#692

vis vitalis gmbh

January 17, 2017

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

Subject: GRAS Notification for Quinoa Sprouts Rich in Botanical B Vitamins

Dear Sir/Madam:

In accordance with 21 CFR 170 subpart E, (81 FR 54960; August 17, 2016), VIS VITALIS gmbh, Austria, hereby provides notice of a claim that the food ingredient quinoa sprouts extract rich in botanical B-vitamins as a nutrient described in the enclosed notification document is exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because it has been determined to be Generally Recognized As Safe (GRAS), based on scientific procedures.

If you have any questions or require additional information, please feel free to contact me by Phone at +43 6476 80 52 13 or by E-mail at office@panmol.com.

Alternatively, in the US you can also contact Dr. Soni who assisted us with this notice. You can reach him by phone at +1-772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,

vis vitalis gmbh

(b) (6) [redacted]

585 Unternberg
Fax: +43(0)6476/80 52 21

Mag. Norbert Fuchs
General Manager

Enclosure: Copy of the GRAS notice
Electronic copy CD

RECEIVED
FEB 7 2017
OFFICE OF
FOOD ADDITIVE SAFETY

GENERALLY RECOGNIZED AS SAFE (GRAS) DETERMINATION OF QUINOA SPROUTS RICH IN BOTANICAL B-VITAMINS AS A NUTRIENT SOURCE

Submitted by:
VIS VITALIS gmbh
A-5585 Unternberg - Moosham 29
AUSTRIA

Submitted to:
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
HFS-200
5100 Paint Branch Parkway
College Park, MD 20740-3835
USA

Contact for Technical and Other Information
Madhu Soni, PhD
Soni & Associates Inc.
749 46th Square
Vero Beach, FL 32968

February, 2017

GENERALLY RECOGNIZED AS SAFE (GRAS) DETERMINATION OF QUINOA SPROUTS RICH IN BOTANICAL B-VITAMINS AS A NUTIRIENT SOURCE

TABLE OF CONTENTS

1. Part 1 - SIGNED STATEMENTS AND CERTIFICATION....................4

1.1. Name and Address of Notifier 4

1.2. Name of Notified Substance 4

1.3. Intended Conditions of Use 4

1.4. Statutory Basis for GRAS Determination 4

1.5. Exclusion from Premarket Approval 4

1.6. Availability of Data & Information 4

1.7. Data Exemption from Disclosure 5

1.8. Certification 5

1.9. Name, Position/Title of Responsible Person who Signs the Dossier and Signature..5

1.10. FSIS/USDA – Use in Meat and/or Poultry 5

2. Part 2 – IDENTITY, SPECIFICATION, MANUFACTURING AND TECHNICAL EFFECTS....................6

2.1. Identity 6

2.1.1. Description....................6

2.1.2. Taxonomy of Botanical Source....................6

2.1.3. Quinoa Seeds 7

2.1.4. Quinoa Sprouts....................7

2.2. Specifications....................7

2.3. Manufacturing Process....................9

2.4. Technical Effects 10

3. Part 3 - DIETARY EXPOSURE 11

3.1. Intended Use Levels and Food Categories....................11

3.1.1. Estimated Daily Intake from the Intended Uses 11

3.1.1.1. Use of USDA Data....................11

4. Part 4 - SELF LIMITING LEVELS OF USE....................13

5. Part 5 - EXPERIENCE BASED ON COMMON USE IN FOODS BEFORE 1958..........14

6. Part 6 - NARRATIVE 15

6.1. Traditional and Current Uses 15
6.1.1. Quinoa Seed Uses 15
6.1.1.1. Common Knowledge of Safe Use of Quinoa 16
6.1.1.2. Nutritional Value of Source Material 17
6.1.2. Quinoa Sprout Uses 19
6.2. Safety Related Studies 20
6.2.1. Nutritional Value of Quinoa Sprout 20
6.2.2. Safety of Vitamin B Complex 21
6.2.3. Human Studies 24
6.2.4. Animal Studies 27
6.3. Summary and Discussion 32
6.4. Expert Panel Conclusion 34
7. Part 7 – SUPPORTING DATA AND INFORMATION 36
8. APPENDIX I 41
9. APPENDIX II 48

1. Part 1 - SIGNED STATEMENTS AND CERTIFICATION

1.1. Name and Address of Notifier

VIS VITALIS gmbh
A-5585 Unternberg - Moosham 29
AUSTRIA

1.2. Name of Notified Substance

The name of the substance that is subject of this GRAS determination is quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) preparation.

1.3. Intended Conditions of Use

VIS VITALIS GmbH (Vis Vitalis) intends to use quinoa sprouts extract rich in botanical B-vitamins as a nutrient at a maximum concentration of up to 300 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in foods such as Baked Goods, Ready-to-eat cereals, and Snack Foods. It is recognized that there are Standard of Identity requirements for some of these specified foods and these foods will not be referred by their commonly recognized names. Additionally, foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, as well as meat and poultry products that come under USDA jurisdictions are excluded from the list of intended food uses of the subject quinoa sprouts extract rich in botanical B-vitamins preparation.

1.4. Statutory Basis for GRAS Determination

This GRAS conclusion is based on scientific procedures in accordance with 21 CFR 170.30(a) and 170.30(b).

1.5. Exclusion from Premarket Approval

Vis Vitalis has determined that the use of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) preparation is Generally Recognized As Safe, consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This GRAS conclusion has been reached in accordance with requirements in 21 CFR 170.220. Therefore, the use of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) preparation is exempt from the requirement of premarket approval requirements of the FD&C Act.

1.6. Availability of Data & Information

The data and information that are the basis for this GRAS conclusion will be made available to FDA upon request by contacting Mr. Fuchs or Dr. Soni at the below addresses. The data and information will be made available to FDA in a form in accordance with that requested under 21 CFR 170.225(c)(7)(ii)(A) or 21 CFR 170.225(c)(7)(ii)(B).

Mr. Norbert Fuchs
General Manager
VIS VITALIS gmbh
A-5585 Unternberg - Moosham 29
AUSTRIA

Phone: +43 6476 / 80 52 13
E-Mail: office@panmol.com

or

Madhu G. Soni, PhD, FACN, FATS
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968

Phone: (772) 299-0746;
E-mail: sonim@bellsouth.net

1.7. Data Exemption from Disclosure

Privileged or confidential information such as trade secrets and/or commercial or financial information have been redacted from this document and the information contained in this dossier can be made publicly available.

1.8. Certification

Vis Vitalis certifies that, to the best of its knowledge, this GRAS conclusion is based on a complete, representative, and balanced dossier that includes all relevant information, available and obtainable by Vis Vitalis, including any favorable or unfavorable information, and pertinent to the evaluation of the safety and GRAS status of the use of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) preparation. Vis Vitalis accepts responsibility for the GRAS determination that has been made for quinoa sprouts rich in botanical B-vitamins as described in this dossier.

1.9. Name, Position/Title of Responsible Person who Signs the Dossier and Signature

Ms. Norbert Fuchs
General Manager
VIS VITALIS gmbh
A-5585 Unternberg - Moosham 29
AUSTRIA

Phone: +43 6476 / 80 52 13
E-Mail: office@panmol.com

Signature: ______________________________

1.10. FSIS/USDA – Use in Meat and/or Poultry

Vis Vitalis does not intend to add quinoa sprouts rich in botanical B-vitamins to any meat and/or poultry products that come under USDA jurisdiction. Therefore, 21 CFR 170.270 does not apply.

Phone: +43 6476 / 80 52 13
E-Mail: office@panmol.com

or

Madhu G. Soni, PhD, FACN, FATS
Soni & Associates Inc.,
749 46th Square,
Vero Beach FL, 32968

Phone: (772) 299-0746;
E-mail: sonim@bellsouth.net

1.7. Data Exemption from Disclosure

Privileged or confidential information such as trade secrets and/or commercial or financial information have been redacted from this document and the information contained in this dossier can be made publicly available if warranted.

1.8. Certification

Vis Vitalis certifies that, to the best of its knowledge, this GRAS conclusion is based on a complete, representative, and balanced dossier that includes all relevant information, available and obtainable by Vis Vitalis, including any favorable or unfavorable information, and pertinent to the evaluation of the safety and GRAS status of the use of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) preparation. Vis Vitalis accepts responsibility for the GRAS determination that has been made for Oak wood extract as described in this dossier.

1.9. Name, Position/Title of Responsible Person who Signs the Dossier and Signature

Ms. Norbert Fuchs
General Manager
VIS VITALIS gmbh
A-5585 Unternberg - Moosham 29
AUSTRIA

Phone: +43 6476 / 80 52 13
E-Mail: office@panmol.com

vis vitalis gmbh
(b) (6)

29 | 5585 Unternberg
52 00 | Fax: +43(0)6476/80 52 21

Signature: ______[redacted]

1.10. FSIS/USDA – Use in Meat and/or Poultry

Vis Vitalis does not intend to add Oak wood extract to any meat and/or poultry products that come under USDA jurisdiction. Therefore, 21 CFR 170.270 does not apply.

2. Part 2 – IDENTITY, SPECIFICATION, MANUFACTURING AND TECHNICAL EFFECTS

2.1. Identity

2.1.1. Description

The subject of this GRAS assessment is a standardized extract prepared from the quinoa (*C. quinoa* Willd) sprout. The quinoa sprout extract is rich in botanical B-vitamins. It is an off-white to yellow color dry powder with a characteristic grain odor and nutty taste. The quinoa sprout extract rich in B-vitamins produced by Vis Vitalis is marketed under the trade name PANMOL® B-COMPLEX US100. General descriptive characteristics and properties of quinoa sprout extract manufactured by Vis Vitalis are summarized in Table 1.

Table 1. General Descriptive Characteristics of Quinoa Sprout Extract

Parameter	Description*
Botanical source	*Chenopodium quinoa* Willd
Botanical family	Celastraceae
Plant part used	Quinoa sprouts
Appearance	Off white to yellow powder
Color	Yellowish
Odor	Typical of grain
Taste	Nutty
Functional use	Dietary supplement; Food ingredient
Shelf life	30 months

*Based on information provided by Vis Vitalis (2016)

2.1.2. Taxonomy of Botanical Source

The hierarchical classification of the source plant *C. quinoa* Willd is presented in Table 2. The taxonomical classification of quinoa was first made from the color of the plant and fruits. Subsequently, it was based on the morphological types of the plant. Despite the wide variation observed, quinoa is considered to be one single species. For practical reasons, quinoa, like maize, has been classified as a race. Quinoa collected in Ecuador, Peru, and Bolivia has been classified into 17 races; however, more races may exist. Two types of inflorescence have been described (Valencia-Chamorro, 2003): (1) Glomerulates – small groups of flowers (glomeruli) originating from tertiary axes; (2) Amaranthiformes have glomeruli originating mainly from secondary axes. Botanically, quinoa is related to beets, chard and spinach, and in fact the leaves can be eaten as well as the grains.

Table 2. Classification of *Chenopodium quinoa* Willd

Kingdom	Plantae – Plantae - plantes, Planta, Vegetal, plants
Subkingdom	Viridiplantae
Infrakingdom	Streptophyta – land plants
Superdivision	Embryophyta
Division	Tracheophyta – vascular plants, tracheophytes
Subdivision	Spermatophytina – spermatophytes, seed plants, phanérogames
Class	Magnoliopsida
Superorder	Caryophyllanae
Order	Caryophyllales
Family	Amaranthaceae – pigweed, amaranths
Genus	*Chenopodium* L. – goosefoot
Species	*Chenopodium quinoa* Willd. – quinoa

Quinoa is generally considered to be a single species within the Chenopodiaceae. Quinoa is used much as a cereal crop, yet it is not a grain of grass species and has been classified as a pseudocereal. Wilson (1990) states that over 120 species have been found within the genus *Chenopodium*. Two species, *C. berlandieri* and *C. hircinum* contain the same chromosome number as quinoa ($2n = 36$). Wilson (1988) has obtained interspecific hybridization between these species. The most commonly cultivated and commercialized are white (sometimes known as yellow or ivory) quinoa, red quinoa, and black quinoa. The plant grows 1-3 m high. The roots can reach the depth of up to 30 cm. The stem is cylindrical, 3.5 cm in diameter, it can be either straight or branched and its color is variable. Depending on the variety, it changes from white, yellow, or light brown to red.

2.1.3. Quinoa Seeds

Quinoa seeds are flat, oval-shaped and usually pale yellow, but the color can range from pink to black, and the taste can vary from bitter to sweet. The quinoa seeds, which are small, round, and flattened on two surfaces, measure about 1.5 mm in diameter and about 350 seeds weigh 1 g (Ruales and Nair 1993). The seeds are covered by perigonium, which has the same color as the plant such as white, yellow, gray, light brown, pink, black, or red. When dried the seed can be easily removed. Additional two layers enclose the seed. Pericarp adheres to the seed; it contains saponins which transmit the bitter taste characteristic of quinoa. Episperm encloses the cylindrical seed as a thin layer. The embryo can make up to 60% of the seed weight. It forms a ring around the perisperm. The high protein content in quinoa, as compared to cereals, is explained by the high proportion of embryo (Valencia-Chamorro, 2003).

Quinoa seed contains saponins, which are normally removed mechanically prior to being sold, or otherwise need to be carefully rinsed off prior to cooking to remove their bitter taste.The seed pericarp contains a resin with 2 to 6% saponin (Cusack, 1984) which must be removed prior to consumption. Unless these saponins are removed, the grain tastes quite bitter. Quinoa has a very delicate taste, often described as nutty or earthy. Quinoa has an interesting texture that can add crunchiness to almost any recipe. Quinoa can be classified into "bitter" and "sweet" varieties that reflect the saponin content, which is much lower in the sweet varieties (FAO, 2013). Quinoa produces super nutritious sprouts very quickly.

2.1.4. Quinoa Sprouts

The practice of sprouting is widely used to improve the nutritional value of grain seeds. Several nutritive factors such as vitamin concentrations and bioavailability of trace elements and minerals increase during germination (Lintschinger et al., 1997). The germ of each quinoa grain is larger than that of any other grain and encircles the outer surface, explaining its exceptionally high protein content. Allowing the seeds to sprout seems to increase the antioxidant content even further (Pasko et al., 2009). In recent years, quinoa sprouts are rapidly gaining popularity because of a wide variety of health benefits. As a result, quinoa sprout has been extensively investigated as a means of delivering nutrients.

2.2. Specifications

Food grade specifications of quinoa sprout extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) have been established by Vis Vitalis and are summarized in Table 3. The analytical results from three lots are provided in Appendix I, while current standard food grade specifications and analysis from two additional lots are provided at the end of this document. It should be noted that during the course of the time (from 2013 to 2016) Vis Vitalis has made some changes/improvements in matters of quality parameters, for example reduced requirements of "plate count" to 50,000 cfu/g. The certificate of analysis from two lots with higher requirement (from earlier years) are included separately at the end of this document. The certificate of analysis from all lots demonstrate that PANMOL® B-COMPLEX US100 is consistently manufactured to meet the current specifications. The product is standardized to the content of individual vitamin B complex that includes B1, B2, B3, B5, B6, B7, B9, and B12. General compositional analysis of quinoa sprout extract rich in botanical B-vitamins is presented in Table 4. PANMOL® B-COMPLEX US100 is certified as Kosher and Halal.

Table 3. Specifications of Quinoa Sprout Extract PANMOL® B-COMPLEX US100

Test Parameter	Specification	Assay method
Description	Off white to yellow powder	Visual
Vitamin B1 as thiamin	≥ 150 mg/100 g	HPLC + FLD*
Vitamin B2 as riboflavin	≥ 170 mg/100 g	HPLC + DAD*
Vitamin B3 as total niacine	≥ 2000 mg/100 g	HPLC + DAD*
Vitamin B5 as pantothenic acid	≥ 1000 mg/100 g	HPLC + DAD*
Vitamin B6 as pyrodoxin	≥ 200 mg/100 g	HPLC + DAD*
Vitamin B7 as biotin	≥ 30 mg/100 g	Vita Fast**
Vitamin B9 as folic acid (folate)	≥ 20 mg/100 g (40 mg/100 g)	Vita Fast**
Vitamin B12 as cobalamine	≥ 0.6 mg/100 g	Vita Fast**
Loss on drying	Max. 8%	SOP-02-082
Heavy metals		
Lead	< 1.0 ppm	SAM07***
Arsenic	< 1.0 ppm	SAM07***
Mercury	< 0.1 ppm	SAM07***
Cadmium	< 1.0 ppm	SAM07***
Microbiological assays		
Total plate count	< 50,000 cfu/g	SOP-02-062
Mold	< 500 cfu/g	SOP-02-035
Yeast	< 500 cfu/g	SOP-02-035
Enterobacteriaceae	< 100 cfu/g	SOP-02-034
Coliforms	absent/g	SOP-02-090

*HPLC-method based on internal SOPs; **VitaFast-Testkit by R-Biopharm, microbiologic vitamin assay; ***ICP-MS standard addition method for analysis of heavy metals, with certified CertiPur Standards
Based on information provided by Vis Vitalis (2016)

Table 4. Typical Compositional Analysis and Nutritional Value of Quinoa Sprout Extract (PANMOL® B-COMPLEX US100)*

Assay	Typical value
Carbohydrate (g/100 g)	68.5
Fiber (g/100 g)	4.5
Sugars (g/100 g)	3.1
Fat total (g/100 g)	7.1
Saturated	0.8
Protein (g/100 g)	13.5
Sodium (g/100g)	<0.1
Energy /100 g	401 kcal (1693 kj)

*Based on information provided by Vis Vitalis (2016)

2.3. Manufacturing Process

Quinoa sprout extract PANMOL® B-COMPLEX US100 is manufactured at facility operating according to the principles of Good Manufacturing Practice [according to regulation (EC) No. 852/2004], as presented in Figure 1. After delivery to the production facility, quinoa grains are inspected and washed to remove extraneous material. The grains are then dried, followed by soaking in water to induce sprout germination in the presence of a nutrient cocktail containing a mixture of B vitamins. After germination to the desired stage, the sprouts are dried, ground into flour and sterilized. The product is tested and standardized to meet the prescribed specifications. The product is packaged, labeled, and stored for distribution. The preparation procedure assures a consistent and high-quality product. All ingredients used in the manufacturing of PANMOL® B-COMPLEX US100 are either approved as food additives or are GRAS substances.

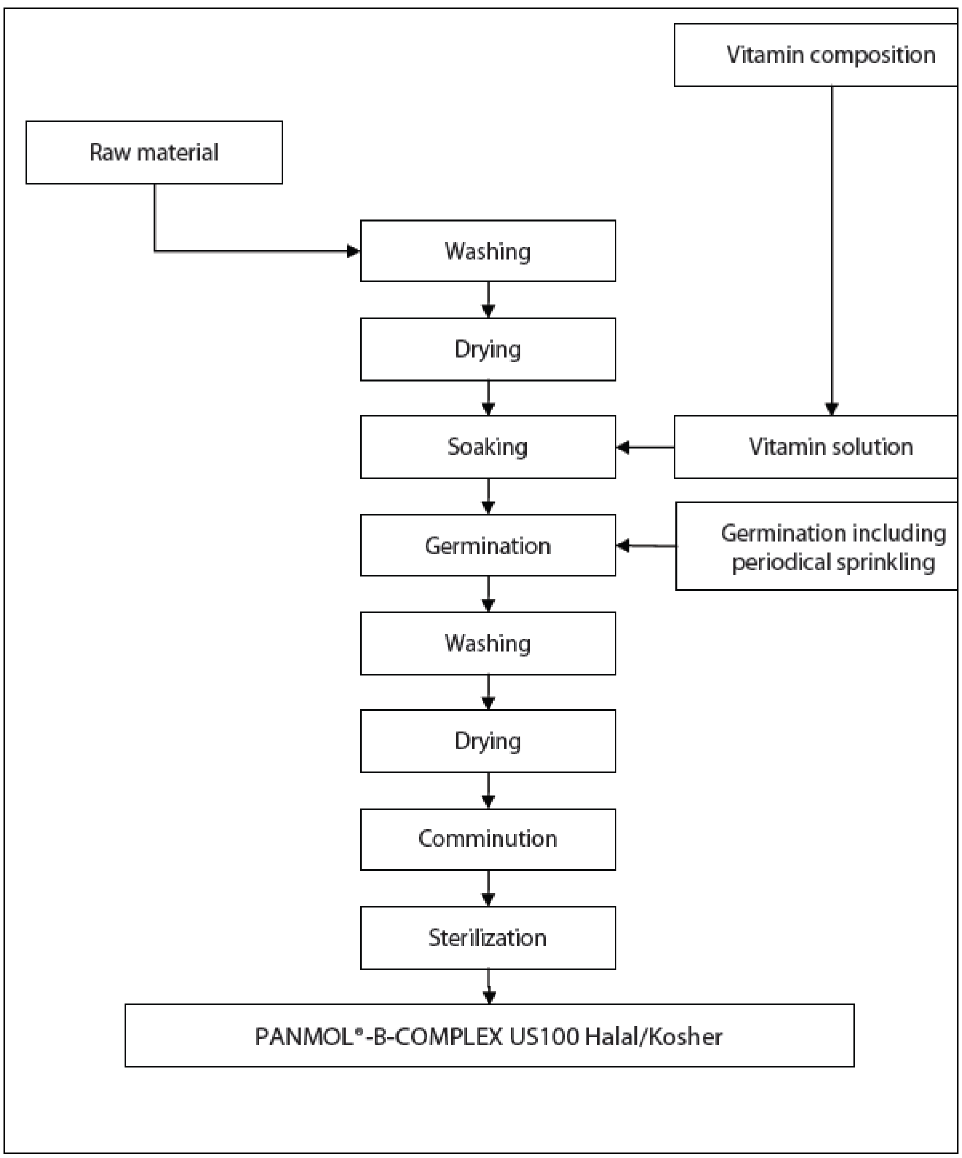

Figure 2. Manufacturing process of Quinoa Sprout Extract (PANMOL® B-COMPLEX US100)

2.4. Technical Effects

The intended uses of quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) are as a nutrient source [21 CFR 170.3(o)(20)] in selected foods. The nutritive values of quinoa and, in turn, quinoa sprouts are well recognized. The traditionally known biological functions of quinoa and quinoa sprouts include nutrient supplementation and rehydration. Thus, the intended use of quinoa sprouts extract rich in botanical B-vitamins is as an added nutrient to specific foods for individuals who wish to increase and/or supplement their daily intake of specific nutrients such as the B vitamins.

3. Part 3 - DIETARY EXPOSURE

3.1. Intended Use Levels and Food Categories

Vis Vitalis intends to use quinoa sprouts extract rich in botanical B-vitamins as a nutrient source at a maximum concentration of 300 mg/serving in foods such as Baked Goods, Ready-to-eat cereals, and Snack Foods. It is recognized that there are Standard of Identity requirements for some foods and these foods will not be referred by their commonly recognized names. Additionally, foods that are intended for infants and toddlers, such as infant formulas or foods formulated for babies or toddlers, as well as meat and poultry products that come under USDA jurisdictions are excluded from the list of intended food uses of the subject quinoa sprouts extract rich in botanical B-vitamins preparation. The proposed use levels of PANMOL® B-COMPLEX US100 in the various food categories are summarized in Table 5.

3.1.1. Estimated Daily Intake from the Intended Uses

3.1.1.1. Use of USDA Data

The possible daily intake of quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) is estimated as per FDA guidelines using "maximum" intended use levels of PANMOL® B-COMPLEX US100 and mean consumption estimates of designated food categories using intake by USDA, Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96 database (Smiciklas-Wright et al., 2002). Based on USDA CSFII surveys for quantities of foods consumed daily, the mean and 90th percentile consumption of quinoa sprouts extract rich in botanical B-vitamins from the proposed uses in Baked Goods, Ready-to-eat cereals, and Snack Foods (Table 5). The CSFII data provides the intake levels of several different types of baked goods. In Table 5, values for biscuits are included. The intended use of quinoa sprouts extract rich in botanical B-vitamins at levels up to 300 mg *per* serving will result in mean and 90th percentile intake of 775.07 and 1487.28 mg/person/day, respectively. For safety assessment purposes high levels of 1500 mg/person/day is considered.

Table 5. Intended Use Levels and Possible Mean and 90th Percentile Daily Intake of PANMOL® B-COMPLEX US100 Based on USDA Data[1]

Food category	Consumption of food product (g/day)		Use levels/ serving (mg)	Serving size; RACC (g)	Daily intake by adult (mg/person)	
	Mean	90th %			Mean	90th %
Baked Goods[2]	64	118	300	55	349.01	643.64
Ready-to-eat cereals	56	104	300	110	152.73	283.64
Snack Foods	41	84	200	30	273.33	560.00
				Total (mg/person/day)	**775.07**	**1487.28**

[1]The daily intake calculations are based on USDA data (CSFII) and mean portion size; [2]Biscuits intake is used to represent baked good- also represents intake of waffles, snack/bars and frozen snacking cereals. Serving size is based on Reference Amounts Customarily Consumed per Eating Occasion (21 CFR 101.12) and other related information.

As the subject of present GRAS assessment, PANMOL® B-COMPLEX US100 contains B vitamins, the resulting intake of individual vitamin Bs from the intended uses is summarized in Table 6.

Table 6. Possible Maximum Daily Intake of Individual B Vitamins from the Uses of PANMOL® B-COMPLEX US100

B Vitamin	Maximum Daily Intake
B1 as thiamin	2.25 mg
B2 as riboflavin	2.55 mg
B3 as niacin	30.00 mg
B5 as pantothenic acid	15.00 mg
B6 as pyridoxine	3.00 mg
B7 as biotin	450 µg
B9 as folate	600 µg
B12 as cobalamine	9 µg

4. Part 4 - SELF LIMITING LEVELS OF USE

Quinoa sprout extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) will cost more as a source of B-complex vitamins. As such, users will control the amounts used due to economic reasons.

5. Part 5 - EXPERIENCE BASED ON COMMON USE IN FOODS BEFORE 1958

The statutory basis for the conclusion of GRAS status of quinoa sprout extract rich in botanical B-vitamins in this document is not based on common use in food before 1958. The GRAS determination is based on scientific procedures. As described below, quinoa sprouts and its preparations have been commonly used in food prior to 1958. Notwithstanding this, it is reasonable to conclude that, since the source material is food, humans are exposed to quinoa suggesting that it was present in food prior to 1958.

6. Part 6 - NARRATIVE

6.1. Traditional and Current Uses

Quinoa (pronounced *KEEN-wah*) is a pseudocereal native to the Andean regions of South America. It is one of the oldest crops of the American continent. Archeological findings in northern Chile have shown that quinoa was used prior to 3000 BC in Ayacucho, Peru, The available evidence indicate that quinoa was cultivated in Chile before 5000 BC. Before the Spanish conquest, quinoa plant was widely cultivated in the whole Andrean region, in Columbia, Equador, Peru, Bolivia, and Chile. However, the habits and traditional foods of natives were replaced with foreign crops such as wheat and barley. Therefore, quinoa was cultivated either in small plantations in rural areas for domestic consumption or as borders for other crops such as potatoes or maize. For this reason, it was classified as food for poor people (Valencia-Chamorro, 2003). Although, quinoa is actually not a grain, it is a seed (an achene) that is prepared and consumed like a grain. The nutrient content of quinoa is higher than most grains. It has a crunchy texture and nutty flavor. Quinoa is gluten-free, so it can be consumed by individuals sensitive to gluten or wheat. Because of its high nutritional value, indigenous peoples and researchers often refer to it as "the golden 'grain' of the Andes."

Quinoa, as a food grain, has been recognized for centuries as an important food crop in the high Andes of South America. The very name quinoa in the Quechua and Aymara languages means "Mother Grain." In South and Central America, two closely-related species, Canihua (*C. pallidacuale*) and huazontle (*C. nuttaliae*) are also utilized for food. The descendants of the Inca Empire, 8 to 10 million Quechua and Aymara Indians, still use quinoa as an important component of their diet. Quinoa's food value in the developed world lies primarily with its seed. The whole grain can be boiled and combined with other foods as part of a meal, such as in a soup, or made into flour to be used to make breads or drinks, among other food types. There are several products derived from quinoa, such as puffs, flour, pastas, flakes, granola, energy bars, etc (FAO, 2013).

6.1.1. Quinoa Seed Uses

After removal of pericarp, quinoa is cooked like rice. Its flavor is generally regarded as nutty with a texture similar to North American wild rice. The grain has been used in soups, pasta, as puffed cereals, in extruded foods (in blends with corn and with oats), as desserts and side dishes. The seeds are ground to flour to produce toasted and baked goods (cookies, breads, biscuits, noodles, flakes, tortillas, pancakes). Its flour works well with wheat flour or grain or corn meal for breads and biscuits. Cooked quinoa consists of water (71.6%), carbohydrates (21.3%), protein (4.4%) and fat (1.92%). One cup of cooked quinoa (185 grams) contains 222 calories. It is usually boiled and consumed as a side dish, as breakfast porridge, added to salads, or used to thicken soups. Furthermore, quinoa seeds can be fermented to make beer, or a traditional ceremonial alcoholic beverage from South America called “chicha” (Graf et al., 2015). The available information suggests that quinoa is a nutritious food because it is a good source of many nutrients, which when consumed with other foods can be a great part of a balanced diet.

Quinoa (*Chenopodium quinoa* Willd), which is considered a pseudocereal or pseudograin, has been recognized as a complete food (Abugoch James, 2009). It is one of the oldest crops of the American continent and has been consumed for thousands of years. In recent years, its composition has attracted the attention of the scientific community for its high nutritional value, being rich in proteins, lipids, fibers, vitamins and minerals, with an extraordinary balance of essential amino acids. Its grains have higher nutritive value than traditional cereals and it is a promising worldwide cultivar for human consumption and nutrition (Vega-Galvez et al., 2010). The available information suggests that quinoa has remarkable nutritional properties. Because of all these properties, it has been used as a novel functional food.

6.1.1.1. Common Knowledge of Safe Use of Quinoa

There is common knowledge of human consumption of quinoa without any safety concerns. As described earlier, quinoa is a long-time staple of the Andes and newly emerged favorite of health-minded eaters around the world. Quinoa was cultivated and used by pre-Columbian civilizations and was replaced by cereals on the arrival of the Spanish, despite being a local staple food at the time. Thus, it is one of the oldest crops of the American continent and has been consumed for thousands of years. Quinoa is considered as a highly nutritious product that provides all of the body's requirements for carbohydrates, fats, protein, vitamins, minerals, and fiber. Due to the high content of essential amino acids in its protein, quinoa is considered the only plant food that provides all essential amino acids, which are extremely close to human nutrition standards established by the Food and Agricultural Organization (FAO). The balance of essential amino acids in quinoa protein is superior to wheat, barley and soybeans, comparing favorably with milk protein (FAO, 2013).

The Food and Agricultural Organization of the United Nations declared 2013 as the International Year of Quinoa in recognition of the indigenous peoples of the Andes, who have maintained, controlled, protected and preserved quinoa as food for present and future generations thanks to their traditional knowledge and practices of living in harmony with nature. In declaring 2013 as the "International Year of Quinoa", the UN General Assembly also pointed out that quinoa's nutritional qualities and its adaptability to different agro-ecological conditions. Quinoa is considered as an "ally in the fight against hunger and food insecurity."[1]

The majority of quinoa consumed in the United States comes from South America. Peru remains the largest commercial producer of quinoa, harvesting 41,079 metric tons in 2010. Bolivia was the second largest producer with 29,500 metric tons. Together, these two South American countries produced nearly 99% of all commercially grown quinoa in 2010. In terms of export sales, quinoa has risen to the level of an $87 million dollar business in these two countries. Some commercial quinoa production takes place in the United States (Colorado Rockies), although total cultivation remains under 10,000 pounds. The USDA National Nutrient Database for Standard Reference has listed five food products under three categories that contain quinoa (USDA, 2016). These food categories includes Cereal Grains and Pasta; Legumes and Legume Products; and Branded Food Products Database. Additionally, sprout quinoa is also available as salad.

In recent years, and given the popularity of quinoa, an amazing range of products are made with quinoa, from breakfast cereals to beverages. Quinoa pasta is popular among those following a gluten-free diet, and the grain is a favorite ingredient in granolas, breads, and crackers. Home bakers can try "ancient grain" blends or cook with quinoa flakes and flours. In the restaurant world, the National Restaurant Association named quinoa as the hottest trend in side dishes in its 2010 "What's Hot" survey of chefs.[2]

---

[1] Available at: http://www.fao.org/quinoa-2013/faqs/en/

[2] Available at: http://www.restaurant.org/News-Research/Research/What-s-Hot

In summary, quinoa is a grain-like food crop that has provided nutrition and sustenance to Andean indigenous cultures for thousands of years and now plays an increasing role in human diets worldwide. Quinoa has been promoted as an alternative agricultural crop due to its stress-tolerant characteristics and marketed as a "super food" for its nutritious qualities. The available information suggests that there is a long history and common knowledge of exposure to quinoa as a food (staple) in South America as well as in the USA. This also suggests that quinoa and its sprouts can be safely consumed by human beings.

6.1.1.2. Nutritional Value of Source Material

Nutritionally, quinoa is considered to be a whole grain. Whole grains, like quinoa, provide essential vitamins, minerals and fiber which help regulate the digestive system and keep you fuller and more satisfied. Quinoa is naturally gluten-free and contains iron, B-vitamins, magnesium, phosphorus, potassium, calcium, vitamin E and fiber. In comparison with wheat, barley and yellow corn, quinoa was found to be higher in calcium, phosphorus, magnesium, potassium, iron, copper, manganese and, zinc and was lower in sodium than the other grains (Oelke et al., 2016). It is one of only a few plant foods that are considered to be a complete protein and comprised of all nine essential amino acids (Johnson and Aguilera, 1979). The protein content (12-18%) is relatively high compared to conventional cereal grains (Johnson and Croissant, 1985). Quinoa also has a high protein to carbohydrate ratio when compared to other grain products. It was proposed by NASA to be an ideal food for long duration space flights (FAO, 2013). Quinoa also contains healthy fatty acids. Approximately 25% of quinoa's fatty acids come in the form of oleic acid, a heart-healthy monounsaturated fat, and about 8% comes in the form of alpha-linolenic acid (ALA), the omega-3 fatty acid most commonly found in plants. The proximate analysis of quinoa is provided in Table 7, while nutrient content comparison, essential amino acids comparison and mineral content comparison with other common foods are presented in Tables 8, 9 and 10, respectively. The detailed information on the nutrients in quinoa from the USDA National Nutrient Database for Standard Reference Release 28 (USDA, 2016) are provided in Appendix II.

Table 7. Proximate analysis of Quinoa

Component	Percent of seed
Protein (N x 6.25)	15.8
Starch	65.5
Sugars	3.2
Oil	7.1
Ash	4.3
Crude fiber	2.5
Saponin	3.7

Table 8. Nutrient contents of quinoa and selected foods, per 100 g dry weight

Parameters	Quinoa	Quinoa Sprout*	Maize	Rice	Wheat
Protein (g/100 g)	16.5	13.5	10.2	7.6	14.3
Fat (g/100 g)	6.3	7.1	4.7	2.2	2.3
Total Carbohydrates (g/100 g)	69.0	68.5	81.1	80.4	78.4
Iron (mg/100 g)	13.2		2.1	0.7	3.8
Zinc (mg/100 g)	4.4		2.9	0.6	4.7
Energy (Kcal/100 g)	399	401	408	372	392

Adapted from FAO, 2013; Koziol, 1992; *subject of present GRAS

Table 9. Essential amino acid pattern of quinoa compared to wheat, soy, and FAO reference pattern (1973) for evaluating proteins

	Amino acid content (g/16 g N)			
Amino acid	**Quinoa**	**Wheat**	**Soy**	**FAO**
Isoleucine	4.0	3.8	4.7	4.0
Leucine	6.8	6.6	7.0	7.0
Lysine	5.1	2.5	6.3	5.5
Phenylalanine	4.6	4.5	4.6	
Tyrosine	3.8	3.0	3.6	
Cystine	2.4	2.2	1.4	
Methionine	2.2	1.7	1.4	
Threonine	3.7	2.9	3.9	4.0
Tryptophan	1.2	1.3	1.2	1.0
Valine	4.8	4.7	4.9	5.0

Table 10. Comparison of mineral content in barley, yellow corn, wheat and quinoa*.

Crop	**Ca (%)**	**P (%)**	**Mg (%)**	**K (%)**	**Na (ppm)**	**Fe (ppm)**	**Cu (ppm)**	**Mn (ppm)**	**Zn (ppm)**
Barley	0.08	0.42	0.12	0.56	200	50	8	16	15
Yellow Corn	0.07	0.36	0.14	0.39	900	21	—	—	
Wheat	0.05	0.36	0.16	0.52	900	50	7	14	
Quinoa	0.19	0.47	0.26	0.87	115	205	67	128	50

*The quinoa values are an average of 15 cultivars analyzed (Ballon, 1987).

Quinoa is considered to be a nutritious food because it is a good source of many nutrients, which when consumed with other foods comprise a great part of a balanced diet. For a long time, it has been recognized that the nutritional value of quinoa is superior to traditional cereals and is, in fact, superior to milk solids in feeding trials (White et al., 1955). Protein content ranges from 10 to 18% with a fat content of 4.1 to 8.8%. Starch, ash, and crude fiber average 60.1, 4.2, and 3.4%, respectively (DeBruin, 1964). The ash has been found to primarily consist of potassium and phosphorus (65% of total). Calcium and iron are significantly higher in quinoa than in rice, maize, wheat, or oats (White et al., 1955; DeBruin, 1964).

Carbohydrates make up 21% of cooked quinoa, which is comparable to barley and rice. About 83% of the carbohydrates are starches. The rest consists mostly of fiber, but also a small amount of sugars (4%), such as maltose, galactose and ribose (USDA, 2016). Quinoa has a relatively low glycemic index score of 53, which means that it should not cause a rapid spike in blood sugar after consumption. The carbohydrates in quinoa consist mainly of starch, insoluble fibers and small amounts of sugars. Quinoa also contains some resistant starch, which escapes digestion and feeds the friendly gut bacteria.

Quinoa provides 16% protein (dry weight), which is higher than most cereal grains, such as barley, rice, and corn (Abugoch, 2009; USDA, 2016; Dixit, et al., 2011). The protein is considered to be comparable to casein, a high-quality protein from dairy products. Quinoa is considered to be a "complete" protein source, which means that it provides all the essential amino acids (Dixit, et al., 2011; Lee, et al., 2003). It is exceptionally high in the amino acid lysine, which is usually lacking in the plant kingdom. It is also high in methionine and histidine, making it an excellent plant-based protein source (UMASS, 2016; Abugoch, 2009).

Quinoa is a good source of antioxidants and minerals, providing more magnesium, iron, fiber and zinc than many common grains (Abugoch, 2009; Alvarez-Jubete, et al., 2009a; Alvarez-Jubete, et al., 2009b). One study concluded that quinoa had the highest antioxidant content of 10 cereals, pseudocereals and legumes (Mizui, et al., 1990). Quinoa seeds can also be sprouted, ground and used as flour, or they can be popped like popcorn. Quinoa is an excellent food for babies (Abugoch, 2009; Jancurova, et al., 2009).

In summary, the above information demonstrate that as a staple food commodity, quinoa is similar, in its contents of carbohydrates, protein, essential amino acids, fats, fiber and minerals, to other commonly consumed foods. This also suggests that quinoa is as nutritive as any other commonly consumed food and is unlikely to cause any health hazards. The available literature also suggests that unique benefits of quinoa are related to its high nutritional value. The composition of quinoa sprout preparation, subject of present GRAS assessment, is also similar to other common foods.

6.1.2. Quinoa Sprout Uses

Sprouted quinoa has been used in salads and sandwiches just like alfalfa sprouts. The raw quinoa sprouts are used on sandwiches or in stir fries and salads. Quinoa leaves have also been eaten similar to spinach, and the germinated quinoa seedlings (quinoa sprouts) have been incorporated in salads (Graf et al., 2015). In recent years, quinoa sprouts are rapidly gaining popularity because of a wide variety of health benefits. As a result, quinoa sprouts have been extensively investigated as a means of delivering nutrients. Quinoa sprouts rich in botanical B-vitamins have been used in the tropics as a nutritive and as a rehydrating agent to restore electrolyte balance in cases of diarrhea (Adams and Bratt, 1992). It is also gaining popularity as a sports beverage because of its higher levels of electrolytes such as potassium and magnesium. It is well recognized by several researchers and nutritionists that many individuals across different subpopulations are deficient in the B vitamins (Kennedy, 2016; Lanska, 2010; Busse, 2013). Quinoa grain and sprouts have both traditional and non-traditional uses, as well as value-added industrial innovations which are now commercially available, such as ready-to-eat cereals, pasta, granola bars, or breads. Quinoa seeds can also be sprouted, ground and used as flour, or they can be popped like popcorn. Quinoa is an excellent food for babies (Abugoch, 2009; Jancurova, et al., 2009).

Quinoa sprouts rich in B vitamins (PANMOL® B-COMPLEX US100) can be consumed as grounded sprouts in the same recipes as the normal quinoa sprouts with the noted addition of extra source of B vitamins. In European countries, quinoa sprouts rich in botanical B-vitamins, manufactured by Vis Vitalis, are marketed according to effective food laws [VO (EG) 178/2002] as a food or food ingredient. The declaration of these quinoa sprouts rich in B-vitamins in the list of ingredients of food, food supplements or dietary products as: Quinoa sprouts and/or quinoa sprouts rich in natural B-vitamins and/or quinoa sprouts with biologically active B-vitamin is legally allowed and corresponds to effective European food labeling directives (VO 2000/13/EG).

Quinoa sprouts enriched with B vitamins is approved by Health Canada as a source of folate and the other B-vitamins[3].

In a study with immunocompromized subjects, Fuchs et al. (1996) reported that the immune parameters of the patients supplemented with micronutrients obtained from botanical sources (whole wheat), recovered quite rapidly. This led to an increased search for botanical source providers of vitamins, minerals and trace elements. Since, at the time, various general categories of raw materials such as yeast or liver extracts provided only limited sources, the research team began to investigate the potential of grain sprouts. Of special interest was quinoa as it was free from gluten and can efficiently absorb exogenously applied minerals. Quinoa can germinate even in the presence of high electrolyte concentrations (Lintschinger et al., 1997). Quinoa germinates exceptionally fast (radicle protrusion within few hours), and it is able to grow in areas too dry or too saline for the major cereal crops. A patent exist on the treatment of germinating quinoa with a vitamin B complex solution. Germination of quinoa in vitamin-rich medium is a promising strategy to enhance the nutritional value of this matrix (Pitzschke et al., 2015). The resultant seedlings contain elevated amounts of B vitamins, which remain present after wash cycles (Fuchs et al., 2007).

6.2. Safety Related Studies

As such, the use of quinoa products are accepted as safe and has limited the need for detailed scientific studies to further demonstrate the safety of these products or how quinoa functions in the human body. However, given its increasing popularity and use, recent investigations have increased the need to evaluate its utility and the efficacy for different health conditions. A plethora of research has recently emerged on quinoa's chemical constituents and therapeutic properties, depicting the crop as an important resource for functional food development. A comprehensive search of the published literature did not uncover any significant adverse effects associated with quinoa, quinoa sprouts food products, or quinoa rich in botanical B-vitamins (PANMOL® B-COMPLEX US100). Most of the reports uncovered dealt with research aimed at therapeutic applications and health benefits of quinoa or quinoa sprouts. Given the use of quinoa and quinoa sprouts as food, these studies will not be discussed in detail. Rather, a select few will be summarized to illustrate the utility and safety of these types of food products.

6.2.1. Nutritional Value of Quinoa Sprout

It is recognized that sprouting induces desirable changes from a nutritional point of view, and the pseudocereal sprouted seeds, such as quinoa are nutritionally superior compared with the non-sprouted seeds. The increase in antioxidant activity with sprouting is one of the many metabolic changes that take place upon sprouting of seeds, mainly due to an increase in the activity of the endogenous hydrolytic enzymes. Other common metabolic changes include improved protein and starch digestion, increased sugar and B vitamin content and decreased levels of phytate and proteases inhibitors (Alvarez-Jubete, et al., 2009a).

The quinoa sprouts preparation rich in botanical B-vitamins, obtained by a proprietary production process, is a patented, standardized product of quinoa with increased B-vitamin content as compared to normal quinoa sprouts. As presented in Table 8, the compositional

---

[3] B-vitamins-enriched Quinoa sprout Available at: http://webprod.hc-sc.gc.ca/nhpid-bdipsn/ingredReq.do?id=14687&lang=eng.

analysis of quinoa sprout rich in B-vitamins, the subject of present GRAS, is similar to other common foods such as maize, rice, wheat for its carbohydrate, fats, protein energy levels.

Quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) contains all the members of vitamin B complex family. The preparation contains not only the 8 familiar group B-vitamins but also a multitude of organically bound and biologically active B-vitamins that can otherwise be found only in highly nutritious foodstuffs such as whole meal grain or wheat sprouts. A comparison of B-vitamins from PANMOL® B-COMPLEX US100, common quinoa sprout and yeast is presented in Table 11. As yeast extract is considered a good source of supplements, particularly for B-vitamins, the levels of B-vitamins from quinoa sprouts rich in botanical B-vitamins, the subject of this present GRAS determination, are compared in Table 11. This information shows that, as compared to yeast, the levels of B-complex vitamins present in PANMOL® B-COMPLEX US100 is higher for thiamin, riboflavin, niacin, pantothenic acid, pyridoxine, biotin, cobalamine and folic acid.

Table 11. Content of B-Vitamins in 100 g PANMOL® B-COMPLEX US100, Compared to Common Quinoa Sprouts and Yeast.

Vitamins	Panmol®-B-Complex	Common Quinoa sprout	Yeast*
B1 as thiamin	150 mg	0.198 mg	1.43 mg
B2 as riboflavin	170 mg	0.396 mg	2.31 mg
B3 as niacin	2000 mg	2.930 mg	17.40 mg
B5 as pantothenic acid	1000 mg	1.047 mg	3.46 mg
B6 as pyridoxine	200 mg	0.223 mg	0.684 mg
B7 as biotin	30000 µg	0.00 µg	33.00 µg
B9 as folate	40000 µg	0.00 µg	716.00 µg
B12 as cobalamine	600 µg	0.00 µg	0.00 µg

*Adapted from- Food Composition and Nutrition Tables; 6th Revised and Completed Edition. CRC Press. p1127

Based on the available information related to quinoa, quinoa sprouts and other similar foods, as well as data related to the compositional analysis (Table 4 or Table 11) of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) and as described below, it is unlikely that the preparation by itself, or any of its constituents, raise any safety related concerns following its consumption as a food ingredient at the intended use levels proposed in this GRAS document. As the preparation contains B-complex vitamins, an attempt has been made in the following sections to make sure that the intended uses of quinoa sprouts rich in botanical B-vitamins preparation (PANMOL® B-COMPLEX US100) and resulting intake of B-complex vitamins is safe.

6.2.2. Safety of Vitamin B Complex

The vitamin B-complex refers to all of the known essential water-soluble vitamins except for vitamin C. "Vitamin B" was once thought to be a single nutrient. Researchers later discovered these extracts contained several vitamins, which were given distinguishing numbers and names. These include thiamin (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), pantothenic acid (vitamin B5), pyridoxine (vitamin B6), biotin, folic acid and the cobalamine (vitamin B12). Each member of the B-complex family has a unique structure and performs unique functions in the human body. Vitamins B1, B2, B3, and biotin participate in different aspects of energy production, vitamin B6 is essential for amino acid metabolism, and vitamin B12 and folic acid facilitate steps required for cell division. Each of these vitamins has many additional functions, though none that require all B-complex vitamins simultaneously. Human requirements for each B vitamin vary considerably- from 3 µg/day for vitamin B12 to 18 mg/day for vitamin B3 in adult males, for example.

The available information indicate that many individuals do not get enough B vitamins. According to the USDA, deficiencies in folic acid, B12, and B6 are especially common. The ways in which the B vitamins are important in nutrition are indicated in Table 12. A food product, like quinoa sprouts rich in botanical B-vitamins preparation (PANMOL® B-COMPLEX US100) can help alleviate this deficiency.

Table 12. Role and Function of the Vitamin B-complex in the Body

Vitamins	Role/function in the body	Signs of deficits
Vitamin B1 (Thiamin)	Essential for metabolism of fats and carbohydrates; important in energy metabolism for the central and peripheral nervous systems; control the transmission of neuronal stimuli; supports the collagen synthesis.	Fatigue, lack of concentration, glucose in- tolerance, cardiovascular diseases, neuritis, depression, delayed wound healing.
Vitamin B2 (Riboflavin)	As a coenzyme of flavin enzymes it participates in the hydrogen transfer of the respiratory chain, the oxidative deamination of amino acids and the dehydrogenation of fatty acids; anti- oxidant characteristics.	Fatigue, apathy, muscular fatigue, skin disorders, immunodeficiency, macular degeneration.
Vitamin B3 (Niacin)	Structural element of the glucose tolerance factor GTF; as a structural element of NADH and NADPH with a control function in energy metabolism; as cofactor of various oxidases it plays a central function in cellular metabolic synthesis.	Glucose- and carbohydrate-intolerance, fatigue, tenseness, anxiety state, psycho- sis, depression, dementia, polymorphic light eruption, hyperpigmentation, in-creased sunburn risk from UV-exposure, liver dysfunction.
Vitamin B5 (Pantothenic acid)	As a structural element of various co- enzymes. It plays a central role in the energy metabolism, essential for the acetylcholine synthesis, supports the endogenous synthesis of sex hormones, from vitamin D and phospholipids.	Fatigue, burning feet-syndrome, depression, paresthesia, retarded wound healing, anemia, tenseness, insomnia, nervousness, disturbance of memory, lack of concentration.
Vitamin B6 (Pyridoxine)	Supports the metabolism of homocysteine to cysteine; essential for haemoglobin formation; regulates the synthesis and the interaction of central neurotransmitters (dopamine, serotonin, GABA); important in amino acid metabolism; supports phospholipid- and spingomyelin synthesis; supports the activity of liver transaminases.	Cardiovascular diseases, fatigue, avolition, anxiety state, insomnia, poor dream recall, aggressive/depressive mood, hyperactivity, diseases of skin and nervous system.
Vitamin B7 (Biotin)	Element of enzymes, the carboxylases, which regulate the basic metabolic reactions of carbohydrates, fats and amino acids.	Depression, panic attacks, hairloss, brittle nails, muscle pain, anorexia.

Vitamin B9 (Folic acid)	Crucial for proper brain function. It aids in the production of DNA and RNA and is especially important when cells and tissues are growing rapidly, such as in infancy, adolescence, and pregnancy.	Poor growth, Loss of appetite, Shortness of breath, Diarrhea, Irritability, Forgetfulness, Mental sluggishness
Vitamin B12 (Cobalamine)	Regulates myelin metabolism; metabolizes homocysteine to methionine.	Fatigue, apathy, paleness, brittle hair and nails, depression, arteriosclerosis, impaired resistance to infections.

It is generally assumed that the B vitamins are harmless as they are water soluble and, therefore, are unlikely to accumulate in the body as can the fat-soluble vitamins (A, D, E, and K). However, the available information suggest that too high an intake of certain vitamin B's can present adverse effects. The Institute of Medicine (IOM, 1998) has extensively reviewed the available information on nutrients, including vitamins, and developed Daily Reference Intake (DRI) values. DRIs are a set of reference values used for planning and assessing nutrient intake for healthy people. These values include Recommended Dietary Allowances (RDA), Adequate Intakes (AI), and Tolerable Upper Intake Levels (UL). The RDA recommends the average daily intake that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in each age and gender group. An AI is set when there is insufficient scientific data available to establish a RDA, but these values meet or exceed the amount needed to maintain a nutritional state of adequacy in nearly all members of a specific age and gender group. The UL is the maximum daily intake unlikely to result in adverse health effects. The UL is important from a safety perspective and has been established after a thorough review of the underlying safety information. It is the maximum amount a person could consume without negative effects, based on available scientific information.

In order to make sure that the resulting maximum amount (90th percentile) of individual vitamin B's from the intended uses of quinoa sprouts preparation (PANMOL® B-COMPLEX US100) is safe for human consumption, these levels are compared with the FDA Daily Value [21 CFR 101.9(c)(8)(iv)] and IOM (1998) established RDA/AI for adult (men and women) and tolerable upper limit (UL) for these vitamins (Table 13). The data presented in Table 13 shows that the resulting intake is higher than RDA/AI for all vitamins except for folic acid. For niacine, pyridoxine and folic acid the resulting intake is lower than the upper limit established by IOM. For the remaining B vitamins the upper levels have not been established due to lack of suitable data. However, it should be noted and as discussed below the higher intake from the proposed uses is unlikely to cause any adverse effects.

Table 13. Comparison of B-Vitamins from PANMOL® B-COMPLEX US100 with Daily Value, Recommended Daily Allowance and Upper Tolerable Limit

B-Vitamins	Panmol®-B-Complex	Daily Value*	RDA/AI** (men)	RDA/AI (women)	Upper Limit (UL)***
B1 as thiamin (mg)	2.25	1.5	1.2	1.1	Not established
B2 as riboflavin (mg)	2.55	1.7	1.3	1.1	Not established
B3 as niacin (mg)	30.00	20.00	16.00	14.00	35
B5 as pantothenic acid (mg)	15.00	10.00	5.00*	5.00*	Not established
B6 as pyridoxine (mg)	3.00	2.00	1.3	1.3	100
B7 as biotin (µg)	450	300	300	300	Not established
B9 as folate (µg)	600	400	400	400	1000
B12 as cobalamin (µg)	9	6	2.4	2.4	Not established

*Daily Value (DV) adapted from 21 CFR 101.9(c)(8)(iv); **RDA not established; Adequate Intake (AI)

provided; ***A Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population.
Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline (IOM, 1998)

Unlike some vitamins that can be stored in the body for future use, such as vitamins A and D, B-complex vitamins are not stored, with the exception of vitamin B-12. This means that any excess of B vitamin is excreted in urine from the body. As a result, individuals need a daily supply of B vitamins.

Oral thiamin (B1) is virtually nontoxic, as demonstrated by a long history of use as an oral supplement - often as many multiples of recommended intakes - without adverse effects. In fact, there are no reports of adverse effects of oral thiamin, even at dosages of several hundred milligrams (Hathcock, et al., 2014). Riboflavin (B2) consumed orally has no reported toxicity (IOM, 1998; Hathcock, et al., 2014). Reports of adverse effects from riboflavin all relate to animal studies or cell culture research involving either drugs with phototoxicity, intense exposure of lens tissue to ultraviolet light, or both in combination with high levels of riboflavin. There are no reports of adverse reactions that can be attributed to riboflavin consumed orally from foods or dietary supplements. The toxicity of oral pantothenic acid (B5) is extremely low, and no adverse cases have been reported in humans. Intakes as high as 200 mg/kg/day for animals and 10 g/day for humans have been tolerated for extended periods without adverse effects (IOM, 1998). Although most studies relate to daily consumption of 5 to 10 mg, daily amounts as high as 10 g have been consumed orally in clinical studies for many weeks without toxic effects (Hathcock, et al., 2014).

Oral administration of biotin has not been reported to cause toxic effects in humans. Infants given injections of up to 10 mg for 6 months, and oral intakes of up to 10 mg have not produced adverse effects, suggesting that biotin must have an extremely low order of toxicity. Only marginal adverse effects are produced in animals as a result of biotin doses in the hundreds of milligrams per kilogram of body weight. In view of the absence of adverse effects in humans at even extremely high doses, these effects in animals are not relevant to the safety of supplemental biotin (Hathcock, et al., 2014). No toxic effects of B12 have been encountered in humans or animals at any level of oral intake (IOM 1998; Hathcock, et al., 2014). The overall evidence indicates that vitamin B12 is virtually nontoxic. Doses of 1000 µg/day were administered to a child by intravenous injection for a year without adverse effect. The IOM (1998) concluded that “no adverse effects have been associated with excess B12 intake from food or supplements in healthy individuals” and concluded that there was no basis for a UL value.

In summary, the above described information suggest that the resulting intake of B vitamins from the intended uses of quinoa sprouts rich in botanical B-vitamins preparation (PANMOL® B-COMPLEX US100) is unlikely to cause any adverse effects.

6.2.3. Human Studies

In recent years, some clinical trials have been conducted with oral administered quinoa preparation to humans. The objectives of the majority of these studies were to examine the therapeutic applications and health benefits of quinoa or quinoa sprouts. These studies provide an indirect opportunity to access the safety and ‘tolerability’ of quinoa preparation in a diverse population. No dose-limiting toxicity was reported. A few of these studies are discussed below along with a summary including their design, doses used, and effects observed and are provided in Table 14. While most of the studies below deal with quinoa grain, it is reasonable to believe that quinoa sprouts will elicit the same effects.

In an open label, multicenter, observational clinical study, Fuchs et al. (2008) investigated the physical and mental health status of 259 subjects. Participation in the study was voluntary, and subjects were informed about the course, purpose and risks associated with the investigation. The efficacy of the test product was determined by measuring acidity quotients and by questionnaire, which the subjects themselves completed. Invasive investigations were not conducted. Subjects received 2 x 2 capsules containing the test product daily. Although the levels of Quinoa sprout extract in the capsule is not mentioned in the publication, it appears to be 500 mg/capsule (total of 2000 mg/person/day). After the first examination, the study participants were supplemented with Botanical B Complex powder from sprouted quinoa (PANMOL® B-COMPLEX US100) for a period of four months. The subjects were given medical history questions comprising of neurological, cardiological, immunological, gastrointestinal, dermatological and rheumatological natures and any non-specific complaints. In addition to general questions on eating habits, there were also questions relevant to long-term medication and additional supplementation with multivitamins. Additionally, data on health problems associated with stress, with imbalances in the acid-base status as well as on questions of the health-related quality of life were collected. The investigators reported that evaluation of the almost 4,000 laboratory analyses and approximately 75,000 medical history entries show that targeted nutriological (nutritional), acid-base balance-correcting measures can improve quality of life and complaints that limit daily well-being. The results of this study showed statistically significant improvements in the circadian acidity quotients after two and/or four months. Clear improvement of health problems associated with imbalances in the acid-base state as well as a statistically significant improvement of the social and psychological well-being was noted. No adverse effects of PANMOL® B-COMPLEX US100 ingestion (4 capsules/day for 4 months) were reported.

In a study in children, Ruales et al. (2002) investigated the effects of infant food formulated with quinoa in boys aged 50 to 65 months from low-income families in Ecuador. In this study, children received infant food formulated with quinoa (100 g twice per day for 15 days). Following consumption of food containing quinoa, there was significantly increased plasma IGF-1 levels, whereas IGF-1 levels were unchanged in the control group. The positive effects observed for the quinoa-treated group were attributed to the complete essential amino acid profile of the quinoa-formulated food, as well as its high digestibility (95.3%), which was higher than that of 5 commercially available infant foods derived from milk and soy. The findings from this study indicate that infant food derived from quinoa provides sufficient protein and other essential nutrients crucial for reducing child malnutrition (Ruales et al., 2002).

In a human study, investigating the *in vivo* metabolic responses to gluten-free foods, Berti et al. (2004) reported that quinoa lowered free fatty acid levels and triglyceride concentrations as compared to other gluten-free pastas and breads studied. In another human clinical study, Zevallos et al. (2014) investigated the use of quinoa seeds as a safe, gluten-free alternative to cereal grains in celiac patients. In this study, 19 celiac patients consumed 50 g quinoa daily for 6 weeks, as part of their usual gluten free diet. Gastrointestinal parameters (the ratio of villus height to crypt depth, surface-enterocyte cell height, and number of intra-epithelial lymphocytes/100 enterocytes) and serum lipid levels were evaluated before and after intervention. The study found that gastrointestinal parameters improved following the quinoa diet. Median values for all the blood tests remained within normal ranges, although total cholesterol (n=19) decreased from 4.6 to 4.3 mmol/l, low-density lipoprotein decreased from 2.46 to 2.45 mmol/l, high-density lipoprotein decreased from 1.8 to 1.68 mmol/l and triglycerides decreased from 0.80 to 0.79 mmol/l. The investigators concluded that quinoa is safe for consumption by celiac patients.

In another study, Farinazzi-Machado et al. (2012) investigated the effects of quinoa on the biochemical and anthropometric profile and blood pressure in humans, parameters related to cardiovascular disease risk. In this study, 22 students (9 males, 13 females; 18 to 45 year-old) were treated daily for 30 days with quinoa in the form of a cereal bar. Blood samples were collected before and after 30 days of treatment to determine glycemic and biochemical profile of the group. The cereal bars were administered daily, including weekends. The students consumed two bars per day, at a total concentration of 19.5 g of quinoa (9.75 g quinoa/bar). The results indicated that quinoa reduces the levels of total cholesterol, triglycerides, and LDL-c. Meanwhile, blood glucose levels, body weight, and blood pressure each decreased, though non-significantly.

In a prospective, double-blind human clinical trial among postmenopausal women with excess weight, quinoa flake consumption (25 g/day for 4 weeks) also modulated metabolic parameters post-treatment compared to baseline (De Carvalho et al., 2014). In this study, serum triglycerides and thiobarbituric acid-reactive (TBAR) values were both significantly reduced. Furthermore, quinoa intervention non-significantly reduced total cholesterol (191 ± 35 to 181 ± 28 mg/dL) and LDL-cholesterol (129±35 to 121±26 mg/dL), while glutathione (GSH, a marker of antioxidant defense) was increased (1.78 ± 0.4 to 1.91 ± 0.4 mmol/L). In a parallel intervention group that consumed corn flakes, similar decreases in triglycerides and TBAR values were observed, but total cholesterol, LDL, and GSH levels were not affected, indicating a possible unique benefit from quinoa consumption.

Table 14. Clinical Trials Investigating the Effects of Quinoa Products in Humans

References	Therapeutic application	Study participants and location	Treatment	Endpoints (measured before and after intervention) and outcomes	Conclusions
Ruales et al., 2002	Child growth and development	Boys ages 50-65 months from low-income families in Ecuador	Infant food formulated from quinoa (100 g x 2/d for 15 days) compared with no treatment	High plasma levels of IGF-1, a marker of malnutrition, known to increase body weight gain	Quinoa-based infant food may play a role in reducing childhood malnutrition
Zevallos et al., 2014	Celiac disease	19 celiac patients	Cooked quinoa (50 g/d for 6 weeks)	All gastrointestinal parameters (villus, height:cryptic depth), surface-enterocyte cell height, number of intra-epithelial lymphocytes per 100 enterocytes; improved following quinoa diet; serum lipid levels remained	Quinoa is safe for consumption by celiac patients

				normal with small decrease in total cholesterol, LDL, HDL, and triglycerides	
Farinazzi-Machado et al., 2012	Risk of cardiovascular disease	22 students aged 18-45 years 9 males and 13 females	Quinoa cereal bar daily for 30 days	Low triglycerides, low cholesterol, low LDL	Quinoa intake may reduce risk of developing cardiovascular disease
De Carvalho et al., 2014	Postmenopausal symptoms	35 post-menopausal women with excess weight (menopausal for ≥ 2 years, waist circumference > 80 cm, serum estradiol 10-20 pg/mL, follicle-stimulating hormone ≥ 35 mIU/mL, not undergoing hormone therapy or isoflavone supplements in the past 6 months, not taking lipid lowering drugs in the last 2 weeks)	Quinoa flakes (QF) compared with corn flakes (CF), 25 g/d for 4 weeks	QF consumption increased protein and fiber intake but not total caloric intake Low triglycerides, low TBARS, low cholesterol, low LDL, high GSH	Quinoa intake beneficially modulates metabolic parameters

IFG-1 – insulin-like growth factor; TBARS: thiobarbituric acid reactive substances; GSH: glutathione; LDL: low-density lipoprotein; HDL: high-density lipoprotein

In summary, the above described studies, and other studies from the literature, indicate that, as a nutritious food also rich in many minerals and plant compounds, quinoa can be a healthy addition to the diet. Some data shows that adding quinoa to the diet can increase its overall nutritional value, and may help to reduce blood sugar levels and lower blood triglycerides. The available human clinical studies suggest that quinoa or its sprout preparation rich in vitamins is unlikely to cause any adverse effects.

6.2.4. Animal Studies

In several animal studies, the effects of quinoa as a potential food source have been investigated. In these studies, the investigators studied the effects of quinoa as compared to control on weight gain, metabolic outcomes, lipid profiles and antioxidant profile. A summary of the animal species, animal age, number of animals, duration of study, control and intervention diet, quinoa concentration in the diet, as well as the main findings from the available animal studies is summarized in Table 15.

In one study, Pasko et al. (2010) reported that feeding quinoa in a diet to rats on a high-fructose diet, reduced most of the adverse effects caused by the fructose, all of which are associated with type 2 diabetes. It lowered blood cholesterol by 26%, triglycerides by 11% and blood sugar levels by 10%.

Table 15. Summary of Animal Studies with Quinoa and its Preparations*

Reference	Animal species; age at start; Sample size (n)	Trial length	Control diet; Intervention diet	Quinoa in diet (g/kg)	Main outcome measure	Main findings
Jacobsen et al., 1997	Male broilers (ASA Chick A/S); 6 days; 525	31 days	Regular broiler feed; Regular broiler feed with raw or processed quinoa	100, 200, 400	Weight gain	Control group gain – 1323 g. Weight gain (with increasing raw quinoa content) 1247 g (p>0.05), 1065 g (p<0.05) and 765 g (p<0.05). Weight gain (with increasing processed quinoa content) 1232 g (p>0.05), 1079 g (p>0.05), and 875 g (p<0.05).
	0 days 960	39 days	Regular broiler feed; Regular broiler feed with raw or processed quinoa	50, 150		Control group gain after 20 days – 627 g. Weight gain (group eating 150 g/kg) processed quinoa) 593 g (p<0.05) after 20 days. Weight gain did not differ between groups at 39 days (p>0.05).
Carlson et al., 2012	Landrace Yorkshire Duroc cross-breed piglets; 28 days; 400	28 days	Basal diet without quinoa; Basal diet with South American or Denmark quinoa hull meal	0.1, 0.3, 0.5	Weight gain	Control group gain – 294 g/day. Quinoa groups gained 280-307 g/day (p=0.41). Jejunum epithelial conductance of control group – 22mS/cm^2. In quinoa groups, conductance was 24-25 mS/cm^2 (p=0.04).
Meneguetti et al., 2011	Wistar rats; 60 days; 64	30 days	Rodent chow (Nuvilab®); Nuvilab® with hydrolyzed quinoa	2	Weight gain	Sedentary control group gain – 60.2 g, exercised control group gain – 94.2 g. Weight gain (among quinoa fed groups) sedentary – 16.5 g (p<0.05) and exercised – 60.0 g (p<0.05).
					Lipids	Sedentary control group triglycerides – 92.9 mg/dL, exercised control group – 63.1 mg/dL. Triglycerides (among quinoa fed groups) sedentary – 73.9 mg/dL (p<0.05) and exercised – 60.9 mg/dL (p>0.05). Non-significant difference in cholesterol between control and quinoa group (p>0.05).

Foucault et al., 2012	C57BL/6 J Mice; 6 weeks; 36	3 weeks	1. Low fat (LF) diet 2. High fat (HF) diet; High fat diet with added quinoa extract (HFQ)	Not stated	Weight gain Lipids	LF group gain – 3.0 g. HF group and HFQ group gain 5.1 g ($p<0.001$) and 5.6 g ($p<0.001$) respectively. HF group epididymal adipose tissue (EAT) – 28.8 mg/g body weight. HFQ EAT – 21.7 mg/g body weight ($p<0.01$). HF group plasma leptin – 6.0 ng/ml. HFQ group plasma leptin – 3.9 ng/ml ($p<0.05$). Plasma adiponectin and expression of mRNA for SREBP-1c[2] and PAI-1 were lower in HFQ compared to LF group ($p<0.05$). Expression of mRNA for LPL[3], PPAR-γ, PEPCK, Leptin, TLR4, MCP1, CD68, GILZ, OST and PAI-1 were lower in the HFQ group and mRNA expression for UCP2[4] and UCP3 were higher in HFQ group compared to the HF group (all $p<0.05$). LF and HF group triglycerides – 0.50 g/l and 0.53 g/l. HFQ group triglycerides – 0.51 g/l ($p>0.05$) LF and HF group plasma cholesterol – 1.25 g/l and 1.33 g/l. HFQ group plasma cholesterol – 1.35 g/l ($p>0.05$)
Pasko et al., 2010a	Male Wistar rats; Not stated; 24	5 weeks	Corn or corn with 31% fructose; Quinoa or quinoa with 31% fructose	310	Antioxidant activity	The quinoa group had lower liver GPX[5] and CAT, lower CAT in the testis and higher GPX in the spleen (all $p<0.05$) compared to the corn control. The quinoa with fructose group showed lower MDA[6] levels compared to the corn with fructose group ($p<0.01$).
Pasko et al., 2010b	Male Wistar rats; Not stated; 24	5 weeks	Corn or corn with 31% fructose; Quinoa or quinoa with 31% fructose	310	Lipids	Cholesterol, triglycerides and LDL of the quinoa group were significantly lower ($p<0.05$, $p<0.05$, and $p<0.008$, respectively) than levels in the corn control group.

Mahoney et al., 1975	Male Sprague-Dawley rats; Not stated; 15	4 weeks	Casein; 1. Quinoa flour 2. Cooked quinoa	680	Weight gain	Control group gain – 57 g. Weight gain for the quinoa flour group – 43 g ($p>0.05$) and for cooked quinoa group – 89 g ($p<0.01$). Control group protein efficiency ratio (PER) – 2.67. PER for quinoa flour group – 2.09 ($p<0.01$) and 2.71 ($p>0.05$) for cooked quinoa group.
Improta and Kellems, 2001	Male broiler chicks; 3 days; 90	28 days	Maize diet (13.2% protein); Raw or polished quinoa (13.2% protein)	953.5	Weight gain	After 14 days, control group gain – 76 g. Weight gain in raw and polished quinoa group 64.2 and 67.6 g, respectively (both $p<0.05$).
	90	28 days	Maize diet (18% protein); Raw or polished quinoa (18% protein)	835		After 21 days, control group gain – 486.9 g. Weight gain in raw and polished quinoa group 118.6 and 210.1 g respectively (both $p>0.05$).
	120	14 days	Maize diet (13.3% protein); Raw, polished or washed quinoa (13.3% protein)	962.5		After 7 days, control group gain – 87.5 g. Weight gain in raw, polished and washed quinoa group 53.0 g ($p<0.05$), 54.9 g ($p<0.05$) and 92.9 g ($p>0.05$) respectively.
	120	31 days	Maize diet (23% protein); Raw, polished or washed quinoa (23% protein)	800		After 31 days, control group gain – 891.4 g. Weight gain in raw, polished and washed quinoa group 160.4, 383.3 and 737.6 g (all $p<0.05$) respectively.
Matsuo 2005	Male Wistar-ST rats; 4 weeks; 10	13 days	Diet free of quinoa; Control diet with methanolic quinoa extract	11	Weight gain	Control group gain – 14.5 g. Quinoa group gain – 15.1 g ($p>0.05$).
					Antioxid ant activity	Control and quinoa group serum α-Tocopherol – 8.5 µg/ml and 5.6 µg/ml ($p<0.05$) respectively. Control group serum and liver MDA 2.0 nmol/mL and 33.3 nmol/g respectively. Quinoa group serum and liver MDA 3.0 nmol/mL and 40.3 nmol/g (both $p<0.05$) respectively. No differences in serum or liver GPX ($p>0.05$)

Takao et al., 2005	Male Crj:CD-1 (ICR) mice; 7 weeks; 18	4 weeks	0.5% cholesterol, 20% casein; Control diet with casein substituted for a quinoa protein extract	25, 50	Weight gain	Control group gain – 11.28 g. Weight gain (with increasing quinoa extract) 12.02 and 10.78 g ($p>0.05$)
					Lipids	Plasma cholesterol (0-5% quinoa) 268.2 mg/dl, 199.9 mg/dl ($p<0.05$), 204.5 mg/dl ($p<0.05$). Liver cholesterol (0-5% quinoa) 10.31 mg/dl, 8.16 mg/dl ($p>0.05$), 6.30 mg/dl ($p<0.05$). Plasma triglycerides (0-5% quinoa) 84.5 mg/dl, 55.4 mg/dl, 45.2 mg/dl ($p>0.05$). Liver triglycerides (0-5% quinoa) 14.06 mg/g. 10.36 mg/g, 9.24 mg/g ($p>0.05$). Daily fecal bile acid (0-5% quinoa) 125.8, 212.3 ($p<0.05$), 202.5 µg/50 g body weight ($p<0.05$). Expression of HMG-CoA[7] reductase was significantly lower ($p<0.05$) in the quinoa groups than the control group.
Mithila and Khanum, 2015	Male Wistar rats (albino strain); Not stated; 16	15 days	Casein; Quinoa in place of casein	200	Weight gain	No difference in weight gain between control and quinoa group ($p>0.05$). Control group and quinoa group postprandial CCK[8] levels 8.63 and 12.56 ng/ml ($p<0.01$), respectively. No differences in fasting CCK, ghrelin and leptin and postprandial ghrelin and leptin between groups ($p>0.05$).
					Lipids	Cholesterol in the quinoa group was significantly lower ($p<0.01$) than the control group
Gee et al., 1993	Wistar rats; Not stated; 40	14 days	Milled and cooked wheat cereal; Bitter, washed bitter or sweet quinoa	862, 866, 873	Weight gain	The control group gained more weight than the bitter, washed bitter and sweet quinoa groups (no statistics provided).
Diaz et al., 1995	Y DY commercial cross piglets; 8 weeks; 144	5 weeks	Maize and wheat meal; Maize and wheat meal with quinoa	50, 100	Weight gain	Control group gain- 294 g/day. Weight gain (with increasing quinoa content), 285 g/day and 248 g/day (both $p>0.05$)

Foucault et al., 2014	Male C57BL/6 J ;mice 6 weeks; Not stated	3 weeks	High fat (HF) diet; High fat quinoa (HFQ) diet	2.8	Weight gain	Over a 24h period, the respiratory quotient and glucose oxidation of the HFQ group was higher than the control group (both p<0.05). Control and HFQ plasma leptin – 4.2 and 3.6 ng/ml (p>0.05), respectively.
					Lipids	Control and HFQ plasma triglycerides – 0.62 and 0.68 g/L (p>0.05), respectively. Over a 24h period, HFQ fecal lipid content was higher than the control group (p<0.05)
Ranhotra et al., 1993	Rats; Not stated; 20	4 weeks	Corn starch with casein; Dehulled quinoa	641	Weight gain	Control and quinoa group gain – 130 and 126 g (p>0.05), respectively. Control and quinoa protein efficiency ratio – 3.5 and 3.8 (p<0.05), respectively.
Grant et al., 1995	Male Hooded-Lister rats; 32 days; 8	10 days	Basal diet with casein; Basal diet with quinoa	758	Weight gain	Control and quinoa group gain – 11.0 and 1.2 g/day respectively. No statistics provided.
Ruales et al., 2002	Male Sprague-Dawley rats; Not stated 10	9 days	Maize starch with casein; Maize starch with quinoa	Not stated	Weight gain	The quality of protein from quinoa was poorer than the protein from the control diet (no statistics provided).
Ruales and Nair, 1992	Male Sprague-Dawley rats; Not stated; Not stated	9 days	Maize starch with casein; Maize starch with quinoa	Not stated	Weight gain	Gain (in increasing order) was control group, washed quinoa group and raw quinoa group (no statistics provided).

*Adapted from Simnadis et al. (2015)

In summary, physiological effects of quinoa consumption with potential application for human health were investigated in several animal studies (Table 15). In these studies effects of quinoa consumption included decreased weight gain, improved lipid profile and improved capacity to respond to oxidative stress. As such these animal studies did not reveal any adverse effects of quinoa.

6.3. Summary and Discussion

Vis Vitalis intends to use a standardized quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) as a nutrient source at use levels up to 300 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in various food products such as Baked Goods, Ready-to-eat cereals, and Snack Foods (not restricted by a Standard of identity). The product is a off-white to yellowish powder with a grainy odor and nutty taste. It is manufactured at a facility operating according to the principles of GMP from quinoa sprouts germinated in the presence of a nutrient-rich cocktail containing a mixture of B vitamins. The product is standardized to the content of individual B vitamins such as B1, B2, B3, B5, B6, B7, B9, and B12. The intended use of quinoa sprouts extract rich in botanical B-vitamins in the specified foods will result in mean and 90th percentile intake of 775.07 and 1487.48 mg/person/day, respectively. For safety assessment purposes high levels of 1500 mg/person/day is considered.

Quinoa and quinoa sprouts have been consumed for centuries in food to maintain good health with no published evidence of safety concerns associated with its use. Quinoa and quinoa sprouts have been extensively consumed in many countries, including the United States, as a food product. Quinoa sprouts enriched with B vitamins is approved by Health Canada. In European countries, quinoa sprouts rich in botanical B-vitamins are marketed as a food or food ingredient. Quinoa and quinoa sprouts are a foodstuff and are listed in the USDA's inventory of grains used as food sources.

Despite the fact that there are no modern scientific safety studies related to vitamin B enriched quinoa sprouts (PANMOL® B-COMPLEX US100), the safety of PANMOL® B-COMPLEX US100 can be extrapolated from the safe use of quinoa and quinoa sprouts and the products of quinoa and quinoa sprouts. Vis Vitalis did not uncover, and, is not aware, of any significant adverse safety issues associated with the consumption of quinoa and/or quinoa sprouts, vitamin B complex when added to food products or consumed as dietary supplements. Vis Vitalis recognizes that future studies can determine how to most effectively use PANMOL® B-COMPLEX US100 in a variety of food products. Notwithstanding this, it is concluded that the existing data package can support the safe use of PANMOL® B-COMPLEX US100 in selected foods resulting in a daily intake of 1.5 g PANMOL® B-COMPLEX US100/person/day.

There is sufficient qualitative and quantitative scientific information to determine the safety-in-use of PANMOL® B-COMPLEX US100 for its proposed uses. The GRAS status of PANMOL® B-COMPLEX US100 for its intended use in food is supported by:

- Quinoa is known as an "ancient grain," that has been consumed by humans for thousands of years with no known significant adverse effects.
- Quinoa is a valuable food source which has a reputation of a "complete food".
- Quinoa sprouts are used extensively as a food source with no safety concerns.
- Quinoa sprouts are gluten free thus making them a good food for gluten sensitive people.
- Quinoa is higher in nutrients than most other grains, and is also relatively high in quality protein.
- It contains high amounts of vitamins, minerals and plant compounds, and is especially high in antioxidants.
- There is recognition that many individuals are deficient in the B vitamins.
- The B vitamins are water soluble with no known significant adverse effects.
- PANMOL® B-COMPLEX US100 is manufactured at facility operating according to the principles of GMP and meets appropriate food-grade specifications described in this dossier.

- The safety of PANMOL® B-COMPLEX US100 for the intended use in food at levels resulting in daily intake of 1.5 g/person/day is supported by current use levels in which no adverse effects have been reported in the published literature;
- PANMOL® B-COMPLEX US100 is approved by Health Canada as a supplement and is marketed in European countries as a food ingredient.
- There is adequate data supporting the safety of PANMOL® B-COMPLEX US100 available in the published literature.

In summary, the cumulative scientific information on PANMOL® B-COMPLEX US100 --- specifically considering the human experiences and associated testing, anticipated human consumption levels, and germane supporting information --- provides the basis for the conclusion that daily exposure of PANMOL® B-COMPLEX US100 at levels up to 1.5 g/person is safe. Thus, on the basis of scientific procedures[4], corroborated by history of exposure and use, the consumption of PANMOL® B-COMPLEX US100 at use levels of 300 mg/serving in food is considered as safe. The proposed uses are compatible with current regulations, *i.e*., PANMOL® B-COMPLEX US100 is used as a food nutrient in a variety of foods when not otherwise precluded by a Standard of Identity, and is produced at facility operating according to the principles of GMP.

6.4. Expert Panel Conclusion

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)[5], qualified by their scientific training and relevant national and international experience to evaluate the safety of food and food ingredients, was convened by Soni & Associates Inc., USA, at the request of Vis Vitalis GmbH, Austria (Vis Vitalis), to determine the Generally Recognized As Safe (GRAS) status of quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) as a nutrient source [21 CFR 170.3(o)(20)][6] at use levels up to 300 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in food products such as Baked Goods, Ready-to-eat cereals, and Snack Foods (not restricted by a Standard of identity). A comprehensive search of the scientific literature for safety and toxicity information on quinoa sprouts rich in botanical B-vitamins and its constituents was conducted through December 2016 and made available to the Expert Panel. The Expert Panel independently and critically evaluated materials submitted by Vis Vitalis, and other information deemed appropriate or necessary. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed to the conclusion described herein.

In arriving at this decision that quinoa sprouts rich in botanical B-vitamins is GRAS for the proposed use, the Expert Panel relied upon the fact that quinoa sprouts has a centuries-long use as a therapeutic agent and as a food, without any known safety concerns, as well as the published articles relating to the use of quinoa sprouts rich in botanical B-vitamins (PANMOL® B-COMPLEX US100) and the safety of other food products from quinoa sprouts rich in botanical B-vitamins.

---

[4] 21 CFR §170.3 Definitions. (h) Scientific procedures include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

[5] Modeled after that described in section 201(s) of the Federal Food, Drug, and Cosmetic Act, As Amended. See also attachments (curriculum vitae) documenting the expertise of the Panel members.

[6] "Nutrient supplements": Substances which are necessary for the body's nutritional and metabolic processes.

Based on a critical evaluation of the publicly available data, summarized above, the Expert Panel members whose signatures appear below, have individually and collectively concluded that quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100), meeting the specifications cited above, and when used as a nutrient [21 CFR 170.3(o)(20)] at maximum use levels of up to 300 mg/serving in a variety of foods such as Baked Goods, Ready-to-eat cereals, and Snack Foods, when not otherwise precluded by a Standard of Identity, and resulting in the 90th percentile all-user estimated intake of 1.5 g/person/day is safe and GRAS.

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that PANMOL® B-COMPLEX US100, when used as described, is GRAS based on scientific procedures.

Signatures

______________________________ ______________

Robert L. Martin, Ph.D. Date

______________________________ ______________

John A. Thomas, Ph.D., F.A.C.T., F.A.T.S. Date

______________________________ ______________

Madhusudan G. Soni, Ph.D., F.A.C.N., FA.T.S. Date

Based on a critical evaluation of the publicly available data summarized above, the Expert Panel members whose signatures appear below, have individually and collectively concluded that quinoa sprouts extract rich in botanical B-vitamins (PANMOL® B-COMPLEX US100), meeting the specifications cited above, and when used as a nutrient [21 CFR § 170.3(o)(20)] at maximum use levels of up to 300 mg/serving in a variety of foods such as Baked Goods, Ready-to-eat cereals, and Snack Foods, when not otherwise precluded by a Standard of Identity, and resulting in the 90th percentile all-user estimated intake of 1.5 g/person/day is safe and GRAS.

It is also our opinion that other qualified and competent scientists reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, we have also concluded that PANMOL® B-COMPLEX US100, when used as described, is GRAS based on scientific procedures.

Signatures

(b) (6)

Robert L. Martin, Ph.D. — Jan. 21, 2017 Date

(b) (6)

John A. Thomas, Ph.D., F.A.C.T., F.A.T.S. — Jan 26, 2017 Date

(b) (6)

Madhusudan G. Soni, Ph.D., F.A.C.N., FA.T.S. — Jan 28, 2017 Date

7. Part 7 – SUPPORTING DATA AND INFORMATION

Abugoch, J.L.E. 2009. Quinoa (*Chenopodium quinoa* Willd.): composition, chemistry, nutritional, and functional properties. Adv Food Nutr Res. 58:1-31.

Alvarez-Jubete L., Arendt, E.K., Gallagher, E. 2009a. Nutritive value and chemical composition of pseudocereals as gluten-free ingredients. Int J Food Sci Nutr. 60 Suppl 4:240-257.

Alvarez-Jubete L., Holse, M., Hansen, Å., Arendt, E.K., Gallagher, E. 2009b. Impact of baking on vitamin E content of pseudocereals amaranth, quinoa, and buckwheat. L. Cereal Chem. September/October 86(5):511-515.

Berti, C., Riso, P., Monti, L.D., Porrini, M. 2004. *In vitro* starch digestibility and in vivo glucose response of gluten-free foods and their gluten counterparts. Eur J Nutr. Aug 43(4):198-204.

Busse, M. 2013. Vitamin B Complex Deficiency Symptoms. [available at: http://www.livestrong.com/article/342433-vitamin-b-complex-deficiency-symptoms/].

Carlson, D., Fernandez, J.A., Poulsen, H.D., Nielsen, B., Jacobsen, S.E. 2012. Effects of quinoa hull meal on piglet performance and intestinal epithelial physiology. J Anim Physiol Anim Nutr 96(2):198-205.

Cusack, D. 1984. Quinoa: grain of the Incas. The Ecologist 14:21-31.

DeBruin, A. 1964. Investigation of the food value of quinoa and canihua seed. J. Food Sci. 29:872-876.

De Carvalho, F.G., Ovidio, P.P., Padovan, G.J., Jordao, Junior A.A., Marchini, J.S., Navarro, A.M. 2014. Metabolic parameters of postmenopausal women after quinoa or corn flakes intake - a prospective and double-blind study. Int J Food Sci Nutr 65(3):380–385.

Diaz, J., Diaz, M.F., Cataneda, S. 1995. A note on the use of *Chenopodium quinoa* forage meal in pre-fattening pigs. Cuban J Agric Sci 29(2):223-226.

Dixit, A.A., Azar, K.M., Gardner, C.D., Palaniappan, L.P. 2011. Incorporation of whole, ancient grains into a modern Asian Indian diet to reduce the burden of chronic disease. Nutr Rev. Aug 69(8):479-488.

FAO. 2013. Food and Agriculture Organization/World Health Organization. Quinoa 2013 International year. Available at: http://www.fao.org/quinoa-2013/faqs/en/

FAO, 1973. Food and Agriculture Organization/World Health Organization. WHO Technical Report Series No. 522, FAO Nutrition Meetings Report Series No. 52. FAO/WHO, Geneva.

Farinazzi-Machado, F.M.V., Barbalho, S.M., Oshiiwa, M., Goulart, R., Pessan, Junior O. 2012. Use of cereal bars with quinoa (*Chenopodium quinoa* W.) to reduce risk factors related to cardiovascular diseases. Cienc Technol Aliment Campinas 32(3):239–244.

Foucault, A-S., Even, P., Lafont, R., Dioh, W., Veillet, S., Tome, D., Huneau, J-F., Hermier, D., Quignard-Boulange, A. 2014. Quinoa extract enriched in 20-hydroxyecdysone affects energy homeostasis and intestinal fat absorption in mice fed a high-fat diet. Physiol Behav 128:226-231.

Foucault, A-S., Mathe, V., Lafont, R., Even, P., Dioh, W., Veillet, S., Tome, D., Huneau, J-F., Hermier, D., Quignard-Boulange, A. 2012. Quinoa extract enriched in 20-hydroxyecdysone protects mice from diet-induced obesity and modulates adipokines expression. Obesity 20(2):270-277.

Fuchs, N., Loidl, R., Sadeghi, B. 2007. Process for the preparation of a plant enriched with B vitamins. Google Patents EP1867728 A1.

Fuchs, N., Markolin G., Kulklinski, B., Jager R., Zelch, N., Guth, I., Schicka, G., Neumann, K., 1996. Ergebnisse einer offenen Studie zur Evaluierung von Wirksamkeit und Verträglichkeit der adjuvanten Zufuhr des ISF-Nährstoffprogramms bei HIV-positiven Patienten (Results of an open study Evaluation of efficacy and Tolerability of adjuvant access drove the ISF nutrient program in HIV-positive patients). WMW (Wiener Medizinische Wochenschrift) 146:486-493.

Gee, J.M., Price, K.R., Ridout, C.L., Wortley, G.M., Hurrell, R.F., Johnson, I.T. 1993. Saponins of quinoa (*Chenopodium quinoa*): effects of processing on their abundance in quinoa products and their biological effects on intestinal mucosal tissue. J Sci Food Agric 63(2):201-209.

Graf, B. L., Rojas-Silva, P., Rojo, L. E., Delatorre-Herrera, J., Baldeón, M. E. and Raskin, I. 2015. Innovations in Health Value and Functional Food Development of Quinoa (*Chenopodium quinoa* Willd.). Comprehensive Reviews in Food Science and Food Safety, 14: 431–445. doi: 10.1111/1541-4337.12135

Grant, G., More, L.J., McKenzie, N.H., Dorward, P.M., Buchan, W.C., Telek, L., Pusztai, A. 1995. Nutritional and hemagglutination properties of several tropical seeds. J Agric Sci 124(3):437-445.

Hathcock, J.N., MacKay, D., Wong, A., Nguyen, H. 2014. Vitamin and Mineral Safety. 3rd Edition. Council for Responsible Nutrition (CRN), Washington, D.C. pp 1-190.

Improta, F., Kellems, R.O. 2001. Comparison of raw, washed and polished quinoa (*Chenopodium quinoa* Willd.) to wheat, sorghum or maize based diets on growth and survival of broiler chicks. Livest Res Rural Dev 13(1):1-10.

IOM, 1998. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. Institute of Medicine (US), Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline. Washington (DC): National Academies Press (US); 1998. ISBN-10: 0-309-06411-2 ISBN-13: 978-0-309-06411-8

Jacobsen, E.E., Jacobsen, S.E., Skadhauge, B. 1997. Effect of dietary inclusion of quinoa on broiler growth performance. Anim Feed Sci Technol 65(1):5-14.

Jancurová, M., Minarovičová, L., Dandár, A. 2009. Quinoa – a review. Czech J. Food Sci. 27:71–79.

Johnson, R., Aguilera, R., 1979. Processing varieties of oilseeds (lupine and quinoa), Table 6 Report to Natural Fibers and Foods Commission of Texas, 1979-80. (From D. Cusack, 1984, The Ecologist. 14:21-31).

Johnson, D.L., Croissant, R. 1985. Quinoa production in Colorado. Service-in-Action 112. Colorado State Univ. Coop. Ext. Ft. Collins.

Kennedy, D. 2016. B Vitamins and the Brain: Mechanisms, Dose and Efficacy – A Review" Nutrients 8(2):68. doi:10.3390/nu8020068.

Koziol, M.J. 1992. Chemical composition and nutritional evaluation of quinoa (*Chenopodium quinoa* Willd.). Journal of Food Composition Analysis 5:35–68.

Lanska, D.J. 2010. Chapter 30: Historical aspects of the major neurological vitamin deficiency disorders: the water-soluble B-vitamins" Handb Clin Neurol. 95:445-476. Doi: 10.1016/S0072-9752(08)02130-1.

Lee, A., Newman, J.M. 2003. Celiac diet: its impact on quality of life. J Am Diet Assoc. Nov 103(11):1533-1555.

Lintschinger, J., Fuchs, N., Moser, H., Jager, R., Hlebeina, T., Markolin, G., Gössler, W. 1997. Uptake of various trace elements during germination of wheat, buckwheat and quinoa. Plant Foods Hum. Nutr. 50:223–237.

Mahoney, A.W., Lopez, J.G., Hendricks, D.G. 1975. An evaluation of the protein quality of quinoa. J Agric Food Chem 23(2):190-193.

Matsuo, M. 2005. *In vivo* antioxidant activity of methanol extract from quinoa fermented with *Rhizopus oligoporus*. J Nutr Sci Vitaminol (Tokyo) 51(6):449-452.

Meneguetti, Q.A., Brenzan, M.A., Batista, M.R., Bazotte, R.B., Silva, D.R., Garcia Cortez, D.A. 2011. Biological effects of hydrolyzed quinoa extract from seeds of *Chenopodium quinoa* Willd. J Med Food 14(6):653-657.

Mithila, M.V., Khanum, F. 2015. Effectual comparison of quinoa and amaranth supplemented diets in controlling appetite; a biochemical study in rats. J Food Sci Technol 1-7.

Mizui F, Kasai R, Ohtani K, Tanaka O. 1990. Saponins from brans of quinoa, *Chenopodium quinoa* Willd. II. Chem Pharm Bull 38:375–377.

Oelke, E.A., Putnam, D.H., Teynor, T.M., Oplinger, E.S., 2016. Quinoa. Alternative Field Crop Manual. Available at: https://www.hort.purdue.edu/newcrop/afcm/quinoa.html

Pasko, P., Barton, H., Zagrodzki, P., Izewska, A., Krosniak, M., Gawlik, M., Gawlik, M., Gorinstein, S. 2010a. Effect of diet supplemented with quinoa seeds on oxidative status in plasma and selected tissues of high fructose-fed rats. Plants Foods Hum Nutr 65(2):146-151.

Pasko, P., Zagrodzki, P., Barton, H., Chlopicka, J., Gorinstein, S. 2010b. Effect of quinoa seeds (*Chenopodium quinoa*) in diet on some biochemical parameters and essential elements in blood of high fructose-fed rats. Plants Food Hum Nutri 65(4):333-338.

Pasko, P., Barton, H., Zagrodzki, P., Gorinstein, S., Folta, M., Zachwieja, Z. 2009. Anthocyanin, total polyphenols and antioxidant activity in amaranth and Quinoa seeds and sprouts during their growth. Food Chemistry 115:994- 998.

Pitzschke, A., Fraundorfer, A., Guggemos, M., Fuchs, N., 2015. Antioxidative responses during germination in quinoa grown in vitamin B-rich medium. Food Sci. Nutr. 3(3):242-251.

Ranhotra, G.S., Gelroth, J.A., Glaser, B.K., Lorenz, K.J., Johnson, D.L., 1993. Composition and protein nutritional quality of quinoa. Cereal Chem. 70(3):303-305

Ruales, J., de Grijalva, Y., Lopez-Jaramillo, P., Nair, B.M. 2002. The nutritional quality of an infant food from quinoa and its effect on the plasma level of insulin-like growth factor-1 (IGF-1) in undernourished children. Int J Food Sci 53(2):143-154.

Ruales, J., Nair, B.M. 1993. Content of fat, vitamins and minerals in quinoa (*Chenopodium quinoa*, Willd) seeds. Food Chemistry 48:131–136.

Ruales, J., Nair, B.M. 1992. Nutritional quality of the protein in quinoa (*Chenopodium quinoa*, Willd.) seeds. Plants Foods Hum Nutri 42(1):1-11.

Simnadis, T.G., Tapsell, L.C., Beck, E.J., 2015. Physiological Effects Associated with Quinoa Consumption and Implications for Research Involving Humans: a Review. Plant Foods Hum. Nutr. 70(3):238-249.

Smiciklas-Wright, H., Mitchell, D.C., Mickle, S.J., Cook, A.J., Goldman, J.D., 2002. Foods Commonly Eaten in the United States: Quantities Consumed Per Eating Occasion and in a Day, 1994-1996. U.S. Department of Agriculture NFS Report No. 96-5, 252 pp.

Takao, T., Watanabe, N., Yuhara, K., Itoh, S., Suda, S., Tsuruoka, Y., Nakatsugawa, K., Konishi, Y. 2005. Hypocholesterolemic effect of protein isolated from quinoa (*Chenopodium quinoa* Willd.) seeds. Food Sci Technol Res 11(2):161-167.

UMASS, 2016. University Massachusetts. Incomplete proteins. Available at: http://www.umass.edu/nibble/infofile/incprot.html

USDA, 2016. United States Department of Agriculture. Nutrients in quinoa from USDA National Nutrient Database for Standard Reference Release 28. Available at: https://ndb.nal.usda.gov/ndb/search/list

Valencia-Chamorro, S.A. 2003. Quinoa. In: Caballero B.: Encyclopedia of Food Science and Nutrition. Vol. 8. Academic Press, Amsterdam: 4895–4902.

Vega-Galvez, A, Miranda, M., Vergara, J., Uribe, E., Puente, L., Martínez, E.A., 2010 Nutrition facts and functional potential of quinoa (*Chenopodium quinoa* willd.), an ancient Andean grain: a review. J. Sci. Food Agric. 90(15):2541-2547.

Vis Vitalis, 2016. Information on General description, specifications, composition and manufacturing of quinoa sprout rich in botanical B-vitamins provided for this GRAS assessment. (unpublished).

White, P.L., Alvistur, E., Dias, C., Vinas, E., White, H.S., Collazos, C. 1955. Nutrient content and protein quality of quinoa and canihua, edible seed products of the Andes mountains. J. Agr. Food Chem. 3:531-534.

Wilson, H.D. 1988. Allozyme variation and morphological relationships of *Chenopodium hircinum*. Syst. Bot. 13:215-228.

Wilson, H.D. 1990. Quinoa and relatives (*Chenopodium* sect. *Chenopodium* subsect. *Cellulata*. Econ. Bot. 44:92-110.

Zevallos, V.F., Herencia, L.I., Chang, F., Donnelly, S., Ellis, H.J., Ciclitira, P.J. 2014. Gastrointestinal effects of eating quinoa (*Chenopodium quinoa* Willd.) in celiac patients. Am J Gastroenterol 109:270–278.

8. APPENDIX I

Certificate of analysis from different manufacturing lots

Batch 1

FB-02-033V1

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL®-B-COMPLEX US100 (Halal/Kosher)		**Supplier:** vis vitalis gmbh
Product code: 911030 (R008.146)		**Version:** 8
Batch Number: L14040085 – manufactured 28.04.2014		

Specification released of QA / Date: 03.11.2014	
Name: Sabine Stampfl	**Sign:** (b) (6)

Certificate of analysis released of QA / Date: 3.11.2014	
Name: Anton Hlebaina	**Sign:** (b) (6)

Definition
PANMOL®-B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in biologically active vitamins)

Characters	**Reference**	**Requirements**	**Observations**
Appearance	SOP-02-019	Powder	Complies
Colour	SOP-02-019	Off-white to yellow	Complies

Assay	**Reference**	**Requirements**	**Observations**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg/100g	209.09 mg/100g
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg/100g	304.24 mg/100g
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2000 mg/100g	2256.46 mg/100g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1000 mg/100g	1307.18 mg/100g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg/100g	271.88 mg/100g
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg/100g	44.22 mg/100g
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg/100g (≥ 40 mg/100g)	38.72 mg/100g
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 0,6 mg/100g	0.623 mg/100g

Tests	**Reference**	**Requirements**	**Observations**
Total plate count	SOP-02-062	max. 50,000 cfu/g	420 cfu/g
Enterobacteriaceae	SOP-02-034	max. 100 cfu/g	<10 cfu/g
Mould	SOP-02-035	max. 500 cfu/g	<10 cfu/g
Yeast	SOP-02-035	max. 500 cfu/g	10 cfu/g
Coliform	SOP-02-080	n.d. /g	n.d. /g
Loss on drying	SOP-02-082	max. 8 %	5.14 %

Release data and Storage	**Reference**	**Requirements**	**Observations**
Retest schedule	SOP-02-040	2.5 years	10.2016
Containers	SOP-02-040	Tightly closed, cool, dark and dry	Complies

Specification / Certificate of Analysis
Raw Material

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 (R008.146)	**Version:** 8	
Batch Number:	L14040085 – manufactured 28.04.2014		

Specification released of QA / Date: 03.11.2014		(b) (6)
Name: Sabine Stampfl	**Sign:**	

Certificate of analysis released of QA / Date: 3.11.2014		(b) (6)
Name: Anton Hlebaina	**Sign:**	

Characteristic properties		Reference
Arsenic	SAM07 ***	max. 1 ppm
Cadmium	SAM07 ***	max. 1 ppm
Mercury	SAM07 ***	max. 0,1 ppm
Lead	SAM07 ***	max. 1 ppm
Nutritional values:		
Energy	~ 1590 kJ / 380 kcal	calculated
Fat	~ 4.9 %	§64 LFGB L 06.00-6
of which saturated	~ 0.53 %	DGF-C-VI 11d
Carbohydrates	~ 65,0 %	calculated
of which sugars	~ 11.9 %	calculated
Protein	~ 13,7 %	§64 LFGB L 06.00-7
Fibre	~ 8.9 %	§64 LFGB L 00.00-18
Sodium	< 0.1 %	§64 LFGB L 00.00-19/2

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

Batch 2

FB-02-033V1

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 (R008.146)	**Version:** 8	
Batch Number:	L15010063 – manufactured 14.01.2015		

Specification released of QA / Date: 23.10.2014	(b) (6)
Name: Sabine Stampfl	**Sign:**

Certificate of analysis released of QA / Date: 08.04.2015	(b) (6)
Name: Anton Hlebaina	**Sign:**

Definition
PANMOL®-B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in biologically active vitamins)

Characters	**Reference**	**Requirements**	**Observations**
Appearance	SOP-02-019	Powder	Complies
Colour	SOP-02-019	Off-white to yellow	Complies

Assay	**Reference**	**Requirements**	**Observations**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg/100g	195.43 mg/100g
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg/100g	224.94 mg/100g
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2000 mg/100g	2472.75 mg/100g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1000 mg/100g	1270.51 mg/100g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg/100g	279.16 mg/100g
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg/100g	37.51 mg/100g
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg/100g (≥ 40 mg/100g)	24.98 mg/100g
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 0,6 mg/100g	0.806 mg/100g

Tests	**Reference**	**Requirements**	**Observations**
Total plate count	SOP-02-062	max. 50,000 cfu/g	330 cfu/g
Enterobacteriaceae	SOP-02-034	max. 100 cfu/g	<10 cfu/g
Mould	SOP-02-035	max. 500 cfu/g	<10 cfu/g
Yeast	SOP-02-035	max. 500 cfu/g	110 cfu/g
Coliform	SOP-02-080	n.d. /g	n.d. /g
Loss on drying	SOP-02-082	max. 8 %	5.63 %

Release data and Storage	**Reference**	**Requirements**	**Observations**
Retest schedule	SOP-02-040	2.5 years	07.2017
Containers	SOP-02-040	Tightly closed, cool, dark and dry	Complies

vis vitalis GmbH · Mooshan 29 · 5585 Unternberg · Tel: +43(0)6476/80 52 00 · Fax: +43(0)6476/80 52 22 · office@vis-vitalis.com · www.vis-vitalis.com

Formblatt erstellt:	Letzte Änderung am:	Formblatt freigegeben / gültig ab:	Änderungsgrund:
08.05.2008 / jk	08/04/2015	08.05.2008 / ah, mig	Total plate count corr.

Seite 1 von 2

Specification / Certificate of Analysis
Raw Material

vis vitAlis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 (R008.146)	**Version:** 8	
Batch Number:	L15010063 – manufactured 14.01.2015		

Specification released of QA / Date: 23.10.2014	(b) (6)
Name: Sabine Stampfl	**Sign:**

Certificate of analysis released of QA / Date: 08.04.2015	(b) (6)
Name: Anton Hlebaina	**Sign:**

Characteristic properties		**Reference**
Arsenic	SAM07 ***	max. 1 ppm
Cadmium	SAM07 ***	max. 1 ppm
Mercury	SAM07 ***	max. 0,1 ppm
Lead	SAM07 ***	max. 1 ppm
Nutritional values:		
Energy	~ 1590 kJ / 380 kcal	calculated
Fat	~ 4.9 %	§64 LFGB L 06.00-6
of which saturated	~ 0.53 %	DGF-C-VI 11d
Carbohydrates	~ 65,0 %	calculated
of which sugars	~ 11.9 %	calculated
Protein	~ 13,7 %	§64 LFGB L 06.00-7
Fibre	~ 8.9 %	§64 LFGB L 00.00-18
Sodium	< 0.1 %	§64 LFGB L 00.00-19/2

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

vis vitalis GmbH - Moosham 29 - 5585 Unternberg - Tel: +43(0)6476/80 52 00 - Fax: +43(0)6476/80 52 22 - office@vis-vitalis.com - www.vis-vitalis.com

Formblatt erstellt:	Letzte Änderung am:	Formblatt freigegeben / gültig ab:	Änderungsgrund:
08.05.2008 / jk	08/04/2015	08.05.2008 / ah, mig	Total plate count corr.

Batch 3

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 (R008.146)	**Version:** 10	
Batch Number:	L15090061 – manufactured 15.09.2015		

Specification released of QA / Date: 16.02.2016	(b) (6)
Name: Sabine Stampfl	**Sign:**

Certificate of analysis released of QA / Date: 18.05.2016	(b) (6)
Name: Anton Hlebaina	**Sign:**

Definition
PANMOL®-B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in biologically active vitamins)

Characters	**Reference**	**Requirements**	**Observations**
Appearance	SOP-02-009	Powder	Complies
Colour	SOP-02-009	Off-white to yellow	Complies

Assay	**Reference**	**Requirements**	**Observations**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg/100g	204.63 mg/100g
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg/100g	219.25 mg/100g
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2000 mg/100g	2536.09 mg/100g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1000 mg/100g	1307.78 mg/100g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg/100g	281.03 mg/100g
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg/100g	39.04 mg/100g
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg/100g (≥ 40 mg/100g)	26.16 mg/100g
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 0,6 mg/100g	0.8 mg/100g

Tests	**Reference**	**Requirements**	**Observations**
Total plate count	SOP-02-062	max. 50,000 cfu/g	700 cfu/g
Enterobacteriaceae	SOP-02-034	max. 100 cfu/g	<100 cfu/g
Mould	SOP-02-035	max. 500 cfu/g	<100 cfu/g
Yeast	SOP-02-035	max. 500 cfu/g	120 cfu/g
Coliform	SOP-02-090	n.d. /g	n.d. /g
Loss on drying	SOP-02-082	max. 8 %	5,41 %

Release data and Storage	**Reference**	**Requirements**	**Observations**
Retest schedule	SOP-02-040	2.5 years	03.2018
Containers	SOP-02-040	Tightly closed, cool, dark and dry	Complies

Specification / Certificate of Analysis
Raw Material

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 (R008.146)	**Version:** 10	
Batch Number:	L15090061 – manufactured 15.09.2015		

Specification released of QA / Date: 16.02.2016	(b) (6)
Name: Sabine Stampfl	**Sign:**

Certificate of analysis released of QA / Date: 18.05.2016	(b) (6)
Name: Anton Hlebaina	**Sign:**

Characteristic properties		**Reference**
Arsenic	SAM07 ***	max. 1 ppm
Cadmium	SAM07 ***	max. 1 ppm
Mercury	SAM07 ***	max. 0,1 ppm
Lead	SAM07 ***	max. 1 ppm
Nutritional values:		
Energy	~ 1693 kJ / 401 kcal	calculated
Fat	~ 7.1 %	ASU L 17.00-4
of which saturated	~ 0.77 %	WES 027
Carbohydrates	~ 68.5 %	Calculation WES 026
of which sugars	~ 3.1 %	WES 650 calculated
Protein	~ 13.5 %	ASU L 06.00-7
Fibre	~ 4.5 %	ASU L 00.00-18
Sodium	~ 0.001 %	DIN EN ISO 11885 (E 22) 2009-09

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

9. APPENDIX II

Nutrients in quinoa from USDA National Nutrient Database for Standard Reference Release 28
Full Report (All Nutrients): 20137, Quinoa, cooked
Food Group: Cereal Grains and Pasta
Scientific Name: *Chenopodium quinoa* Willd.
Carbohydrate Factor: 4 Fat Factor: 9 Protein Factor: 4 Nitrogen to Protein Conversion Factor: 6.25

Nutrient values and weights are for edible portion.

Nutrient	Unit	Value per 100 g	# of Data Points	Std. Error	cup 185g
Water [1]	g	71.61	3	3.951	132.48
Energy	kcal	120	--	--	222
Energy	kJ	503	--	--	931
Protein [1]	g	4.40	3	0.823	8.14
Total lipid (fat) [1]	g	1.92	3	0.272	3.55
Ash [1]	g	0.76	3	0.104	1.41
Carbohydrate, by difference	g	21.30	--	--	39.40
Fiber, total dietary [1]	g	2.8	3	0.371	5.2
Sugars, total	g	0.87	--	--	1.61
Starch [1]	g	17.63	3	2.184	32.62
Calcium, Ca [1]	mg	17	3	2.887	31
Iron, Fe [1]	mg	1.49	3	0.295	2.76
Magnesium, Mg [1]	mg	64	3	12.365	118
Phosphorus, P [1]	mg	152	3	29.400	281
Potassium, K [1]	mg	172	3	25.129	318
Sodium, Na [1]	mg	7	3	3.170	13
Zinc, Zn [1]	mg	1.09	3	0.211	2.02
Copper, Cu [1]	mg	0.192	3	0.031	0.355
Manganese, Mn [1]	mg	0.631	3	0.145	1.167

Nutrient	Unit	Value per 100 g	# of Data Points	Std. Error	cup 185g
Selenium, Se [1]	µg	2.8	3	0.562	5.2
Vitamin C, total ascorbic acid	mg	0.0	--	--	0.0
Thiamin [1]	mg	0.107	3	0.022	0.198
Riboflavin [1]	mg	0.110	3	0.021	0.204
Niacin [1]	mg	0.412	3	0.073	0.762
Vitamin B-6 [1]	mg	0.123	3	0.033	0.228
Folate, total [1]	µg	42	3	3.756	78
Folic acid	µg	0	--	--	0
Folate, food [1]	µg	42	3	3.756	78
Folate, DFE	µg	42	--	--	78
Choline, total	mg	23.0	--	--	42.6
Vitamin B-12	µg	0.00	--	--	0.00
Vitamin B-12, added	µg	0.00	--	--	0.00
Vitamin A, RAE	µg	0	--	--	0
Retinol	µg	0	--	--	0
Carotene, beta	µg	3	--	--	6
Carotene, alpha	µg	0	--	--	0
Cryptoxanthin, beta	µg	0	--	--	0
Vitamin A, IU	IU	5	--	--	9
Lycopene	µg	0	--	--	0
Lutein + zeaxanthin	µg	53	--	--	98
Vitamin E (alpha-tocopherol) [1]	mg	0.63	3	0.128	1.17
Vitamin E, added	mg	0.00	--	--	0.00
Tocopherol, beta [1]	mg	0.03	3	0.007	0.06
Tocopherol, gamma [1]	mg	1.19	3	0.331	2.20
Tocopherol, delta [1]	mg	0.11	3	0.037	0.20
Vitamin D (D2 + D3)	µg	0.0	--	--	0.0
Vitamin D	IU	0	--	--	0
Vitamin K (phylloquinone)	µg	0.0	--	--	0.0

Nutrient	Unit	Value per 100 g	# of Data Points	Std. Error	cup 185g
Fatty acids, total monounsaturated	g	0.528	--	--	0.977

[1] *Nutrient Data Laboratory, ARS, USDA* **National Food and Nutrient Analysis Program, Wave 9o** , 2005 Beltsville MD

National Nutrient Database for Standard Reference
Release 28 slightly revised May, 2016 Software v.2.6.1
The National Agricultural Library

Current Food Grade Specifications
and
Certificate of Analysis from two additional lots

As described in Section 2.2., over the years (from 2013 to 2016) Vis Vitalis has made some changes/improvements to specifications, particularly quality parameters, for example reduced requirements of “plate count” to 50,000 cfu/g. The certificate of analysis from two lots with higher requirement (from earlier years) are included.

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL® B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh
Product code: 911030 (R008.146)	**Version:** 11
Batch Number:	

Specification release by production manager / Date: 30.06.2016	(b) (6) [redacted]
Name: Mag. Sabine Stampfl	**Sign:**

Certificate of Analysis release by quality assurance / Date:	
Name: Mag. Anton Hlebaina	**Sign:**

Definition
PANMOL® B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in biologically active vitamins)

Characteristics	**Reference**	**Requirements**	**Results**
Appearance	SOP-02-009	Powder	
Colour	SOP-02-009	Off-white to yellow	
Loss on drying	SOP-02-082	max. 8 %	

Assay	**Reference**	**Requirements / 100g**	**Results**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg	
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg	
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2 g	
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1 g	
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg	
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg	
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg (≥ 40 mg)	
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 600 mcg	

Microbiology	**Reference**	**Requirements**	**Results**
Total plate count	SOP-02-062	max. 50,000 cfu/g	
Enterobacteriaceae	SOP-02-034	max. 100 cfu/g	
Mould	SOP-02-035	max. 500 cfu/g	
Yeast	SOP-02-035	max. 500 cfu/g	
Coliform	SOP-02-090	n.d. /g	

Stability and Storage	**Reference**	**Requirements**	**Results**
Shelf life	SOP-02-040	2,5 years	
Storage	SOP-02-040	Tightly closed, cool, dark and dry	

vis vitalis GmbH · Moosham 29 · 5585 Unternberg · Tel: +43(0)6476/80 52 00 · Fax: +43(0)6476/80 52 22 · office@vis-vitalis.com · www.vis-vitalis.com

Version of the Specification	Date	Par.	Reason for change:
11	30.06.2016	AW	Specification revised general

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL® B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh
Product code: 911030 (R008.146)	**Version:** 11
Batch Number:	

Specification release by production manager / Date: 30.06.2016	(b) (6)
Name: Mag. Sabine Stampfl	**Sign:**

Certificate of Analysis release by quality assurance / Date:	
Name: Mag. Anton Hlebaina	**Sign:**

Heavy metals	Reference	Requirements	Results
Arsenic	SAM07 ***	max. 1 ppm	
Cadmium	SAM07 ***	max. 1 ppm	
Mercury	SAM07 ***	max. 0.1 ppm	
Lead	SAM07 ***	max. 1 ppm	

Nutritional values	in 100g	Reference
Energy	~ 1693 kJ / 401 kcal	calculated
Fat	~ 7.1 g	ASU L 17.00-4
of which saturated	~ 0.8 g	WES 027
Carbohydrates	~ 68.5 g	Calculation WES 026
of which sugars	~ 3.1 g	WES 650 calculated
Fibre	~ 4.5 g	ASU L 00.00-18
Protein	~ 13.5 g	ASU L 06.00-7
Salt	~ 0.004 g	Calculated according LMIV

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

Version of the Specification	Date	Par.	Reason for change:
11	30.06.2016	AW	Specification revised general

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 R008.146	**Version:** 3	
Batch Number:	L0359514 – manufactured 19.03.2014		

Specification released of QA / Date: 28.06.2013	(b) (6) [redacted]
Name: DI Guggemos	**Sign:**

Certificate of analysis released of QA / Date: 27.03.2014	(b) (6) [redacted]
Name: Mag. Hlebaina	**Sign:**

Definition
PANMOL®-B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in biologically active vitamins)

Characters	**Reference**	**Requirements**	**Observations**
Appearance	SOP-02-026	Powder	Complies
Colour	SOP-02-026	Off-white to yellow	Complies

Assay	**Reference**	**Requirements**	**Observations**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg/100g	179.268 mg/100g
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg/100g	212.272 mg/100g
Vitamin B_3 as niacin	HPLC-DAD *	≥ 2000 mg/100g	2413.953 mg/100g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1000 mg/100g	1089.179 mg/100g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg/100g	252.068 mg/100g
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg/100g	33.905 mg/100g
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg/100g (≥ 40 mg/100g)	28.964 mg/100g
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 0,6 mg/100g	0.895 mg/100g

Tests	**Reference**	**Requirements**	**Observations**
Arsenic	SAM07 ***	max. 1 ppm	0.056 ppm
Cadmium	SAM07 ***	max. 1 ppm	0.150 ppm
Mercury	SAM07 ***	max. 0.1 ppm	0.009 ppm
Lead	SAM07 ***	max. 1 ppm	0.123 ppm
Total plate count	SOP-02-032	max. 100,000 cfu/g	2400 cfu/g
Enterobacteriaceae	SOP-02-032	max. 100 cfu/g	<100 cfu/g
Mould	SOP-02-032	max. 500 cfu/g	<100 cfu/g
Loss on drying	SOP-02-001	max. 8 %	5,86 %

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 R008.146	**Version:** 3	
Batch Number:	L0359514 – manufactured 19.03.2014		

Specification released of QA / Date: 28.06.2013	(b) (6)
Name: DI Guggemos	**Sign:** [redacted]

Certificate of analysis released of QA / Date: 27.03.2014	(
Name: Mag. Hlebaina	**Sign:** [redacted]

Release data and Storage	Reference	Requirements	Observations
Retest schedule	SOP-02-040	2.5 years	09.2016
Containers	SOP-02-040	Tightly closed, cool, dark and dry	Complies

Characteristic properties		Reference
Nutritional values:		
Energy	~ 1524 kJ / 360 kcal	
Protein	~ 13,7 %	§64 LFGB L 06.00-7
Carbohydrates	~ 65,0 %	calculated
of which sugars	~ 11.9 %	calculated
Fat	~ 4.9 %	§64 LFGB L 06.00-6
of which saturated	~ 0.53 %	§64 LFGB L 06.00-6
Fibre	~ 8.9 %	§64 LFGB L 00.00-18
Natrium	< 0.1 %	

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 R008.146	**Version:** 2	
Batch Number:	L0840513 – manufactured 22.08.2013	(b) (6)	

Specification released of QA / Date: 28.06.2013	
Name: DI Guggemos	**Sign:**

(b) (6)

Certificate of analysis released of QA / Date: 12.11.2013	
Name: Mag. Hlebaina	**Sign:**

Definition
PANMOL®-B-COMPLEX US100 (Halal/Kosher) (quinoa sprouts rich in botanical vitamins)

Characters	Reference	Requirements	Observations
Appearance	SOP-02-026	Powder	Complies
Colour	SOP-02-026	Off-white to yellow	Complies

Assay	Reference	Requirements	Observations
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg/100g	166.297 mg/100g
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg/100g	209.087 mg/100g
Vitamin B_3 as niacin	HPLC-DAD *	≥ 2000 mg/100g	2260.232 mg/100g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1000 mg/100g	1089.179 mg/100g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg/100g	212.245 mg/100g
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg/100g	38.882 mg/100g
Vitamin B_9 as folic acid *(as folate)*	VitaFast® **	≥ 20 mg/100g (≥ 40 mg/100g)	47.522 mg/100g
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 0,6 mg/100g	0.693 mg/100g

Tests	Reference	Requirements	Observations
Arsenic	SAM07 ***	max. 1 ppm	Complies
Cadmium	SAM07 ***	max. 1 ppm	Complies
Mercury	SAM07 ***	max. 0.1 ppm	Complies
Lead	SAM07 ***	max. 1 ppm	Complies
Total plate count	SOP-02-032	max. 100,000 cfu/g	Complies
Enterobacteriaceae	SOP-02-032	max. 100 cfu/g	Complies
Mould	SOP-02-032	max. 500 cfu/g	Complies
Loss on drying	SOP-02-001	max. 8 %	Complies

*) HPLC-Method, based on internal SOPs.
**) VitaFast®-testkit by R-Biopharm, microbiologic vitamin assay.
***) ICP-MS standard addition method for analysis of heavy metals, with certified CertiPUR® Standards.

vis vitalis GmbH - Moosham 29 - 5585 Unternberg - Tel: +43(0)6476/80 52 00 - Fax: +43(0)6476/80 52 22 - office@vis-vitalis.com - www.vis-vitalis.com

Formblatt erstellt:	Letzte Änderung am:	Formblatt freigegeben / gültig ab:	Änderungsgrund:
08.05.2008 / jk	12.11.2013	08.05.2008 / ah, mig	

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material:	PANMOL®-B-COMPLEX US100 (Halal/Kosher)	**Supplier:** vis vitalis gmbh	
Product code:	911030 R008.146	**Version:** 2	
			(b) (6) [redacted]
Batch Number:	L0840513 – manufactured 22.08.2013		

Specification released of QA / Date: 28.06.2013	
Name: DI Guggemos	**Sign:**

Certificate of analysis released of QA / Date: 12.11.2013	(b) (6) [redacted]
Name: Mag. Hlebaina	**Sign:**

Release data and Storage	Reference	Requirements	Observations
Retest schedule	SOP-02-040	2.5 years	02.2016
Containers	SOP-02-040	Tightly closed, cool, dark and dry	Complies

Characteristic properties		Reference
Nutritional values:		
Energy	~ 1524 kJ / 360 kcal	
Protein	~ 13,7 %	§64 LFGB L 06.00-7
Carbohydrates	~ 65,0 %	calculated
of which sugars	~ 11.9 %	calculated
Fat	~ 4.9 %	§64 LFGB L 06.00-6
of which saturated	~ 0.53 %	§64 LFGB L 06.00-6
Fibre	~ 8.9 %	§64 LFGB L 00.00-18
Natrium	< 0.1 %	