxicity concerns related to the consumption of water lentils or Lemnature's products.

Lemnature has completed four, Good Laboratory Practice (GLP) compliant, comprehensive toxicity studies on Lemnature's LENTEIN® Complete (LC) by Shriram Institute for Industrial Research, Delhi India: repeated dose (90 days) oral toxicity study (OECD 408) in male and female Wistar rats, an acute oral toxicity study (LD_{50}) (OECD 420) was conducted as a limit test at 2g/kg bw, *in vivo* micronucleus study (OECD 474), and bacterial reverse mutation test (AMES Study; OECD 471). Shriram Institute is GLP compliant, and a Drug Establishment registered in the FDA under identifier number 3002808145. The final reports and supporting data for the oral toxicity studies were provided with the GRN 742 submission and summary reports for the acute oral and 90-day repeat dose studies can be found in Appendix O of GRN 742. The final summary reports for the AMES and micronucleus studies are provided in Appendix H.

Based on the data presented in the toxicity reports, Lemnature's LC LD_{50} (lethal dose in 50% of animals) in Wistar rats was between 2 and 5 g/kg body weight and is categorized as Category 5 or unclassified as per the Globally Harmonized Classification System (GHS). Similarly, "under the conditions of the repeated dose oral toxicity study, the repeated oral administration of Lemnature's LC in Wistar rats at the dose level of 1g/kg body weight daily for 90 days, Lemnature's LC did not induce any observable toxic effects, when compared to its corresponding control group of animals. Hence, 1 g/kg body weight is considered to be the 'No Observed Adverse Effect Level.'"

Lemnature's LC was evaluated for mutagenic potential using the bacterial reverse mutation (AMES) assay, which was conducted using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA102, with and without metabolic activation. The LC was diluted in dimethyl sulfoxide (DMSO). A preliminary toxicity study was conducted in strain TA100 using the plate incorporation method, with and without metabolic activation. An initial and confirmatory assay was conducted, both with and without metabolic activation, as a plate incorporation assay based on the results of the preliminary toxicity study. Vehicle and positive controls were included in both assays. Under the condition of the AMES study, Lemnature's LC at dosage up to 5000 µg/plate did not produce either a 2-fold increase in the mean numbers of revertant colonies in the strains TA98, TA100 and TA102, or a 3-fold increase in the mean numbers of revertant colonies in the strains TA1535 and TA1537 either in the presence or absence of metabolic activation system when compared to the respective vehicle control plates. Positive controls were included in the study and produced a more than 3-fold increase in the mean numbers of revertant colonies as compared to the respective vehicle controls. Therefore, it is concluded that Lemnature's LC did not elicit mutagenic potential in this bacterial reverse mutation test at the tested doses.

The *in vivo* mammalian erythrocyte micronucleus test was conducted in male and female Swiss albino mice (n=5/sex/group). An initial dose range finding study was completed to assess the toxicity of LC to bone marrow. The LC was prepared in corn oil and mice were given an oral dose of 2000 mg/kg bw by oral gavage for two consecutive days. The vehicle control group was dosed with corn oil and the positive control group was dosed with a single intraperitoneal injection of cyclophosphamide. Mice were euthanized between 18 and 24 hours after the last dose, the femurs removed, bone marrow collected and prepared to produce smears for evaluation. The slides were then evaluated for the presence of micronucleated polychromatic erythroctyes (MNPCE). Under the conditions of the micronucleus, the results did not reveal any significant difference in percent MNPCE (%MNPCE) in mice belonging to the treatment group at a dose level of 2000 mg/kg body weight concurrent when compared to the respective vehicle control. There was a significant increase in %MNPCE in mice in the positive control group. These results suggest that Lemnature's LC does not have micronucleus induction potential in male and female mice up to the dose level of 2000 mg/kg body weight, following oral administration for two consecutive days.

All four toxicity studies were evaluated by the FDA, and the Federal agency stated in their No Objection letter to Lemnature's (under the company name Parabel) GRAS Notification 742 (Parabel, 2017) "no mortality or signs of toxicity were observed in an acute oral toxicity study in rats administered [water lentil] powder protein concentrate by gavage at 2,000 mg/kg BW, the highest dose tested. No adverse toxicological effects were observed from a sub-chronic 90-day oral toxicity study in rats administered [Parabel's water lentil] powder protein concentrate by gavage, up to 1,000 mg/kg BW/day, the highest dose tested". Even though Lemnature's LF has not been tested in these toxicity studies, both fractionated products from Lemnature's water lentils are similar in composition to LC, derived from the same source, and intended to be consumed significantly below the 1000 mg/kg bw/day NOAEL in rats. In GRN 742, the intake of LC was estimated to be 27.8 – 55.6 g/day and the estimated daily intake of LF (29g) is within this range. As a result, Lemnature does not see any evidence that LF poses a toxicity risk upon human consumption under the conditions of intended use.

III.J. Studies with similar ingredients

III.J.1. *Safety studies*

A substantial body of research exists examining the complete or partial substitution of *Lemnaceae* for traditional protein meal in a variety of animals. In laying hens, water lentils were found to be a suitable replacement for traditional protein sources, such as soy and fishmeal, with no negative impact on the animals or their eggs (Chantiratikul et al., 2010; Haustein et al., 1992; 1990). Similarly, no adverse effects were reported in similar feed replacement studies for other poultry, swine, and ruminants (Domínguez et al., 1996; Gwaze and Mwale, 2015; Men et al., 2002; 1996; Putra and Ritonga, 2018; Tanuwiria and Mushawwir, 2020).

Toxicity studies in rats provide further compelling evidence for the safety of *Lemnaceae* consumption. A rat feeding study was conducted to investigate the nutritional quality of protein

extracted from several aquatic plants, including *Lemna minor*, compared to a reference diet of casein (Dewanji and Matai, 1996). Authors evaluated protein efficiency ratio, digestibility, liver moisture, body weight, and nitrogen and serum protein and albumin. The rats were fed the experimental or control diet for 28 days. At the end of the study, the rats were sacrificed, and a visual inspection of their livers was performed. No abnormalities were identified in any of the groups.

More recently, a GLP compliant, 90-day dietary toxicity study was performed on Sprague-Dawley rats to test a cultivated strain of *Wolffia globosa* (Kawamata et al., 2020). The study was conducted in accordance with OECD Guideline 408. A total of 92 rats (46 males, 46 females) were fed the dry and pulverized crop powder. The animals were distributed randomly into four feeding groups, with 10 male and 10 female rats assigned per group according to body weight. Each group was exposed to the dry crop powder at different inclusion rates of 0%, 5%, 10%, and 20% (w/w); the mean intakes of dry *Wolffia globosa* throughout the administration period were 0, 3.18, 6.49, and 13.16 g/kg/day for males, while females consumed 0, 3.58, 7.42, 15.03 g/kg/day. No statistically significant differences were identified among groups for food intake quantity or body weight, and no abnormal ophthalmologic or post-mortem histopathological findings were reported. Among female rats, decreased fibrinogen was observed in the 10% and 20% crop powder inclusion groups ($p \leq 0.05$), but there were no hematological differences among males.

Extracts from seven duckweed species were evaluated for cytotoxic effects and anti-proliferative activity effects on human cell lines. The human cell lines, HUVEC, K-562 and HeLa were used for the cytotoxicity experiments and HUVEC and K-562 were used for the anti-proliferative activity evaluations (Sree et al., 2019). To prepare the extracts, whole plants were freeze dried, homogenized in methanol, purified, dried, and then dissolved in DMSO. The maximum dose used in the assays was 50 µg/ml and no cytotoxic or anti-proliferative effects were reported.

III.J.2. *Other Studies*

In a clinical trial evaluating the dynamics of fasting ghrelin levels during weight loss interventions, participants were divided into three groups; a healthy diet, a Mediterranean diet, and a green Mediterranean diet (Tsaban et al., 2021). Details regarding the specific different interventions of each group are not relevant to the safety of water lentils and are not discussed here. In addition to other changes, the green-MED group were given 100g of *Wolffia globosa* (strain *Mankai*) to consume as a shake to replace dinner for the 18-month study duration. This study was not designed as a safety study and adverse effects of *W. globosa* were not specifically measured; however, no indication was given in the results that it was not well tolerated.

Mes et al. (2022) conducted a study to evaluate the safety and tolerance of *Lemna minor* in a randomized, controlled parallel trial. Twenty-four healthy adults consumed 170 g/day (fresh weight) of either steamed *L. minor* or steamed spinach with a regular meal for 11 consecutive days. The *L. minor* plants were grown indoors under controlled conditions, harvested, washed, and then frozen until used. The harvested material was analyzed for nutritional, microbiological

and toxicological content before use. The trial participants were told to report any gastric complaints, hunger or fullness, desire to eat, thirst, nausea, stool consistency and general health on a daily basis. Blood and urine were collected at the start and end of the study to analyze general health including kidney and liver function, cardiovascular health, inflammation, and iron status. There were no adverse effects reported following the consumption of *L. minor* for 11 days and there were no significant changes in any of the blood and urine parameters evaluated. The authors concluded that the *L. minor* was well tolerated and is safe for human consumption.

Neither published animal studies nor Lemnature's commissioned research indicate any mutagenic or toxic components from animal consumption of water lentils or LC. Given that most of the *Lemnaceae* species investigated in the scientific publications were not the result of a controlled food grade cultivation and production process, they would have a greater risk of toxic exposures. The European Union (EU) has recognized water lentil pulp, meal, and concentrate as legal compounds in the EU Feed Registry, indicating a lack of safety concerns, and the studies summarized in this section are considered corroborative to the principal published safety data.

III.K. Safety studies on components in Lemnature™ Fiber

In 1973, cellulose was recognized as a GRAS substance (SCOGS, 1973a). The comprehensive review by Anderson et al. (1992) concluded that human exposure to cellulose would not result in any adverse health effects. Details of the review are described below and in Table 16. Overall, most cellulose is recovered in feces as it remains largely undigested in the upper gastrointestinal tract and may be poorly fermented in the colon to gases and SCFA. Thus, gastrointestinal discomfort is not expected with consumption of cellulose. Consumption of a large quantity of cellulose also did not affect gastrointestinal morphology. The only possible effect might be on body weight mostly due to its caloric dilution effect. Therefore, the metabolism of cellulose does not raise safety concerns and no systemic toxicity is expected following ingestion of cellulose.

As shown in Table 3, the dietary fiber composition of LF falls within range of other GRAS fibers, such as rice bran fiber GRN 373 (>40% dietary fiber) and pea fiber GRN 525 (>60% dietary fiber). Both rice bran fiber and pea fiber have similar ratios of soluble to insoluble fiber as LF (LF: 5% soluble, 95% insoluble; rice bran fiber: <10% soluble, >90% insoluble; pea fiber: <1% soluble, >99% insoluble). Compared to rice bran fiber, LF contains a lower percentage of cellulose (LF: 26%, rice bran fiber: 30%), hemicellulose (LF: 12%, rice bran fiber: 20%), and starch (LF: <5%, rice bran fiber: <25%). As the fiber components of LF do not exceed other GRAS fibers, many of which are over 80% dietary fiber, additional safety studies are not warranted.

The following studies evaluate the effect of cellulose and hemicellulose on animals and humans, demonstrating that neither fiber component should raise safety concerns as no systemic risks are expected from the metabolism of the cellulose and hemicellulose fraction in LF.

1. **Effects of cellulose on tumor formation**

In mice and rats, chronic ingestion of purified cellulose over the lifespan did not increase spontaneous disease or neoplasia (in the mammary glands, colon, or bladder of rats), nor did it significantly alter the absorption or metabolism of dietary components (Anderson et al., 1992). Several studies evaluated the role of exogenous cellulose on tumor incidence based on the assumption that diets containing exogenous cellulose should lead to an increased cancer rate when administered following a dose of a site-specific carcinogen. In various models, cellulose did not display tumor-promoting activity at large doses.

2. Effects of cellulose on reproductive performance and growth

No adverse effects were noted on reproduction or neonate development in rats using 30% cellulose in the diet (Anderson et al., 1992; SCOGS, 1973a). Also, a 5% cellulose diet did not cause any abnormal reproductive performance such as pups per litter, pup survival, or pup growth in mice and rats ('Report of the American Institute of Nutrition Ad Hoc Committee on Standards for Nutritional Studies,' 1977; Anderson et al., 1992). Teratogenic effects were not observed.

Evaluation of effects of cellulose on growth revealed that cellulose had no adverse effects in rats and mice. Growth rates for up to 18 weeks after weaning were not affected in either rats or mice when a 5% cellulose diet was administered (Anderson et al., 1992; Hove & King, 1979; "Report of the American Institute of Nutrition Ad Hoc Committee on Standards for Nutritional Studies," 1977). Dietary concentrations of 20% cellulose for 4 weeks did not retard growth of rats (Hove and King, 1979). Rat pups consuming a diet containing 28.6% cellulose had decreased carcass fat due to lower calorie intake related to caloric dilution effects of cellulose (Wojcik and Delorme, 1982). Also, rat pups consuming 10% and 20% cellulose diets gained less body weight due to caloric dilution of the diet and no increased food consumption to compensate caloric dilution (Sundaravalli et al., 1971).

3. Effects of cellulose on the gastrointestinal tract

As the gastrointestinal tract is directly exposed to ingested cellulose, which remains intact in the large intestine, the effect on intestinal structure and physiology are important endpoints for the safety evaluation of cellulose. Several studies showed that large doses of cellulose did not adversely alter cell morphology or cell dynamics in the gastrointestinal tract in mice and rats (Goodlad and Wright, 1983; Lupton et al., 1988; Vahouny et al., 1981).

4. Additional cellulose studies

As presented in Table 16, a number of studies have tested the effect of cellulose on glycemic responses and digestibility and reported no adverse effects of cellulose in cats, dogs, mice, and rats (Delorme et al., 1981; Hasegawa et al., 1990; Nelson et al., 1991; 1998; 2000; Schwartz and Levine, 1980; Vahouny et al., 1987; 1988). Doses up to 20% cellulose in the diet were tested and the duration of the studies were up to 8 months.

Table 16. Studies showing no adverse effects of cellulose in animals

Animal	Cellulose in diet (%)	Duration	Primary measurement endpoints	Reference
Carcinogenesis				
Rats treated with AOM [a]	10, 20, or 30	24 weeks	Large bowel cancer incidence	Nigro et al. (1979)
Rats treated with DMBA [b]	8-46	120 or 134 days	Mammary tumor promotion	Kritchevsky et al. (1984)
Reproductive performance and growth				
Rat	30	3 generations	Reproductive performance	SCOGS (1973a)
Rats and mice	5	Up to 18 weeks after weaning	Teratogenic effects and growth rates	'Report of the American Institute of Nutrition Ad Hoc Committee on Standards for Nutritional Studies' 1977)
Rats, weaning males	20	4 weeks	Weight gain, food consumption, cecal wt, cecal SCFA	Hove and King (1979)
Rat pups	4.8, 9.1, 16.7, or 28.6	4 weeks	Weight gain, food consumption, carcass fat	Wojcik and Delorme (1982)
Rat pups	5, 10, or 20	4 weeks	Weight gain, food consumption	Sundaravalli et al. (1971)
Gastrointestinal effects				
Mice	30	1 weeks	Body weight, histology of the intestine	Goodlad and Wright (1983)
Rat	15	6 weeks	Body weight, histology of the intestine	Vahouny et al. (1981)
Rat	10	35 weeks	Body weight, histology of the intestine	Lupton et al. (1988)
Efficacy studies showing no adverse effects of cellulose				
Cats with naturally acquired diabetes mellitus	12	24 weeks	Caloric intake, body weight, or postprandial serum glucose concentration	Nelson et al. (2000)
Dogs with naturally acquired diabetes mellitus	12	8 months	Pre- and postprandial serum glucose concentration; urinary excretion of glucose	Nelson et al. (1998)
Dogs with alloxan-induced diabetes mellitus	15	8 weeks	Postprandial serum glucose concentration	Nelson et al. (1991)
Rats	10	5 weeks	Intestinal glucose absorption	Schwartz and Levine (1980)
Rats, weaning	5, 10, 20, or 40	4 weeks	Growth and digestibility	Delorme et al. (1981)
Streptozocin-induced diabetic mice	20	8 weeks	Growth rate, insulin secretion	Hasegawa et al. (1990)
Rats	10	4 weeks	Fecal mass	Vahouny et al. (1987); (1988)

[a] AOM=azoxymethane; [b] DMBA=7,12-dimethylbenz-alpha-anthracene.

5. Human clinical studies of cellulose showing no adverse effects of cellulose, a major component of rice hull fiber

A review of human studies reported that cellulose intake of 10-24 g/day significantly increased stool weights, reduced mean transit time, and increased stool frequency (Eastwood et al., 1973; Fleming et al., 1983; Kies et al., 1984; Slavin et al., 1985; Stephen, 1989; Wrick et al., 1983). No adverse effects of cellulose were reported.

Table 17 outlines additional human clinical studies showing no adverse effects of cellulose (Mickelsen et al., 1979; Niemi et al., 1988; Park and Jhon, 2009; Spiller et al., 1980). Doses up to 25 g/day were tested for a maximum duration of 8 weeks. In generaTstsTsl, cellulose intake decreased intestinal transit time and increased fecal weight (relieving constipation) without having adverse effects. In observational studies with 203 consecutive post-appendectomy children with histologically proved appendicitis and 1922 controls, cellulose intake was correlated to lower incidence of appendicitis (Adamidis et al., 2000). In another observational study with 291 children with constipation and 1602 controls, only cellulose and pentose intakes were independently inversely correlated with chronic constipation (Roma et al., 1999). No studies reported adverse effects of cellulose.

Table 17. Human clinical studies showing no adverse effects of cellulose

Subject	Cellulose dosage/day	Duration	Results/Primary measurement endpoints	Reference
10 healthy volunteers	14 g powdered cellulose	3 weeks	Decreased transit time; increased fecal bulk	Spiller et al. (1980)
6 college males	23 g powdered cellulose	8 weeks	Increased weight loss and satiety	Mickelsen et al. (1979)
8 constipated volunteers	25 g powdered cellulose	6 days	Lower blood triglycerides; increased HDL, stool volume and quality, and bowel movement comfort; no change in serum glucose	Park and Jhon (2009)
18 subjects with T2D	5 g/day increasing daily over 2 weeks to 15 g/day	12 weeks	No effect on fasting serum glucose or lipid profiles	Niemi et al. (1988)

g- grams; HDL= high density lipoprotein; T2D= type 2 diabetes

6. Safety of hemicelluloses, a second major component of Lemnature™ Fiber

Other fiber ingredients containing an arabinoxylan backbone, such as wheat bran (52-64% arabinoxylan; up to 70% hemicelluloses) and psyllium (85% arabinoxylan), are known for their fecal bulking effects and gastrointestinal regularity improvement without having negative effects on mineral bioavailability. These hemicellulose-rich fibers are fermented by intestinal microflora to produce SCFA that support colonic health. However, fermentation in the large intestine can result in the formation of gases (including hydrogen, carbon dioxide, and methane), which often is associated with flatulence and intestinal discomfort. Intestinal

discomfort can be a transient symptom since the human body is able to adapt to higher intakes of dietary fiber over time. Overall, metabolites of hemicelluloses such as SCFA, CO_2, and H_2, do not raise safety concerns and no systemic risks are expected from the metabolism of the hemicellulose fraction of LF.

As it pertains to human clinical studies, hemicellulose (mostly arabinoxylan)-rich fiber such as psyllium (85% arabinoxylan) has been proven safe for human consumption. Based on numerous human randomized controlled trials, the FDA has approved health claims for psyllium and oat bran and risk reduction of heart disease (FDA, 2008). No safety concerns have been reported for arabinoxylan-rich fibers.

III.L. Allergenicity

Although water lentils have not been consumed extensively as a human food or food ingredient in the USA, they have a long history of use in Southeast Asia (Bhanthumnavin and McGarry, 1971; Van der Spiegel et al., 2013). To Lemnature's knowledge, there is no evidence that suggests a high risk of allergenicity from water lentils. In a comprehensive review article focused on the human safety of novel protein sources, including insects, algae, rapeseed, and water lentil, the potential for allergenicity issues with several sources are discussed (Van der Spiegel et al., 2013). However, allergenicity to water lentils is not mentioned as a safety concern, indicating that that the authors do not view them as a high-risk potential allergen.

Lemnature has conducted an extensive, English-language literature search, from year 2014 through present, to investigate the question of allergenicity for water lentils using the following terms: "*lemna*" OR "*wolffia*" OR "duckweed" OR "*Lemnaceae*" OR "*Araceae*" OR "water lentils" AND "allergen" OR "allergenicity" OR "cross-reactivity." In addition, Lemnature commissioned GRAS Associates LLC to examine the question of allergenicity together with subject matter expert Dr. Steven Taylor of the Food Allergy Research and Resource Program of the University of Nebraska. Dr. Taylor presented his opinion based on scientific literature reviews and the historical use of water lentils as human food and this was presented as Appendix I of GRN 742.

Lemnature's LENTEIN® Complete has been marketed since 2018 and has conducted post-market surveillance, including tracking any allergenicity concerns and during this time, no reports of allergic reactions have been received. A Lemnature statement of post-market surveillance related to consumer reporting on allergens/allergic reactions is provided in Appendix I.

Therefore, Lemnature does not see any evidence that water lentils pose an allergenic risk in the scientific literature or in the long history of human consumption of water lentils in Southeast Asia. Conducting any prospective testing would be unfeasible and unlikely to yield definitive results. Lemnature intends to use a common or usual name on the label of foods containing this ingredient to ensure that should any allergy issues arise in the future, and consumers will be able to recognize the source and avoid consumption (*Code of Federal Regulations (21CFR102)- Common or Usual Name for Nonstandardized Foods*, 2020).

III.M. Conclusion

Lemnature AquaFarms USA, Inc. has critically evaluated the published and unpublished data and information, summarized in this safety evaluation, and concludes that Lemnature™ Fiber derived from Lemnature's water lentils is GRAS, on the basis of scientific procedures, for use in conventional food products as described in Part I.C.

Lemnature™ Fiber is manufactured in accordance with CGMP and is well characterized. LF will be added to food products as a fiber ingredient substitute, either alone or in conjunction with other fiber sources; thus, LF will not contribute to any additional exposure to fiber for consumers. When the EDI for LF was calculated based on the NHANES 2017 – 2018 survey as well as the proposed intended uses in the identified food categories, the EDI was a gross overestimation at 63.4 and 125.3 g/day for the mean and 90th percentile, respectively. It is not realistic to assume that the actual consumption of foods containing LF would result in a daily consumption which is greater that the recommended intake for dietary fiber. FDA recently increased the Daily Value for dietary fiber for adults to 28 g (FDA, 2016a).

Lemnature's whole water lentil powder, "LENTEIN® Complete" (LC) and its degreened version are both recognized as GRAS (FDA, 2018b). LF is also derived from Lemnature's *Lemnaceae* and the chemical compositions between the two products in terms of macronutrients, elements and secondary metabolites is very similar but at different concentrations as a result of the manufacturing process. For the evaluation of the safety of LF it was assumed that half of the daily fiber intake of 28 g would be from LF. The fiber content of LF ranges from 48-66% so 48% was used to calculate the potential LF daily intake of 29 g. Estimated daily intake of LF is within the amount of LC that has been successfully notified as GRAS (27.8 – 55.6 g/day). Lemnature has evaluated the antinutritional factors in LF including oxalic acid, tannins, trypsin inhibitors and phytic acid, as well as secondary metabolites including biogenic amines, mycotoxins, microcystin, nucleotides and nitrates. No safety concerns were identified with any of these at the EDI of 29 g/day for LF.

No specific safety studies were conducted with LF but safety information from preclinical and clinical studies on "LENTEIN®" and other water lentil preparations were evaluated. The potential for allergenicity concerns with the consumption of LF was evaluated and it was determined that it is unlikely that consumption of LF would pose an allergenic risk.

General recognition of Lemnature's GRAS conclusion is supported by the unanimous consensus rendered by an independent Panel of Experts (the GRAS Panel), qualified by experience and scientific training, to evaluate the use of Lemnature™ Fiber in food, who similarly concluded that the proposed uses of Lemnature™ Fiber are GRAS on the basis of scientific procedures. The Expert Panel report is provided in Appendix J.

Lemnature ensured that all reasonable efforts were made to identify and select a balanced Expert Panel with expertise in food safety, toxicology, and nutrition. Efforts were placed on identifying conflicts of interest or relevant "appearance issues" that could potentially bias the outcome of the deliberations of the Expert Panel and no such conflicts of interest or "appearance issues" were identified. The Expert Panel received a reasonable honorarium as

compensation for their time; the honoraria provided to the Expert Panel were not contingent upon the outcome of their deliberations.

Lemnature™ Fiber may therefore be marketed and sold for its intended purpose in the U.S. without the declaration of a food additive regulation under Title 21, Section 170.3 of the Code of Federal Regulations.

LIST OF SUPPORTING DATA AND INFORMATION

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APPENDIX A – CERTIFICATE OF AMENDMENT FOR NAME CHANGE

APPENDIX B – 36-MONTH STABILITY DATA FOR LENTEIN® COMPLETE

APPENDIX C - TECHNICAL REPORT: USE OF *LEMNACEAE* FLOUR AS A FUNCTIONAL INGREDIENT IN COMMINUTED AND WHOLE MUSCLE MEAT PRODUCTS

APPENDIX D – INTAKE REPORT -FOOD CODES AND FOOD INTAKE

APPENDIX E – TOTAL ADDA MICROCYSTINS/NODULARINS REPORT

APPENDIX F – ANALYTICAL REPORTS FOR *LEMNACEAE* (WATER LENTIL) FIBER POWDER

APPENDIX G – WATER LENTIL RECIPES

APPENDIX H – SUMMARY REPORTS AND RESULTS OF AMES AND MCRONUCLEUS TESTS ON LC

APPENDIX I – STATEMENT OF LC'S POST-MARKET SURVEILLANCE

APPENDIX J – EXPERT PANEL REPORT

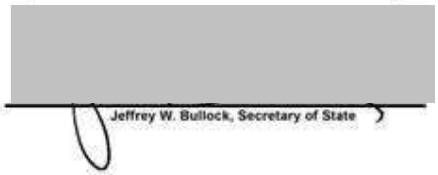
END

APPENDIX A - CERTIFICATE OF AMENDMENT FOR NAME CHANGE

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "PARABEL USA INC.", CHANGING ITS NAME FROM "PARABEL USA INC." TO "LEMNATURE AQUAFARMS USA, INC.", FILED IN THIS OFFICE ON THE FIFTEENTH DAY OF MARCH, A.D. 2022, AT 1:29 O`CLOCK P.M.



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Authentication: 202918376
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You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Amendment
to the Certificate of Incorporation
of Parabel USA Inc.

The corporation organized and existing under and by virtue of the General Corporation Law of The State of Delaware does hereby certify:

FIRST: That the Sole Shareholder of Parabel USA Inc., duly adopted resolutions setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable. The resolution setting forth the proposed amendment is as follows:

RESOLVED that the Certificate of Incorporation of Parabel USA Inc. be amended by changing the Article thereof numbered "Article I" so that as amended, said Article shall be and read as follows:

The name of the corporation is Lemnature AquaFarms USA, Inc.

SECOND: That thereafter, pursuant to a Written Resolution of its Sole Shareholder, executed in accordance with Section 228 of the General Corporation Law of the State of Delaware the amendment is hereby approved.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said corporation has caused this certificate to be signed this 15th day of March, 2022.

Parabel USA Inc.

By: [redacted]
Frank Jimenez, Sole Director and CEO

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:29 PM 03/15/2022
FILED 01:29 PM 03/15/2022
SR 20221008889 - File Number 5308764

Memorandum of Corporate Name Change

TO: U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

FROM: Gene A. Lang, Ph.D., General Counsel
Lemnature AquaFarms USA, Inc.

DATE: March 30, 2022

RE: Notice of Corporate Name Change

Effective March 15, 2022, our company name has been changed as follows:

from **"Parabel USA Inc."**

to "**Lemnature AquaFarms USA, Inc.**"

Other than the company name, all other details and structures of the company remain unchanged.

Our registered address remains:

Lemnature AquaFarms USA, Inc.
1991 74th Avenue, Suite B
Vero Beach, FL 32966
Phone: 772-207-4794

For inquiries or further information, please contact:

legal@lemnatureusa.com

Lemnature AquaFarms USA, Inc.

By: [redacted]
Gene A. Lang, Ph.D., General Counsel

Attachment "A": Certificate of Amendment File No. 5308764, Secretary of State, State of Delaware

APPENDIX B - 36-MONTH STABILITY DATA FOR LENTEIN® COMPLETE

Stability Data for Parabel's LENTEIN Complete

LENTEIN Complete and its degreened version (DGLC) are expected to be stable for at least 3 years (36 months) under recommended storage conditions that Parabel will provide to its customers, as follows:

> Recommended storage is cool temperature (below 25 °C/ 75 °F) with low relative humidity (< 60% humidity). Maintain the product in the provided packaging, air-tight sealed bags, and store away from direct light.

Parabel has initiated a six-month and 12-month accelerated shelf life stability study for Parabel's LENTEIN Complete, on four representative commercial samples. The parameters tested address physiochemical, biochemical and microbiological stability, including Peroxide Value, Hexanal, p-Anisidine value, Total Oxidation Value (TOTOX), and fatty acids Omega 3 and 6 to determine fat stability; crude protein, amino acid profile, pH, Aerobic Plate Count, Yeast and Mold Count, and visual appearance (color, texture and aroma). Refer to Appendix A for analytical results, lab proposal and summary of raw data. Results indicate that no significant difference is detected across the time periods among the different parameters, except for the Peroxide Value (PV) in sample CSPBWL-170308 which is recognized as an outlier. PV values in the two products is highly unlikely to develop under real time, ambient conditions of storage. Also, according to the sensory profile of the product, "no off odors" are detected which is an indicator that oxidation of the product is present (refer to Appendix A).

In addition, Parabel has conducted two internal studies to determine the real-time shelf-life of LENTEIN Complete (LC) powder from microbial, chemical, oxidative, and sensory stability data. Details as follows:

Study 1

LC samples from batch SPBWL160310 were packaged in aluminum foil bags and stored at 20 °C/50%RH for 36 months. Samples were pulled at 0, 6, 12, 18, 24, and 36 months to conduct the following analysis:

- Chemical Stability
  - Proximate composition
  - Protein quality (Protein Digestibility Adjusted Amino Acid Score [PDCAAS])
  - Fatty acid composition
- Oxidative Stability
  - Peroxide value
  - TBA Rancidity
- Microbial Stability
  - Aerobic plate count (APC)
  - Yeast and Mold
  - *Clostridium perfringens*
- Sensory Stability

- Color and odor

Results

LC samples packaged in aluminum foil zip lock bags and stored at 20 °C/50%RH remained stable and within product specifications for nutritional and microbial quality parameters during the 36 month storage period. Protein quality was not significantly altered during storage. Samples from the 6th and 12th month appeared to have a significantly lower amino acid score than samples from the 18th and 24th month. This difference is mostly due to analytical error as the samples from 6th and 12th month were analyzed by a different laboratory from the 18th to 36th month samples. However, amino acid scores between the 6th and 12th month or the 18th to 36th month are comparable. Microbial growth during storage can reduce protein quality as the microbes degrade amino acids. However, being a low water activity (<0.6) product, microbial growth and activity was not supported, so protein quality was unaltered. Peroxide value remained relatively low (≤11 mEq/Kg) up to the 24 month storage period. Peroxide values between 30-40 mEq/Kg are generally associated with a rancid taste. TBA rancidity increased between the 6th and 12th month but remained relatively stable between the 18th and 36th month. This increase in TBA rancidity, which is indicative of the formation of secondary lipid oxidation products, did not cause a detectable change in product sensory or odor, nor has any expected health implications. Furthermore, there was no perceptible change in product color. Direct exposure to light is known to alter LC color due to photo-oxidation of pigments like chlorophylls and carotenoids. The sample packaging excluded light exposure, therefore, product color was stable. Omega 3 and 6 fatty acids consistently made up about 70% of total fatty acids throughout the 36-month storage period which indicates that polyunsaturated fatty acids were also stable.

Parameter	Specification	0 month	6 month	12 month	18 month	24 month	36 month
Moisture (%)	<10	3.36	4.69	4.81	5.13	4.88	5.09
Crude Protein (%, dmb)	45-50	48.49	49.21	48.76	47.47	47.40	47.40
Protein Digestibility (%)		N/R	0.90	0.90	0.90	0.90	0.90
Amino Acid Score		N/R	0.969	0.974	1.137	1.144	1.182
PDCAAS		N/R	0.87	0.88	1.02	1.03	1.06
Crude Fat (%, dmb)	<10	N/R	8.77	8.61	8.07	10.03	7.90
Total Fatty Acids (% w/w)		6.99	N/R	6.59	6.01	7.04	7.00
Total Omega 3		3.61	N/R	3.54	4.2	3.65	3.57
Total Omega 6		1.18	N/R	1.19	1.39	1.23	1.23
Peroxide value (meq/Kg fat)		N/A	0.96	< 2.0	11	6.2	N/R
TBA Rancidity (mg/Kg)		N/A	2.5	11.3	9.3	9.6	10.0
Ash (%, dmb)	<10	5.09	4.91	4.96	5.11	5.03	5.08
Total Dietary Fiber (%, dmb)	30-45	N/R	33.25	N/R	N/R	N/R	N/R
Water activity (measured in-house)		N/R	N/R	0.140	0.139	0.255	0.462
APC (cfu/g)	< 100,000	N/R	31,000	23,000	3,200	13,000	470
Yeast (cfu/g)	< 100	N/R	< 10	< 10	<10	20	<10
Moulds (cfu/g)	< 100	N/R	20	< 10	10	10	<10
C. perfringens (cfu/g)	< 100	N/R	< 10	< 10	<10	<10	N/R
Color		Vivid green	Vivid green	Vivid green	Vivid green	Vivid green	Vivid green
Odor		Fresh, grassy	Fresh, grassy	Fresh, grassy	Fresh, grassy	Fresh, grassy	Fresh, grassy

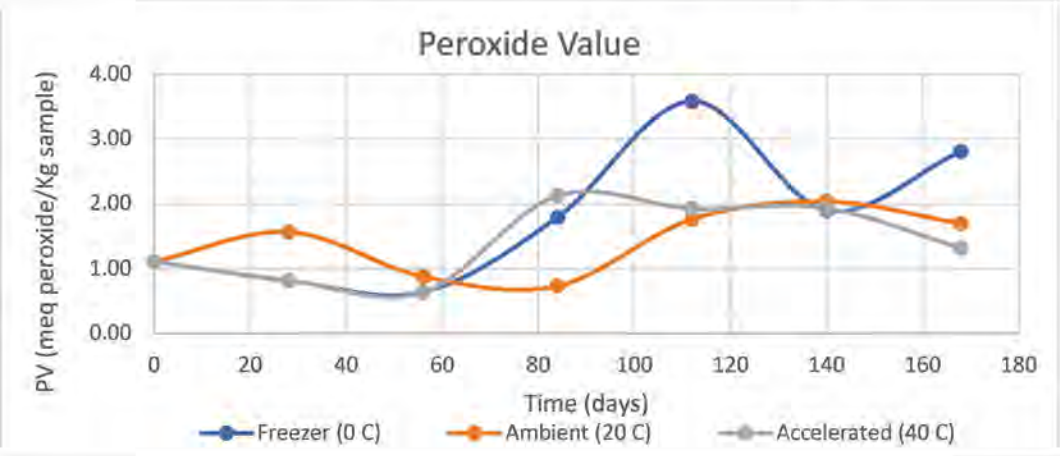
N/R = Not Reported

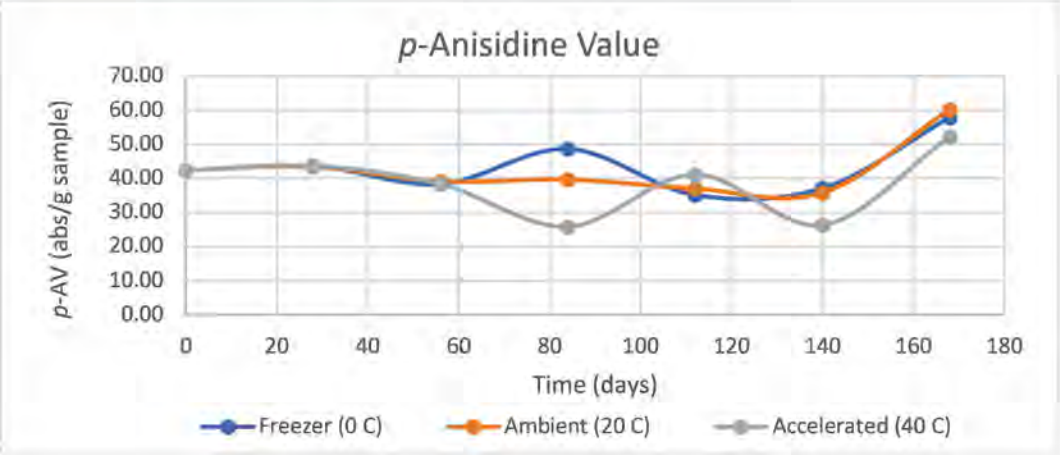
Study 2

LC samples from batch SPBWL160902 were packaged in aluminum foil zip lock bags and stored at 0°C (freezer), 20°C (ambient), or 40°C (accelerated). Samples were pulled at 0, 1, 2, 3, 4, 5, and 6 months for oxidative stability analysis (peroxide and p-anisidine value). Protein contents of samples were analyzed at 0 and 6 months.

Results

LC samples stored for 6 months at 0, 20, and 40 °C were analyzed for peroxide value (PV), *p*-anisidine value (*p*-AnV), and crude protein. The PV corresponds to hydroperoxides formed as primary oxidation products during lipid oxidation. The LC samples were stable to lipid oxidation under freezer, ambient, and accelerated conditions over the 6-month period. The highest PV (3.58 meq /kg) was observed for the 0 °C sample, at month 4, possibly due to slower breakdown of hydroperoxides. However, as stated previously, the PV did not increase significantly under storage conditions tested during 6 months. *p*-Anisidine value (*p*-AnV) is a measure of non-volatile secondary oxidation products from the degradation of hydroperoxides. The *p*-AnV for all samples were stable for the first 5 months but increased by the 6th month. The initial protein content of LC samples was 46.35% (dmb). After 6-month storage, protein content of samples stored at 0, 20, and 40 °C was 46.28, 46.02, and 45.53 % (dmb), respectively. The protein content of the LC sample was stable for 6 months under accelerated conditions. This can be extrapolated to a shelf stability of up to 12 months which is in agreement with data from Study 1 (Laboratory Certificate of Analysis are available upon request). At last, Parabel will continue to assess the stability of the product at real-time every six month, up to 60 months.





Conclusion

LC samples packaged in aluminum foil zip lock bags and stored at 20 °C/50%RH remained stable and within product specifications for crude protein, fat, ash, and microbes after 36 months. Under accelerated (40 °C) conditions, protein and peroxide values did not change significantly over the six (6) month storage period. Based on the data presented, LC is expected to be stable for at least 36 months from date of manufacture, when stored at dry, cool conditions in packaging that excludes light exposure.

APPENDIX C - TECHNICAL REPORT: USE OF LEMNACEAE FLOUR AS A FUNCTIONAL INGREDIENT IN COMMINUTED AND WHOLE MUSCLE MEAT PRODUCTS Redacted due to Business Confidential/Trade Secret Information

APPENDIX D – INTAKE REPORT -FOOD CODES AND FOOD INTAKE

Proposed Use and Food Codes Utilized for Intake Calculation

The food codes utilized to calculate the estimated daily intake were selected from the National Health and Nutrition Examination Survey (NHANES) 2017 – 2018 survey. Food codes that most appropriately match the intended use were selected.

Food code	Main Food Description
	Baked goods and baking mixes
53100100	Cake or cupcake, NS as to type
53101100	Cake, angel food, without icing or filling
53101200	Cake, angel food, with icing or filling
53101250	Cake, angel food, with fruit and icing or filling
53105500	Cake, chocolate, with icing, diet
53108220	Snack cake, chocolate, with icing or filling, reduced fat and calories
53109220	Snack cake, not chocolate, with icing or filling, reduced fat and calories
53116000	Cake, pound, without icing or filling
53116020	Cake, pound, with icing or filling
53116390	Cake, pound, reduced fat, cholesterol free
53122080	Cake, shortcake, biscuit type, with fruit
53123080	Cake, shortcake, sponge type, with fruit
53124110	Cake or cupcake, zucchini
53204840	Cookie, brownie, reduced fat, NS as to icing
53204860	Cookie, brownie, fat free, NS as to icing
53206030	Cookie, chocolate chip, reduced fat
53207020	Cookie, chocolate or fudge, reduced fat
53220000	Cookie, fruit-filled bar
53220010	Cookie, fruit-filled bar, fat free
53224250	Cookie, lemon bar
53225000	Cookie, macaroon
53228000	Cookie, meringue
53231400	Cookie, multigrain, high fiber
53233040	Cookie, oatmeal, reduced fat, NS as to raisins
53239010	Cookie, shortbread, reduced fat

Food code	Main Food Description
53241500	Cookie, butter or sugar
53246000	Cookie, tea, Japanese
53260030	Cookie, chocolate chip, sugar free
53260200	Cookie, oatmeal, sugar free
53260400	Cookie, sugar or plain, sugar free
53261000	Cookie, gluten free
53300100	Pie, NFS
53300170	Pie, individual size or tart, NFS
53450000	Turnover or dumpling, apple
53450300	Turnover or dumpling, berry
53450500	Turnover or dumpling, cherry
53450800	Turnover or dumpling, lemon
53451000	Turnover or dumpling, peach
53451500	Turnover, guava
53452100	Pastry, fruit-filled
53510100	Danish pastry, with fruit
53520200	Churros
53610100	Coffee cake, crumb or quick-bread type
53610170	Coffee cake, crumb or quick-bread type, with fruit
51165000	Coffee cake, yeast type
52302020	Muffin, fruit, low fat
52304040	Muffin, bran with fruit, lowfat
52306550	Muffin, zucchini
51154510	Roll, diet
51620000	Roll, multigrain
51620020	Roll, multigrain, hot dog bun
51620030	Roll, multigrain, hamburger bun
51808100	Roll, gluten free
	Beverages and beverages bases – Protein and nutritional powders, Smoothies and grain drinks
95201000	Nutritional powder mix (Carnation Instant Breakfast)
95201010	Nutritional powder mix, sugar free (Carnation Instant Breakfast)
95201500	Nutritional powder mix, high protein (Herbalife)
95201600	Nutritional powder mix (Isopure)

Food code	Main Food Description
95202000	Nutritional powder mix (Muscle Milk)
95202010	Nutritional powder mix, light (Muscle Milk)
95210000	Nutritional powder mix (Slim Fast)
95210010	Nutritional powder mix, sugar free (Slim Fast)
95210020	Nutritional powder mix, high protein (Slim Fast)
95220000	Nutritional powder mix, NFS
95220010	Nutritional powder mix, high protein, NFS
95230000	Nutritional powder mix, whey based, NFS
95230010	Nutritional powder mix, protein, soy based, NFS
95230020	Nutritional powder mix, protein, light, NFS
95230030	Nutritional powder mix, protein, NFS
11553120	Fruit smoothie, with whole fruit and dairy, added protein
64134020	Fruit smoothie, with whole fruit, no dairy, added protein
78101110	Fruit and vegetable smoothie, added protein
78101118	Fruit and vegetable smoothie, non-dairy, added protein
11553120	Fruit smoothie, with whole fruit and dairy, added protein
64134015	Fruit smoothie, with whole fruit, no dairy
64134020	Fruit smoothie, with whole fruit, no dairy, added protein
64134025	Fruit smoothie, with whole fruit, non-dairy
64134030	Fruit smoothie juice drink, no dairy
64134100	Fruit smoothie, light
64134200	Fruit smoothie, bottled
78101110	Fruit and vegetable smoothie, added protein
78101115	Fruit and vegetable smoothie, non-dairy
78101118	Fruit and vegetable smoothie, non-dairy, added protein
78101120	Fruit and vegetable smoothie, bottled
78101125	Fruit and vegetable smoothie, no dairy
78101130	Vegetable smoothie
	Breakfast Cereal
57100100	Cereal, ready-to-eat, NFS
57227000	Cereal, granola
57229000	Cereal (Kellogg's Low Fat Granola)
57308190	Cereal, muesli
57000100	Cereal, oat, NFS

Food code	Main Food Description
57137000	Cereal, corn puffs
57151000	Cereal, crispy rice
57206700	Cereal (General Mills Fiber One)
57206710	Cereal (General Mills Fiber One Honey Clusters)
57207000	Cereal, bran flakes
57208000	Cereal (Kellogg's All-Bran Complete Wheat Flakes)
57301500	Cereal (Kashi 7 Whole Grain Puffs)
57301510	Cereal (Kashi GOLEAN)
57304100	Cereal (Quaker Life)
57308400	Cereal (General Mills Cheerios Multigrain)
57337000	Cereal, rice flakes
57340000	Cereal, puffed rice
57401100	Cereal, toasted oat
57416000	Cereal, puffed wheat, plain
	Cheese (Imitation cheese and cheese dips)
41420050	Soybean curd cheese
14620150	Cheese dip with chili pepper
14620200	Cheese dip
14502000	Imitation cheese
	Nutrition Bars & Cereal Bars
53710800	Cereal or granola bar (Kashi Chewy)
53710802	Cereal or granola bar (Kashi Crunchy)
53720100	Nutrition bar (Balance Original Bar)
53720200	Nutrition bar (Clif Bar)
53720300	Nutrition bar (PowerBar)
53720400	Nutrition bar (Slim Fast Original Meal Bar)
53720600	Nutrition bar (South Beach Living Meal Bar)
53720610	Nutrition bar (South Beach Living High Protein Bar)
53729000	Nutrition bar or meal replacement bar, NFS
53710400	Cereal or granola bar (General Mills Fiber One Chewy Bar)
53712100	Cereal or Granola bar, NFS
53712200	Cereal or granola bar, lowfat, NFS
53712210	Cereal or granola bar, nonfat
53713000	Cereal or granola bar, reduced sugar, NFS

Food code	Main Food Description
53713010	Cereal or granola bar, fruit and nut
53714200	Cereal or granola bar, chocolate coated, NFS
53714210	Cereal or granola bar, with coconut, chocolate coated
53714220	Cereal or granola bar with nuts, chocolate coated
53714230	Cereal or granola bar, oats, nuts, coated with non-chocolate coating
53714250	Cereal or granola bar, coated with non-chocolate coating
53714300	Cereal or granola bar, high fiber, coated with non-chocolate yogurt coating
53714400	Cereal or granola bar, with rice cereal
53714500	Breakfast bar, NFS
53714510	Breakfast bar, date, with yogurt coating
53714520	Breakfast bar, cereal crust with fruit filling, lowfat
	Spreads and Condiments
81302040	Sandwich spread
83100200	Salad dressing, NFS, for sandwiches
83108000	Vegan mayonnaise
74401110	Ketchup, reduced sodium
74402010	Tomato chili sauce
74406010	Barbecue sauce
63409020	Chutney
75534550	Wasabi paste
	Confections and Frostings and Hard Candy
91708020	Soft fruit confections
91745020	Hard candy
91745040	Butterscotch hard candy
91770020	Dietetic or low calorie hard candy
91770050	Dietetic or low calorie mints
91770000	Dietetic or low calorie candy, NFS
	Dairy Product Analogs
11300100	Non-dairy milk, NFS
11320000	Soy milk
11320100	Soy milk, light
11320200	Soy milk, nonfat
11321000	Soy milk, chocolate
11321100	Soy milk, light, chocolate

Food code	Main Food Description
11321200	Soy milk, nonfat, chocolate
11350000	Almond milk, sweetened
11350010	Almond milk, sweetened, chocolate
11350020	Almond milk, unsweetened
11350030	Almond milk, unsweetened, chocolate
11360000	Rice milk
11370000	Coconut milk
11512030	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk
11512120	Hot chocolate / Cocoa, ready to drink, made with non-dairy milk and whipped cream
11513310	Chocolate milk, made from dry mix with non-dairy milk
11513375	Chocolate milk, made from reduced sugar mix with non-dairy milk
11513385	Chocolate milk, made from dry mix with non-dairy milk (Nesquik)
11513395	Chocolate milk, made from no sugar added dry mix with non-dairy milk (Nesquik)
11513750	Chocolate milk, made from syrup with non-dairy milk
11513805	Chocolate milk, made from light syrup with non-dairy milk
11513855	Chocolate milk, made from sugar free syrup with non-dairy milk
11514150	Hot chocolate / Cocoa, made with dry mix and non-dairy milk
11514360	Hot chocolate / Cocoa, made with no sugar added dry mix and non-dairy milk
11519215	Strawberry milk, non-dairy
12200100	Coffee creamer, NFS
12210520	Coffee creamer, soy, liquid
12320100	Sour cream, imitation
12220200	Whipped topping
12220270	Whipped topping, fat free
12220280	Whipped topping, sugar free
	Fats and Oils – Salad Dressings and Vegetable Oils
83100100	Salad dressing, NFS, for salads
83112000	Avocado dressing
83115000	Yogurt dressing
83200100	Salad dressing, light, NFS
83201400	Coleslaw dressing, light
83203000	Caesar dressing, light
83206500	Sesame dressing, light
83210100	Creamy dressing, light

Food code	Main Food Description
83300200	Caesar dressing, fat free
83300300	Creamy dressing, fat free
83300900	Salad dressing, fat free, NFS
	Fish Products
27250050	Fish cake or patty, NS as to fish
27250070	Salmon cake or patty
27250160	Tuna cake or patty
27250310	Haddock cake or patty
27250400	Shrimp cake or patty
	Frozen Dairy Desserts
11459990	Frozen yogurt, NFS
11460000	Frozen yogurt, vanilla
11460500	Frozen yogurt, soft serve, vanilla
13110000	Ice cream, NFS
13110102	Ice cream, vanilla, with additional ingredients
13110112	Ice cream, chocolate, with additional ingredients
13130100	Light ice cream, NFS
13130300	Light ice cream, vanilla
13130310	Light ice cream, chocolate
13150000	Sherbet, all flavors
41480020	Frozen dessert, non-dairy
	Gelatins, Puddings and Pie Fillings
13200110	Pudding, chocolate, NFS
13210280	Pudding, flavors other than chocolate, NFS
13210300	Custard
13210350	Flan
13210410	Pudding, rice
13210520	Pudding, tapioca, made from dry mix
13220110	Pudding, flavors other than chocolate, made from dry mix
13220120	Pudding, chocolate, made from dry mix
13220210	Pudding, flavors other than chocolate, made from dry mix, sugar free
13220220	Pudding, chocolate, made from dry mix, sugar free
13230110	Pudding, flavors other than chocolate, ready-to-eat
13230120	Pudding, flavors other than chocolate, ready-to-eat, sugar free

Food code	Main Food Description
13230130	Pudding, chocolate, ready-to-eat
13230140	Pudding, chocolate, ready-to-eat, sugar free
13230500	Pudding, tapioca, ready-to-eat
13241000	Banana pudding
13250000	Mousse
32401000	Meringues
63403150	Lime souffle
	Grain Products and Pasta
56104000	Pasta, vegetable, cooked
56113990	Noodles, vegetable, cooked
56116990	Long rice noodles, made from mung beans, cooked
56117090	Rice noodles, cooked
56130000	Pasta, cooked
41425010	Vermicelli, made from soybeans
	Gravies and Sauces
42204050	Peanut sauce
42204100	Gravy, vegetarian
14650160	Alfredo sauce
14650165	Alfredo sauce with added vegetables
28522000	Mole sauce
81302070	Pesto sauce
81312100	Curry sauce
74402260	Enchilada sauce, green
74402350	Salsa verde or salsa, green
89901010	Cream sauce, for use with vegetables
89901030	Gravy, for use with vegetables
89901040	Soy based sauce, for use with vegetables
89901050	Tomato sauce, for use with vegetables
74404010	Spaghetti sauce
74404020	Spaghetti sauce with added vegetables
74404050	Spaghetti sauce, reduced sodium
74404060	Spaghetti sauce, fat free
	Jams and Jellies
91401000	Jelly, all flavors

Food code	Main Food Description
91402000	Jam, preserve, all flavors
91403000	Fruit butter, all flavors
91404000	Marmalade, all flavors
91405000	Jelly, sugar free, all flavors
91405500	Jelly, reduced sugar, all flavors
91406000	Jam, preserve, marmalade, sugar free, all flavors
91406500	Jam, preserve, marmalade, sweetened with fruit juice concentrates, all flavors
91406600	Jam, preserve, marmalade, reduced sugar, all flavors
	Processed Meat/Poultry Products
25220105	Beef sausage
25220106	Beef sausage, reduced fat
25220108	Beef sausage, reduced sodium
25220650	Turkey or chicken and beef sausage
25221400	Sausage, NFS
25221405	Pork sausage
25221406	Pork sausage, reduced fat
25221408	Pork sausage, reduced sodium
25221460	Pork and beef sausage
25221830	Turkey or chicken sausage
25221855	Turkey or chicken sausage, reduced sodium
25221860	Turkey or chicken sausage, reduced fat
24198671	Chicken patty, breaded
25210110	Frankfurter or hot dog, NFS
25210220	Frankfurter or hot dog, beef and pork
25210240	Frankfurter or hot dog, beef and pork, reduced fat or light
25210250	Frankfurter or hot dog, meat and poultry, fat free
27160100	Meatballs, NS as to type of meat, with sauce
27260050	Meatballs, with breading, NS as to type of meat, with gravy
22300120	Ham, fried, NS as to fat eaten
22300130	Ham, fried, lean and fat eaten
22300140	Ham, fried, lean only eaten
22300150	Ham, breaded or floured, fried, NS as to fat eaten
22300160	Ham, breaded or floured, fried, lean and fat eaten
22300170	Ham, breaded or floured, fried, lean only eaten

Food code	Main Food Description
22311000	Ham, smoked or cured, cooked, NS as to fat eaten
22311010	Ham, smoked or cured, cooked, lean and fat eaten
22311020	Ham, smoked or cured, cooked, lean only eaten
22311450	Ham, prosciutto
22311500	Ham, smoked or cured, canned, NS as to fat eaten
22311510	Ham, smoked or cured, canned, lean and fat eaten
22311520	Ham, smoked or cured, canned, lean only eaten
22321110	Ham, smoked or cured, ground patty
25230210	Ham, prepackaged or deli, luncheon meat
25230220	Ham, prepackaged or deli, luncheon meat, reduced sodium
25230420	Ham luncheon meat, loaf type
25230530	Ham and pork, canned luncheon meat, chopped, minced, pressed, spiced
25230540	Ham, pork and chicken, canned luncheon meat, chopped, minced, pressed, spiced, reduced fat and reduced sodium
25230550	Ham, pork, and chicken, canned luncheon meat, chopped, minced, pressed, spiced, reduced sodium
	Plant Protein Products
41440000	Textured vegetable protein, dry
41810200	Bacon strip, meatless
41810400	Breakfast link, pattie, or slice, meatless
41810600	Chicken, meatless, NFS
41810610	Chicken, meatless, breaded, fried
41811400	Frankfurter or hot dog, meatless
41811600	Luncheon slice, meatless-beef, chicken, salami or turkey
41811800	Meatball, meatless
41811890	Vegetarian burger or patty, meatless, no bun
41812000	Sandwich spread, meat substitute type
41812600	Vegetarian, fillet
41901020	Soyburger, meatless, with cheese on bun
59003000	Meat substitute, cereal- and vegetable protein-based, fried
27564420	Frankfurter or hot dog sandwich, meatless, plain, on bun
27564430	Frankfurter or hot dog sandwich, meatless, plain, on bread
27564570	Frankfurter or hot dog sandwich, meatless, on bread, with meatless chili
27564560	Frankfurter or hot dog sandwich, meatless, on bun, with meatless chili
41811950	Swiss steak, with gravy, meatless

Food code	Main Food Description
41812400	Vegetarian pot pie
41812450	Vegetarian chili, made with meat substitute
41812850	Vegetarian stroganoff
	Processed Fruit and Vegetable Juices
92530610	Fruit juice drink, with high vitamin C
92530950	Vegetable and fruit juice drink, with high vitamin C
92541010	Fruit flavored drink, powdered, reconstituted
92542000	Fruit flavored drink, with high vitamin C, powdered, reconstituted
92550030	Fruit juice drink, with high vitamin C, light
92550035	Fruit juice drink, light
92550040	Fruit juice drink, diet
92550405	Vegetable and fruit juice drink, with high vitamin C, light
92552020	Fruit juice drink, reduced sugar (Sunny D)
92550400	Vegetable and fruit juice drink, with high vitamin C, diet
92550610	Fruit flavored drink, with high vitamin C, diet
92550620	Fruit flavored drink, diet
92552000	Fruit flavored drink, with high vitamin C, powdered, reconstituted, diet
92552010	Fruit flavored drink, powdered, reconstituted, diet
61213800	Fruit juice blend, citrus, 100% juice
61213900	Fruit juice blend, citrus, 100% juice, with calcium added
78101000	Vegetable and fruit juice, 100% juice, with high vitamin C
78101000	Vegetable and fruit juice, 100% juice, with high vitamin C
74303000	Tomato and vegetable juice, 100%
74303100	Tomato and vegetable juice, 100%, low sodium
75132000	Mixed vegetable juice
	Snack Foods/Chips
41310900	Bean chips
41410015	Soy chips
54318000	Chips, rice
54401021	Corn chips, plain
54401026	Corn chips, flavored
54401075	Tortilla chips, plain
54401085	Tortilla chips, flavored
54401090	Corn chips, reduced sodium

Food code	Main Food Description
54401095	Tortilla chips, popped
54401121	Tortilla chips, reduced fat, plain
54401122	Tortilla chips, reduced fat, flavored
54401170	Tortilla chips, low fat, unsalted
54402080	Tortilla chips, reduced sodium
71220000	Vegetable chips
54408016	Pretzels, hard, plain, salted
54408070	Pretzels, hard, multigrain
54408081	Pretzels, hard, plain, gluten free
54408082	Pretzels, hard, flavored, gluten free
54408485	Pretzels, soft, gluten free
54420220	Snack mix, plain (Chex Mix)
	Soft Candy
91700010	Candy, NFS
91705050	Milk chocolate candy, with fruit and nuts
91705310	Chocolate, sweet or dark, with almonds
91706000	Coconut candy, chocolate covered
91706100	Coconut candy, no chocolate covering
	Soups and Soup Mixes
28310230	Meatball soup, home recipe, Mexican style
28315160	Italian Wedding Soup
28355450	Seafood soup with potatoes and vegetables including carrots, broccoli, and/or dark-green leafy
28355470	Seafood soup with vegetables including carrots, broccoli, and/or dark-green leafy; no potatoes
72302000	Broccoli soup, prepared with milk, home recipe, canned or ready-to-serve
72307000	Spinach soup
74601000	Tomato soup, NFS
74606010	Tomato vegetable soup, prepared with water
74606020	Tomato vegetable soup with noodles, prepared with water
75600150	Soup, cream of, NFS
75601000	Asparagus soup, cream of, NS as to made with milk or water
75601010	Asparagus soup, cream of, prepared with milk
75601020	Asparagus soup, cream of, prepared with water
75605010	Leek soup, cream of, prepared with milk
75611010	Vegetable soup, cream of, prepared with milk

Food code	Main Food Description
75647000	Seaweed soup
75649010	Vegetable soup, canned, prepared with water or ready-to-serve
75649040	Vegetable soup, reduced sodium, canned, ready to serve
75649050	Vegetable soup, made from dry mix
75651020	Vegetable beef soup, canned, prepared with water, or ready-to-serve
75651030	Vegetable beef noodle soup, prepared with water
75651040	Vegetable noodle soup, canned, prepared with water, or ready-to-serve
75651070	Vegetable rice soup, canned, prepared with water or ready-to-serve
75651080	Vegetable beef soup with rice, canned, prepared with water or ready-to-serve
75651110	Vegetable chicken rice soup, canned, prepared with water or ready-to-serve
75651140	Vegetable soup with chicken broth, home recipe, Mexican style
75651150	Vegetable noodle soup, reduced sodium, canned, prepared with water or ready-to-serve
75652030	Vegetable beef soup, canned, prepared with milk
75654010	Vegetarian vegetable soup, prepared with water
75656010	Vegetable soup, Spanish style, stew type
75656020	Vegetable soup, chunky style
75656040	Vegetable soup, with pasta, chunky style
75656060	Vegetable beef soup, chunky style
75657000	Vegetable broth, bouillon
	Sweet Sauces, Toppings and Syrups
61113500	Lemon pie filling
63113030	Cherry pie filling
63203700	Blueberry pie filling
91304030	Topping, fruit

The intended uses in the various food categories are provided below. For purposes of intake calculation, the highest intended use for each category was utilized.

INTENDED USE	MAXIMUM USE LEVEL (%)
FOOD CATEGORY	LF
Baked goods and baking mixes	2-5%
Bars- Meal replacement/nutritional bars, cereal and granola bars	0.5-2%

Beverages and bases-Protein and nutritional drinks	1-10%
Breakfast cereals	1-5%
Candy- soft candy	0.5-2%
Cheese-vegetarian/imitation cheese and cheese dip	0.5-4%
Condiments and spreads	0.5-4%
Confections and frostings	0.5-2%
Dairy product analogs	1-3%
Fats and oils- salad dressing	0.5-3%
Fish products	1-7%
Frozen dairy desserts (ice cream)	0.5-4%
Gelatins, puddings, pie fillings	0.5-4%
Gravies and sauces	0.5-1%
Hard candy	0.5-2%
Jams and jellies	0.5%
Pasta	2%
Protein foods -processed meat/poultry products	1-3%
Protein foods - plant protein products (meat analogs)	1-10%
Processed fruit and vegetable juice	0.5-2%
Snack foods/chips	1-5%
Soups and soup mixes	0.5-2%
Spices, seasonings and blends	1-5%
Sweet sauces, toppings, and syrups	0.5-2%

Food Intake Reports of the food categories are provided below. All intakes are in grams and N equals the number of individuals reporting eating the foods and the "Percentage" is the percent of the population the "N" represents. "Per capita" intake refers to the estimated intake averaged over all individuals surveyed, regardless of whether they consumed food products the ingredient is intended to be added. from the selected food codes in one of the two days of the survey. Individuals were considered "consumers" if they reported consumption of one or more food products on either Day 1 or Day 2 of the survey. The asterisk (*) following the value for the Mean and 90th percentile intake estimates denote that sample sizes of less than 30 and 80, respectively, may not be considered statistically reliable due to the limited sampling size.

Summary of Consumption of Bakery-Muffins and Breads (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	1.34	0	4	1.3%	67.74*	71.98*
Children (1-5 years)	Female	0	0	0	0.0%	0	0
Children (6-11 years)	Male	0.06	0	1	0.3%	155.00*	155.00*
Children (6-11 years)	Female	0.03	0	1	0.3%	35.00*	35.00*

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Teenage (12-18 years)	Male	0.02	0	1	0.3%	21.50*	21.50*
Teenage (12-18 years)	Female	0	0	0	0.0%	0	0
Adults (19+ years)	Male	0.02	0	4	0.2%	27.05*	27.75*
Adults (19+ years)	Female	0.39	0	14	0.6%	43.16*	84.15*
All ages	Total Population	0.21	0	25	0.4%	45.57*	83.30*

Summary of Consumption of Sweet Bakery (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.09	0	3	1.9%	5.03*	8.66*
Infants	Female	0.22	0	1	0.7%	30.00*	30.00*
Children (1-5 years)	Male	1.61	0	17	5.3%	27.05*	61.69*
Children (1-5 years)	Female	2.01	0	18	5.9%	40.20*	64.39*
Children (6-11 years)	Male	3.72	0	19	5.8%	47.65*	126.28*
Children (6-11 years)	Female	2.32	0	28	8.0%	31.43*	54.91*
Teenage (12-18 years)	Male	2.81	0	18	4.5%	46.53*	74.04*
Teenage (12-18 years)	Female	2.99	0	29	7.3%	33.82*	67.50*
Adults (19+ years)	Male	4.76	0	160	7.9%	59.35	99.58
Adults (19+ years)	Female	2.91	0	173	7.8%	37.80	83.53
All ages	Total Population	3.49	0	466	7.0%	46.10	84.42

Summary Of Consumption of Beverages and Beverages Bases – Protein and Nutritional Powders, Smoothies And Grain Drinks (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0.89	0	7	2.2%	38.34*	69.64*
Children (1-5 years)	Female	1.99	0	11	3.6%	49.89*	65.64*
Children (6-11 years)	Male	0.45	0	3	0.9%	68.66*	156.16*
Children (6-11 years)	Female	4.12	0	10	2.8%	101.21*	192.89*
Teenage (12-18 years)	Male	4.11	0	16	4.0%	108.26*	225.48*
Teenage (12-18 years)	Female	5.22	0	17	4.3%	89.57*	223.39*
Adults (19+ years)	Male	15.70	0	125	6.2%	215.62	483.76
Adults (19+ years)	Female	12.97	0	151	6.8%	167.40	387.97
All ages	Total Population	11.48	0	340	5.1%	176.64	402.41

Summary of Consumption of Breakfast Cereals (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.03	0	1	0.6%	5.38*	5.38*
Infants	Female	0.07	0	1	0.7%	6.57*	6.57*
Children (1-5 years)	Male	1.63	0	25	7.9%	18.31*	25.36*
Children (1-5 years)	Female	0.98	0	22	7.2%	15.77*	29.15*
Children (6-11 years)	Male	1.06	0	13	4.0%	32.65*	41.60*
Children (6-11 years)	Female	1.04	0	15	4.3%	21.96*	31.14*
Teenage (12-18 years)	Male	0.45	0	7	1.8%	24.54*	52.82*
Teenage (12-18 years)	Female	1.40	0	19	4.8%	24.42*	39.90*
Adults (19+ years)	Male	1.81	0	104	5.1%	35.00	64.88
Adults (19+ years)	Female	1.72	0	108	4.9%	32.20	61.92
All ages	Total Population	1.58	0	315	4.7%	30.96	56.26

Summary of Cheese (Imitation cheese and cheese dips) (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0.56	0	9	2.8%	13.43*	20.82*
Children (1-5 years)	Female	0.07	0	5	1.6%	4.99*	10.64*
Children (6-11 years)	Male	0.19	0	5	1.5%	33.11*	72.15*
Children (6-11 years)	Female	0.63	0	7	2.0%	34.16*	47.05*
Teenage (12-18 years)	Male	0.05	0	3	0.8%	17.47*	30.31*
Teenage (12-18 years)	Female	0.17	0	3	0.8%	10.56*	4.73*
Adults (19+ years)	Male	1.50	0	24	1.2%	56.59*	96.84*
Adults (19+ years)	Female	0.87	0	33	1.5%	37.42	87.47*
All ages	Total Population	0.95	0	89	1.3%	42.58	93.50

Summary of Consumption of Nutrition Bars and Cereal Bars (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0.07	0	1	0.7%	12.50*	12.50*
Children (1-5 years)	Male	1.79	0	15	4.7%	26.40*	39.19*
Children (1-5 years)	Female	0.99	0	12	3.9%	17.66*	21.10*
Children (6-11 years)	Male	1.22	0	17	5.2%	22.90*	33.09*
Children (6-11 years)	Female	1.44	0	11	3.1%	32.72*	42.24*
Teenage (12-18 years)	Male	1.44	0	21	5.3%	42.00*	84.12*
Teenage (12-18 years)	Female	2.06	0	22	5.5%	25.52*	36.91*

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Adults (19+ years)	Male	2.45	0	86	4.2%	34.99	68.02
Adults (19+ years)	Female	1.85	0	98	4.4%	28.26	39.56
All ages	Total Population	1.96	0	283	4.3%	30.72	55.36

Summary of Consumption of Spreads and Condiments (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0.01	0	1	0.7%	0.71*	0.71*
Children (1-5 years)	Male	0.33	0	13	4.1%	11.84*	16.93*
Children (1-5 years)	Female	0.30	0	10	3.3%	10.39*	16.04*
Children (6-11 years)	Male	1.28	0	25	7.6%	16.02*	33.41*
Children (6-11 years)	Female	1.08	0	23	6.5%	16.81*	35.29*
Teenage (12-18 years)	Male	1.25	1.16	38	9.6%	11.40	21.15*
Teenage (12-18 years)	Female	0.85	0	19	4.8%	15.90*	33.86*
Adults (19+ years)	Male	1.88	4.03	172	8.5%	17.48	33.80
Adults (19+ years)	Female	0.78	0	139	6.3%	11.76	16.95
All ages	Total Population	1.20	0	440	6.6%	14.93	33.44

Summary of Consumption of Confections and Frosting and Hard Candy

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0.02	0	1	0.7%	10.50*	10.50*
Children (1-5 years)	Male	0.88	1.89	38	11.9%	8.18	13.74*
Children (1-5 years)	Female	0.64	0.49	34	11.1%	6.07	9.75*
Children (6-11 years)	Male	1.80	2.82	44	13.4%	13.38	40.60*
Children (6-11 years)	Female	2.12	5.59	56	15.9%	13.74	38.72*
Teenage (12-18 years)	Male	0.44	0	21	5.3%	8.38*	12.24*
Teenage (12-18 years)	Female	0.96	0	47	11.8%	9.77	15.80*
Adults (19+ years)	Male	0.46	0	84	4.1%	9.84	32.77
Adults (19+ years)	Female	0.30	0	117	5.3%	7.38	14.58
All ages	Total Population	0.54	0	442	6.7%	9.51	24.48

Summary of Consumption of Dairy Product Analogs (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	3.76	0	2	1.3%	791.60*	957.17*
Infants	Female	5.29	0	2	1.4%	421.85*	492.37*
Children (1-5 years)	Male	9.19	0	15	4.7%	221.71*	417.87*
Children (1-5 years)	Female	14.33	0	20	6.5%	174.35*	483.48*
Children (6-11 years)	Male	8.41	0	13	4.0%	221.62*	280.60*
Children (6-11 years)	Female	2.73	0	8	2.3%	110.07*	125.48*
Teenage (12-18 years)	Male	4.46	0	13	3.3%	134.25*	383.29*
Teenage (12-18 years)	Female	13.85	0	22	5.5%	157.68*	240.66*
Adults (19+ years)	Male	8.17	0	97	4.8%	134.74	271.17
Adults (19+ years)	Female	10.68	0	180	8.1%	116.73	244.00
All ages	Total Population	9.20	0	372	5.6%	131.87	257.59

Summary of Consumption of Fats and Oils – Salad Dressings and Vegetable Oils (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0.02	0	2	0.6%	3.99*	8.91*
Children (1-5 years)	Female	0.24	0	6	2.0%	8.81*	13.58*
Children (6-11 years)	Male	0.21	0	7	2.1%	11.89*	21.13*
Children (6-11 years)	Female	0.38	0	7	2.0%	13.53*	22.36*
Teenage (12-18 years)	Male	0.45	0	9	2.3%	28.87*	59.03*
Teenage (12-18 years)	Female	0.17	0	8	2.0%	13.20*	24.08*
Adults (19+ years)	Male	0.76	0	58	2.9%	28.91	62.39*
Adults (19+ years)	Female	0.53	0	78	3.5%	14.21	30.69*
All ages	Total Population	0.55	0	175	2.6%	19.23	40.90

Summary of Consumption of Fish Products (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0	0	0	0.0%	0	0
Children (1-5 years)	Female	0	0	0	0.0%	0	0
Children (6-11 years)	Male	0	0	0	0.0%	0	0
Children (6-11 years)	Female	0	0	0	0.0%	0	0
Teenage (12-18 years)	Male	0	0	0	0.0%	0	0
Teenage (12-18 years)	Female	0.11	0	2	0.5%	21.18*	29.47*

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Adults (19+ years)	Male	0.22	0	5	0.2%	125.08*	146.18*
Adults (19+ years)	Female	0.49	0	19	0.9%	64.28*	87.68*
All ages	Total Population	0.28	0	26	0.4%	71.44*	125.55*

Summary of Consumption of Frozen Dairy (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	1.79	0	10	3.1%	42.71*	65.79*
Children (1-5 years)	Female	0.99	0	12	3.9%	35.36*	61.97*
Children (6-11 years)	Male	5.11	0	23	7.0%	65.81*	90.56*
Children (6-11 years)	Female	8.07	0	32	9.1%	92.22	145.10*
Teenage (12-18 years)	Male	5.45	0	29	7.3%	86.57*	153.01*
Teenage (12-18 years)	Female	12.25	36.78	39	9.8%	114.77	240.48*
Adults (19+ years)	Male	6.00	0	126	6.2%	98.06	182.70
Adults (19+ years)	Female	6.59	0	140	6.3%	82.93	159.27
All ages	Total Population	6.17	0	411	6.2%	88.37	164.44

Summary of Consumption of Gelatin, Puddings, & Pie Fillings (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.05	0	2	1.3%	4.28*	8.18*
Infants	Female	0.08	0	1	0.7%	8.13*	8.13*
Children (1-5 years)	Male	0.43	0	3	0.9%	16.29*	23.58*
Children (1-5 years)	Female	0.87	0	8	2.6%	41.42*	50.99*
Children (6-11 years)	Male	1.19	0	6	1.8%	66.02*	75.37*
Children (6-11 years)	Female	2.18	0	12	3.4%	60.69*	73.75*
Teenage (12-18 years)	Male	0.61	0	5	1.3%	78.27*	102.16*
Teenage (12-18 years)	Female	1.20	0	7	1.8%	156.86*	250.89*
Adults (19+ years)	Male	2.60	0	43	2.1%	108.21	202.89*
Adults (19+ years)	Female	1.88	0	55	2.5%	81.09	129.95*
All ages	Total Population	1.93	0	142	2.1%	87.09	167.55

Summary of Consumption of Grain Products and Pastas (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	1.23	0	2	1.3%	74.04*	79.87*
Infants	Female	0.04	0	1	0.7%	26.25*	26.25*
Children (1-5 years)	Male	0.64	0	7	2.2%	49.23*	70.52*
Children (1-5 years)	Female	2.23	0	14	4.6%	47.54*	65.00*
Children (6-11 years)	Male	2.11	0	8	2.4%	113.28*	174.55*
Children (6-11 years)	Female	1.23	0	6	1.7%	77.85*	111.05*
Teenage (12-18 years)	Male	4.63	0	6	1.5%	200.07*	263.31*
Teenage (12-18 years)	Female	2.86	0	13	3.3%	92.46*	119.00*
Adults (19+ years)	Male	2.52	0	35	1.7%	133.14	218.72*
Adults (19+ years)	Female	1.89	0	54	2.4%	79.39	139.89*
All ages	Total Population	2.24	0	146	2.2%	101.68	223.44

Summary of Consumption of Gravies and Sauces (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.05	0	2	1.3%	7.14*	7.64*
Infants	Female	0.20	0	2	1.4%	13.67*	30.06*
Children (1-5 years)	Male	0.71	0	12	3.8%	17.44*	49.99*
Children (1-5 years)	Female	0.51	0	14	4.6%	12.69*	18.29*
Children (6-11 years)	Male	1.40	0	30	9.1%	18.44	43.08*
Children (6-11 years)	Female	0.49	0	23	6.5%	14.17*	32.31*
Teenage (12-18 years)	Male	0.88	0	16	4.0%	20.52*	31.77*
Teenage (12-18 years)	Female	2.00	0	23	5.8%	34.33*	66.58*
Adults (19+ years)	Male	3.10	0	147	7.3%	36.54	75.56
Adults (19+ years)	Female	2.13	0	165	7.4%	32.44	64.03
All ages	Total Population	2.21	0	434	6.5%	32.35	66.31

Summary of Consumption of James and Jellies (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0.02	0	2	1.4%	3.34*	3.34*
Children (1-5 years)	Male	0.43	0	17	5.3%	7.39*	12.46*
Children (1-5 years)	Female	0.13	0	13	4.2%	6.00*	11.07*
Children (6-11 years)	Male	0.51	0	20	6.1%	7.45*	9.49*
Children (6-11 years)	Female	0.50	0	16	4.5%	7.63*	11.44*
Teenage (12-18 years)	Male	0.84	0	13	3.3%	20.12*	27.24*

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Teenage (12-18 years)	Female	1.38	0	10	2.5%	28.92*	37.56*
Adults (19+ years)	Male	0.84	0	133	6.6%	12.54	20.28
Adults (19+ years)	Female	0.57	0	146	6.6%	8.67	16.95
All ages	Total Population	0.69	0	370	5.6%	11.08	25.28

Summary of Consumption of Processed Meats/Poultry Products (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.07	0	2	1.3%	9.62*	9.85*
Infants	Female	0.46	0	4	2.8%	16.96*	26.67*
Children (1-5 years)	Male	5.43	19.53	73	23.0%	28.43	55.48*
Children (1-5 years)	Female	5.31	21.04	68	22.2%	23.13	42.33*
Children (6-11 years)	Male	7.51	32.48	82	24.9%	29.81	50.59
Children (6-11 years)	Female	6.36	26.69	79	22.4%	33.23	70.62*
Teenage (12-18 years)	Male	12.84	53.41	94	23.7%	46.77	96.18
Teenage (12-18 years)	Female	4.73	19.77	69	17.4%	31.69	56.61*
Adults (19+ years)	Male	10.60	40.86	463	22.9%	46.95	89.22
Adults (19+ years)	Female	6.43	27.80	408	18.4%	35.04	63.63
All ages	Total Population	8.08	29.82	1342	20.2%	39.53	74.87

Summary of Consumption of Plant Protein Products (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.29	0	1	0.6%	64.75*	64.75*
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0.02	0	1	0.3%	19.00*	19.00*
Children (1-5 years)	Female	0.33	0	2	0.7%	108.00*	118.80*
Children (6-11 years)	Male	0.13	0	2	0.6%	60.00*	63.74*
Children (6-11 years)	Female	0.03	0	1	0.3%	35.00*	35.00*
Teenage (12-18 years)	Male	0	0	0	0.0%	0	0
Teenage (12-18 years)	Female	0	0	0	0.0%	0	0
Adults (19+ years)	Male	0.30	0	18	0.9%	37.51*	50.34*
Adults (19+ years)	Female	0.56	0	28	1.3%	59.59*	110.55*
All ages	Total Population	0.35	0	53	0.8%	50.65	107.40*

Summary of Consumption of Fruit and Vegetable Juice (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.70	0	2	1.3%	59.81*	67.32*
Infants	Female	3.15	0	4	2.8%	138.80*	197.76*
Children (1-5 years)	Male	40.70	123.96	73	23.0%	199.93	450.92*
Children (1-5 years)	Female	24.52	102.60	63	20.6%	127.73	244.23*
Children (6-11 years)	Male	59.19	175.40	94	28.6%	219.17	410.81
Children (6-11 years)	Female	37.28	121.63	95	27.0%	153.40	319.23
Teenage (12-18 years)	Male	50.14	234.72	69	17.4%	274.93	422.38*
Teenage (12-18 years)	Female	27.53	119.21	70	17.6%	209.98	304.08*
Adults (19+ years)	Male	33.26	0	221	10.9%	336.31	677.54
Adults (19+ years)	Female	32.32	0	220	9.9%	337.29	642.86
All ages	Total Population	34.25	92.54	911	13.7%	284.34	541.61

Summary of Consumption of Snack Foods and Chips (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0.04	0	3	1.9%	2.60*	2.84*
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	3.13	9.79	49	15.4%	17.09	42.15*
Children (1-5 years)	Female	2.49	9.88	51	16.7%	13.83	22.59*
Children (6-11 years)	Male	7.95	21.80	63	19.1%	36.32	65.37*
Children (6-11 years)	Female	3.60	17.72	61	17.3%	19.15	32.85*
Teenage (12-18 years)	Male	3.09	12.49	53	13.4%	20.65	31.84*
Teenage (12-18 years)	Female	2.96	11.59	57	14.4%	19.35	39.08*
Adults (19+ years)	Male	4.59	13.49	218	10.8%	32.85	67.96
Adults (19+ years)	Female	3.56	13.50	295	13.3%	21.49	46.26
All ages	Total Population	3.97	13.78	850	12.8%	25.31	52.42

Summary of Consumption of Soft Candy (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0.04	0	1	0.3%	7.00*	7.00*
Children (1-5 years)	Female	0.00	0	1	0.3%	2.63*	2.63*
Children (6-11 years)	Male	0.25	0	2	0.6%	24.20*	22.92*
Children (6-11 years)	Female	0.01	0	2	0.6%	1.65*	1.71*
Teenage (12-18 years)	Male	0.00	0	1	0.3%	4.40*	4.40*

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Teenage (12-18 years)	Female	0.21	0	6	1.5%	14.23*	16.07*
Adults (19+ years)	Male	0.14	0	17	0.8%	15.66*	21.00*
Adults (19+ years)	Female	0.08	0	25	1.1%	9.88*	18.17*
All ages	Total Population	0.10	0	55	0.8%	12.96	22.31*

Summary of Consumption of Soups and Soup Mixes (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0.08	0	1	0.7%	45.19*	45.19*
Children (1-5 years)	Male	2.12	0	4	1.3%	87.22*	138.72*
Children (1-5 years)	Female	0.84	0	4	1.3%	37.71*	44.33*
Children (6-11 years)	Male	4.51	0	6	1.8%	105.54*	141.30*
Children (6-11 years)	Female	2.72	0	5	1.4%	179.05*	315.78*
Teenage (12-18 years)	Male	1.31	0	5	1.3%	169.13*	224.26*
Teenage (12-18 years)	Female	2.55	0	7	1.8%	122.13*	156.05*
Adults (19+ years)	Male	4.39	0	51	2.5%	216.12	399.82*
Adults (19+ years)	Female	3.48	0	73	3.3%	178.78	268.68*
All ages	Total Population	3.51	0	156	2.3%	175.24	352.86

Summary of Consumption on Sweet Sauces, Toppings, and Syrups (grams)

		Per Capita Intake		Consumer-only Intake			
Age Group	Gender	Mean	90th	N	Percentage	Mean	90th
Infants	Male	0	0	0	0.0%	0	0
Infants	Female	0	0	0	0.0%	0	0
Children (1-5 years)	Male	0	0	0	0.0%	0	0
Children (1-5 years)	Female	0.70	0	1	0.3%	80.00*	80.00*
Children (6-11 years)	Male	0	0	0	0.0%	0	0
Children (6-11 years)	Female	0	0	0	0.0%	0	0
Teenage (12-18 years)	Male	0	0	0	0.0%	0	0
Teenage (12-18 years)	Female	0	0	0	0.0%	0	0
Adults (19+ years)	Male	0.09	0	5	0.2%	20.21*	29.16*
Adults (19+ years)	Female	0.24	0	5	0.2%	27.79*	36.85*
All ages	Total Population	0.15	0	11	0.2%	27.89*	38.06*

GreenWater laboratories — aquatic analysis ... research ... consultation

Total Adda Microcystins/Nodularins Report

Project: Parabel USA Inc.

Submitted to: Valentina Carpio
Organization: Parabel USA Inc.
Address: 1991 74th Ave., Ste. B, Vero Beach, FL, 32996
Email: vcarpio@parabel.com; rsmith@parabel.com

Sample Receipt Date: 05 November 2021
Sample Condition: 23.3 ºC upon arrival
Report# 211103_Parabel
Date Prepared: 12 November 2021
Prepared by: Amanda Foss

Table 1: Samples analyzed

Sample Identification	Site	Collection Date	Collection Time
LF-210630-D3-RW	Parabel	03 November 2021	Lemnaceae
LF-210709-D3-RW	Parabel	03 November 2021	Lemnaceae
LF-210902-D3	Parabel	03 November 2021	Lemnaceae
LF-210915-D3	Parabel	03 November 2021	Lemnaceae
LF-210923-D3	Parabel	03 November 2021	Lemnaceae

Analytes: Microcystins/Nodularins (MCs/NODs), 3-methoxy-2-methyl-4-phenylbutyric acid (MMPB)

Qualifier	Flag
CL	Analytical result is estimated due to ineffective quenching.
J	Analyte was positively identified; the associated numerical value is estimated.
PT	The reported result is estimated because the sample was not analyzed within required holding time.
B	Analytical result is estimated. Analyte was detected in associated reagent blank as well as the samples.
E	Analytical result is estimated. Values achieved were outside calibration range.
N	Spiked sample control was outside limits
T	The reported result is estimated because the sample exceeded temperature threshold when received

Sample Preparation

Extraction

MMPB Oxidation & Extraction

Material was oxidized as 10 mg subsets with pre-oxidation LFSMs (Table 2). Subsets were fortified with IS (d_3-MMPB) and oxidized with the addition of 2.5 mL of oxidant composed of 0.2 M K_2CO_3, 0.1 M $KMnO_4$ and 0.1 M $NaIO_4$. Oxidation was stopped by the addition of sodium bisulfite (40%). The oxidized aliquots were cleaned using Strata X solid phase extraction (SPE) followed with simplified liquid extraction (SLE). Samples were redissolved in 5% MeOH, filtered (0.2 µm PVDF), and analyzed for MMPB.

Analytical Techniques

Liquid chromatography mass spectrometry/mass spectrometry (LC-MS/MS)

MMPB

A Phenomenex Kinetex 2.6µm 2.1 x 150 mm F5 column was used in separation with mobile phases methanol and water containing acetic acid. The $[M-H]^-$ ion of MMPB (*m/z* 207) was fragmented and the product ion *m/z* 131 was monitored. An internal standard curve (Figure 1) was used to determine LFSM returns.

Quality Control

Table 2: Quality Assurance/Quality Control (QA/QC) samples (IS and LFSM) prepared for analyses pre-extraction. Additional QA/QC checks included LFBs, continued calibration checks and external curves.

Analyte	Concentration (µg/g)	Sample ID	QC Type	Return
MC-LR (as MMPB)	5.0	LF-210709-D3-RW	LFSM	70%
MC-LR (as MMPB)	0.5	LF-210923-D3	LFSM	93%
d_3-MMPB	0.10	all aliquots	IS	58 ± 4%

**Control limits: water LFSM ± 30%; complicated matrix LFSM and when LFSM within 2x MDL ±50%; IS ± 50%*

Table 3: The percent reproducibility (%RPD) between lab duplicates or LFSM/LFSMDs prepared and analyzed

QC Type	Sample ID	Analyte	Value 1	Value 2	% RPD	Pass/Fail (< 40%)
LDs	LF-210923-D3	MCs	< 0.01	< 0.01	NA	Pass

%RPD is NA when values are below method detection limits

Summary of Results

Table 4: Total Adda microcystins/nodularins (MCs/NODs) results reported in µg/g (ppm).

Sample ID	Total Adda MCs/NODs
LF-210630-D3-RW	ND
LF-210709-D3-RW	ND
LF-210902-D3	ND
LF-210915-D3	ND
LF-210923-D3	ND
MDL (µg/g):	*0.01*
Analyst Initials:	*AF*
Date Analyzed"	*11/12/2021*

Interpretation:
Total Adda microcystins/nodularins were not detected above 10 µg/kg (0.01 µg/g) dry weight in the submitted samples.

Abbreviations

NA	Not Applicable	LFSM	Lab Fortified Sample Matrix
MDL	Method Detection Limit	LFSMD	Lab Fortified Sample Matrix Duplicate
MQL	Method Quantification Limit	LD	Lab Duplicate
ND	Not Detected above the MDL	IS	Internal Standard
Blank	Regent Water free from interferences	—	Not Analyzed
LFB	Lab Fortified Blank	MRL	Method Reporting Limit
CCC	Continued Calibration Check	CV	Low-range calibration verification

Submitted by: [redacted]
Mark T. Aubel, Ph.D.
Date: November 12, 2021

APPENDIX F – ANALYTICAL REPORTS FOR LEMNACEAE (WATER LENTIL) FIBER POWDER

NQAC Dublin
PO Box 1516
6625 Eiterman Road
Dublin, Ohio 43017-6516

TEL (614) 526-5200
FAX (480) 379-6703

NQAC
Nestlé Quality Assurance Center
Dublin

Amended Final Laboratory Report

Valentina Carpio
Parabel USA Inc.
1991 74th Ave. suite B
Vero Beach, FL 32966
USA

cc: C. Lindsell - Vero Beach

PO/Ref #: Not Specified
Date Received: October 19, 2021
Date Reported: October 28, 2021
Report Number: 2142-0464 10/28/2021 2:28:03PM
Customer ID: 150160
Project Name: Stability Samples 101821

Sample Description: **LENTEIN Flour -Lemnaceae (water lentil) flour**

Project #: 2142-0464 **Sample #:** 10136203 **Condition Upon Receipt:** INTACT

This report has been amended to reflect updates to the following: Sample Information

Nestle SAP Material ID : N/A **Raw Material ID:** Not Specified

Web Submission # : 65081 **Web Sample # :** 335651

Keydate/Lot#: 210630-LF-D3-RW **Client Sample ID:** 150160

Analysis : Method # : Aliquot Number

Mold & Yeast : NQA-00.4100 : 10137032

	Result	Units
Mold Result	<100	CFU/g
Yeast Result	<100	CFU/g
Date Analyzed	10/24/2021	-

Salmonella iQ-Check : LI-00.759 : 10137032
Reference Method: AOAC 2017.06

	Result	Units
Salmonella Final	Absent	/25 g
Date Analyzed	10/20/2021	-

Aerobic Plate Count - Pour Plate (37°C) : LI-00.701 : 10137032

	Result	Units
APC Result (37°C)	1900	CFU/g
Date Analyzed	10/21/2021	-

Enumeration of Coliform/E. coli Petrifilm : LI-00.738 : 10137032

	Result	Units
Coliform Result	<100	CFU/g
Date Analyzed - Coliform	10/20/2021	-
E. coli Result	<100	CFU/g
Date Analyzed - E. coli	10/21/2021	-

Sample Description: **LENTEIN Flour -Lemnaceae (water lentil) flour**

Project #: 2142-0464 **Sample #:** 10136205 **Condition Upon Receipt:** INTACT

This report has been amended to reflect updates to the following: Sample Information

Nestle SAP Material ID : N/A **Raw Material ID:** Not Specified

Web Submission # : 65081 **Web Sample # :** 335652

Keydate/Lot#: 210923-LF-D3 **Client Sample ID:** 150160

Analysis : Method # : Aliquot Number

Mold & Yeast : NQA-00.4100 : 10137033

	Result	Units
Mold Result	100 est.	CFU/g
Yeast Result	100 est.	CFU/g
Date Analyzed	10/24/2021	-

Salmonella iQ-Check : LI-00.759 : 10137033

Reference Method: AOAC 2017.06

	Result	Units
Salmonella Final	Absent	/25 g
Date Analyzed	10/20/2021	-

Aerobic Plate Count - Pour Plate (37°C) : LI-00.701 : 10137033

	Result	Units
APC Result (37°C)	400 est.	CFU/g
Date Analyzed	10/21/2021	-

Enumeration of Coliform/E. coli Petrifilm : LI-00.738 : 10137033

	Result	Units
Coliform Result	<100	CFU/g
Date Analyzed - Coliform	10/20/2021	-
E. coli Result	<100	CFU/g
Date Analyzed - E. coli	10/21/2021	-

NA or N/A: Not Applicable | NP: Not Performed | NQ: Not Quantitated | QL: Quantitation Limit

* Not Determinable | EST: Estimate | IP: In Progress | LOD: Limit of Detection

TNTC: Too Numerous to Count | SPC: Standard Plate Count | PAC: Petrifilm™ Aerobic Count | PCC: Petrifilm™ Coliform Count

STC: Screening Target Concentration

Results relate only to the items tested.

Unless you request otherwise, this sample will be discarded 5 days from the date of this report.

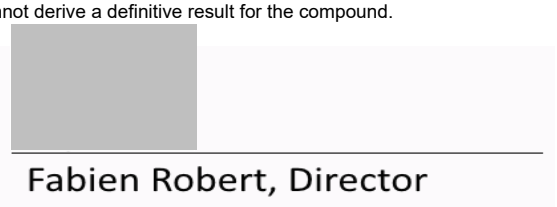
NQAC Confidential: This document is the property of Nestlé Quality Assurance Center.

All appropriate QC checks were performed and found acceptable for this set of samples.

NQAC is not responsible for customer sampling procedures.

Methods run under the quoted Method Number; reference Method are additional information only.

*The Component of the analysis had an interference with the sample matrix and cannot derive a definitive result for the compound.



For questions regarding the report, reply to all or contact Customer Service at nqacdublincustomerservice@us.nestle.com or call 614-526-5200.

Note to Nestle Suppliers: This report is not an indication of Nestle's acceptance of the product. Release and ship decisions must be made by the Nestle supplier per approved microbiological specifications. Contact Nestle factory QA with any questions regarding release & acceptance of the product.

eurofins | Eurofins Central Analytical Laboratories

Eurofins Central Analytical Laboratories

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PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-088632-01

Client Code: QA0001818
PO#: 21-2287

Received On: 30Sep2021
Reported On: 20Oct2021

Eurofins Sample Code: 468-2021-09300182
Client Sample Code: 210915-LF-D3

Sample Description: LENTEIN Flour

Sample Registration Date: 30Sep2021
Condition Upon Receipt: acceptable, 25°C

Sample Reference: Lemnaceae Flour

FS046 - Total Polyphenols	Reference	Completed	Sub
	Methods in Enzymology 1999, Vol. 299, Modified	07Oct2021	3

Parameter	Result
Total Polyphenols	2.17 mg/g

FS07J - Nickel	Reference	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	07Oct2021	3

Parameter	Result
Nickel	2.03 ppm

FSM15 - Elemental Profile for 15 nutritional minerals	Reference	Accreditation	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	ISO/IEC 17025:2017 A2LA 2918.01	07Oct2021	3

Parameter	Result
Aluminum	11.2 ppm
Barium (Ba)	3.41 ppm
Boron (B)	1,390 ppm
Calcium (Ca)	16,400 ppm
Chromium (Cr)	4.19 ppm
Copper (Cu)	0.472 ppm
Iron (Fe)	666 ppm
Magnesium (Mg)	2,770 ppm
Manganese (Mn)	171 ppm
Molybdenum (Mo)	<2.45 ppm
Phosphorus	4,150 ppm
Potassium (K)	15,300 ppm

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ANALYTICAL REPORT

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Received On: 30Sep2021
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Eurofins Sample Code: 468-2021-09300182
Client Sample Code: 210915-LF-D3
Sample Description: LENTEIN Flour

Sample Registration Date: 30Sep2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference: Lemnaceae Flour

FSM15 - Elemental Profile for 15 nutritional minerals	Reference	Accreditation	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	ISO/IEC 17025:2017 A2LA 2918.01	07Oct2021	3

Parameter	Result
Sodium (Na)	3,360 ppm
Strontium (Sr)	411 ppm
Zinc (Zn)	93.0 ppm

IR079 - Trypsin inhibitor	Reference	Completed	Sub
	AOCS Ba 12-75	20Oct2021	2

Parameter	Result
Trypsin inhibitor	10,907.00 TIU/g

QA005 - Selenium (ICP-MS)	Reference	Completed
	AOAC 2013.06	01Oct2021

Parameter	Result
Selenium (Se)	<0.02 mg/kg

QA008 - Cobalt (ICP-AES)	Reference	Completed
	AOAC 2011.14	06Oct2021

Parameter	Result
Cobalt (Co)	0.74 mg/kg

QA0KS - Chlorate and Perchlorate (LC-MS/MS)	Reference	Accreditation	Completed
	FDA method	ISO/IEC 17025:2017 A2LA 2993.01	08Oct2021

Parameter	Result
Chlorate	0.62 mg/kg
Perchlorate	<0.01 mg/kg

QA133 - Arsenic (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	01Oct2021

Parameter	Result
Arsenic (As)	0.05 mg/kg

QA13A - Ash	Reference	Completed
	AOAC 923.03 / 32.1.05 16th Ed.	06Oct2021

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ANALYTICAL REPORT

AR-21-QA-088632-01

Client Code: QA0001818
PO#: 21-2287
Received On: 30Sep2021
Reported On: 20Oct2021

Eurofins Sample Code: 468-2021-09300182
Client Sample Code: 210915-LF-D3
Sample Description: LENTEIN Flour

Sample Registration Date: 30Sep2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference: Lemnaceae Flour

QA13A - Ash	Reference		Completed
	AOAC 923.03 / 32.1.05 16th Ed.		06Oct2021

Parameter	Result
Ash	8.16 g/100 g

QA205 - Cadmium (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	01Oct2021

Parameter	Result
Cadmium (Cd)	<0.01 mg/kg

QA265 - Crude Fat (Acid Hydrolysis)	Reference		Completed
	AOAC 922.06		04Oct2021

Parameter	Result
AH Fat	3.48 %

QA354 - Moisture (Air Oven 130C 2 hrs)	Reference	Accreditation	Completed
	AOCS Ba 2a-38	ISO/IEC 17025:2017 A2LA 2993.01	06Oct2021

Parameter	Result
Moisture and Volatile Matter	7.90 %

QA417 - Lead (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	01Oct2021

Parameter	Result
Lead (Pb)	<0.02 mg/kg

QA821 - Crude Protein (Combustion)	Reference	Accreditation	Completed
	AOAC 990.03	ISO/IEC 17025:2017 A2LA 2993.01	05Oct2021

Parameter	Result
Crude Protein	19.76 %

QD053 - Fiber, Dietary Complete	Reference	Accreditation	Completed	Sub
	AOAC 991.43	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Soluble Dietary Fiber	5.4 %

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Received On: 30Sep2021
Reported On: 20Oct2021

Eurofins Sample Code: 468-2021-09300182
Client Sample Code: 210915-LF-D3
Sample Description: LENTEIN Flour

Sample Registration Date: 30Sep2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference: Lemnaceae Flour

QD053 - Fiber, Dietary Complete	Reference	Accreditation	Completed	Sub
	AOAC 991.43	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Insoluble Dietary Fiber	48.6 %
Total Dietary Fiber - Calculated	54.0 %

QD234 - AOAC Total Starch	Reference	Accreditation	Completed	Sub
	AOAC 996.11	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Starch (AOAC 996.11)	11.8 %

QD495 - Phytic Acid	Reference	Completed	Sub
	Analytical Biochemistry Vol. 77:536-539 (1977)	08Oct2021	1

Parameter	Result
Phytic Acid	< 0.14 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	01Oct2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Fructose	<0.15 %
Glucose	0.24 %
Lactose	<0.15 %
Maltose	<0.15 %
Sucrose	<0.15 %
Total sugars	<0.35 %

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

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ANALYTICAL REPORT

AR-21-QA-088632-01

Client Code: QA0001818
PO#: 21-2287

Received On: 30Sep2021
Reported On: 20Oct2021

Eurofins Sample Code: 468-2021-09300182
Client Sample Code: 210915-LF-D3
Sample Description: LENTEIN Flour

Sample Registration Date: 30Sep2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference: Lemnaceae Flour

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Tryptophan	0.38 %

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Alanine	1.19 %
Arginine	1.04 %
Aspartic Acid	1.70 %
Glutamic Acid	2.05 %
Glycine	1.04 %
Histidine	0.36 %
Isoleucine	0.83 %
Leucine	1.57 %
Phenylalanine	0.94 %
Proline	0.88 %
Serine	0.91 %
Threonine	0.84 %
Total Lysine	1.19 %
Tyrosine	0.56 %
Valine	1.12 %

QQ177 - Cystine & Methionine (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 994.12 mod.	ISO/IEC 17025:2017 A2LA 2927.01	08Oct2021	1

Parameter	Result
Cystine	0.19 %
Methionine	0.34 %

Subcontracting partners:

1 - Eurofins Scientific Inc. (Des Moines), IA
2 - Eurofins Analytical Services India (Bangalore), Karnataka
3 - Eurofins Food Chemistry Testing US Madison, WI

PARABEL USA, INC.

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FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-088632-01

Client Code: QA0001818
PO#: 21-2287

Received On: 30Sep2021
Reported On: 20Oct2021

Respectfully Submitted,

Dana Walkenhorst
Analytical Services Manager

eurofins | **Eurofins Central Analytical Laboratories**

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FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	2.69 mg/kg
Cadaverine	7.50 mg/kg
Histamine	1.09 mg/kg
Putrescine	140 mg/kg
Spermidine	1.05 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	7.74 mg/kg
Tyramine	4.72 mg/kg

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	4

Parameter	Result
Adenosine-3-monophosphate	1,120 µg/g
Cytidine-3-monophosphate	1,840 µg/g
Guanosine-3-monophosphate	2,470 µg/g
Uridine-3-monophosphate	1,230 µg/g
3' Nucleotides from Natural Sources	6,660 µg/g

QA133 - Arsenic (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Arsenic (As)	<0.02 mg/kg

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ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA156 - Fatty Acid Profile

Reference
AOAC 996.06

Completed
12Nov2021

Parameter	Result
C 6:0 (Caproic acid)	<0.020 g/100 g
C 8:0 (Caprylic acid)	<0.020 g/100 g
C 10:0 (Capric acid)	<0.020 g/100 g
C 12:0 (Lauric acid)	<0.020 g/100 g
C 14:0 (Myristic acid)	<0.020 g/100 g
C 14:1 (Myristoleic acid)	<0.020 g/100 g
C 15:0 (Pentadecanoic acid)	<0.020 g/100 g
C 15:1 (Pentadecenoic acid)	<0.020 g/100 g
C 16:0 (Palmitic acid)	0.700 g/100 g
C 16:1 (Palmitoleic acid)	0.031 g/100 g
C 17:0 (Margaric acid)	<0.020 g/100 g
C 17:1 (Heptadecenoic acid)	<0.020 g/100 g
C 18:0 (Stearic acid)	0.038 g/100 g
C 18:1 (Oleic acid)	0.048 g/100 g
C 18:1n7 (Vaccenic acid)	<0.020 g/100 g
C 18:2n6 (Linoleic acid)	0.569 g/100 g
C 18:3n3 (alpha-Linolenic Acid)	0.756 g/100 g
C 18:3n6 (gamma-Linolenic Acid)	0.027 g/100 g
C 18:4n3 (Stearidonic acid)	0.037 g/100 g
C 20:0 (Arachidic acid)	<0.020 g/100 g
C 20:1 (Eicosenoic acid)	<0.020 g/100 g
C 20:2n6 (Eicosodienoic acid)	<0.020 g/100 g
C 20:3n3 (Eicosatrienoic acid)	<0.020 g/100 g
C 20:3n6 (homo-gamma-Linolenic acid)	<0.020 g/100 g
C 20:4n6 (Arachidonic Acid)	<0.020 g/100 g
C 20:5n3 (Eicosapentaenoic acid)	<0.020 g/100 g
C 21:0 (Heneicosanoic acid)	<0.020 g/100 g
C 22:0 (Behenic acid)	<0.020 g/100 g
C 22:1n9 (Erucic acid)	<0.020 g/100 g
C 22:2n6 (Docosadienoic acid)	<0.020 g/100 g
C 22:6n3 (Docosahexaenoic acid)	<0.020 g/100 g
C 22-5n3 (Docosapentaenoic acid)	<0.020 g/100 g
C 22-5n6 (Docosapentaenoic acid)	<0.020 g/100 g
C 23:0 (Tricosanoic acid)	<0.020 g/100 g
C 24:0 (Lignoceric acid)	0.086 g/100 g

PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA156 - Fatty Acid Profile

Reference: AOAC 996.06
Completed: 12Nov2021

Parameter	Result
C 24:1 (Nervonic acid)	<0.020 g/100 g
Omega-3 fatty acids	0.800 g/100 g
Omega-6 fatty acids	0.600 g/100 g
Monounsaturated Fat	0.100 g/100 g
Polyunsaturated Fat	1.400 g/100 g
Saturated Fat	0.920 g/100 g
Total Fat	2.42 g/100 g

QA205 - Cadmium (ICP-MS)

Reference: AOAC 2013.06
Accreditation: ISO/IEC 17025:2017 A2LA 2993.01
Completed: 09Nov2021

Parameter	Result
Cadmium (Cd)	<0.01 mg/kg

QA417 - Lead (ICP-MS)

Reference: AOAC 2013.06
Accreditation: ISO/IEC 17025:2017 A2LA 2993.01
Completed: 09Nov2021

Parameter	Result
Lead (Pb)	0.02 mg/kg

QD002 - Fiber, Acid Detergent

Reference: ANKOM ADF for A2000 mod.
Accreditation: ISO/IEC 17025:2017 A2LA 2927.01
Completed: 15Nov2021
Sub: 2

Parameter	Result
Fiber, Acid Detergent	26.5 %

QD039 - Cellulose

Reference: Ankom ADF/Ankom Lignin
Completed: 15Nov2021
Sub: 2

Parameter	Result
Cellulose	25.5 %

QD101 - Hemicellulose

Reference: Ankom NDF/Ankom ADF
Completed: 15Nov2021
Sub: 2

Parameter	Result
Hemicellulose	8.6 %

PARABEL USA, INC.

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ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QD112 - Lignin	Reference		Completed	Sub
	Ankom Lignin		15Nov2021	2

Parameter	Result
Lignin	1.0 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	35.1 %

QD234 - AOAC Total Starch	Reference	Accreditation	Completed	Sub
	AOAC 996.11	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Starch (AOAC 996.11)	9.5 %

QD237 - Trypsin Inhibitor	Reference		Completed	Sub
	AOCS Ba 12-75		15Nov2021	2

Parameter	Result
Trypsin inhibitor	1,800 TIU/g

QD495 - Phytic Acid	Reference		Completed	Sub
	Analytical Biochemistry Vol. 77:536-539 (1977)		15Nov2021	2

Parameter	Result
Phytic Acid	< 0.14 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result

PARABEL USA, INC.

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FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fructose	0.19 %
Glucose	<0.15 %
Lactose	<0.15 %
Maltose	<0.15 %
Sucrose	<0.15 %
Total sugars	<0.35 %

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Tryptophan	0.35 %

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Alanine	1.03 %
Arginine	0.94 %
Aspartic Acid	1.56 %
Glutamic Acid	1.77 %
Glycine	0.96 %
Histidine	0.33 %
Isoleucine	0.75 %
Leucine	1.46 %
Phenylalanine	0.87 %
Proline	0.77 %
Serine	0.81 %
Threonine	0.75 %
Total Lysine	1.02 %
Tyrosine	0.48 %
Valine	1.00 %

PARABEL USA, INC.

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FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QQ177 - Cystine & Methionine (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 994.12 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Cystine	0.19 %
Methionine	0.31 %

ZVPA6 - Quantitative multi pesticide screening LC-MSMS	Reference	Accreditation	Completed	Sub
	Own method	(ACCREDITATION DEPENDS ON MATRICES)	17Nov2021	3

Parameter	Result
Screened pesticides	Not Detected

ZVPZ1 - Quantitative multi pesticide screening GC-MSMS	Reference	Accreditation	Completed	Sub
	Own method	(ACCREDITATION DEPENDS ON MATRICES)	17Nov2021	3

Parameter	Result
Screened pesticides	Not Detected

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Lab Zeeuws-Vlaanderen, NETHERLANDS
4 - Eurofins Botanical Testing US Brea, CA

Respectfully Submitted,

Dana Walkenhorst
Analytical Services Manager

PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 17Nov2021

eurofins | Eurofins Scientific Inc. (Des Moines)

Eurofins Scientific Inc. (Des Moines)

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Des Moines, IA 50321
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Parabel USA Inc.

Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

ANALYTICAL REPORT

AR-21-QD-204441-01

Client Code: QD0007548
PO#: Stability Study #3439-3441

Received On: 07Oct2021
Reported On: 18Oct2021

Eurofins Sample Code: 464-2021-10070646
Client Sample Code: Baseline – Lot: 210915-LF-D3
Sample Description: Stability Study #3441 – LENTEIN Flour

Sample Registration Date: 07Oct2021
Condition Upon Receipt: acceptable, non-perishable
Sample Reference: Lemnaceae (water lentil) Flour

QD00T - Visual Appearance	Reference		Completed
	Internal Method		11Oct2021

Parameter	Result
Appearance	-
Fine, free-flowing green powder. Grassy odor.	

QD148 - Moisture by Vacuum Oven	Reference	Accreditation	Completed
	AOAC 925.09	ISO/IEC 17025:2017 A2LA 2927.01	13Oct2021

Parameter	Result
Moisture and Volatiles - Vacuum Oven	8.4 %

QD230 - Fiber, Total Dietary	Reference	Accreditation	Completed
	AOAC 991.43	ISO/IEC 17025:2017 A2LA 2927.01	15Oct2021

Parameter	Result
Total Dietary Fiber	48.5 %

QQ167 - Water Activity	Reference	Accreditation	Completed
	AOAC 978.18 mod.	ISO/IEC 17025:2017 A2LA 2927.01	12Oct2021

Parameter	Result
Water Activity at 25°C	0.344

UM5DP - Coliforms - AOAC 991.14	Reference	Accreditation	Completed	Sub
	AOAC 991.14	ISO/IEC 17025:2017 A2LA 3329.01	14Oct2021	1

Parameter	Result
Total Coliforms	<10 cfu/g

Parabel USA Inc.

Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

ANALYTICAL REPORT

AR-21-QD-204441-01

Client Code: QD0007548
PO#: Stability Study #3439-3441
Received On: 07Oct2021
Reported On: 18Oct2021

Eurofins Sample Code: 464-2021-10070646
Client Sample Code: Baseline – Lot: 210915-LF-D3
Sample Description: Stability Study #3441 – LENTEIN Flour
Sample Registration Date: 07Oct2021
Condition Upon Receipt: acceptable, non-perishable
Sample Reference: Lemnaceae (water lentil) Flour

UM5DP - Coliforms - AOAC 991.14	Reference	Accreditation	Completed	Sub
	AOAC 991.14	ISO/IEC 17025:2017 A2LA 3329.01	14Oct2021	1

Parameter	Result
E. coli	<10 cfu/g

UMDTC - Salmonella - AOAC-RI 121501	Reference	Accreditation	Completed	Sub
	AOAC-RI 121501	ISO/IEC 17025:2017 A2LA 3329.01	14Oct2021	1

Parameter	Result
Salmonella spp.	Not Detected /25 g

UMN2K - Moulds - FDA BAM Chapter 18 mod.	Reference	Accreditation	Completed	Sub
	FDA BAM Chapter 18 mod.	ISO/IEC 17025:2017 A2LA 3329.01	14Oct2021	1

Parameter	Result
Mold	80 (est) cfu/g
Yeast	<10 cfu/g

UMVEP - Aerobic Plate Count - AOAC 966.23	Reference	Accreditation	Completed	Sub
	AOAC 966.23	ISO/IEC 17025:2017 A2LA 3329.01	14Oct2021	1

Parameter	Result
Aerobic Plate Count	380 cfu/g

Subcontracting partners:
1 - Eurofins Microbiology Laboratories (Des Moines), IA

Parabel USA Inc.

Valentina Carpio
7898 S. Headwaters Commerce St. Bldg 3
Fellsmere, FL 32948

ANALYTICAL REPORT

AR-21-QD-204441-01

Client Code: QD0007548
PO#: Stability Study #3439-3441

Received On: 07Oct2021
Reported On: 18Oct2021

Respectfully Submitted,

Ben Pointer
Associate Scientist III

MERIEUX NutriSciences

CERTIFICATE OF ANALYSIS

SILLIKER, Inc.

Gainesville Florida Laboratory

2183 SE Hawthorne Road, Gainesville, FL 32641

Tel. 1-844-277-1739 Fax. 352-378-6483

Email: getresults10@mxns.com

COA No:	GNV-45072837-0
Supersedes:	None
COA Date	8/18/21
Page 1 of 4	

TO:

Ms. Valentina Telle Carpio
Regulatory and Products Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Vero Beach, FL
Received Date:	8/13/21
P.O.# / ID:	21-1955
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 412207496 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210630
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	1600	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	<10	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/15/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	<10	/g			

Laboratory ID: 412207502 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210706
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	28000	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	30	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/18/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	160	/g			

SILLIKER, Inc.
Gainesville Florida Laboratory
2183 SE Hawthorne Road, Gainesville, FL 32641
Tel. 1-844-277-1739 Fax. 352-378-6483
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CERTIFICATE OF ANALYSIS

COA No:	GNV-45072837-0
Supersedes:	None
COA Date	8/18/21
Page 2 of 4	

TO:
Ms. Valentina Telle Carpio
Regulatory and Products Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Vero Beach, FL
Received Date:	8/13/21
P.O.# / ID:	21-1955
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 412207507 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210709
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	2400	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	<10	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/15/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	<10	/g			

Laboratory ID: 412207512 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210716
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	26000	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	50	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/18/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	<10	/g			

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COA No:	GNV-45072837-0
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Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Vero Beach, FL
Received Date:	8/13/21
P.O.# / ID:	21-1955
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 412207515 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210720
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	14000	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	<10	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/15/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	<10	/g			

Laboratory ID: 412207518 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 21.0
Desc. 1: LF-210628
Desc. 2: LENTEIN Fiber
Desc. 3: Parabel's water lentil fiber powder

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	28000	/g	AOAC 966.23	8/15/21	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	8/14/21	
* Coliform - Petrifilm	40	/g	AOAC 991.14	8/14/21	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	8/18/21	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	8/15/21	
Salmonella PCR	Negative	/25g	AOAC-RI100201	8/15/21	
* Yeast and Mold			FDA-BAM, 7th ed.	8/18/21	
Yeast	<10	/g			
Mold	<10	/g			

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Supersedes:	None
COA Date	8/18/21
Page 4 of 4	

TO:
Ms. Valentina Telle Carpio
Regulatory and Products Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Vero Beach, FL
Received Date:	8/13/21
P.O.# / ID:	21-1955
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Guy McWhorter Laboratory Director

I Customer supplied information * ISO17025 Accredited Analysis † Indicates reason for COA amendent when applicable

SILLIKER, Inc.
Gainesville Florida Laboratory
2183 SE Hawthorne Road, Gainesville, FL 32641
Tel. 1-844-277-1739 Fax. 352-378-6483
Email: getresults10@mxns.com

CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 1 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965267 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210628-LF-D3-RW
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	10/29/21	CHG
TDF	66.02	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	54.07	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	8.49	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 2 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470

Location of Test: (except where noted)
Gainesville, FL

Analytical Results

Laboratory ID: 413965270 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210701-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	10/29/21	CHG
TDF	61.63	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	49.52	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.32	% (w/w)			

SILLIKER, Inc.
Gainesville Florida Laboratory
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Tel. 1-844-277-1739 Fax. 352-378-6483
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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 3 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965272 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210702-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	56.70	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	49.88	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	6.22	% (w/w)			

SILLIKER, Inc.
Gainesville Florida Laboratory
2183 SE Hawthorne Road, Gainesville, FL 32641
Tel. 1-844-277-1739 Fax. 352-378-6483
Email: getresults10@mxns.com

CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 4 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965273 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210707-LF-D3-RW
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	58.90	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	48.51	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.00	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 5 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470

Location of Test: (except where noted)
Gainesville, FL

Analytical Results

Laboratory ID: 413965274 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210902-LF-D3-1
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	51.71	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	43.39	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	5.96	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 6 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965276 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210915-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	48.63	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	40.02	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.65	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 7 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965279 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210917-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	55.45	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	44.70	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.71	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 8 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965281 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210921-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	52.49	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	43.72	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.20	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 9 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965284 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210922-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	50.50	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	40.58	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.34	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 10 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470

Location of Test: (except where noted)
Gainesville, FL

Analytical Results

Laboratory ID: 413965287 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210923-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	48.86	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	40.80	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/5/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	6.97	% (w/w)			

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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 11 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965288 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210924-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	50.72	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	41.12	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	5.18	% (w/w)			

SILLIKER, Inc.
Gainesville Florida Laboratory
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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 12 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965289 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 210928-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	48.57	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	41.17	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.74	% (w/w)			

SILLIKER, Inc.
Gainesville Florida Laboratory
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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 13 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965292 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 21105-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	47.96	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	37.73	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	7.87	% (w/w)			

SILLIKER, Inc.
Gainesville Florida Laboratory
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CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 14 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470

Location of Test: (except where noted)
Gainesville, FL

Analytical Results

Laboratory ID: 413965294 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 211012-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	48.69	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	42.07	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	6.66	% (w/w)			

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Gainesville Florida Laboratory
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Email: getresults10@mxns.com

CERTIFICATE OF ANALYSIS

COA No:	GNV-45353765-1
Supersedes:	GNV-45353765-0
COA Date	11/9/21
Page 15 of 15	

TO:
Ms. Carolyn Lindsell
Quality Manager
Parabel USA Inc.
1991 74th Ave
Vero Beach, FL 32968

Received From:	Fellsmere, FL
Received Date:	10/25/21
P.O.# / ID:	21-2470
Location of Test: (except where noted)	Gainesville, FL

Analytical Results

Laboratory ID: 413965295 **Condition Rec'd:** NORMAL **Temp Rec'd (°C):** 20.0
Desc. 1: 211013-LF-D3
Desc. 2: Lentein Fiber

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Dietary Fiber			AOAC 991.43 (Mod.)	11/3/21	CHG
TDF	48.21	% (w/w)			
Sample Modifications	None	-			
* Insoluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
IDF as is	39.66	% (w/w)			
* Soluble Dietary Fiber			AOAC 991.43	11/8/21	CHG
Dried during analysis	No	-			
Defatted during analysis	No	-			
SDF as is	6.48	% (w/w)			

[redacted]
Guy McWhorter Laboratory Director

Noted Test Locations: CHG-Silliker, Inc. Illinois Laboratory, 3600 Eagle Nest Drive, North Building, Crete, IL 60417

I Customer supplied information * ISO17025 Accredited Analysis † Indicates reason for COA amendent when applicable

MERIEUX NutriSciences

CERTIFICATE OF ANALYSIS

SILLIKER, Inc.

Gainesville Florida Laboratory

2183 SE Hawthorne Road, Gainesville, FL 32641

Tel. 1-844-277-1739 Fax. 352-378-6483

Email: getresults10@mxns.com

COA No:	GNV-44211708-0
Supersedes:	None
COA Date	11/30/20
Page 1 of 1	

TO:

Ms. Valentina Telle Carpio
Regulatory and Products Manager
Parabel USA Inc.
1991 74th Avenue, Suite B
Vero Beach, FL 32966

Received From:	Vero Beach, FL
Received Date:	11/25/20
P.O.# / ID:	20-1632

Location of Test: (except where noted)
Gainesville, FL

Analytical Results

Desc. 1: LF-201005-COMP
Desc. 2: LENTEIN Fiber
Desc. 3: Light Olive Green

Laboratory ID: 405636216
Condition Rec'd: NORMAL
Temp Rec'd (°C): 22.0

Analyte	Result	Units	Method Reference	Test Date	Loc.
* Aerobic Plate Count	1300	/g	AOAC 966.23	11/27/20	
Coagulase Positive Staph Petrifilm	<10	/g	AOAC 2003.07	11/26/20	
* Coliform - Petrifilm	<10	/g	AOAC 991.14	11/26/20	
* E. coli - 3 tube MPN	<3	/g	AOAC 966.24	11/29/20	
* PCR Genus Listeria	Negative	/25g	AOAC RI 030502	11/27/20	
Salmonella PCR	Negative	/25g	AOAC-RI100201	11/27/20	
* Yeast and Mold			FDA-BAM, 7th ed.	11/30/20	
Yeast	<10	/g			
Mold	50	/g			

Guy McWhorter Laboratory Director

I Customer supplied information * ISO17025 Accredited Analysis † Indicates reason for COA amendent when applicable

SKALA CONTROL

Date: 12/May/2021 14:56
User: clindsell@parabel.com

All readings

Lemna Fiber

Lot	Reading time	Stage	Reading type	Value	Users
LF-201005 COMP	06/Oct/20 18:13	Water Activity	Water Activity	0.4113	twilliams@parabel.com
LF-201005 COMP 40	06/Oct/20 18:21	Water Activity	Water Activity	0.3727	twilliams@parabel.com
LF-201005 COMP 55	06/Oct/20 18:47	Water Activity	Water Activity	0.4475	twilliams@parabel.com

Eurofins Central Analytical Laboratories

2219 Lakeshore Drive Suite 100
New Orleans, LA 70122
+1 504 297 3400
ECALservice@eurofinsUS.com

PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-20-QA-094894-02
Report Supersedes AR-20-QA-094894-01

Client Code: QA0001818

Received On: 28Oct2020
Reported On: 16Mar2022

Eurofins Sample Code:	468-2020-10280093	**Sample Registration Date:**	28Oct2020
Client Sample Code:	LF-GRAS B1 Lot number: LF-201005-COMP	**Condition Upon Receipt:**	acceptable, 25°C
Sample Description:	LENTEIN Fiber	**Sample Reference:**	green powder

QA133 - Arsenic (ICP-MS)	**Reference**	**Accreditation**	**Completed**
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	04Nov2020

Parameter	**Result**
Arsenic (As)	<0.02 mg/kg

QA13A - Ash	**Reference**	**Completed**
	AOAC 923.03 / 32.1.05 16th Ed.	03Nov2020

Parameter	**Result**
Ash	6.99 g/100 g

QA205 - Cadmium (ICP-MS)	**Reference**	**Accreditation**	**Completed**
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	04Nov2020

Parameter	**Result**
Cadmium (Cd)	<0.01 mg/kg

QA265 - Crude Fat (Acid Hydrolysis)	**Reference**	**Completed**
	AOAC 922.06	02Nov2020

Parameter	**Result**
AH Fat	4.85 %

QA285 - Crude Fiber (Oilseed Meals, AOCS)	**Reference**	**Accreditation**	**Completed**
	AOCS Ba 6a-05	ISO/IEC 17025:2017 A2LA 2993.01	03Nov2020

Parameter	**Result**
Crude Fiber	37.5 %

PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

Client Code: QA0001818

ANALYTICAL REPORT

AR-20-QA-094894-02
Report Supersedes AR-20-QA-094894-01

Received On: 28Oct2020
Reported On: 16Mar2022

Eurofins Sample Code:	468-2020-10280093	**Sample Registration Date:**	28Oct2020
Client Sample Code:	LF-GRAS B1 Lot number: LF-201005-COMP	**Condition Upon Receipt:**	acceptable, 25°C
Sample Description:	LENTEIN Fiber	**Sample Reference:**	green powder

QA354 - Moisture (Air Oven 130C 2 hrs)	**Reference**	**Accreditation**	**Completed**
	AOCS Ba 2a-38	ISO/IEC 17025:2017 A2LA 2993.01	03Nov2020

Parameter	**Result**
Moisture and Volatile Matter	9.10 %

QA417 - Lead (ICP-MS)	**Reference**	**Accreditation**	**Completed**
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	04Nov2020

Parameter	**Result**
Lead (Pb)	0.03 mg/kg

QA821 - Crude Protein (Combustion)	**Reference**	**Accreditation**	**Completed**
	AOAC 990.03	ISO/IEC 17025:2017 A2LA 2993.01	03Nov2020

Parameter	**Result**
Crude Protein	23.68 %

QD053 - Fiber, Dietary Complete	**Reference**	**Accreditation**	**Completed**	**Sub**
	AOAC 991.43	ISO/IEC 17025:2017 A2LA 2927.01	18Nov2020	1

Parameter	**Result**
Soluble Dietary Fiber	5.4 %
Insoluble Dietary Fiber	53.9 %
Total Dietary Fiber - Calculated	59.3 %

QD610 - Mercury (ICP-MS)	**Reference**	**Accreditation**	**Completed**
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	04Nov2020

Parameter	**Result**
Mercury (Hg)	<0.010 mg/kg

Comments:
Rev.01: Client Sample Code updated per client request.

Subcontracting partners:
1 - Nutrition Analysis Center, IA

PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-20-QA-094894-02
Report Supersedes AR-20-QA-094894-01

Client Code: QA0001818

Received On: 28Oct2020
Reported On: 16Mar2022

Respectfully Submitted,

Dana Walkenhorst
Analytical Services Manager

Eurofins Central Analytical Laboratories

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PARABEL USA, INC.

Carolyn Lindsell
7898 Headwaters Commerce Street
FELLSMERE, FL 32948

ANALYTICAL REPORT

AR-21-QA-096848-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040079
Client Sample Code: LF-210630-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	2.36 mg/kg
Cadaverine	8.62 mg/kg
Histamine	2.01 mg/kg
Putrescine	211 mg/kg
Spermidine	1.36 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	7.31 mg/kg
Tyramine	9.24 mg/kg

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	3

Parameter	Result
Adenosine-3-monophosphate	1,020 µg/g
Cytidine-3-monophosphate	1,710 µg/g
Guanosine-3-monophosphate	2,290 µg/g
Uridine-3-monophosphate	1,150 µg/g
3' Nucleotides from Natural Sources	6,170 µg/g

QA101 - Aflatoxin B1 B2 G1 G2 (LC-MSMS)	Reference	Accreditation	Completed
	AOAC 999.07 Modified	ISO/IEC 17025:2017 A2LA 2993.01	12Nov2021

Parameter	Result
Aflatoxin B1	<1.0 µg/kg
Aflatoxin B2	<1.0 µg/kg

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QA101 - Aflatoxin B1 B2 G1 G2 (LC-MSMS)	Reference	Accreditation	Completed
	AOAC 999.07 Modified	ISO/IEC 17025:2017 A2LA 2993.01	12Nov2021

Parameter	Result
Aflatoxin G1	<1.0 µg/kg
Aflatoxin G2	<1.0 µg/kg
Aflatoxins total	<4 µg/kg

QA133 - Arsenic (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Arsenic (As)	<0.02 mg/kg

QA156 - Fatty Acid Profile	Reference	Completed
	AOAC 996.06	12Nov2021

Parameter	Result
C 6:0 (Caproic acid)	<0.020 g/100 g
C 8:0 (Caprylic acid)	<0.020 g/100 g
C 10:0 (Capric acid)	<0.020 g/100 g
C 12:0 (Lauric acid)	<0.020 g/100 g
C 14:0 (Myristic acid)	<0.020 g/100 g
C 14:1 (Myristoleic acid)	<0.020 g/100 g
C 15:0 (Pentadecanoic acid)	<0.020 g/100 g
C 15:1 (Pentadecenoic acid)	<0.020 g/100 g
C 16:0 (Palmitic acid)	0.630 g/100 g
C 16:1 (Palmitoleic acid)	0.024 g/100 g
C 17:0 (Margaric acid)	<0.020 g/100 g
C 17:1 (Heptadecenoic acid)	<0.020 g/100 g
C 18:0 (Stearic acid)	0.036 g/100 g
C 18:1 (Oleic acid)	0.049 g/100 g
C 18:1n7 (Vaccenic acid)	<0.020 g/100 g
C 18:2n6 (Linoleic acid)	0.518 g/100 g
C 18:3n3 (alpha-Linolenic Acid)	0.652 g/100 g
C 18:3n6 (gamma-Linolenic Acid)	0.022 g/100 g
C 18:4n3 (Stearidonic acid)	0.029 g/100 g
C 20:0 (Arachidic acid)	<0.020 g/100 g
C 20:1 (Eicosenoic acid)	<0.020 g/100 g

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Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA156 - Fatty Acid Profile	Reference	Completed
	AOAC 996.06	12Nov2021

Parameter	Result
C 20:2n6 (Eicosodienoic acid)	<0.020 g/100 g
C 20:3n3 (Eicosatrienoic acid)	<0.020 g/100 g
C 20:3n6 (homo-gamma-Linolenic acid)	<0.020 g/100 g
C 20:4n6 (Arachidonic Acid)	<0.020 g/100 g
C 20:5n3 (Eicosapentaenoic acid)	<0.020 g/100 g
C 21:0 (Heneicosanoic acid)	<0.020 g/100 g
C 22:0 (Behenic acid)	<0.020 g/100 g
C 22:1n9 (Erucic acid)	<0.020 g/100 g
C 22:2n6 (Docosadienoic acid)	<0.020 g/100 g
C 22:6n3 (Docosahexaenoic acid)	<0.020 g/100 g
C 22-5n3 (Docosapentaenoic acid)	<0.020 g/100 g
C 22-5n6 (Docosapentaenoic acid)	<0.020 g/100 g
C 23:0 (Tricosanoic acid)	<0.020 g/100 g
C 24:0 (Lignoceric acid)	0.074 g/100 g
C 24:1 (Nervonic acid)	<0.020 g/100 g
Omega-3 fatty acids	0.690 g/100 g
Omega-6 fatty acids	0.545 g/100 g
Monounsaturated Fat	0.095 g/100 g
Polyunsaturated Fat	1.235 g/100 g
Saturated Fat	0.830 g/100 g
Total Fat	2.16 g/100 g

QA205 - Cadmium (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Cadmium (Cd)	<0.01 mg/kg

QA299 - Fumonisin, total (LC-MSMS)	Reference	Accreditation	Completed
	J AOAC, 92 (2), 496.	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
Fumonisin, total	<30 µg/kg

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Sample Reference:

QA404 - Ochratoxin A (LC-MSMS)	Reference	Accreditation	Completed
	AOAC 999.07 Modified	ISO/IEC 17025:2017 A2LA 2993.01	12Nov2021

Parameter	Result
Ochratoxin A	<1.0 µg/kg

QA417 - Lead (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Lead (Pb)	0.04 mg/kg

QA907 - T-2 Toxin (LC-MSMS)	Reference	Accreditation	Completed
	Food Addit Contam Part A, 2013:30(3),541-9.	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
T-2 Toxin	<1 µg/kg

QAA05 - HT-2 Toxin (LC-MSMS)	Reference	Accreditation	Completed
	Food Addit Contam Part A, 2013:30(3),541-9.	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
HT-2 Toxin	<10.0 µg/kg

QAA07 - Vomitoxin (Deoxynivalenol, DON) LC-MSMS	Reference	Accreditation	Completed
	Food Addit Contam Part A, 2013:30(3),541-9.	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
Vomitoxin (Deoxynivalenol) Adjusted LOQ for this matrix.	<50 µg/kg

QAA19 - Zearalenone (LC-MSMS)	Reference	Accreditation	Completed
	Food Addit Contam Part A, 2013:30(3),541-9.	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
Zearalenone	<5.0 µg/kg

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

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Sample Reference:

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Acid Detergent	27.5 %

QD039 - Cellulose	Reference	Completed	Sub
	Ankom ADF/Ankom Lignin	15Nov2021	2

Parameter	Result
Cellulose	26.5 %

QD101 - Hemicellulose	Reference	Completed	Sub
	Ankom NDF/Ankom ADF	15Nov2021	2

Parameter	Result
Hemicellulose	9.8 %

QD112 - Lignin	Reference	Completed	Sub
	Ankom Lignin	15Nov2021	2

Parameter	Result
Lignin	1.0 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	37.3 %

QD234 - AOAC Total Starch	Reference	Accreditation	Completed	Sub
	AOAC 996.11	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Starch (AOAC 996.11)	9.1 %

QD237 - Trypsin Inhibitor	Reference	Completed	Sub
	AOCS Ba 12-75	15Nov2021	2

Parameter	Result
Trypsin inhibitor	1,400 TIU/g

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Sample Reference:

QD495 - Phytic Acid	Reference	Completed	Sub
	Analytical Biochemistry Vol. 77:536-539 (1977)	15Nov2021	2

Parameter	Result
Phytic Acid	< 0.14 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fructose	0.16 %
Glucose	<0.15 %
Lactose	<0.15 %
Maltose	<0.15 %
Sucrose	<0.15 %
Total sugars	<0.35 %

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Tryptophan	0.32 %

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Alanine	0.94 %
Arginine	0.88 %
Aspartic Acid	1.44 %
Glutamic Acid	1.61 %
Glycine	0.89 %
Histidine	0.31 %

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QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Isoleucine	0.70 %
Leucine	1.35 %
Phenylalanine	0.81 %
Proline	0.71 %
Serine	0.75 %
Threonine	0.70 %
Total Lysine	1.01 %
Tyrosine	0.44 %
Valine	0.93 %

QQ177 - Cystine & Methionine (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 994.12 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Cystine	0.18 %
Methionine	0.29 %

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Botanical Testing US Brea, CA

Respectfully Submitted,

A2LA ACCREDITED

Dana Walkenhorst
Analytical Services Manager

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Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	2.69 mg/kg
Cadaverine	7.50 mg/kg
Histamine	1.09 mg/kg
Putrescine	140 mg/kg
Spermidine	1.05 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	7.74 mg/kg
Tyramine	4.72 mg/kg

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	4

Parameter	Result
Adenosine-3-monophosphate	1,120 µg/g
Cytidine-3-monophosphate	1,840 µg/g
Guanosine-3-monophosphate	2,470 µg/g
Uridine-3-monophosphate	1,230 µg/g
3' Nucleotides from Natural Sources	6,660 µg/g

QA133 - Arsenic (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Arsenic (As)	<0.02 mg/kg

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QA156 - Fatty Acid Profile

Reference
AOAC 996.06

Completed
12Nov2021

Parameter	Result
C 6:0 (Caproic acid)	<0.020 g/100 g
C 8:0 (Caprylic acid)	<0.020 g/100 g
C 10:0 (Capric acid)	<0.020 g/100 g
C 12:0 (Lauric acid)	<0.020 g/100 g
C 14:0 (Myristic acid)	<0.020 g/100 g
C 14:1 (Myristoleic acid)	<0.020 g/100 g
C 15:0 (Pentadecanoic acid)	<0.020 g/100 g
C 15:1 (Pentadecenoic acid)	<0.020 g/100 g
C 16:0 (Palmitic acid)	0.700 g/100 g
C 16:1 (Palmitoleic acid)	0.031 g/100 g
C 17:0 (Margaric acid)	<0.020 g/100 g
C 17:1 (Heptadecenoic acid)	<0.020 g/100 g
C 18:0 (Stearic acid)	0.038 g/100 g
C 18:1 (Oleic acid)	0.048 g/100 g
C 18:1n7 (Vaccenic acid)	<0.020 g/100 g
C 18:2n6 (Linoleic acid)	0.569 g/100 g
C 18:3n3 (alpha-Linolenic Acid)	0.756 g/100 g
C 18:3n6 (gamma-Linolenic Acid)	0.027 g/100 g
C 18:4n3 (Stearidonic acid)	0.037 g/100 g
C 20:0 (Arachidic acid)	<0.020 g/100 g
C 20:1 (Eicosenoic acid)	<0.020 g/100 g
C 20:2n6 (Eicosodienoic acid)	<0.020 g/100 g
C 20:3n3 (Eicosatrienoic acid)	<0.020 g/100 g
C 20:3n6 (homo-gamma-Linolenic acid)	<0.020 g/100 g
C 20:4n6 (Arachidonic Acid)	<0.020 g/100 g
C 20:5n3 (Eicosapentaenoic acid)	<0.020 g/100 g
C 21:0 (Heneicosanoic acid)	<0.020 g/100 g
C 22:0 (Behenic acid)	<0.020 g/100 g
C 22:1n9 (Erucic acid)	<0.020 g/100 g
C 22:2n6 (Docosadienoic acid)	<0.020 g/100 g
C 22:6n3 (Docosahexaenoic acid)	<0.020 g/100 g
C 22-5n3 (Docosapentaenoic acid)	<0.020 g/100 g
C 22-5n6 (Docosapentaenoic acid)	<0.020 g/100 g
C 23:0 (Tricosanoic acid)	<0.020 g/100 g
C 24:0 (Lignoceric acid)	0.086 g/100 g

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Sample Reference:

QA156 - Fatty Acid Profile	Reference		Completed
	AOAC 996.06		12Nov2021

Parameter	Result
C 24:1 (Nervonic acid)	<0.020 g/100 g
Omega-3 fatty acids	0.800 g/100 g
Omega-6 fatty acids	0.600 g/100 g
Monounsaturated Fat	0.100 g/100 g
Polyunsaturated Fat	1.400 g/100 g
Saturated Fat	0.920 g/100 g
Total Fat	2.42 g/100 g

QA205 - Cadmium (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Cadmium (Cd)	<0.01 mg/kg

QA417 - Lead (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Lead (Pb)	0.02 mg/kg

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Acid Detergent	26.5 %

QD039 - Cellulose	Reference	Completed	Sub
	Ankom ADF/Ankom Lignin	15Nov2021	2

Parameter	Result
Cellulose	25.5 %

QD101 - Hemicellulose	Reference	Completed	Sub
	Ankom NDF/Ankom ADF	15Nov2021	2

Parameter	Result
Hemicellulose	8.6 %

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QD112 - Lignin	Reference		Completed	Sub
	Ankom Lignin		15Nov2021	2

Parameter	Result
Lignin	1.0 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	35.1 %

QD234 - AOAC Total Starch	Reference	Accreditation	Completed	Sub
	AOAC 996.11	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Starch (AOAC 996.11)	9.5 %

QD237 - Trypsin Inhibitor	Reference		Completed	Sub
	AOCS Ba 12-75		15Nov2021	2

Parameter	Result
Trypsin inhibitor	1,800 TIU/g

QD495 - Phytic Acid	Reference		Completed	Sub
	Analytical Biochemistry Vol. 77:536-539 (1977)		15Nov2021	2

Parameter	Result
Phytic Acid	< 0.14 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result

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QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fructose	0.19 %
Glucose	<0.15 %
Lactose	<0.15 %
Maltose	<0.15 %
Sucrose	<0.15 %
Total sugars	<0.35 %

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Tryptophan	0.35 %

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Alanine	1.03 %
Arginine	0.94 %
Aspartic Acid	1.56 %
Glutamic Acid	1.77 %
Glycine	0.96 %
Histidine	0.33 %
Isoleucine	0.75 %
Leucine	1.46 %
Phenylalanine	0.87 %
Proline	0.77 %
Serine	0.81 %
Threonine	0.75 %
Total Lysine	1.02 %
Tyrosine	0.48 %
Valine	1.00 %

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Reported On: 17Nov2021

Eurofins Sample Code: 468-2021-11040080
Client Sample Code: LF-210709-D3-RW
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QQ177 - Cystine & Methionine (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 994.12 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Cystine	0.19 %
Methionine	0.31 %

ZVPA6 - Quantitative multi pesticide screening LC-MSMS	Reference	Accreditation	Completed	Sub
	Own method	(ACCREDITATION DEPENDS ON MATRICES)	17Nov2021	3

Parameter	Result
Screened pesticides	Not Detected

ZVPZ1 - Quantitative multi pesticide screening GC-MSMS	Reference	Accreditation	Completed	Sub
	Own method	(ACCREDITATION DEPENDS ON MATRICES)	17Nov2021	3

Parameter	Result
Screened pesticides	Not Detected

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Lab Zeeuws-Vlaanderen, NETHERLANDS
4 - Eurofins Botanical Testing US Brea, CA

Respectfully Submitted,

ACCREDITED

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ANALYTICAL REPORT

AR-21-QA-097920-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 17Nov2021

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ANALYTICAL REPORT

AR-21-QA-096849-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	1.38 mg/kg
Cadaverine	3.68 mg/kg
Histamine	<1 (LOQ) mg/kg
Putrescine	130 mg/kg
Spermidine	1.42 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	<5 (LOQ) mg/kg
Tyramine	5.25 mg/kg

FS07J - Nickel	Reference	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	11Nov2021	3

Parameter	Result
Nickel	<0.990 ppm

FSM15 - Elemental Profile for 15 nutritional minerals	Reference	Accreditation	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	ISO/IEC 17025:2017 A2LA 2918.01	11Nov2021	3

Parameter	Result
Aluminum	8.55 ppm
Barium (Ba)	3.44 ppm
Boron (B)	1,410 ppm
Calcium (Ca)	16,400 ppm
Chromium (Cr)	<2.50 ppm

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ANALYTICAL REPORT

AR-21-QA-096849-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

FSM15 - Elemental Profile for 15 nutritional minerals	Reference	Accreditation	Completed	Sub
	AOAC 984.27 (mod), 985.01 (mod), 2011.14 (mod)	ISO/IEC 17025:2017 A2LA 2918.01	11Nov2021	3

Parameter	Result
Copper (Cu)	0.435 ppm
Iron (Fe)	197 ppm
Magnesium (Mg)	2,980 ppm
Manganese (Mn)	146 ppm
Molybdenum (Mo)	2.80 ppm
Phosphorus	3,650 ppm
Potassium (K)	13,700 ppm
Sodium (Na)	4,040 ppm
Strontium (Sr)	624 ppm
Zinc (Zn)	104 ppm

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	4

Parameter	Result
Adenosine-3-monophosphate	1,070 µg/g
Cytidine-3-monophosphate	1,820 µg/g
Guanosine-3-monophosphate	2,420 µg/g
Uridine-3-monophosphate	1,210 µg/g
3' Nucleotides from Natural Sources	6,520 µg/g

QA005 - Selenium (ICP-MS)	Reference	Completed
	AOAC 2013.06	09Nov2021

Parameter	Result
Selenium (Se)	<0.02 mg/kg

QA008 - Cobalt (ICP-AES)	Reference	Completed
	AOAC 2011.14	09Nov2021

Parameter	Result
Cobalt (Co)	0.44 mg/kg

QA04U - Phosphate (Ion Chromatography)	Reference	Completed
	J. AOAC Int., 2005, 88(6), 1793-1796	12Nov2021

Parameter	Result
Phosphate (as PO4)	4,273.90 mg/kg

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AR-21-QA-096849-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA04U - Phosphate (Ion Chromatography)	**Reference** J. AOAC Int., 2005, 88(6), 1793-1796		**Completed** 12Nov2021

Parameter	**Result**

QA133 - Arsenic (ICP-MS)	**Reference** AOAC 2013.06	**Accreditation** ISO/IEC 17025:2017 A2LA 2993.01	**Completed** 09Nov2021

Parameter	**Result**
Arsenic (As)	0.02 mg/kg

QA13A - Ash	**Reference** AOAC 923.03 / 32.1.05 16th Ed.		**Completed** 10Nov2021

Parameter	**Result**
Ash	8.03 g/100 g

QA205 - Cadmium (ICP-MS)	**Reference** AOAC 2013.06	**Accreditation** ISO/IEC 17025:2017 A2LA 2993.01	**Completed** 09Nov2021

Parameter	**Result**
Cadmium (Cd)	<0.01 mg/kg

QA265 - Crude Fat (Acid Hydrolysis)	**Reference** AOAC 922.06		**Completed** 08Nov2021

Parameter	**Result**
AH Fat	4.19 %

QA354 - Moisture (Air Oven 130C 2 hrs)	**Reference** AOCS Ba 2a-38	**Accreditation** ISO/IEC 17025:2017 A2LA 2993.01	**Completed** 10Nov2021

Parameter	**Result**
Moisture and Volatile Matter	9.20 %

QA417 - Lead (ICP-MS)	**Reference** AOAC 2013.06	**Accreditation** ISO/IEC 17025:2017 A2LA 2993.01	**Completed** 09Nov2021

Parameter	**Result**
Lead (Pb)	<0.02 mg/kg

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ANALYTICAL REPORT

AR-21-QA-096849-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA821 - Crude Protein (Combustion)	Reference	Accreditation	Completed
	AOAC 990.03	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Crude Protein	20.32 %

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Acid Detergent	25.1 %

QD039 - Cellulose	Reference	Completed	Sub
	Ankom ADF/Ankom Lignin	15Nov2021	2

Parameter	Result
Cellulose	22.5 %

QD101 - Hemicellulose	Reference	Completed	Sub
	Ankom NDF/Ankom ADF	15Nov2021	2

Parameter	Result
Hemicellulose	7.0 %

QD112 - Lignin	Reference	Completed	Sub
	Ankom Lignin	15Nov2021	2

Parameter	Result
Lignin	2.6 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	32.0 %

QD234 - AOAC Total Starch	Reference	Accreditation	Completed	Sub
	AOAC 996.11	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Starch (AOAC 996.11)	8.2 %

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Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QD237 - Trypsin Inhibitor	Reference		Completed	Sub
	AOCS Ba 12-75		15Nov2021	2

Parameter	Result
Trypsin inhibitor	1,800 TIU/g

QD495 - Phytic Acid	Reference		Completed	Sub
	Analytical Biochemistry Vol. 77:536-539 (1977)		15Nov2021	2

Parameter	Result
Phytic Acid	< 0.14 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

QQ129 - Sugar Profile (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.14, mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Fructose	0.25 %
Glucose	0.22 %
Lactose	<0.15 %
Maltose	<0.15 %
Sucrose	<0.15 %
Total sugars	0.47 %

QQ141 - Tryptophan (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 988.15 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Tryptophan	0.40 %

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result

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AR-21-QA-096849-01

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Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040081
Client Sample Code: LF-210902-D3
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QQ176 - Amino Acids by AH (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 982.30 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Alanine	1.17 %
Arginine	1.06 %
Aspartic Acid	1.77 %
Glutamic Acid	2.13 %
Glycine	1.06 %
Histidine	0.38 %
Isoleucine	0.86 %
Leucine	1.65 %
Phenylalanine	1.00 %
Proline	0.87 %
Serine	0.90 %
Threonine	0.84 %
Total Lysine	1.27 %
Tyrosine	0.57 %
Valine	1.12 %

QQ177 - Cystine & Methionine (AOAC, Most Matrices)	Reference	Accreditation	Completed	Sub
	AOAC 994.12 mod.	ISO/IEC 17025:2017 A2LA 2927.01	15Nov2021	2

Parameter	Result
Cystine	0.21 %
Methionine	0.36 %

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Food Chemistry Testing US Madison, WI
4 - Eurofins Botanical Testing US Brea, CA

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ANALYTICAL REPORT

AR-21-QA-096849-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 15Nov2021

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ANALYTICAL REPORT

AR-21-QA-096741-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040082
Client Sample Code: LF-210915-D3
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	<1 (LOQ) mg/kg
Cadaverine	3.80 mg/kg
Histamine	<1 (LOQ) mg/kg
Putrescine	85.1 mg/kg
Spermidine	8.34 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	7.24 mg/kg
Tyramine	3.98 mg/kg

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	3

Parameter	Result
Adenosine-3-monophosphate	1,240 µg/g
Cytidine-3-monophosphate	2,380 µg/g
Guanosine-3-monophosphate	3,620 µg/g
Uridine-3-monophosphate	1,480 µg/g
3' Nucleotides from Natural Sources	8,720 µg/g

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	10Nov2021	2

Parameter	Result
Fiber, Acid Detergent	20.8 %

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ANALYTICAL REPORT

AR-21-QA-096741-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040082
Client Sample Code: LF-210915-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QD039 - Cellulose	Reference	Completed	Sub
	Ankom ADF/Ankom Lignin	10Nov2021	2

Parameter	Result
Cellulose	20.8 %

QD101 - Hemicellulose	Reference	Completed	Sub
	Ankom NDF/Ankom ADF	10Nov2021	2

Parameter	Result
Hemicellulose	12.3 %

QD112 - Lignin	Reference	Completed	Sub
	Ankom Lignin	10Nov2021	2

Parameter	Result
Lignin	<0.5 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	10Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	33.1 %

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Botanical Testing US Brea, CA

Respectfully Submitted,

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ANALYTICAL REPORT

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Reported On: 15Nov2021

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Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040082
Client Sample Code: LF-210915-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

DJ700 - Biogenic Amines (dansyl)	Reference	Accreditation	Completed	Sub
	Czech J. Food Sci. Vol.21	DS EN ISO/IEC 17025 DANAK 581	11Nov2021	1

Parameter	Result
2-Phenylethylamine	<1 (LOQ) mg/kg
Cadaverine	3.80 mg/kg
Histamine	<1 (LOQ) mg/kg
Putrescine	85.1 mg/kg
Spermidine	8.34 mg/kg
Spermine	<1 (LOQ) mg/kg
Tryptamine	7.24 mg/kg
Tyramine	3.98 mg/kg

KK206 - 3' Nucleotides from Natural Sources (CE)	Reference	Completed	Sub
	Internal Method	15Nov2021	3

Parameter	Result
Adenosine-3-monophosphate	1,240 µg/g
Cytidine-3-monophosphate	2,380 µg/g
Guanosine-3-monophosphate	3,620 µg/g
Uridine-3-monophosphate	1,480 µg/g
3' Nucleotides from Natural Sources	8,720 µg/g

QD002 - Fiber, Acid Detergent	Reference	Accreditation	Completed	Sub
	ANKOM ADF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	10Nov2021	2

Parameter	Result
Fiber, Acid Detergent	20.8 %

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ANALYTICAL REPORT

AR-21-QA-096741-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 15Nov2021

Eurofins Sample Code: 468-2021-11040082
Client Sample Code: LF-210915-D3
Sample Description: Lemnaceae (water lentil) flour
Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QD039 - Cellulose	Reference	Completed	Sub
	Ankom ADF/Ankom Lignin	10Nov2021	2

Parameter	Result
Cellulose	20.8 %

QD101 - Hemicellulose	Reference	Completed	Sub
	Ankom NDF/Ankom ADF	10Nov2021	2

Parameter	Result
Hemicellulose	12.3 %

QD112 - Lignin	Reference	Completed	Sub
	Ankom Lignin	10Nov2021	2

Parameter	Result
Lignin	<0.5 %

QD161 - Fiber, Neutral Detergent	Reference	Accreditation	Completed	Sub
	ANKOM NDF for A2000 mod.	ISO/IEC 17025:2017 A2LA 2927.01	10Nov2021	2

Parameter	Result
Fiber, Neutral Detergent	33.1 %

Subcontracting partners:
1 - Eurofins Vitamin Testing Denmark, DENMARK
2 - Eurofins Scientific Inc. (Des Moines), IA
3 - Eurofins Botanical Testing US Brea, CA

Respectfully Submitted,

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ANALYTICAL REPORT

AR-21-QA-096741-01

Client Code: QA0001818
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ANALYTICAL REPORT

AR-21-QA-095468-01

Client Code: QA0001818
PO#: 21-2575

Received On: 04Nov2021
Reported On: 10Nov2021

Eurofins Sample Code: 468-2021-11040083
Client Sample Code: LF-210923-D3
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA133 - Arsenic (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Arsenic (As)	0.04 mg/kg

QA13A - Ash	Reference	Completed
	AOAC 923.03 / 32.1.05 16th Ed.	10Nov2021

Parameter	Result
Ash	8.58 g/100 g

QA205 - Cadmium (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Cadmium (Cd)	<0.01 mg/kg

QA265 - Crude Fat (Acid Hydrolysis)	Reference	Completed
	AOAC 922.06	08Nov2021

Parameter	Result
AH Fat	4.68 %

QA354 - Moisture (Air Oven 130C 2 hrs)	Reference	Accreditation	Completed
	AOCS Ba 2a-38	ISO/IEC 17025:2017 A2LA 2993.01	10Nov2021

Parameter	Result
Moisture and Volatile Matter	8.85 %

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ANALYTICAL REPORT

AR-21-QA-095468-01

Client Code: QA0001818
PO#: 21-2575
Received On: 04Nov2021
Reported On: 10Nov2021

Eurofins Sample Code: 468-2021-11040083
Client Sample Code: LF-210923-D3
Sample Description: Lemnaceae (water lentil) flour

Sample Registration Date: 04Nov2021
Condition Upon Receipt: acceptable, 25°C
Sample Reference:

QA417 - Lead (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Lead (Pb)	<0.02 mg/kg

QA821 - Crude Protein (Combustion)	Reference	Accreditation	Completed
	AOAC 990.03	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Crude Protein	24.63 %

QD610 - Mercury (ICP-MS)	Reference	Accreditation	Completed
	AOAC 2013.06	ISO/IEC 17025:2017 A2LA 2993.01	09Nov2021

Parameter	Result
Mercury (Hg)	<0.010 mg/kg

Respectfully Submitted,

Dana Walkenhorst
Analytical Services Manager

APPENDIX G – WATER LENTIL RECIPES

The Appendix herein describes several meal recipes typical in South East Asia, using water lentil (*Lemnaceae*) or watermeal (*Wolffia)* as the main ingredient.

1. Egg curry

Reference: Taisakon Sawang. 2015. Egg curry. Isan Hundred and Eighty. *https://www.tnews.co.th/contents/458317* *also in* *https://sites.google.com/site/saebxisan/xahar-khaw/kaeng-khi-pha*

Ingredients: eggs, pork, grilled fish or chicken, dried peppers, onions, garlic, lemongrass, onion, shrimp paste, local washed watermeal (locally known as "Pham", "Khai Nam", "Khai Pham", and "Nai Khai"), fish sauce, fermented fish, kaffir lime leaves.

1. Wash the eggs, put the pot over the heat. Add a little water.
2. Prepare a chili curry or curry paste by pounding together with a mortar and pestle the dried chili-peppers, onion, garlic, lemongrass, shrimp paste, kaffir lime leaves until finely pounded.
3. Cut the pork into pieces and chop the onions.
4. When water reaches boiling point, boil the eggs, add pork, chili paste, the fish sauce. Add seasoning and chopped onions. Add the watermeal.
5. If the menu is Ubon, curry the eggs and add the grilled fish. The method is similar.

2. Asian Watermeal (Gang Kai Pum)

Reference: *http://www.khiewchanta.com/archives/vegetarian/asian-watermeal-gang-kai-pum-1.html*

Ingredients:

- 100 g. Asian watermeal
- 2 Lemongrass
- 3 Small Red Onion
- 3-5 Chilies
- 3-4 Kaffir Lime Leaves
- 1 Tablespoon Fish Sauce (use Soy for Vegetarian)
- Dill and Basil

Preparation:

1. Chop the lemongrass into fine shreds.
2. Pound and blend the lemongrass, red onion, chili and kaffir leaves in Thai mortar.
3. Rinse the watermeal, and place in boiling water. It needs to be cooked for 3-5 minutes.
4. You can also dry fry it, if you prefer, for around 5 minutes in a non-stick frying pan, but keep it moving so as not to burn it.
5. Garnish with dill and basil.

3. Watermeal Omelette

Reference: Recipes Thai Food. 2016. http://recipesthaifood.com/watermeal-omelette/. Retrieved on March 6, 2019.

Ingredients:

- 2 Eggs
- 1 cup Watermeal
- cooking oil
- seasoning sauce
- garlic

Preparation:

1. Crack the eggs into a bowl. Beat with fork.
2. Heat cooking oil and minced garlic in pan fry.
3. When garlic cooked, add beaten eggs and watermeal, also sauce.

4. Watermeal Eggs

Reference: p_lmm. 2014.
http://www.siamfishing.com/content/view.php?nid=181130&cat=recipe

Ingredients:

- Watermeal
- Garlic, Sliced
- Eggs

- Carrots
- Clam Sauce
- White Sugar

Preparation:

1. Add oil to wok and heat.
2. Add sliced garlic and heat until fragrant.
3. Cook eggs and stir.
4. Add chopped carrot.
5. Add white sugar and clam sauce and stir.
6. Add watermeal and allow to simmer until cooked.

5. Curry Dish, Pork, Meat or Fish

By Kaewka. Reference:
https://www.bing.com/search?q=googel+translate+&form=EDNTHT&mkt=en-us&httpsmsn=1&refig=282575f2eafe476b80a9145211518822&sp=-1&ghc=1&pq=googel+translate+&sc=8-17&qs=n&sk=&cvid=282575f2eafe476b80a9145211518822

Servings: 5

Ingredients:

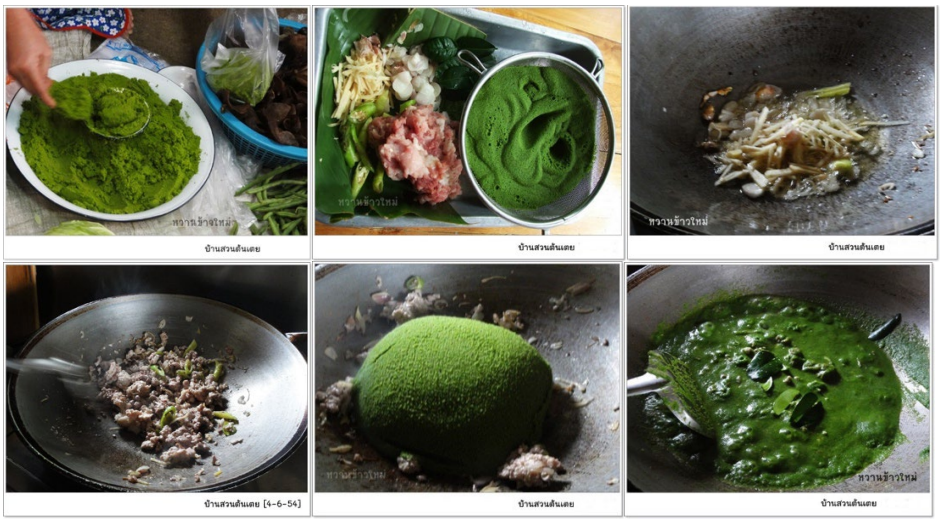
- Watermeal
- 500 gr Pork, Sliced
- Rice with Chili Sauce
- 1 T. 3 Grains Fish Sauce
- Lemon Leaves
- Salt, Lemongrass, Ginger, Garlic, to taste

Preparation:

1. Wash the watermeal thoroughly.
2. Put on a pot of rice, soak the chili, and scoop the watermeal and place into the rice pot.
3. Add half a glass to 3 T. water to rice pot. Add pork.
4. Add the fish sauce and lemon leaves to pot and allow to finish cooking.

6. Roasted Pham by Kin Mung

Reference: https://pantip.com/topic/30183431



Ingredients:

- Pork, Minced
- Young Chili
- Ginger
- Soy Sauce
- Shallots
- Garlic
- Lemongrass
- Kaffir Lime Leaves

Preparation:

1. Heat oil in wok until hot.
2. Add shallots and garlic and fry until fragrant.
3. Add ginger and stir fry a little more.
4. Followed by lemongrass.
5. Continue with young chili.
6. Place the pork chops in wok mixture and stir.
7. After pork has cooked, add watermeal.
8. No need to add water, the water will come out of the watermeal as it is heated.
9. When cooked, it will turn into a slightly yellowish, green color and become a bit watery.
10. Add the fish sauce and sprinkle with kaffir lime leaves. Cook until fragrant and serve with parboiled rice.

7. Pham (watermeal), Roasted or Cooked with Egg Curry

Reference: Urapapattanapong, T. 2018. KitchenPedia Wolffia globosa. The Momentum.
https://themomentum.co/local-alive-wolffia-globosa-advertorial/

Preparation:

1. Beginning with the preparation of spices consisting of dried chillies, shallots, galangal, lemongrass, salt, shrimp paste, add together before stirring with oil until fragrant.
2. At this stage, add pork if you want, then add kaffir lime leaves, lemongrass, galangal and stir until cooked.
3. In the North-eastern region, it is popular to add fermented fish and fish sauce.
4. Tip: An easier dish is to make as an omelette.

8. Watermeal Curry

Reference: Thid Mu Mak Muan. 2018. Thai Wolffia cooking and nutritional info. https://www.isangate.com/new/food-list/379-lab-tao-kai-pam.html

Ingredients:

- Watermeal, rinsed well
- Shallots, Shredded
- Dried Chillies
- Lemongrass, Shredded
- Kaffir Lime Leaves, Whole
- Basil Leaves, Whole
- Onion, Shredded
- Green Onion, Sliced
- Pork, Pork Ribs, Chicken, Frog or Grilled Fish (according to your preference), Shredded
- Bamboo Shoots or Wicker, Boiled
- Fish Sauce
- Salt

Preparation:

1. Combine shallots, dried chillies, shredded lemongrass in a bowl and pound into a curry.
2. Place in a pot with a little water, set to boil.
3. Place the Kaffir lime leaves, shredded pork, pork ribs or other meats in the pot and continue heating.

4. Add fermented fish sauce.
5. Then add the watermeal and continue cooking to a simmer and until cooked through.
6. Add green onion and basil and stir to combine.

9. Watermeal Curry by Sabkhak Eleeidae

Reference: https://www.77jowo.com/contents/73055

Ingredients:

- Watermeal, rinsed well
- Pork, Pork Ribs or Fish, Grilled (depends on preference), cut into pieces
- Chillies
- Dried Chillies
- Onions
- Garlic
- Lemongrass
- Onion, Diced
- Shrimp Paste
- Basil Leaves, Whole
- Kaffir Lime Leaves, Whole
- Fish Sauce
- Water

Preparation:

1. In a bowl, pound chili, dried chili, onion, garlic, lemongrass, shrimp paste, kaffir lime leaves into a paste.
2. In a pot, add paste and a little water and mix.
3. Heat pot until hot and add watermeal.
4. Once mixture simmers add pork pieces, chili curry and fish sauce.
5. Bring to a boil and add onion and basil leaves.
6. When cooked through serve hot.

10. Water lentil Stir-fry

Reference: Thai PBS. 2014. PBS Video on Wolffia Harvest, Market, and Curry Making https://www.youtube.com/watch?v=54Lb4g3--34

Ingredients:

- Pork Bone, Chopped
- Garlic Paste
- Hot Pepper, sliced

- Ginger, sliced
- Kaffir Lime Leaves

Preparation:

1. Clean water meal with water.
2. Drain water meal using cheesecloth.
3. Heat oil in wok.
4. When hot, add garlic paste to wok.
5. Add pork and stir.
6. Add spicy peppers and stir.
7. Add ginger and stir.
8. Add fish/soy sauce and stir.
9. Add water meal and stir. Allow to simmer.
10. Add Kaffir Lime Leaves.

Shriram Institute For Industrial Research : Delhi
(A Unit of Shriram Scientific and Industrial Research Foundation)

Summary Report

Result:

1. Bacterial Reverse Mutation Test in *Salmonella typhimurium*

Under the condition of the study, the test item, 'Lentein Complete' at dosage up to 5000 µg/plate did not produce either a 2-fold increase in the mean numbers of revertant colonies in the strains TA98, TA100 and TA102, or a 3-fold increase in the mean numbers of revertant colonies in the strains TA1535 and TA1537 either in the presence or absence of metabolic activation system when compared to the respective vehicle control plates.

The positive controls produced more than a 3-fold increase in the mean numbers of revertant colonies when compared to the respective vehicle control, demonstrating the sensitivity of the assay procedure.

All criteria for a valid study were met as described in the study plan. It is concluded that the test item, 'Lentein Complete', did not elicit mutagenic potential in this bacterial reverse mutation test at the tested doses.

The study has been conducted as per OECD Guideline for the testing of Chemicals, (No. 471: Section 4), Bacterial Reverse Mutation Test.

2. Mammalian Erythrocytes Micronucleus Test in Mice

Toxicity to bone marrow [decrease in polychromatic to total erythrocytes ratio (P/E)] was not observed in the animals treated at the dose levels of 500, 1000 and 2000 mg/kg body weight as compare to concurrent vehicle control group animals.

Based on the results of the dose range finding studies, a limit dose of 2000 mg/kg body weight was selected for the main study.

Under the condition of this study, the results did not reveal any significant difference in percent micronucleated polychromatic erythrocytes (%MNPCE) in animals belonging to the treatment group at the maximum recommended dose level of 2000 mg/kg body weight concurrent when compared to the respective vehicle control.

All criteria for a valid study were met as described in the study plan. From the results of the present study, it is concluded that test substance 'Lentein Complete' does not have micronucleus induction potential in male and female mice up to the dose level of 2000 mg/kg body weight, following oral administration for two consecutive days.

This study was performed to assess the possible micronucleus induction potential of 'Lentein Complete' [supplied by Sponsor] in mice. The study has been conducted as per OECD Guideline for the testing of Chemicals, OECD No. 474 (September 2014).

[redacted] 02/6/2017

Study Director

2 JUN 2017

[redacted] 02/6/2017

Head (QA)

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH: DELHI

Confidential

STUDY REPORT

May, 2017

Study No.	:	1704-1-451-1003
Study Title	:	Bacterial Reverse Mutation Test (AMES TEST) of “Lentein complete”
Test item	:	Lentein complete
Study Director	:	Rishi Kumar Mishra

Sponsor’s Name & Address

PARABEL USA Inc.
7898 Headwaters Commerce Street,
Fellsmere, FL 32948,
USA.

Regulatory Guidelines

OECD 471: Guideline for testing of chemical, Bacterial Reverse Mutation Test (Adopted on 21-July-1997)

Test Facility Name & Address

Toxicology Centre
Shriram Institute for Industrial Research
(A Unit of Shriram Scientific & Industrial Research Foundation)
19, University Road, Delhi – 110007
Email ID: sridlhi@vsnl.com
Tel. 27667267, 27667860, 27667432
Fax No. 91+11-27667676, 27667207

STUDY No. : 1704-1-451-1003
TEST ITEM : LENTEIN COMPLETE
STUDY : BACTERIAL REVERSE MUTATION TEST (AMES TEST) of "LENTEIN COMPLETE"
REPORT No. : C1/0000085317
DATE OF COMPLETION OF STUDY : 30.05.2017

STATEMENT OF QUALITY ASSURANCE UNIT

Quality Assurance Unit of the testing facility inspected the conduct of study entitled Bacterial Reverse Mutation Test of "Lentein Complete" with *salmonella typhimurium* on the following dates:

Sr. No	Critical Phases of study	Dates of Inspection	Dates of Reporting	
			Study Director	Management
1.	Study Plan	12.05.2017	12.05.2017	12.05.2017
2.	Plate treatment for initial mutation assay	16.05.2017	16.05.2017	16.05.2017
3.	Result of confirmatory mutation assay	25.05.2017	25.05.2017	25.05.2017
4.	Draft Report with Raw data	29.05.2017	29.05.2017	29.05.2017
5.	Final report	30.05.2017	30.05.2017	30.05.2017

This study was conducted in accordance to approved study plan, OECD guideline for testing of chemicals no. 471 and the Standard Operating Procedures and with the principles of good laboratory practices (GLP) for non-clinical laboratory studies. No findings were noticed during inspection, which would have impaired this study in any way.

Report reflects the raw data of the study.

Dr. M.L. Aggarwal — 30.05.2017

Head Quality Assurance Unit — Signature — Date

STATEMENT OF COMPLIANCE

The study entitled Bacterial Reverse Mutation Test of "Lentein Complete" with *salmonella typhimurium* was performed in accordance with the approved study plan and standard operating procedures of Toxicology Centre, Shriram Institute for Industrial Research.
We hereby attest the authenticity of the study and guarantee that this report represents a true and accurate record of results obtained and shall not be reproduced except in full, without the written approval of the sponsor.

The study was conducted in accordance with the GLP conditions.
All original raw data, documentation, study plan, study schedule, a copy of the final study report and the representative test item will be archived in the archives at Toxicology Centre, Shriram Institute for Industrial Research. There were no known circumstances that may have affected the quality or integrity of the study.

The sponsor is responsible for necessary evaluations of the test item concerning the chemical purity, identity, stability and other required data.

Mr. Rishi Kumar Mishra		30.05.2017
Study Director	Signature	Date

Dr. Binu Bhat		30.05.2017
Test Facility Management	Signature	Date

KEY PERSONNEL INVOLVED IN THE STUDY

Designation		**Name & Address**
Study Director	:	**Rishi Kumar Mishra; M.Sc.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID**:** sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Personnel	:	**Dushyant Singh, Ph.D.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID**:** sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Personnel	:	**Neelima Garg, Ph.D.** Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID**:** sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432

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Summary

'Lentein Complete' was tested for its mutagenic potential in the bacterial reverse mutation assay. The study was conducted using TA98, TA100, TA1535, TA1537 and TA102 strains of *Salmonella typhimurium*. The study consisted of a preliminary toxicity test and two mutation independent experiments. The bacterial tester strains were exposed to the test item in the presence and absence of metabolic activation system (S9 fraction prepared from Aroclor 1254 induced rat liver).

'Lentein Complete' formed a solution in Dimethyl sulfoxide (DMSO) at the required concentration of 50 mg/ mL.

In the preliminary toxicity test, the mean number of revertant colonies was comparable to the DMSO control plates up to the highest tested dose of 5000 µg/plate, both in the presence (5%, v/v S9 mix) and absence of metabolic activation. No toxicity by 'Lentein Complete' was observed, as the intensity of the bacterial background lawn, was comparable to that of the DMSO control plates up to 5000 µg/plate, both in the presence and absence of metabolic activation. No precipitation was observed either in the presence or in the absence of metabolic activation up to the highest tested dose of 5000 µg/plate. Hence, it was decided to test up to a maximum of 5000 µg/plate in the mutation assay.

In the initial mutation assay, 'Lentein Complete' was exposed in triplicate to 312.5, 625, 1250, 2500 and 5000 µg/plate test doses in the presence (5%, v/v S9 mix) and absence of metabolic activation using plate incorporation procedure. In the confirmatory assay, 'Lentein Complete' was exposed in triplicate to doses of 128, 320, 800, 2000 and 5000 µg/plate in the presence (10%, v/v S9 mix) and absence of metabolic activation using plate incorporation procedure. The vehicle control (DMSO) and the appropriate positive controls were tested simultaneously. The mean and standard deviation of numbers of revertant colonies were calculated for each test concentration and the controls for all the tester strains

Under the condition of the study, the test item, 'Lentein Complete' at doses up to 5000 µg/plate did not produce either a 2-fold increase in the mean numbers of revertant colonies in the strains TA98, TA100 and TA102, or a 3-fold increase in the mean numbers of revertant colonies in the strains TA1535 and TA1537 either in the presence or absence of metabolic activation system when compared to the respective vehicle control plates.

The positive controls produced more than a 3-fold increase in the mean numbers of revertant colonies when compared to the respective vehicle controls, demonstrating the sensitivity of the assay procedure.

All criteria for a valid study were met as described in the study plan. It is concluded that the test item, 'Lentein Complete', is '**Non Mutagenic**' in this bacterial reverse mutation test at the tested doses.

The study has been conducted as per OECD Guideline for the testing of Chemicals, (No. 471: Section 4), Bacterial Reverse Mutation Test.

1.0 Introduction

Normally, the *Salmonella typhimurium* synthesizes histidine but the mutant strains are incapable of this function, when these mutant strains are exposed to a mutagen, reverse mutation may take place. These revertants can be detected by their ability to grow on histidine deficient medium. Some compounds may not exert a mutagenic effect until they have been metabolized.

2.0 Objective

The purpose of this non-mammalian *in vitro* Genotoxicity study is to assess the potential of the test item "Lentein Complete" to induce point mutations, viz., substitution, addition or deletion of one or a few DNA base pairs in the *Salmonella typhimurium* reverse mutation assay.

2.1 Testing Guidelines

OECD 471: Guideline for testing of chemical, Bacterial Reverse Mutation Test (Adopted on 21-July-1997) was followed for conducting the study.

2.2 Test Facility and Study Period

This study was performed at Toxicology Centre, Shriram Institute for Industrial Research, Delhi-110007.

Date of initiation of study	: 12.05.2017
Date of initiation of experiment	: 16.05.2017
Date of completion of experiment	: 25.05.2017
Date of completion of study	: 30.05.2017

3.0 Test Item Details

The sponsor is responsible for necessary evaluations of the Test item concerning the chemical purity, identity, stability and other required data. The details of the Test item* provided by the sponsor are:

Test item	LENTEIN ™ Complete
Lot Number	CSPBWL 170125
Date of Mfg.	02/17/2017
Best Used By	02/17/2018
Moisture content, percent by mass	2%
Sponsored by	Parabel USA INC., USA

4.0 Test System

From the approved strains under the 1997 harmonization efforts of the OECD and ICH following strains of bacteria were used in the study:

Histidine auxotrophic strains of Salmonella typhimurium viz.,

a) TA98 & TA1537 → Frame shift mutation
b) TA100, TA102 & TA1535 → Base pair substitution

Source: Moltox, Krishgen Biosystem, Delhi.

4.1 Justification for the selection of Test System:

The *Salmonella typhimurium* strain is selected for this study for the following reasons:

- To meet the regulatory requirement for testing in Bacterial reverse mutation test;
- These strains involve substitution addition or deletion of one or few DNA base pairs.
- This mutation is rapid and inexpensive and easy to perform in the laboratory.
- *Salmonella typhimurium* strain is widely used as a strain of choice for Bacterial reverse mutation studies.

4.2 Storage of Test System

A stock culture of tester strains is preserved in nutrient broth and DMSO in the test facility as frozen vials in liquid nitrogen.

4.3 Genotypic Characterization of Test System

Salmonella typhimurium		
Strains	**Genotype**	**Type of mutations indicated**
TA1535	his G 46; rfa$^-$, uvrB$^-$	Base pair substitutions
TA1537	his C 3076; rfa$^-$, uvrB$^-$	Frame shift mutation
TA98	his D 3052; rfa$^-$, uvrB$^-$, R-Factor	Frame shift mutation
TA100	his G 46; rfa$^-$, uvrB$^-$, R-Factor	Base pair substitutions
TA102	his G 428; rfa$^-$, pAQ1, pKM 101	Base pair substitutions

The growth requirements and the genetic identity of strains like histidine requirement, sensitivity to UV radiation, resistance of strains TA98, TA100 and WP2uvrB (pKM101) to ampicillin and *rfa* mutation of *Salmonella typhimurium* strains were checked.

4.4 Test Medium and Solutions

1	Minimum Glucose Agar
2	Soft agar
3	Soft agar containing 0.5 mM histidine and biotin
4	Nutrient agar
5	Nutrient broth
6	PBS (pH 7.4)

4.5 Instruments Used

1. Sartorious Balance (ASD/ MICRO/ 37) for chemical weighing.
2. Sartorious Balance (SRI / TOX/ TSCO/ 01) for test item weighing.
3. Autoclave (ASD/ MICRO/ 02) for autoclave of the materials.
4. Incubator (ASD/ MICRO/ 32) for incubation of the plates.
5. Colony counter (ASD/ MICRO/ 24) for the counting the colonies.
6. Refrigerator (ASD/ MICRO/ 22) for maintaining of bacterial culture.
7. pH meter (ASD/ MICRO/ 35) for measuring the pH.
8. Laminar air flow hood (ASD/ MICRO/ 15) for the plate incorporation.
9. Water Bath (ASD/ MICRO/ 10).

5.0 Experimental Design

5.1 Outline of the Method

The principle of the Bacterial Reverse Mutation Test is that it detects mutations that revert the mutations already present in the test strains thereby restoring the functional capability of the bacteria to synthesize an essential amino acid. Such revertant bacteria are detected by their ability to grow in the absence of the amino acid (histidine) in the culture medium as required by the parent strain.

In the initial mutation assay, which is a plate incorporation mode of exposure, the bacterial suspensions are exposed to the test item, vehicle and the positive controls in the presence and absence of an exogenous metabolic activation system. These bacterial suspensions are then mixed with overlay agar and plated immediately onto minimal medium viz., his- for *Salmonella typhimurium*.

In the confirmatory assay, which is a pre-incubation mode of exposure, the test constituents are mixed with the bacteria inside a tube, incubated in an incubator shaker, mixed with overlay agar and plated immediately onto minimal medium his- for *Salmonella typhimurium*. After a suitable period of incubation, the revertant colonies are counted and compared with the number of spontaneous revertants in the vehicle control plates.

5.2 Mammalian Microsomal Fraction (S9) Mix

The bacteria to be used in this assay do not possess the enzyme systems, which in mammals are known to convert promutagens into active DNA damaging metabolites. In order to overcome this major drawback, an exogenous metabolic system will be added in form of mammalian microsomal enzyme activation mixture.

Constituent	**5%, v/v S9 mix (10 mL)**	**10%, v/v S9 mix (10 mL)**
Co-factor mix	9.5 mL	9.0 mL
S9 fraction	0.5 mL	1.0 mL

During the experiment, the S9 mix was kept in ice bath.

Co-factor components

D-Glucose-6-phosphate	:	0.80 g
β Nicotinamide adenine dinucleotide Phosphate (β-NADP)	:	1.75 g
Magnesium chloride	:	0.90 g
Potassium chloride	:	1.35 g

Sodium phosphate, dibasic	:	6.40 g
Sodium phosphate, monobasic	:	1.40 g
Distilled water	:	450 mL

The prepared co-factor was dispensed to suitable volumes and stored below 0°C.

5.3 S9 Homogenate

Lyophilized S9 homogenate (liver microsomal enzyme) prepared from male SD rat (Aroclor 1254 induced) was purchased from Krishgen Biosystem, Delhi. (Store at -20°C and expiry date is 02/24/2019). During mutagenicity assay the efficiency of S9 homogenate was checked with 2-Aminoanthracene using *Salmonella typhimurium* TA100 strain.

5.4 Solubility and precipitation Test

The solubility of test substance was determined before performing the Mutation Assay. The solubility of test substance was performed in sterile distilled water and the test item was found to be insoluble in sterile water then solubility of test item was performed in DMSO and it was found to be soluble with suspension. No precipitation was observed in the final mixture (top agar) when poured onto the MGA plate with unaided eye.

5.5 Preliminary Toxicity Test

To evaluate the toxicity of the test item, preliminary toxicity was performed with strain TA100. Based on solubility and precipitation check, eight concentrations *viz* 5000, 3200, 1600, 800, 400, 200, 100 and 50 µg/plate in the absence and presence of metabolic activation system was tested for toxicity and mutation induction with three plates each. The experimental conditions in preliminary toxicity were the same as described below for the Initial Mutation Assay.

5.6 Mutation Assay

Based on preliminary toxicity test results, the mutagenicity test was conducted as two independent experiments viz. Initial Mutation Assay and confirmatory Mutation Assay.

In either of the mutation, the treatment was performed both in the absence and in the presence of metabolic activation system (5 and 10 %, v/v S9 mix).

The treatments were performed by the plate incorporation method in both mutation assays. Plates were maintained in triplicate for each test concentration, vehicle and positive controls. Following materials were mixed in a test tube and poured in the order given below onto minimal glucose agar plate:

5.7 Plate incorporation method:

500 µL Sodium phosphate buffer (in the absence of metabolic activation system) or S9 mix (in the presence of metabolic activation system)

100 µL	Test solution at each dose level, solvent (negative control) or positive control
100 µL	Bacterial suspension
2000 µL	Top agar

After solidification, the plates were incubated upside down for 48 hours a 37 ± 1°C in an incubator.

5.8 Test Strain Cultures

Fresh cultures for the test were prepared by inoculating frozen cultures to a flask containing 10 mL of sterile Nutrient broth. The flasks were incubated at 37 ± 1 °C in an incubator for 17 hrs.

5.9 Positive Controls

***S. typhimurium* Strains**	**-S9**	**+S9**
TA98	2-Nitrofluorene (7.5 µg/plate)	2-Aminoanthracene (5 µg/plate)
TA100	Sodium azide(5 µg/plate)	2-Aminoanthracene (5 µg/plate)
TA102	Mitomycin C (0.5 µg/plate)	2- Aminoanthracene (10 µg/plate)
TA1535	Sodium azide (5 µg/plate)	2- Aminoanthracene (10 µg/plate)
TA1537	9-Aminoacridine (75 µg/plate)	2- Aminoanthracene(10 µg/plate)

5.10 Test Item Stock and Dilutions

For preliminary Toxicity Test, a stock solution of 50000 µg/mL was prepared by mixing Lentein complete in DMSO and making up the volume to 10 mL with the vehicle. This stock was further diluted in vehicle to get the required test concentrations of 500, 1000, 2000, 4000, 8000, 16000 and 32000 50000 µg/mL of 'Lentein complete'.

For initial mutation Assay, a stock solution of 50000 µg/mL was prepared by mixing 500 mg test item in a volumetric flask and made up to the 10 mL volume with vehicle. This stock was further diluted in vehicle to get the test concentrations of 3125, 6250, 12500, 25000 and 50000 µg/mL of 'Lentein complete'.

A volume of 0.1 mL of prepared respective stock solutions was used to get required test concentrations 312.5, 625, 1250, 2500 and 5000 µg/plate (0.1 mL).

For confirmation of mutation Assay, a stock solution of 50000 µg/mL was prepared mixing 500 mg test item in a volumetric flask and made up to the 10 mL volume with vehicle. This stock was further diluted with vehicle to get the required test concentrations of 1280, 3200, 8000, 20000 and 50000 µg/mL of 'Lentein complete'.

A volume of 0.1 mL of prepared respective stock solutions was used to get required test concentrations 128, 320, 800, 2000 and 5000 µg/plate (0.1 mL).

Stock solutions of the test item were prepared fresh on the day of treatment during each experiment.

5.11 Labeling

The petri-dishes were labeled to indicate the study number, strain number, treatment group, experimental phase and activation.

5.12 Viable Counts

The bacterial suspension of each tester strain was diluted up to 10^{-6} dilution in PBS. One hundred microlitres from the 10^{-6} dilution of each tester strain was plated onto nutrient agar plates in triplicate. The plates were incubated at 37 ± 1°C for 48 hours for the initial as well as the confirmatory mutation assays.

5.13 Criteria for Acceptability of the Test

The *Salmonella typhimurium* reverse mutation assay is considered acceptable if it meets the following criteria:

- There must be at least three non-toxic dose levels.
- The top dose selected should demonstrate toxicity. In case of non-toxic test items, the top dose tested should be 5000 µg/plate.
- The positive control substances should produce at least a 3-fold increase in mutant colony frequencies when compared to the respective vehicle control plates.

5.14 Evaluation and Interpretation of the Results

To determine a test item either in the presence or absence of the metabolic activation system, the test will be judged positive, if the increase in mean revertants at the peak of the dose response is equal to or greater than 2 times of concurrent vehicle control value for strains TA98, TA100 and TA102 or equal to or greater than 3 times of concurrent vehicle control value for strains TA1535 and TA1537.

An equivocal response is a biologically relevant increase in a revertant count that partially meets the criteria for evaluation as positive. This could be a dose responsive increase that does not achieve the respective threshold cited above or a non dose responsive increase that is equal to or greater than the respective threshold cited. A response will be evaluated as negative, if it is neither positive nor equivocal.

6.0 Observations

Effect on Bacterial Background Lawn

The condition of the bacterial background lawn was evaluated for evidence of the test item toxicity using the code system (Appendix 3).

Number of Revertant

Revertant colonies of all the tester strains for the controls and each test concentration was counted manually.

7.0 Result

Preliminary Toxicity Test

In a preliminary toxicity test, the mean number of revertant colonies was comparable to the DMSO control plates up to the highest tested dose of 5000 µg/plate, both in the presence and absence of metabolic activation. No toxicity of 'Lentein Complete' was observed as the intensity of the bacterial background lawn and revertant colony count were comparable to that of the DMSO control plates up to 5000 µg/plate, both in the presence and absence of metabolic activation. No precipitation was observed either in the presence or in the absence of metabolic activation up to the highest tested dose of 5000 µg/plate. Hence, it was decided to test up to a maximum of 5000 µg/plate in the mutation assay.

Main Assay

In the initial mutation assay, 'Lentein Complete' was exposed in triplicate to 312.5, 625, 1250, 2500 and 5000 µg/plate test doses in the presence and absence of metabolic activation using plate incorporation procedure. In the confirmatory assay, 'Lentein Complete' was exposed in triplicate to doses of 128, 320, 800, 2000 and 5000 µg/plate in the presence and absence of metabolic activation using plate incorporation procedure. The vehicle control (DMSO) and the appropriate positive controls were tested simultaneously. The mean and standard deviation of numbers of revertant colonies were calculated for each test concentration and the controls for all the tester strains

Under the condition of the study, the test item, 'Lentein Complete' at doses up to 5000 µg/plate did not produce either a 2-fold increase in the mean numbers of revertant colonies in the strains TA98, TA100 and TA102, or a 3-fold increase in the mean numbers of revertant colonies in the strains TA1535 and TA1537 either in the presence or absence of metabolic activation system when compared to the respective vehicle control plates.

The positive controls produced more than a 3-fold increase in the mean numbers of revertant colonies when compared to the respective vehicle controls, demonstrating the sensitivity of the assay procedure.

8.0 Conclusion

All criteria for a valid study were met as described in the study plan. It is concluded that the test item, 'Lentein Complete', is not mutagenic in this bacterial reverse mutation test at the tested doses.

9.0 Quality Assurance

The study was subjected to inspection by the Quality Assurance Unit. The dates of quality assurance inspection and reporting dates were incorporated in study report.

10.0 Archives

On completion of the study all raw data (Signed study plan, study schedule, observation sheet etc.) together with the copy of final report shall be stored in the archives for five years. After the completion of this period sponsor's consent will be sought to either extend the archiving period or return the archived material to the sponsor or for the disposal of the material.

11.0 References

1. OECD 471: Guideline for testing of chemical, Bacterial Reverse Mutation Test (Adopted on 21-July-1997)
2. Errol Zeiger and Kristien Mortelmans, The Salmonella (Ames) Test for Mutagenicity, Current Protocols in Toxicology (1993) 3.1.1-3.1.29.

12.0 Study Plan Amendment and Deviation

No amendment and deviation were recorded the study.

TABLE 1. Results of Preliminary Toxicity Test with 'Lentein Complete'

Treatment (µg/plate)	TA100 revertant colonies/plate*			
	Presence of S9		Absence of S9	
	Mean	Background lawn*	Mean	Background lawn*
DMSO	99	4+	116	4+
50	99	4+	93	4+
100	95	4+	96	4+
200	93	4+	98	4+
400	100	4+	92	4+
800	99	4+	94	4+
1600	100	4+	105	4+
3200	106	4+	101	4+
5000	96	4+	92	4+

* Refer Appendix 3

TABLE 2. Mean Count of His^+ Revertant Colonies in Initial Mutation Assay

Concentration (µg /plate)	His^+ Revertant Colonies/Plate (Absence of Metabolic Activation)									
	TA98		TA100		TA102		TA1535		TA1537	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
VC (DMSO)	25.33	3.51	98.67	5.51	220.67	9.45	12.00	1.73	12.00	2.00
312.5	38.33	2.52	90.33	8.96	216.00	12.29	10.67	3.79	11.33	4.16
625	23.67	2.89	90.67	5.13	205.33	5.03	10.33	5.86	7.46	4.04
1250	22.00	2.00	96.00	6.93	224.33	19.14	9.67	3.06	5.00	1.00
2500	23.67	1.15	93.33	10.41	204.67	8.39	10.67	5.69	5.33	1.53
5000	24.33	3.51	95.67	4.93	207.00	9.54	13.00	1.00	7.33	2.08
PC	501.33	27.33	599.33	31.56	840.67	41.63	230.00	15.62	339.33	16.77

Key: SD: Standard Deviation, VC: Vehicle Control, TA98: 2-NF (7.5 µg/plate), TA100: SA (5µg/plate), TA102: MTC (0.5 µg/plate), TA1535: SA (5 µg/plate), TA1537: 9-Aa (75 µg/plate)

TABLE 3. Mean Count of His$^+$ Revertant Colonies in Initial Mutation Assay

Concentration (µg/plate)	His$^+$ Revertant Colonies/Plate [Presence of Metabolic Activation (5 %, v/v S9 mix)]									
	TA98		TA100		TA102		TA1535		TA1537	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
VC (DMSO)	24.00	6.24	97.00	13.11	224.00	18.25	10.67	5.86	8.33	0.58
312.5	21.00	4.58	88.33	2.89	207.67	16.07	12.67	1.15	6.67	2.52
625	24.00	6.24	85.33	15.37	167.33	29.16	11.00	2.65	7.33	1.53
1250	16.00	3.00	97.67	9.71	160.00	25.98	10.33	2.08	6.00	2.00
2500	26.00	5.57	100.33	4.93	200.00	15.00	11.00	2.65	9.67	0.58
5000	14.00	4.58	100.33	12.74	175.33	5.03	10.33	1.53	7.00	1.00
PC	360.67	9.45	593.67	61.70	817.33	22.48	245.00	15.00	373.33	41.63

Key: SD: Standard Deviation, VC: Vehicle Control, 2-AA: 10 µg/plate for TA1537, TA1535 and TA102, 2-AA: 5µg/plate for TA98 and TA100

TABLE 4. Mean Count of His^+ Revertant Colonies in Confirmation Mutation Assay

Concentration (µg/plate)	His^+ Revertant Colonies/Plate (Absence of Metabolic Activation)									
	TA98		TA100		TA102		TA1535		TA1537	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
VC (DMSO)	29.00	1.00	124.67	7.51	234.00	13.53	14.67	2.25	4.67	1.15
128	27.00	2.00	112.33	8.50	188.33	15.37	12.67	2.25	8.00	1.00
320	26.00	3.00	100.33	18.93	235.33	20.11	11.67	2.08	13.67	2.08
800	12.33	2.08	82.67	8.02	173.00	20.07	12.00	2.00	7.33	1.53
2000	29.67	2.08	84.67	12.34	197.33	34.20	12.33	2.52	7.67	1.53
5000	29.00	2.00	83.33	6.03	169.00	8.54	10.00	1.00	8.33	1.53
PC	460.33	36.83	599.00	30.05	846.33	28.29	552.67	171.16	293.00	71.44
PC-2AA	-	-	102.67	7.51	-	-	-	-	-	-

Key: SD: Standard Deviation, VC: Vehicle Control, TA98: 2-NF (7.5 µg/plate), TA100: SA (5µg/plate), TA102: MTC (0.5 µg/plate), TA1535: SA (5 µg/plate), TA1537: 9-Aa (75 µg/plate)

TABLE 5. Mean Count of His$^+$ Revertant Colonies in Confirmation Mutation Assay

Concentration (µg/plate)	His$^+$ Revertant Colonies/Plate [Presence of Metabolic Activation (10%, v/v S9 mix)]									
	TA98		TA100		TA102		TA1535		TA1537	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
VC (DMSO)	22.67	7.23	95.00	10.00	244.00	37.16	14.67	2.08	12.00	2.00
128	19.67	7.09	81.33	11.59	249.00	20.07	10.00	2.68	6.00	1.00
320	21.67	4.62	84.33	11.50	272.33	58.88	10.33	1.53	7.67	2.52
800	17.33	3.51	74.00	8.00	306.33	11.59	8.00	4.36	5.33	1.53
2000	24.00	5.00	91.67	2.31	239.33	24.11	11.00	1.00	8.00	4.36
5000	133.00	1.00	83.00	6.56	261.33	27.57	10.00	1.00	6.33	2.08
PC	449.33	18.58	637.00	40.34	829.00	35.59	121.67	12.58	301.33	76.56

Key: SD: Standard Deviation, VC: Vehicle Control, 2-AA: 10 µg/plate for TA1537, TA1535 and TA102, 2-AA: 5µg/plate for TA98 and TA100

APPENDIX 1. Individual Plate Count (Initial Mutation Assay)

Absence of Metabolic Activation

Concentration (µg/plate)	Number of Revertant Colonies														
	TA98			TA100			TA102			TA1535			TA1537		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
VC (DMSO)	29	25	22	96	105	95	228	210	224	11	11	14	10	10	12
312.5	36	41	38	80	95	96	230	207	211	9	15	8	8	16	10
625	22	22	27	95	85	92	206	200	210	17	8	6	12	7	9
1250	20	22	24	100	100	88	203	230	240	7	9	13	9	12	10
2500	25	23	23	85	105	90	209	210	195	17	6	9	4	5	9
5000	21	28	24	98	90	99	202	218	201	12	13	14	7	8	5
PC	340	360	420	635	588	575	874	854	794	212	238	240	320	350	348
PC-2AA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Presence of Metabolic Activation (5%, v/v S9 mix)

Concentration (µg/plate)	Number of Revertant Colonies														
	TA98			TA100			TA102			TA1535			TA1537		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
VC (DMSO)	17	26	29	111	95	85	215	212	215	4	13	15	9	8	8
312.5	26	20	17	90	90	85	201	226	196	14	12	12	4	7	9
625	22	31	19	103	78	75	150	151	201	10	14	9	6	9	7
1250	13	16	19	87	106	100	190	145	145	12	11	8	4	8	6
2500	32	25	21	106	97	98	185	200	215	9	10	14	9	7	9
5000	10	19	13	94	115	92	208	170	176	10	12	9	7	6	5
PC	368	350	364	535	588	658	842	798	812	260	245	230	340	360	420

Key: R: Replicate, SD: Standard Deviation, VC: Vehicle Control, TA1537: 9-Aa (75 µg/plate), TA1535: SA (5 µg/plate), TA98: 2-NF (7.5 µg/plate), TA100: SA 5µg/plate), TA102: MTC (0.5 µg/plate), 2-AA: 10 µg/plate for TA1537, TA1535 and TA102, 2-AA: 5µg/plate for TA98 and TA100

APPENDIX 2. Individual Plate Count (Confirmatory Mutation Assay)

Absence of Metabolic Activation

Concentration (µg/plate)	Number of Revertant Colonies														
	TA98			TA100			TA102			TA1535			TA1537		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
VC (DMSO)	28	30	29	132	125	117	221	248	233	12	15	17	4	4	6
128	25	29	27	104	112	121	206	178	181	10	13	15	9	7	8
320	26	29	23	122	87	92	213	241	252	11	14	10	13	16	12
800	10	13	14	75	91	82	187	150	182	10	12	14	7	6	9
2000	29	32	28	95	88	71	214	158	220	10	15	12	9	6	8
5000	27	29	31	84	89	77	161	168	178	11	10	9	7	10	8
PC	485	478	418	565	622	610	872	851	816	698	364	596	320	347	212
PC-2AA	-	-	-	110	95	103	-	-	-	-	-	-	-	-	-

Presence of Metabolic Activation (10%, v/v S9 mix)

Concentration (µg/plate)	Number of Revertant Colonies														
	TA98			TA100			TA102			TA1535			TA1537		
	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3	R1	R2	R3
VC (DMSO)	31	19	18	95	85	105	283	209	240	13	11	13	12	10	14
128	26	12	21	68	89	87	272	235	240	7	12	11	13	9	9
320	19	27	19	96	73	84	210	280	327	12	9	10	10	8	12
800	14	17	21	66	74	82	312	293	314	11	10	11	12	9	11
2000	19	29	24	89	93	93	242	214	262	10	12	11	8	10	9
5000	13	12	14	77	90	82	290	235	259	10	8	9	10	9	8
PC	428	458	462	674	594	643	788	852	847	110	135	120	312	220	372

Key: R: Replicate, SD: Standard Deviation, VC: Vehicle Control, TA1537: 9-Aa (75 µg/plate), TA1535: SA (5 µg/plate), TA98: 2-NF (7.5 µg/plate), TA100: SA 5µg/plate), TA102: MTC (0.5 µg/plate), 2-AA: 10 µg/plate for TA1537, TA1535 and TA102, 2-AA: 5µg/plate for TA98 and TA100

APPENDIX 3. In-house Bacterial Background Lawn Evaluation Codes

Code	Definition	Characteristics
0	No Lawn (Absent)	Distinguished by a complete lack of any background lawn compared to vehicle control plates
1+	Very thin lawn (Extremely reduced)	Distinguished by an extreme thinning of the background lawn compared to vehicle control plates
2+	Thin lawn (Moderately reduced)	Distinguished by a marked thinning of the background lawn compared to vehicle control plates
3+	Slightly thin lawn (slightly reduced)	Distinguished by a noticeable thinning of the background lawn compared to vehicle control plates
4+	Thick lawn (Normal)	Distinguished by a healthy background lawn comparable to vehicle control plates

APPENDIX 4. Genotype Confirmation for Salmonella Tester Strains

Name of Test	*Salmonella typhimurium* Tester Strains				
	TA1535	TA1537	TA98	TA100	TA102
Histidine Dependency	NG	NG	NG	NG	NG
Histidine and Biotin Requirement	G	G	G	G	G
uvr B Deletion	NG	NG	NG	NG	G
rfa Mutation	ZI	ZI	ZI	ZI	ZI
Ampicillin Resistance	NG	NG	G	G	G
Tetracycline Resistance	NG	NG	NG	NG	G

Key: NG: No Growth, G: Growth, ZI: Zone of Inhibition

APPENDIX 5. List of abbreviation

Abbreviation	Explanation
2-AA	2- Aminoanthracene
9-Aa	9-Aminoacridine
CFU	Colony forming unit
DMSO	Dimethyl sulfoxide
g	Gram
GLP	Good Laboratory Practice
his	Histidine
hr	Hours
KCl	Potassium Chloride
kg	Kilogram
M	Molar
mg	Milligram
mL	Millilitre
mM	Millimolar
MGA	Minimum Glucose Agar
MTC	Mitomycin C
2-NF	2-Nitroflurene
µg	Microgram
µL	Microlitre
NADP	Nicotinamide Adenine Dinucleotide Phosphate
OECD	Organization for Economic Co-Operation and Development
PC	Positive control
PBS	Phosphate Buffered Saline
rpm	Revolutions per minute
SD	Standard deviation
SA	Sodium azide
UV	Ultra violet
%	Percent

°C	Degree Celsius
v/v	Volume by volume

Certificate of Analysis:

PARABEL

PARABEL USA Inc. 14655 101 Street, Fellsmere, FL 32948 | Office: 321-473-9520 | www.parabel.com

-CERTIFICATE OF ANALYSIS-

Product Name: LENTEIN™ Complete		Common Name: Lemna Protein Flour	
Plant Part: Whole plant		Family: *Lemnaceae*	
Internal Composition: Extracted solids, no excipients		Ratio: n/a	
Lot Number: CSPBWL-170125	Packing Date: 02/17/2017	Expiration Date: 02/17/2018	
Tests	**Specifications**	**Results**	**Test Methods**
Particle size	<100 µm		Rotap Granulation
Protein dry wt.	45-50%	40%	AOAC 990.03
Dietary Fiber dry wt.	35-45%	39%	AOAC 991.43
Fat (AH) dry wt.	<10%	8%	AOAC 922.06
Ash dry wt.	<10%	6%	AOAC 923.03/32.1.05 16th Ed.
Moisture	<10%	2%	AOCS Ba 2a-38
Heavy Metals-			
Arsenic	<0.50 ppm	0.04	AOAC 2013.06
Cadmium	<0.05 ppm	<0.01	AOAC 2013.06
Lead	<0.20 ppm	0.02	AOAC 2013.06
Mercury	<0.05ppm	<0.01	AOAC 2013.06
Aerobic Plate Count	$<10^5$ cfu/g	7.2×10^3	AOAC 966.23
Clostridium perfringens	<100 cfu/g	<10	AOAC 976.30
Coliforms	<100 cfu/g	70	AOAC 991.14
E. coli	<10 cfu/g	<10	AOAC 991.14
Listeria monocytogenes	Negative/25g	Neg	AOAC RI 080901
Salmonella	Negative/25g	Neg	AOAC 2003.09
Yeast	<100 cfu/g	<10	FDA-BAM, Chapter 18
Molds	<100 cfu/g	<10	
Storage conditions:	Store in original sealed bag with low relative humidity (< 60% humidity) and cool temperature (below 25°C/75°F) in dark conditions		
Country of Origin:	USA		
Note:	Product definition, specification and results above are reported from either in house analysis or vendor's certificate of analysis		
Signature:			
Quality Assurance Name:	Ebenezer Ifedubo		
Date:	05/04/2017		

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH: DELHI

Confidential

STUDY REPORT

May, 2017

Study Number : 1704-1-451-1005

Study Title : Mammalian Erythrocyte Micronucleus Test with 'Lentein Complete' in *Swiss albino* mice.

Test Item : Lentein Complete

Study Director : Dr. B. N. Panda

SPONSOR'S NAME & ADDRESS:

PARABEL USA Inc.
7898 Headwaters Commerce Street,
Fellsmere, FL 32948,
USA.

REGULATORY GUIDELINES:

OECD Guidelines for Testing of chemicals, mammalian erythrocyte micronucleus test (No. 474) adopted on 26th September, 2014.

Test Facility's Name & address

Toxicology Centre
Shriram Institute for Industrial Research
(A Unit of Shriram Scientific & Industrial Research Foundation)
19, University Road, Delhi – 110007
Email ID: sridlhi@vsnl.com
Tel. 27667267, 27667860, 27667432
Fax No. +91-11-27667676, 27667207

STATEMENT OF QUALITY ASSURANCE UNIT

Quality Assurance Unit of the testing facility inspected the conduct of study entitled 'Mammalian Erythrocyte Micronucleus Test with 'Lentein Complete' in *Swiss albino* mice' on the following dates:

Sr.No.	Critical Phases of Study	Dates of Inspection	Dates of Reporting	
			Study Director	Management
1.	Study Plan	19.04.2017	19.04.2017	19.04.2017
2.	Scoring of slides	15.05.2017	15.05.2017	15.05.2017
3.	Records (Raw data)	24.05.2017	24.05.2017	00.03.2017
4.	Draft Report	26.05.2017	26.05.2017	26.05.2017
5.	Final Report	30.05.2017	30.05.2017	30.05.2017

This study was conducted in accordance to approved study plan, OECD guideline for testing of chemicals no. 474 and the Standard Operating Procedures and with the principles of good laboratory practices (GLP) for non-clinical laboratory studies. No findings were noticed during inspection, which would have impaired this study in any way.
Report reflects the raw data of the study.

Dr. M.L. Aggarwal — 30.05.2017

Head Quality Assurance Unit — Signature — Date

STATEMENT OF COMPLIANCE

The study entitled 'Mammalian Erythrocyte Micronucleus Test with 'Lentein Complete' in *Swiss albino* mice' was performed in accordance with the approved study plan and standard operating procedures of Toxicology Centre, Shriram Institute for Industrial Research.

We hereby attest the authenticity of the study and guarantee that this report represents a true and accurate record of results obtained and shall not be reproduced except in full, without the written approval of the sponsor.

The study was conducted in accordance to the sponsor's specifications.

All original raw data, documentation, study plan, study schedule, a copy of the final study report and the representative test item will be archived in the archives at Toxicology Centre, Shriram Institute for Industrial Research. There were no known circumstances that may have affected the quality or integrity of the study.

The sponsor is responsible for necessary evaluations of the test item concerning the chemical purity, identity, stability and other required data.

Dr. B. N. Panda		30.05.2017
Study Director	Signature	Date

Dr. Binu Bhat		30.05.2017
Test Facility Management	Signature	Date

KEY PERSONNEL INVOLVED IN THE STUDY

Designation		**Name & Address**
Study Director	:	**Dr. B. N. Panda**, M. V. Sc. (Vet. Pathology) Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Pathologist	:	**Dr. S. S. Rathore**, M. V. Sc. (Vet. Pathology) Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432 Fax No. 91+11-27667676, 27667207
Study Personnel	:	**Mr. Heera Lal**, B. M. L. T., M.Sc. Toxicology Centre Shriram Institute for Industrial Research 19, University Road, Delhi – 110007 Email ID: sridlhi@vsnl.com Tel. 27667267, 27667860, 27667432

List of Symbols and Abbreviations Used

Abbreviations	Explanation
kg	Kilogram
mg	Milligram
mL	Millilitre
µg	Microgram
µL	Microlitre
rpm	Revolutions per minute
hr	Hour
SD	Standard deviation
B.wt.	Body weight
PCE	Polychromatic Erythrocytes
MNPCE	Micronucleated Polychromatic Erythrocytes
P/E	Polychromatic Erythrocytes/Total Erythrocyte
NCE	Normochromatic Erythrocytes
TE	Total Erythrocytes

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CONTINUED….

SUMMARY

This study was performed to assess the 'Mammalian Erythrocyte Micronucleus Test with 'Lentein Complete' in *Swiss albino* Mice' which was sponsored by 'PARABEL USA Inc.7898 Headwaters Commerce Street, Fellsmere, FL 32948, USA.

This study was conducted as per the OECD Guidelines for Testing of chemicals, mammalian erythrocyte micronucleus test (No. 474) adopted on 26th September, 2014.

Dose Range Finding Studies

A dose range finding study was performed to assess the toxicity to bone marrow (suppression of polychromatic to total erythrocytes ratio). Three animals per sex per group were treated at 500, 1000 and 2000 mg/kg body weight by oral gavage for two consecutive days. Animals from all groups were dosed once per day. No Mortality and clinical symptoms were observed in the any concentration of any treatment group animals as compared to the concurrent vehicle control group animals.

Toxicity to bone marrow [decrease in polychromatic to total erythrocytes ratio (P/E)] was not observed in the animals treated at the dose levels of 500, 1000 and 2000 mg/kg body weight as compare to concurrent vehicle control group animals.

Based on the results of the dose range finding studies, a limit dose of 2000 mg/kg body weight was selected for the main study.

Main Study

Thirty healthy Swiss albino mice (5 mice per sex per groups) were divided into three groups. The test substance 'Lentein Complete' was mixed in corn oil and administered orally at the doses of 2000 mg/kg body weight by oral gavage for two consecutive days. Animals were dosed once per day. The mice from the control group (Group I) received only corn oil by oral gavage. Mice from the positive control group (Group III) received a single intraperitoneal injection of Cyclophosphamide at the dose level of 50.0 mg/kg body weight on day 1 of treatment.

All mice belonging to treatment and control groups were sacrificed between 18-24 hours post receipt of last treatment, while animals belonging to the positive control group were sacrificed at 24 hours after the last treatment. The femur of each animal was dissected out and bone marrowcellswereaspiratedusing2-3 mL of foetal bovine serum (FBS) in centrifuge tubes. The suspension was centrifuged at 2000 rpm for 10 minutes and the supernatant was removed, leaving 0.2-0.3 mL serum with the pellet. Bone marrow smears were made on clean microscopic slides and stained with 5% Giemsa in phosphate buffer.

The slides were coded prior to scoring and examined under a microscope for the presence of micronucleated polychromatic erythrocytes (MNPCE).

A minimum of 500 total erythrocytes (Polychromatic + Normochromatic) to its corresponding polychromatic erythrocytes were observed and P/E ratios were calculated from polychromatic to total erythrocytes. A minimum of 4000 polychromatic erythrocytes per mouse was screened for calculating the percentage frequency of micronucleated polychromatic erythrocytes. The values were compared statistically with the concurrent control group.

Toxicity to bone marrow [decrease in polychromatic to total erythrocytes ratio (P/E)] was not observed in the any animals treated at the dose of 2000 mg/kg body weight when compared with the concurrent control group.

Statistical analysis of the results did not reveal any significant difference in percent micronucleated polychromatic erythrocytes (%MNPCE) in animals belonging to the treatment group at the dose level of 2000 mg/kg body weight concurrent.

The significant increase in percent MNPCE observed in animals of either sex treated with Cyclophosphamide (50.0 mg/kg body weight) demonstrated the sensitivity of the test system, suitability of the procedures and efficiency of the test conditions employed in the test.

From the results of the present study, it is concluded that test substance Lentein Complete does not have micronucleus induction potential in male and female mice up to the dose level of 2000 mg/kg body weight, following oral administration for two consecutive days.

1. INTRODUCTION

This study was conducted to assess the Genotoxicity, or to detect damage induced by the test item to the chromosomes or mitotic apparatus of erythroblasts. The study was conducted to determine the cytogenetic damage produced by the test item on the animals, if any, which results in the formation of micronuclei containing either lagging chromosome fragments or whole chromosomes.

1.1 Study Objectives

To determine the mammalian erythrocyte micronuclei with 'Lentein Complete' in *Swiss albino* mice.

1.2 Testing Guidelines

OECD Guidelines for Testing of chemicals, mammalian erythrocyte micronucleus test (No. 474) adopted on 26th September, 2014 was followed for conducting the study.

1.3 Test Facility and Study Period

This study was performed at Toxicology Centre, Shriram Institute for Industrial Research, Delhi-110007.

Date of initiation of study	: 19.04.2017
Date of initiation of experiment	: 24.04.2017
Date of dose administration of dose	: 01.05.2017
Date of completion of experiment	: 24.05.2017
Date of completion of study	: 30.05.2017

1.4 Archiving

On completion of the study all the study related raw data, observation sheet with the copy of draft and final study report to be retained in the archives of Test Facility 'Toxicology Centre, Shriram Institute for Industrial research, Delhi' for 10 years. After completion of archival period sponsor consent will be sought to either extend the archiving period or return the archived material to the sponsor or for the disposal of the material.

2. EXPERIMENTAL PROCEDURE

2.1 Test Item Details

The sponsor is responsible for necessary evaluations of the test item concerning the chemical purity, identity, stability and other required data. The details of the test item provided by the sponsor are given on next page:

Test item	LENTEIN ™ Complete
Lot Number	CSPBWL 170125
Date of Mfg.	02/17/2017
Best Used By	02/17/2018
Moisture content, percent by mass	2%
Sponsored by	PARABLE USA Inc. USA.

2.2 Instruments and Equipment Used

1. Balance no. SRI /TOX /ANI /41 for animal weighing.
2. Syringe 1 ml disposable Syringe (Batch No. -330015G42)
3. 26 gauze needles (Batch no. - 40652N)

2.3 Test System Details

Name of species : *Mice (Mus musculus*)
Strain : *Swiss albino*

Number of animals per dose : 05 Males and 05 females
Age at start of treatment : 08-12 weeks

Body weight range : 20 to 25gm
Selection of animal : Randomly selected
Acclimatization period : 7 days for all the groups
Room No. : 105
Source of experimental animals: In bred animals of Animal house facility, Toxicology Centre, Shriram Institute for Industrial Research, Delhi

2.4 Name of Test System Used : Swiss albino mice

2.5 Justification for Selection of Test System

Mice were selected as test system for use in this study for the following reasons:

a) To meet the Sponsor's specifications for testing of chemical in rodents.
b) Availability of comprehensive background data related to pathological and clinical parameters.
c) Mice are the preferred rodent species.

2.6 Acclimatization

Before accepting animals for study use, Animal house In-charge declared Swiss albino Mice to be healthy and then released the animals for use in the study. The Swiss albino

Mice were received and kept for a period of 5days for acclimatization in the experimental room number 105 of animal house. Veterinary examination of all the animals was done and recorded on the day of receipt and during acclimatization.

2.7 Selection of Animals

Animals used in this study were within protocol-specified weight range (20 to 25 gm.). The animals were assigned to the study on the basis of their body weights so that their individual body weight fell in an interval within ± 20% of the mean body weight of the group at treatment.

2.8 Husbandry

Care and maintenance of all the animals was carried as per the norms laid by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) Govt. of India.

i. Environmental Conditions

All the rats were maintained in an environment controlled (Centrally Air-Conditioned room at a temperature of 22±3°C, a relative humidity of 50 to 60%, 15–20 air changes/hour, a light intensity of 250–300 lux and a 12 h light/dark cycle and noise intensity of <85 db.

ii. Housing

Animals were housed single in solid floored polypropylene cages in room no. 105 of animal house. Each cage was fitted with a stainless steel top grill having provision for keeping pellet feed and a water bottle. The bottom of the cage was layered with sterilized corn cob. Samples of bedding material were analyzed for specified microbiological and chemical contaminants on a routine basis.

iii. Diet and Feeding

Sterilized pellet diet (Krishna Valley Agrotech LLP, New Delhi) was offered *ad libitum* to the mice throughout the experimental period. Each batch of the feed was analyzed for its nutritional components, microbial load and chemical contaminant. There were no known contaminants in the feed at levels that would have potentially influenced the outcome of this study.

iv. Drinking Water

Ad libitum aqua guard filtered water was served in polypropylene bottles fitted with stainless steel nozzles. Water analysis is conducted twice a year for specified microbial load, for heavy metals, Organophosphates and chlorinated hydrocarbons. There were no

known contaminants in the water at levels that would have potentially influenced the outcome of this study.

v. Room Sanitation

The floor of the experimental room was swept on routine basis, and all work tops and the floor was mopped with a disinfectant solution of D-125/D-256.

2.9. Identification of Animals

All the animals were housed single in polypropylene cages fitted with wire mesh tops and a tag hung on the cage hook mentioning the details of study number, study title, animal number, sex, dose, experiment start date, date of dosing, date of completion of experiment (live phase), name of study director and cage number. Each animal within the cage was identified with discrete body marking.

2.10. Animal Welfare

All animals were handled with due regard for animal welfare. Care of animals complied with the regulations of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) Govt. of India and in accordance to the standard operating procedures.

2.11. Analysis Reports

Analysis of bedding material, drinking water and feed did not reveal any findings that can be considered to have adverse impact on the results of the present study.

2.12. Dose selected for dose range finding study

The following doses were used in this study

Group No.	Dose Level/ mg/kg B.wt.	Day of Dosing	Animals No.		Sacrifice after Last Treatment (hour)
			Male	Female	
I	Vehicle Control/0	Day 1 & 2	1-3	4-6	24
II	Lentein Complete/500	Day 1 & 2	7-9	10-12	24
III	Lentein Complete/1000	Day 1 & 2	13-15	16-18	24
IV	Lentein Complete/2000	Day 1 & 2	19-21	22-24	24

2.13. Dose selected for Main study

The following doses were used in this main study:

Group No.	Dose Level/ mg/kg B.wt.	Day of Dosing	Animals No.		Sacrifice after Last Dosing
			Male	Female	
I	Vehicle Control/0	Day 1 & 2	25-29	30-34	24
II	Lentein Complete/2000	Day 1 & 2	35-39	40-44	24
III	Cyclophosphamide/50	Day 1	45-49	50-54	48

2.14. Justification of selection of doses for dose range finding study

Selected dosages were based on recommendation of guideline for which LD_{50} or any published data is not available.

2.15. Dose Selection criteria for the main Study

The doses which were administered in the main study were derived from the results of the dose range finding study. The highest dose selected should be the maximum tolerable dose (MTD) which:

a. Produces some indication of toxicity in the bone marrow [e.g. a reduction in the proportion of immature erythrocytes (PCE) among total erythrocytes (RBC) in the bone marrow].

b. If the test item produces no observable toxic effects, then a limit dose of 2000 mg/kg will be tested in main study. In this case, one treatment group along with a vehicle control group and a positive control group is tested.

2.16 Selection of Vehicle:

Corn oil was selected as vehicle.

2.17. Justification for Selection of Vehicle

Corn oil is well known and suitable vehicle for animals for use.

2.18. Dose Preparation

Test item of 2000, 1000 and 500 mg was taken and mixed up to 10 mL with corn oil in three volumetric flasks to prepare three different dose formulations of 200, 100 and 50 mg/mL for dose range finding study.

A weighed quantity 2000 mg of Test item was taken and mixed up to 10 mL with corn oil in a volumetric flask to prepared dose formulations of 200 mg/mL for main study.

A weighed quantity 25 mg of Cyclophosphamide was taken and mixed with distilled water in a volumetric flask up to 5 mL to obtain a concentration of 5 mg/mL solution. The dose formulation was administered within 2 hours of preparation to the test system. Individual dose volumes were calculated based on the body weights of animals.

2.19. Route of administration

The route of administration was oral gavage for test item and vehicle control group and intra-peritoneal route was given in case of positive control group.

2.20. Justification for route of administration

The oral route has been chosen to characterize the toxicological profile of the test item as it is the likely route of exposure to humans.

2.21. Dose range finding study

A dose range finding study was performed to assess the toxicity to bone marrow (suppression of polychromatic to total erythrocytes ratio). Three animals per sex per group were treated at 500, 1000 and 2000 mg/kg body weight by oral gavage for two consecutive days. Animals from all the groups were dosed once per day. No Mortality and clinical symptoms were observed at any concentration in any of the treatment group animals as compare to concurrent vehicle control group animals.

Toxicity to bone marrow [decrease in polychromatic to total erythrocytes ratio (P/E)] was not observed in the animals treated at the dose levels of 500, 1000 and 2000 mg/kg body weight as compared to concurrent vehicle control group animals.

Based on the results of the dose range finding studies, a limit dose of 2000 mg/kg body weight was selected for the main study.

2.22. Main study

Thirty healthy Swiss albino mice (5 mice per sex per groups) were divided into three groups. The mice from the control group (Group I) received only corn oil by oral gavage and mice of group II received test item dose formulation by oral gavage for two consecutive days (in interval of 24 hours). Animals were dosed once per day. Mice from the positive control group (Group III) received a single intra-peritoneal injection of Cyclophosphamide at the dose level of 50.0 mg/kg body weight on day 1 of treatment.

2.23. Sacrifice and Necropsy

All mice belonging to treatment and control group were sacrificed between 18-24 hours post receipt of last treatment, while animals belonging to the positive control group were sacrificed at 48 hours after the last treatment. The femur of each animal was dissected

out and bone marrow cells were aspirated using 2-3 mL of foetal bovine serum (FBS) in centrifuge tubes.

The suspension was centrifuged at 2000 rpm for 10 minutes and the supernatant was removed, leaving 0.2-0.3 mL serum with the pellet. Bone marrow smears were made on clean microscopic slides. The slides were stained for 20 minutes with 5% Giemsa in phosphate buffer. The slides were coded prior to scoring and examined under microscope for the presence of micronucleated polychromatic erythrocytes (MNPCE).

3. OBSERVATIONS

3.1. Clinical Signs

All visible clinical signs were made individually after the dosing, at least once during first 30 minutes with special attention during first 4 hours on the day of dosing and then once in a day. (Reference Table 1)

3.2. Mortality

The animals were checked daily for morbidity and mortality. Any animal that shows marked sign of reaction to treatment will be isolated and/ or euthanized. (Reference Table 1)

3.3. Body Weight

The body weights were recorded individually for all animals prior to treatment. (Reference Table 2 & Appendix 1)

3.4. Analysis of Micronucleated Polychromatic Erythrocytes

A minimum of 400 total erythrocytes (Polychromatic + Normochromatic) to its corresponding polychromatic erythrocytes were observed and P/E ratios were calculated from polychromatic to total erythrocytes. A minimum of 4000 polychromatic erythrocytes per mouse was screened for calculating the percentage frequency of micronucleated polychromatic erythrocytes. The values were compared statistically with the concurrent control group.

4. STATISTICAL ANALYSIS

The data of percent micronucleated polychromatic erythrocytes (% MNPCE) for both the sexes were statistically analysed using Bartlett's test and Analysis of Variance (ANOVA).

5. RESULT

Toxicity to bone marrow [decrease in polychromatic to total erythrocytes ratio (P/E)] was not observed in the any animals treated at the dose of 2000 mg/kg body weight when compared with the concurrent control group. (Reference Table 3 & Appendix 2)

Statistical analysis of the results did not reveal any significant difference in percent micronucleated polychromatic erythrocytes (% MNPCE) in animals belonging to the treatment group at the dose level of 2000 mg/kg body weight when compared with concurrent vehicle control. (Reference Table 3)

The significant increase in percent MNPCE observed in animals of either sex treated with Cyclophosphamide (50.0 mg/kg body weight) demonstrated the sensitivity of the test system, suitability of the procedures and efficiency of the test conditions employed in the test. (Reference Table 3)

6. CONCLUSION

Under the condition and results of this study, it is concluded that test item Lentein Complete does not elicit micronucleus induction potential in male and female mice up to the recommended dose level of 2000 mg/kg body weight, following oral administration for two consecutive days.

TABLE 1: TOXIC SIGN & SYMPTOMS

Dose mg/kg B.wt.	Mortality		Toxic Sign & Symptoms
	Male	Female	
G1 Vehicle Control	0/10	0/10	No toxic sign and symptoms were observed during observation.
G2 2000	0/10	0/10	No toxic sign and symptoms were observed during observation
G3 Positive control 50	0/10	0/10	No toxic sign and symptoms were observed during observation

TABLE 2: SUMMARY OF MEAN BODY WEIGHT

Number of Animals = 5 per Sex/Group

Group and Dose		Body Weight (g)			
		Male		Female	
		Day 1	Day 2	Day 1	Day 2
G1 Control (Corn oil)	Mean	23.98	24.12	22.16	22.32
	SD	0.40	0.41	0.80	0.72
G2 Lentein Complete 2000 mg/kg b. wt.	Mean	24	24.2	22.44	22.44
	SD	0.20	0.37	0.89	0.91
G3 Positive control 50 mg/kg b. wt.	Mean	24.08	23.8	22.52	22.48
	SD	0.33	0.40	0.61	0.61

Note: Cyclophosphamide was used as the positive control
Key: SD = Standard deviation

TABLE 3: SUMMARY OF MICRONUCLEATED POLYCHROMATIC ERYTHROCYTES IN BONE MARROW CELLS

Number of Animals = 5 per Sex/Group

Group / Dose (mg/kg b.wt.)	Male					Female				
	PCE	MNPCE			Mean P/E Ratio	PCE	MNPCE			Mean P/E Ratio
		Total	Mean	%			Total	Mean	%	
G1 Control (corn oil)	20064	8	1.60	0.04	0.62	20106	6	1.20	0.03	0.63
G2 Lentein Complete 2000	20165	8	1.60	0.04	0.62	20075	8	1.60	0.04	0.61
G3 Cyclophosphamide 50	20029	187	31.20	0.78↑	0.58	20167	194	34.00	0.59↑	0.84

Note: Cyclophosphamide was used as the positive control

$$\% \text{ MNPCE} = \frac{\text{MNPCE}}{\text{Total PCE}} \times 100$$

Key: ↑ = Significantly higher than the control at 5 % level ($p \leq 0.05$)
PCE = Polychromatic Erythrocytes
MNPCE = Micronucleated Polychromatic Erythrocytes
P/E = Polychromatic Erythrocytes/Total Erythrocyte
b.wt. = Body weight

APPENDIX 1: INDIVIDUAL BODY WEIGHT OF MICE

Group / Dose (mg/ kg b.wt.)	Sex	Animal No.	Body Weight (g)		
			Day 1	Day 2	Before Sacrifice
G1 Vehicle Control (Corn oil)	Male	1	24.0	24.2	24.0
		2	23.5	23.8	23.8
		3	24.6	24.8	24.8
		4	24.0	24.0	24.0
		5	23.8	23.8	23.8
	Female	6	21.5	21.8	21.8
		7	22.0	22.5	22.5
		8	23.5	23.5	23.5
		9	22.2	22.0	22.0
		10	21.6	21.8	21.8
G2 Lentein Complete 2000	Male	11	23.8	24.2	24.2
		12	24.2	24.4	24.4
		13	23.8	23.6	23.6
		14	24.0	24.6	24.6
		15	24.2	24.2	24.2
	Female	16	21.0	21.0	21.0
		17	22.2	22.2	22.2
		18	22.8	22.6	22.6
		19	23.0	23.2	23.2
		20	23.2	23.2	23.2
G3 Cyclophosphamide 50	Male	21	23.8	23.2	23.0
		22	24.2	24.0	23.8
		23	24.6	24.2	24.2
		24	23.8	23.6	23.2
		25	24.0	24.0	24.0
	Female	26	22.0	21.8	21.4
		27	23.2	23.0	22.8
		28	22.6	22.4	22.0
		29	21.8	22.0	21.6
		30	23.0	23.2	23.0

APPENDIX 2: TOTAL ERYTHROCYTES AND P/E RATIO

Group/Dose (mg/kg b.wt.)	Sex	Animal No.	Total PCE	NCE	Total Erythrocytes	P/E Ratio
G1 Vehicle Control (Corn oil)	Male	1	4002	161	412	0.61
		2	4021	156	405	0.61
		3	4010	124	402	0.69
		4	4005	174	419	0.58
		5	4026	162	423	0.62
	Female	6	4024	145	411	0.65
		7	4030	159	408	0.61
		8	4009	161	415	0.61
		9	4025	143	402	0.64
		10	4018	154	409	0.62
G2 Lentein Complete 2000	Male	11	4006	155	412	0.62
		12	4009	160	402	0.60
		13	4102	147	417	0.65
		14	4017	159	415	0.62
		15	4031	168	408	0.59
	Female	16	4008	176	421	0.58
		17	4021	149	415	0.64
		18	4017	163	413	0.61
		19	4022	168	404	0.58
		20	4007	142	406	0.65
G3 Cyclophosphamide 50	Male	21	4001	171	407	0.58
		22	4003	169	408	0.58
		23	4013	175	416	0.58
		24	4009	170	407	0.58
		25	4003	167	415	0.58
	Female	26	4012	173	406	0.57
		27	4102	158	408	0.61
		28	4020	167	402	0.58
		29	4019	172	414	0.58
		30	4014	169	418	0.60

PCE: Polychromatic Erythrocytes; NCE: Normochromatic Erythrocytes; P/E: Polychromatic Erythrocytes/Total Erythrocytes

APPENDIX 3: FREQUENCY OF MICRONUCLEATED POLYCHROMATIC ERYTHROCYTES

Group/ Dose (mg/kg b.wt.)	Sex	Animal No.	Total No. of PCE Scored	No. of MNPCE	% MNPCE
G1 Vehicle Control (Corn oil)	Male	1	4002	0	0.00
		2	4021	2	0.05
		3	4010	2	0.05
		4	4005	0	0.00
		5	4026	4	0.10
	Female	6	4024	0	0.00
		7	4030	2	0.05
		8	4009	2	0.05
		9	4025	0	0.00
		10	4018	2	0.05
G2 Lentein Complete 2000	Male	11	4006	2	0.05
		12	4009	4	0.10
		13	4102	2	0.05
		14	4017	0	0.00
		15	4031	0	0.00
	Female	16	4008	2	0.05
		17	4021	2	0.05
		18	4017	2	0.05
		19	4022	2	0.05
		20	4007	0	0.00
G3 Cyclophosphamide 50	Male	21	4001	41	1.02
		22	4003	22	0.55
		23	4013	19	0.47
		24	4009	34	0.85
		25	4003	40	1.00
	Female	26	4012	43	1.07
		27	4102	41	1.00
		28	4020	21	0.52
		29	4019	34	0.85
		30	4014	31	0.77

PCE: Polychromatic Erythrocytes, MNPCE: Micronucleated Polychromatic Erythrocytes,
% MNPCE: MNPCE x 100/Total PCE

Certificate of Analysis:

PARABEL

PARABEL USA Inc. 14655 101 Street, Fellsmere, FL 32948 | Office: 321-473-9520 | www.parabel.com

-CERTIFICATE OF ANALYSIS-

Product Name: LENTEIN™ Complete		Common Name: Lemna Protein Flour
Plant Part: Whole plant		Family: *Lemnaceae*
Internal Composition: Extracted solids, no excipients		Ratio: n/a
Lot Number: CSPBWL-170125	Packing Date: 02/17/2017	Expiration Date: 02/17/2018

Tests	Specifications	Results	Test Methods
Particle size	<100 µm		Rotap Granulation
Protein dry wt.	45-50%	40%	AOAC 990.03
Dietary Fiber dry wt.	35-45%	39%	AOAC 991.43
Fat (AH) dry wt.	<10%	8%	AOAC 922.06
Ash dry wt.	<10%	6%	AOAC 923.03/32.1.05 16th Ed.
Moisture	<10%	2%	AOCS Ba 2a-38
Heavy Metals-			
Arsenic	<0.50 ppm	0.04	AOAC 2013.06
Cadmium	<0.05 ppm	<0.01	AOAC 2013.06
Lead	<0.20 ppm	0.02	AOAC 2013.06
Mercury	<0.05ppm	<0.01	AOAC 2013.06
Aerobic Plate Count	$<10^5$ cfu/g	7.2×10^3	AOAC 966.23
Clostridium perfringens	<100 cfu/g	<10	AOAC 976.30
Coliforms	<100 cfu/g	70	AOAC 991.14
E. coli	<10 cfu/g	<10	AOAC 991.14
Listeria monocytogenes	Negative/25g	Neg	AOAC RI 080901
Salmonella	Negative/25g	Neg	AOAC 2003.09
Yeast	<100 cfu/g	<10	FDA-BAM, Chapter 18
Molds	<100 cfu/g	<10	

Storage conditions:	Store in original sealed bag with low relative humidity (< 60% humidity) and cool temperature (below 25°C/75°F) in dark conditions
Country of Origin:	USA
Note:	Product definition, specification and results above are reported from either in house analysis or vendor's certificate of analysis
Signature:	
Quality Assurance Name:	Ebenezer Ifeduba
Date:	05/04/2017

APPENDIX I – STATEMENT OF LC'S POST-MARKET SURVEILLANCE

LENTEIN® Complete
Post Market Surveillance Reporting: Consumer Feedback on Allergens

From 2018 - 2020, Parabel Nutrition, Inc. commercially sold LENTEIN® Complete (Water Lentil Powder) based products through the brand Real Source. Although Real Source's commercial operations were centralized to the US, we also shipped internationally to customers, including markets in Europe, Asia, and Australia.

In that time, Parabel ("we") offered (or launched) multiple dry-blended beverage products based on formulations with LENTEIN®, at inclusion levels ranging anywhere from 68% to 100%. We received positive reviews related to flavor, nutritional benefits, and ease with which the end consumer utilized our LENTEIN® Complete-based products. Our business included selling directly online via our website, through the Amazon marketplace, through natural and specialty retail stores, and direct to consumers at farmer's markets throughout Florida.

Feedback channels for our sales were available, monitored, and answered through Social Media (Facebook, Instagram), our Website (Chat), review systems (Yotpo), and our direct assistance channels (email).

We received positive reviews related to flavor, nutritional benefits, and ease with which the end consumer utilized our LENTEIN® Complete-based products. Reports of allergic reactions were not received.

Parabel understands the concerns our customers have surrounding the presence of allergens in food ingredients. If there is anything further, we may assist you with regarding this or any other matter, please do not hesitate to contact us at (+1) 321 405 2134.

Signed:

Gordon Divine
Head of IT & Digital
Parabel Nutrition, Inc.

APPENDIX J – EXPERT PANEL REPORT

The Generally Recognized as Safe (GRAS) Status of the Proposed Uses of Lemnature AquaFarms USA, Inc. Lemnature™ Fiber (*Lemnaceae* Water Lentil Fiber Powder)

April 19, 2022

An independent panel of experts ("Expert Panel") was convened by GRAS Associates, LLC on behalf of Lemnature AquaFarms USA, Inc., (previously Parabel USA, Inc.) to evaluate the safety and Generally Recognized as Safe (GRAS) status of Lemnature's proposed uses of Lemnature™ Fiber (LF) in conventional foods. The members of this Expert Panel are qualified to serve in this capacity by qualification of scientific training and experience in the safety of food and food ingredients.[1]

GRAS Associates and Lemnature ensured that all reasonable efforts were made to identify and select a balanced Expert Panel with expertise in food safety, toxicology, and nutrition. The Expert Panel was selected and convened in accordance with the Food and Drug Administration (FDA)'s guidance for industry on "Best Practices for Convening a GRAS Panel". Efforts were placed on identifying conflicts of interest or relevant "appearance issues" that could potentially bias the outcome of the deliberations of the Expert Panel and no such conflicts of interest or "appearance issues" were identified. The Expert Panel members received a reasonable honorarium as compensation for their time; the honoraria provided to the Expert Panel members were not contingent upon the outcome of their deliberations.

Discussion

Lemnature's whole water lentil powder "LENTEIN® Complete" (LC) and its degreened version are both recognized as GRAS by the FDA, under GRN 742, for use as a source of protein in food at levels ranging from 3-20%. Lemnature's LC is also a product derived 100% from Lemnature's *Lemnaceae*, meaning Lemnature's LF's chemical composition is composed of similar macronutrients, elements, and secondary metabolites to LC, except at different concentration levels due to their differences in the manufacturing process. LC is derived from a simple process where whole water lentils are blanched or heat treated, dewatered and milled into a fine powder. LF follows a similar process except the starting material is lysed and separated to capture only the insoluble material of the plant (fiber or pulp from water lentils), this material is then dewatered, heat treated, and milled into a fine powder. Therefore, LF is concentrating the dietary fiber from water lentils by removing or separating the soluble macronutrients within water lentils (i.e., protein, most fatty acids, and phytonutrients).

[1] The expert panel consisted of Laurie C. Dolan, PhD, DABT, FACN, Paula Trumbo, PhD, and Richard Kraska, PhD. Dr. Dolan (the panel chair) is a board certified (DABT) toxicologist with over 25 years of experience in regulatory submissions and safety assessments. Dr. Trumbo led the Nutrition Science Review Team at the FDA which was responsible for pre-market review of scientific evidence related to food labeling, health claims, and meeting the definition of dietary fiber. Prior to FDA, Dr. Trumbo was Associate Professor of Nutrition at Purdue University and directed study panels at the Institute of Medicine's Food and Nutrition Board. Dr. Kraska holds a PhD in Pharmacology with over 35 years of experience related to assessing safety of food additives, GRAS ingredients and food contact materials. All three panelists have extensive technical backgrounds in the evaluation of food ingredient safety and in participating in deliberations of GRAS Expert Panels.

LF is a naturally derived water lentil (*Lemnaceae*) fiber intended to be used as an ingredient in human food products and a component of the human diet as a dietary fiber source. It is consistently produced under controlled manufacturing yielding product that meets specifications LF consists of approximately 23% cellulose, 12% hemicelluloses, and 5% lignin (typically >90% insoluble fibers), and also contains protein, starch, fat, minerals, and moisture. LF is also intended to be used as a multipurpose food ingredient (e.g., anticaking agent, water binding aid, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, or purge reduction aid.

The ingredient is intended for use as a multipurpose food ingredient at inclusion levels ranging 0.5-10% in a number of different food categories. LF will be used as a substitute for, and/or in conjunction with, other fiber sources (such as citrus fiber, oat fiber, rice bran, among others). Besides LF's nutritional contribution to the listed food categories, LF's intended use is attributed to its functional capabilities (e.g., anticaking agent, water binding, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, purge reduction). The foods in which the substance will be used include baked goods, beverages, breakfast cereals, cheese, spreads and condiments, confections and frostings, dairy product analogs, salad dressings, frozen dairy desserts, puddings and pie fillings, grain products and pasta, gravies and sauces, hard candy and cough drops, herbs and seasoning blends, jam and jellies, meal replacements and nutritional bars, plant protein products, protein products (processed meat and poultry products, processed fruit and vegetable juices, snack foods, soups and soup mixes (commercially prepared), and sweet sauces and toppings. Infant formula is excluded from the intended uses.

Because LF will be added to food products as a fiber ingredient substitute, LF will not contribute to any additional exposure to dietary fiber for consumers, consequently, the fundamental intake of fiber would not likely be impacted. Considering the totality of information and considering LF contains 48-66% dietary fiber (typically 60% fiber on a dry matter basis), the consumption of LF from the intended uses is not expected to exceed 29 g/day (an amount that would provide half of the 28 g Daily Value for dietary fiber, or 14 g/day, assuming 48% fiber in the ingredient). While it is not expected that the intake of LF from the proposed use will exceed the Daily Value for dietary fiber, it is important to note that the IOM opted not to set a UL for dietary fiber stating that due to the bulky nature of fibers, excess consumption is likely to be self-limiting.

Based on the similarity between the LF and LC products, no additional toxicity studies were conducted on LF. Lemnature has completed four comprehensive toxicity studies on LC; a repeated dose (90 days) oral toxicity study, an acute oral toxicity study (LD_{50}), a micronucleus study, and a bacterial reverse mutation test (AMES Study). The results of these studies are publicly available.

The LD_{50} of LC was between 2g-5g/kg body weight and the NOAEL in the 90-day study was 1 g/kg bw/day. LC was not genotoxic in either the reverse mutation or micronucleus assays. Even though Lemnature's LF has not been tested in these toxicity studies, both fractionated products from Lemnature's water lentils are similar in composition to Lemnature's LC, derived from the same source, and intended to be consumed by humans below the 1000 mg/kg bw/day NOAEL in rats. The FDA acknowledged that the estimated human intake of LC is 27.8 – 55.6 g/day, supporting the conclusion that intake of 29/g LF/day would be safe. Lemnature monitors its Lemnature™ Fiber for minerals, secondary metabolites including nucleotides, biogenic amines, mycotoxins, microcystins, nitrates, and antinutritional factors such as oxalic acid, phytic acid, and trypsin inhibitor. Lemnature also monitors its *Lemnaceae* polyculture and its derived fiber for

pesticide residues, annually or as requested by customers. The results for minerals, secondary metabolites and undesirable components do not indicate a cause for concern.

Conclusion

A compelling case can be made that scientific consensus exists regarding the safety of LF, which is intended to provide a dietary source of LF as a food ingredient in selected conventional foods. The Expert Panel concludes that there is sufficient evidence to support the safety of LF given the following conditions:

- The LF continues to meet the designated specifications;
- The proposed intended use and use levels do not change; and
- The LF continues to be produced in accordance with Current Good Manufacturing Practices (cGMP)

The Expert Panel has critically reviewed the data provided by Lemnature for their LF, as well as publicly available published information obtained from peer-reviewed and other safety assessments prepared by other Expert Panels and well-respected international regulatory bodies.

The Expert panel unanimously concludes that the proposed uses of Lemnature™ Fiber , manufactured under cGMP standards, meets the FDA definition of safety in that there is "reasonable certainty of no harm under the intended conditions of use" as described herein, and Lemnature's LF preparation is generally recognized as safe (GRAS).

It is also our opinion that other qualified and competent scientists reviewing the same publicly available information would reach the same conclusion. Therefore, we have concluded that Lemnature™ Fiber, when used as described in this dossier, is GRAS based on scientific procedures.

Laurie C. Dolan, PhD, DABT, FACN
Chair

Paula Trumbo, PhD

Richard Kraska, Ph.D.

END

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: 07/31/2022
(See last page for OMB Statement)

FDA USE ONLY

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

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)*: 2021/02/25

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)*: _____

SECTION B – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position or Title
Gene A. Lang	General Counsel

Organization *(if applicable)*: Lemnature AquaFarms USA, Inc.

Mailing Address *(number and street)*: 1991 74th Ave., Suite B

City	State or Province	Zip Code/Postal Code	Country
Vero Beach	Florida	32966	United States of America

Telephone Number	Fax Number	E-Mail Address
+1 772-207-4794		glang@lemnatureusa.com

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

Name of Contact Person	Position or Title
William Rowe	President

Organization *(if applicable)*: GRAS Associates, LLC

Mailing Address *(number and street)*: 11810 Grand Park Avenue, Suite 500

City	State or Province	Zip Code/Postal Code	Country
North Bethesda	Maryland	20852	United States of America

Telephone Number	Fax Number	E-Mail Address
519-341-3660	1-888-531-3466	wrowe@nutrasource.ca

SECTION C – GENERAL ADMINISTRATIVE INFORMATION

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

Lemnature Fiber (LF) - Lemnaceae water lentil fiber powder

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 _____

Total number of pages _____

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 742

☐ 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) and 170.250(d) and (e))

☒ 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.

Lemnature™ Fiber (Lemnacea water lentil fiber powder) is intended to be used as an ingredient in human food products and a component of the human diet as a dietary fiber source. Lemnature™ Fiber is also intended to be used as a multipurpose food ingredient (e.g., anticaking agent, water binding aid, thickening aid, bulking aid, emulsion stabilizer, formulation aid or binder, or purge reduction aid) at inclusion levels ranging from 0.5-10% in the food categories listed in Part III of the GRAS dossier.

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 Gene A. Lang
(name of notifier)

has concluded that the intended use(s) of Lemnature Fiber (LF) - Lemnaceae water lentil fiber powder
(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. Gene A. Lang 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;
(name of notifier)

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.

Lemnature AquaFarms USA, Inc. 1991 74th Ave., Suite B, Vero Beach, FL 32966, USA
(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)
Amy Mozingo Digitally signed by Amy Mozingo Date: 2022.05.16 12:41:21 -04'00'	Amy Mozingo on behalf of William J. Rowe, President	05/16/2022

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)
	Lemnature AquaFarms_Lemnature Fiber GRAS_19Apr2022_FINAL	N/A
	Appendix A: Certificate of Amendment for Name Change	N/A
	Appendix B: Stability Data Summary for Parabel's LENTEIN Complete (36 month)	N/A
	Appendix C: Technical Report for USDA food_Parabel LF	N/A
	Appendix D: Intake Report_Parabel LF	N/A
	Appendix E: Total Adda Microcystins-Nodularins Repport_Parabel LF	N/A
	Appendix F: Analytical Reports	N/A
	Appendix G: Water Lentil Recipes	N/A
	Appendix H: Summary Reports and Results of Ames and Micronucleus Tests on LC	N/A

Add Continuation Page

PART VIII – LIST OF ATTACHMENTS *(continued)*

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)
	Appendix I: Statement of Post-Market Surveillance on Allergens	N/A
	Appendix J: Expert Panel Report	N/A

From: William J. Rowe
To: Gaynor, Paulette M
Cc: Amy Mozingo
Subject: [EXTERNAL] GRN 001072 Communication Authorization
Date: Friday, January 20, 2023 3:52:49 PM
Attachments: image001.png
image002.png

Dear Dr. Gaynor,

Thank you very much for the call today to discuss GRN 001072. On behalf of the Sponsor, we are requesting that FDA cease evaluation of GRN 001072. I authorize Amy Mozingo to communicate directly with FDA regarding GRN 001072. Should you have any additional questions or communications, please feel free to reach out to me and/or Amy directly.

Regards,

Will

William J. Rowe, BA
President, CEO and Co-founder
O: 519-341-3360 | C: 519-827-8129

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