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FOOD ADDITIVE SAFETY

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Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Subject: Resubmission of GRAS Notification for Quinoa Sprout Powder

Dear Sir/Madam:

This is to bring to your kind notice that in January 17, 2017, vis vitalis gmbh, Austria, submitted a GRAS notice on quinoa sprout powder to US FDA, in accordance with 21 CFR 170 subpart E, (81 FR 54960; August 17, 2016). The agency filed it on March 6, 2017 as GRN 000692. Following discussion with FDA staff, on October 4, 2017 vis vitalis withdrew the GRN 000692. The primary reason for withdrawal was the inclusion of folic acid as a constituent in quinoa sprout powder and it is a food additive under 21 CFR 172.345.
At the time the agency also opined that if vis vitalis decides to exclude folic acid from quinoa sprout powder, then the identity will be substantially different from that described in GRN 000692 and will require a new GRAS conclusion. The FDA strongly encouraged to share the new GRAS notice with the agency through the GRAS Notification Program.

As per FDA recommendations, we hereby submit a new GRAS notice of a claim that the food ingredient quinoa sprout powder without folic acid (or sprouted quinoa enriched with B-vitamins except folic acid) 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 GRAS, based on scientific procedures. In the attached GRAS notice, vis vitalis has also addressed additional questions the FDA raised during its review of GRN 000692.

If you have any questions or require additional information, please feel free to contact me by Phone at +43 6476 805 200 or by email at office@panmol.com. Alternatively, in the US you can also contact Dr. Soni, who assisted us with this notice, by phone at +1-772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,

[redacted]

vis vitalis gmbh
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Norbert Fuchs
General Manager

Enclosure: Copy of the GRAS notice

GENERALLY RECOGNIZED AS SAFE (GRAS) ASSESSMENT FOR THE USE OF SPROUTED QUINOA ENRICHED WITH B-VITAMINS AS A NUTRIENT SOURCE

Submitted by:
vis vitalis gmbh
Moosham 29
5585 Unternberg -
AUSTRIA

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

Contact for Technical and Other Information in USA
Madhu Soni, PhD
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May, 2018

GENERALLY RECOGNIZED AS SAFE (GRAS) ASSESSMENT FOR THE USE OF SPROUTED QUINOA ENRICHED WITH B-VITAMINS AS A NUTRIENT SOURCE

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1. Part I - SIGNED STATEMENTS AND CERTIFICATION

In accordance with 21 CFR §170 Subpart E- Generally Recognized As Safe (GRAS), consisting of §170.203 through 170.285, vis vitalis gmbh (Vis Vitalis) hereby informs the FDA that sprouted quinoa enriched with B-vitamins except folic acid (PANMOL® B-COMPLEX US100 [without Folic Acid]), as manufactured by Vis Vitalis, is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on Vis Vitalis's view that the notified substance is Generally Recognized as Safe (GRAS) under the conditions of its intended use described in Section 1.3 below.

1.1. Name and Address of Notifier

vis vitalis gmbh
Moosham 29
5585 Unternberg
AUSTRIA

1.2. Name of Notified Substance

The name of the substance that is subject of this GRAS assessment is sprouted quinoa enriched with B-vitamins except vitamin B9 (PANMOL® B-COMPLEX US100 [without Folic Acid]). It should be noted that in this submission sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) refers to the preparation that is manufactured from quinoa sprouts germinated in the presence of a nutrient cocktail containing a mixture of water and B-vitamins, except vitamin B9.

1.3. Intended Conditions of Use

Vis Vitalis intends to use sprouted quinoa enriched with B-vitamins (except folic acid) as a nutrient at a maximum concentration of up to 150 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in foods such as Baked Goods, and Ready-to-eat cereals, when standards of identity established under section 401 of the Act do not preclude such use. 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 sprouted quinoa enriched with B-vitamins.

1.4. Statutory Basis for GRAS Conclusion

This GRAS conclusion is based on scientific procedures in accordance with 21 CFR 170.30(a) and 170.30(b), and conforms to the guidance issued by the Food and Drug Administration (FDA) under 21 C.F.R. § 170.36, 81 Fed. Reg. 54960 (Aug. 17, 2016).

1.5. Exclusion from Premarket Approval

Vis Vitalis has determined that the use of sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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 sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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
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or

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E-mail: sonim@bellsouth.net

1.7. Data Exemption from Disclosure

Parts II through VII of this GRAS notification do not contain data or information that is exempt from disclosure under the Freedom of Information Act. There is no privileged or confidential information such as trade secrets and/or commercial or financial information in 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 sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]). Vis Vitalis accepts responsibility for the GRAS conclusion that has been made for sprouted quinoa enriched with B-vitamins as described in this dossier.

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

Mr. Norbert Fuchs

General Manager
vis vitalis gmbh
Moosham 29
5585 Unternberg
AUSTRIA

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

Signature: [redacted] Date May 18, 2018

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

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

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

2.1. Identity

2.1.1. Description

The subject of this GRAS assessment is a preparation from the quinoa (*C. quinoa* Willd) sprout. The sprouted quinoa is enriched with B-vitamins. It is off-white to yellow color dry powder with a characteristic grain odor and nutty taste. The sprouted quinoa enriched with B-vitamins produced by Vis Vitalis is marketed under the trade name PANMOL® B-COMPLEX US100 (without Folic Acid). General descriptive characteristics and properties of sprouted quinoa preparation manufactured by Vis Vitalis are summarized in Table 1.

In the manufacturing of sprouted quinoa enriched with B-vitamins no extraction process is used. The subject of this GRAS assessment is not standardized by adding any excipients or by direct addition of any other substances to the final product. In order to enrich the content of B-vitamins in the final product, the amount of addition of nutrient cocktail, containing a mixture of B-vitamins, during germination is optimized such that the resulting product is consistently produced. As described below, there are no other ingredients present in the cocktail that is used during germination.

Table 1. General Descriptive Characteristics of Quinoa Sprout Preparation

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 (2018)

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 coat (perigonium) can be easily removed. Pericarp, the outer layer which constitutes the hull (adheres to the seed), contains saponins that transmit the bitter taste characteristic of quinoa. Just beneath the pericarp there is a thin layer, episperm. The embryo that constitutes the cotyledon and the root surrounds the major part of the mostly white seeds perisperm underneath the pericarp and episperm. 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).

It should be noted, the available general information on quinoa seeds is described above. The variety *Chenopodium quinoa* Willd, used by Vis Vitalis has a sweet (nutty) taste. The variety of quinoa used in the production of sprouted quinoa does not affect the identity or composition of the final product. During the manufacturing process, the sprouted seeds are washed extensively with water after the germination process. The washing process removes even traces of bitterness. As saponins are water soluble, the washing process removes these bitter principles.

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, explaining its exceptionally high protein content. Allowing the seeds to sprout increases the antioxidant content (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 sprouted quinoa preparation enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) have been established by Vis Vitalis and are summarized in Table 3. The analytical results from three lots are provided in Appendix I. The certificates of analysis from these lots demonstrate that PANMOL® B-COMPLEX US100 (without Folic Acid) 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 and B12. General compositional analysis of quinoa sprout preparation enriched with B-vitamins is presented in Table 4. PANMOL® B-COMPLEX US100 (without Folic Acid) is certified as Kosher and Halal.

It is well recognized that sprouting of seeds increases antioxidant activity and during sprouting many metabolic changes take place, mainly due to an increase in the activity of the endogenous hydrolytic enzymes. Carciochi et al. (2014) reported a 2-fold increase in antioxidant activity of germinated quinoa seeds, while phenolic acids and flavonoids increased by 8.57 fold and 4.4 fold respectively. Similarly, Pasko et al (2009) also reported increase in antioxidant activity of germinated quinoa seeds. Quinoa sprouts are commonly consumed as food by consumers. The addition of the nutrient cocktail during sprouting increases the concentration of the seven B vitamins included in the nutrient cocktail. The nutrient cocktail does not change other constituents that are normally formed during the sprouting.

Table 3. Specifications of Sprouted Quinoa Preparation PANMOL® B-COMPLEX US100 (without Folic Acid)

Test Parameter	Specification	Assay method
Description	Off white to yellow powder	Visual
Vitamin B1 as thiamin	≥ 150 (max 270)# mg/100 g	HPLC + FLD*
Vitamin B2 as riboflavin	≥ 170 (max 306)# mg/100 g	HPLC + DAD*
Vitamin B3 as total niacin	≥ 2000 (max 3600)# mg/100 g	HPLC + DAD*
Vitamin B5 as pantothenic acid	≥ 1000 (max 1800)# mg/100 g	HPLC + DAD*
Vitamin B6 as pyridoxine	≥ 200 (max 360)# mg/100 g	HPLC + DAD*
Vitamin B7 as biotin	≥ 30 (max 54)# mg/100 g	Vita Fast**
Vitamin B12 as cobalamin	≥ 0.6 (max 1.08)# 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

The max value of the individual vitamins is based on in-house defined max levels (180%). *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 (2018)

Table 4. Typical Compositional Analysis and Nutritional Value of Sprouted Quinoa Preparation (PANMOL® B-COMPLEX US100 [without Folic Acid])*

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 fat	0.8
Protein (g/100 g)	13.5
Salt (g/100g)	0.004
Energy /100 g	401 kcal (1693 kj)

*Based on information provided by Vis Vitalis (2018)

2.3. Manufacturing Process

Sprouted quinoa preparation PANMOL® B-COMPLEX US100 (without Folic Acid) is manufactured at the facility operating in accordance 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 B-vitamin (without folic acid) to induce sprout germination. There are no other ingredients in the cocktail. The source ingredients used for the B vitamins is FDA approved food additives, GRAS ingredients, or JECFA, EFSA, listed for food use. The nutrient cocktail is prepared in water and contains all B-vitamins, except folic acid. The amount of each vitamin has been optimized to achieve the ideal concentration for each vitamin to achieve the specified amounts in the final product. The nutrient cocktail does not contain any other substances. The seedlings exposed to the nutrient cocktail contain elevated amounts of the seven B-vitamins, which remain present after wash cycles.

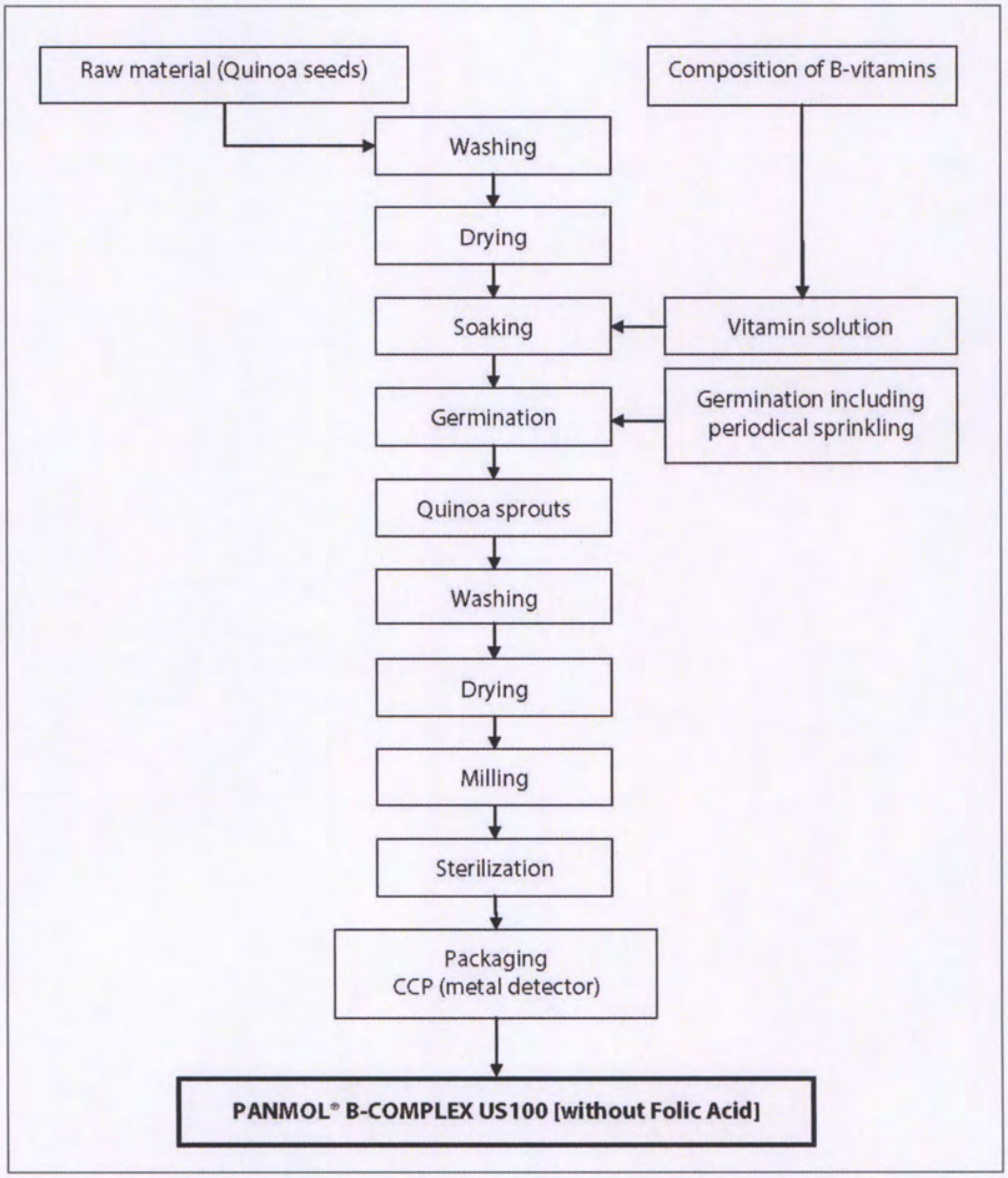

Figure 2. Manufacturing process of Sprouted Quinoa Sprout Preparation (PANMOL® B-COMPLEX US100 [without Folic Acid])

After germination to the desired stage, the sprouts are washed, dried, ground into flour and sterilized. The product is tested to meet the prescribed food grade 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 (without Folic Acid) are either approved as food additives or are GRAS substances.

It should be noted that in the manufacturing of sprouted quinoa enriched with B-vitamins no extraction process is used. The sprouted quinoa enriched with vitamin B (except folic acid) is not standardized by adding any excipients or by direct addition of any other substances to the final product. In order to enrich the content of B-vitamins in the final product, the amount of addition of nutrient cocktail, containing a mixture of B-vitamins (except folic acid), during germination is optimized such that the resulting product is consistently produced and meets the final product specifications.

2.4. Technical Effects

The intended uses of sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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 physical and technical functional effects of quinoa and quinoa sprouts include nutrient supplementation. Thus, the intended use of sprouted quinoa enriched with 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 III - DIETARY EXPOSURE

3.1. Intended Use Levels and Food Categories

Vis Vitalis intends to use sprouted quinoa enriched with B-vitamins as a nutrient source at a maximum concentration of 150 mg/serving in foods such as Baked Goods and Ready-to-eat cereals, when standards of identity established under section 401 of the Food, Drug, and Cosmetic Act do not preclude such use. 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 sprouted quinoa enriched with B-vitamins preparation. The proposed use levels of PANMOL® B-COMPLEX US100 (without Folic Acid) 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 sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) is estimated as per FDA guidelines using "maximum" intended use levels of PANMOL® B-COMPLEX US100 (without Folic Acid) 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 sprouted quinoa enriched with B-vitamins from the proposed uses in Baked Goods and Ready-to-eat cereals (Table 5). Under baked goods, Vis Vitalis intends to target biscuits as the food category, although this category also includes other foods such as waffles, snack/bars and frozen snacking cereals. The intake analysis is performed focusing on biscuits. As per 21 CFR 101.12, the serving size for biscuits under bakery product is given as 55 g. The CSFII data provides the intake levels of several different types of baked goods. In Table 5, values for biscuits are included. For the intake analysis of individual B-Vitamins, maximum concentration of particular vitamin available from different lots as given in specification Table 3 is used.

The intended use of sprouted quinoa enriched with B-vitamins at levels up to 150 mg *per* serving in Baked Goods and Ready-to-eat cereals will result in mean and 90th percentile intake of 327.27 and 605.46 mg/person/day, respectively. For safety assessment purposes high levels of 605 mg/person/day is considered.

Table 5: Intended Use Levels (150 mg/serving) and Possible Mean and 90th Percentile Daily Intake of PANMOL® B-COMPLEX US100 (without Folic Acid) 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	150	55	174.54	321.82
Ready-to-eat cereals	56	104	150	55	152.73	283.64
				Total (mg/person/day)	**327.27**	**605.46**

[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 (without Folic Acid) contains B-vitamins, the resulting maximum (90th percentile) intake of individual B-vitamins from the intended uses is summarized in Table 6. The resulting maximum daily intake of individual vitamin Bs is considered for the safety assessment of individual vitamins.

Table 6: Possible Maximum Levels and Daily Intake of Individual B-Vitamins from the Uses of PANMOL® B-COMPLEX US100 (without Folic Acid)

B-Vitamins	Maximum Levels (mg/100g)	Maximum Daily Intake
B1 as thiamin	270	1.63 mg
B2 as riboflavin	306	1.85 mg
B3 as niacin	3600	21.78 mg
B5 as pantothenic acid	1800	10.89 mg
B6 as pyridoxine	360	2.18 mg
B7 as biotin	54	327 μg
B12 as cobalamin	1.08	6.5 μg

4. Part IV - SELF LIMITING LEVELS OF USE

Sprouted quinoa preparation enriched with B-vitamins (PANMOL® B-COMPLEX US100 without Folic Acid]) will cost more as a source of B-complex vitamins than synthetic B vitamin sources. As such, users will control the amounts used due to economic reasons.

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

The statutory basis for the conclusion of GRAS status of sprouted quinoa preparation enriched with B-vitamins in this document is not based on common use in food before 1958. The GRAS assessment 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 VI - 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 consumed as food by humans 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 cereal 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 addition to *C. quinoa* Willd, 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 the 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 enriched with 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 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, sprouted 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

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

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]

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 (as opposed to milled grain products). 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) is 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

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

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	
Cysteine	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 comprises 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 sprouted quinoa 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 enriched with 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 ingredient because of its considerable 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).

Sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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, sprouted quinoa enriched with 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 sprouted quinoa enriched with B-vitamins in the list of ingredients of food, food supplements or dietary products as: Quinoa sprouts and/or quinoa sprouts enriched with 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. Data Related to Safety

Human consumption of quinoa food products is recognized as safe and has limited the need for detailed scientific studies to further demonstrate the safety of these products or nutritional values for humans. 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 its uses for health benefits, 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 enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]). Most of the reported recent quinoa research focused on 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

Sprouting of seeds involves changes in nutrient composition of the seeds. Sprouted pseudo-cereal seeds, such as quinoa, are viewed as nutritionally superior to 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 associated with the sprouting process

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

include protein and starch digestion, increased sugar and B-vitamin content and decreased levels of phytate and proteases inhibitors (Alvarez-Jubete, et al., 2009a).

The sprouted quinoa preparation enriched with 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 analysis of quinoa sprout enriched with B-vitamins, the subject of present GRAS, is similar to other common foods such as maize, rice, wheat for its carbohydrate, fats, protein and energy levels.

Sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) contains all the members of vitamin B complex family except folic acid. A comparison of B-vitamins from PANMOL® B-COMPLEX US100 (without Folic Acid), 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 sprouted quinoa enriched with B-vitamins, the subject of this present GRAS assessment, are compared in Table 11. PANMOL® B-COMPLEX US100 (without Folic Acid) was developed to be used as a nutritional source of B-vitamins. In Table 11 the levels of B vitamins are compared for 100 g of each of the product, however, it should be noted that the proposed uses of sprouted quinoa enriched with B-vitamins is only 150 mg/serving.

Table 11. Content of B-Vitamins in 100 g PANMOL® B-COMPLEX US100 [without Folic Acid], Compared to Common Quinoa Sprouts and Yeast.

Vitamins	PANMOL® B-COMPLEX US100 (without Folic Acid)	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
B12 as cobalamin	600 μg	0.00 μg	0.00 μg

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

In an attempt to show the relative amounts of B vitamins present in representative enriched foods in two food categories, such as Cherrios ready-to-eat cereals and enriched white bread, is compared with the subject of present GRAS, quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) in Table 12. The levels of these vitamins are compared from one serving of sprouted quinoa enriched with B-vitamins with cup of Cherrios and one slice of bread. This comparison indicates that the relative levels of majority of B vitamins from the currently marketed enriched food categories are somewhat similar to sprouted quinoa enriched with B-vitamins.

Table 12. Comparison of the intake of B-Vitamins from PANMOL® B-COMPLEX US100 [without Folic Acid] with Ready-to-eat cereal and Bread.

Vitamins	PANMOL® B-COMPLEX US100 (without Folic Acid)		CHERRIOS RTE cereal[1]		Enriched White Bread[2]	
	Per 150 mg	% DV	Per cup	% DV	Per slice	% DV
Thiamin	0.225	19%	0.364	30%	0.149	12%
Riboflavin	0.225	20%	0.028	2%	0.068	5%
Niacin	3	19%	5.0	31%	1.34	8%
Pantothenic acid	1.5	30%			0.107	2%
Pyridoxine	0.3	18%	0.5	30%	0.024	1%
Biotin	45	150%				
Cobalamin	0.9	38%	1.9	79%		

[1] USDA National Nutrient Database for Standard Reference; NDB No. 08013
[2] USDA National Nutrient Database for Standard Reference; NDB No. 18069

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 sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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 sprouted quinoa enriched with B-vitamins preparation (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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 preparations 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 and cobalamin (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 facilitates 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 6 μg/day for vitamin B12 to 20 mg/day for vitamin B3 in adult males, for example.

The available information indicates that many individuals do not get enough B-vitamins. According to the USDA, deficiencies in folic acid, B12, and B6 are especially common. The metabolic functions of the B-vitamins are included in Table 13 along with available information on safety or toxicity. A food product, like sprouted quinoa enriched with B-vitamins preparation (PANMOL® B-COMPLEX US100 [without Folic Acid]) can contribute to the B vitamin dietary requirements.

Table 13. Role, Function and Safety of the Vitamin B-complex in the Body

Vitamins	Role/function in the body	Signs of deficits	Safety/Toxicity
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.	Oral toxicity is considered very low. High doses (>7000 mg) may cause adverse effects such as headache, nausea, etc. No evidence of reproductive toxicity exists. In humans 100 mg/day unlikely to cause adverse effects.
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.	No toxic/adverse effects identified in humans; discoloration of urine at high doses; no toxic reports at levels up to 400 mg/day for 3 months; animal studies indicate very low toxicity
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	Evidence is sparse, liver dysfunction reported following long-term dose 3000-9000 mg/day. High levels (>3000 mg/day) cause toxicity. No evidence of fetal toxicity in women receiving up to 2000 mg/day during pregnancy.
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.	Lack of acute or chronic toxicity in case reports at ~ 10000 mg/day; in clinical studies no side effects at ~2000 mg/day for weeks
Vitamin B6 (Pyridoxine)	Supports the metabolism of homocysteine to cysteine; essential for hemoglobin 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.	Long-term use at >200 mg/day causes paranesthesia, somnolence and low serum folic acid; >2000 mg/day can cause nerve damage; several human studies are available- but has limitations; upper safe level determination based on dog study

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.	Anecdotal reports of 10 mg – no adverse effects; 200 mg/day- no toxicity; clinical data did not show adverse effects at 9 mg/day for 4 years; 10 mg/day for 15 days; 4 mg/day for 3 weeks or 2.5 mg/day for 6-15 months
Vitamin B12 (Cobalamin)	Regulates myelin metabolism; metabolizes homocysteine to methionine.	Fatigue, apathy, paleness, brittle hair and nails, depression, arteriosclerosis, impaired resistance to infections.	Few case reports of adverse effects; no adverse effects of cyanocobalamin at doses up to 4.5 mg/day for 14 days; 2 mg/day for up to one year or 1 mg/day for several years; no adverse effects of methylcobalamine at 6 mg/day for several weeks; 2 mg/day unlikely to produce adverse effects

It is generally recognized that the water-soluble B vitamins have a much wider range of safe intake levels than do the fat-soluble vitamins. Vitamins Bs are unlikely to accumulate in the human body as can the fat-soluble vitamins (A, D, E, and K). However, the available information suggests 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. The information in safety/toxicity of individual B vitamins suggest that the toxicity of these vitamins is rare and is noted at very high levels as compared to the daily required intakes.

In order to make sure that the resulting maximum amount (90th percentile) of individual vitamin B's from the intended uses of sprouted quinoa preparation (PANMOL® B-COMPLEX US100 [without Folic Acid]) 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 14). The data presented in Table 14 shows that the resulting maximum daily intake from the proposed uses is slightly higher as compared to Daily Value for all vitamins. Similarly, as compared to the RDA/AI, the resulting intake of all vitamins from the proposed uses is higher (about 8-10%). Of the seven vitamins present in sprouted quinoa preparation, upper limits have been established for niacin and pyridoxine by the IOM. For niacin and pyridoxine the resulting intake is lower than the upper limit established by IOM (Table 14). 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 14. Comparison of Resulting Maximum Intake of B-Vitamins from PANMOL® B-COMPLEX US100 (without Folic Acid) with RDA 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)***	UK, EGVM Safe Level
B1 as thiamin (mg)	1.63	1.5	1.2	1.1	Not established	100 mg/day[2]
B2 as riboflavin (mg)	1.85	1.7	1.3	1.1	Not established	43 mg/day[1]
B3 as niacin (mg)	21.78	20.00	16.00	14.00	35	560 mg/day[1]
B5 as pantothenic acid (mg)	10.89	10.00	5.00*	5.00*	Not established	210 mg/day[1]
B6 as pyridoxine (mg)	2.18	2.00	1.3	1.3	100	10 mg/day[3]
B7 as biotin (μg)	327	300	300	300	Not established	970 μg/day[3]
B12 as cobalamin (μg)	6.5	6	2.4	2.4	Not established	2000 μg/day[4]

*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. [1] Considered as safe, [2] For guidance only; [3] based on dog study; [4] for cyanocobalamin

Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Vitamin B12, Pantothenic Acid, Biotin, and Choline (IOM, 1998)

UK, EGVM safe dose determination is for background intake plus intake from dietary supplement (EGVM, 2003).

In addition to IOM (1998), the UK Expert Group on Vitamins and Mineral published a report on "Safe Upper Levels for Vitamins and Mineral" (EGVM, 2003). The report primarily focused in determining whether the current total intake of individual vitamins from its intake from diet (background exposure) plus intake from dietary supplement is safe. The assessment from the Expert Group on maximum safe levels is provided in Table 14. In establishing these values the Expert Group critically reviewed all available animal and human safety data. The safety values as determined clearly demonstrate that the resulting maximum intake of each of the seven B vitamins from the proposed uses of sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) is several fold lower as compared to the safe levels.

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 bw/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 (B7) 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 cobalamin (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 IOM has not established the upper limits of oral consumption for five B vitamins (B1, B2, B5, B7, and B12), while for two vitamins (B3 and B6) upper limit has been determined as 25 and 100 mg/day, respectively. For B3 (niacin) and B6 (pyridoxine) the resulting intake from proposed uses is lower. The intake of other five B vitamins is slightly/nominally higher than Daily Value or RDA. The UK, EGVM (2003) has critically analyzed the available information to determine whether the current exposure to B vitamins from background exposure plus dietary supplement is safe. As compared to the EGVM safe levels the intake of all seven vitamins from the proposed uses of PANMOL® B-COMPLEX US100 (without Folic Acid) is 3- to 300-fold lower. Thus the available information demonstrate that the daily intake level of the seven B vitamins in enriched quinoa sprout extract, under intended conditions of use, are less than the level of intake determined to have no adverse effects by two independent panels of qualified experts.

6.2.3. Human Studies

In recent years, some clinical trials have been conducted following oral administration of quinoa preparations to human subjects. The objectives of the majority of these studies were to examine the health effects 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 15. 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 consumed 2 capsules twice a day (total 4 capsules) containing the test product daily. Although the levels of quinoa sprout preparation 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 B Complex 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 of basic buffer reserves 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. The publication does not mention about any adverse effects.

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 significant increase in 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 15. 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 normal with small decrease in total cholesterol, LDL, HDL, and triglycerides	Quinoa is safe for consumption by celiac patients
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 show quinoa consumed as food in amounts that are two orders of magnitude greater than what will be the level of consumption for PANMOL® B-COMPLEX US100 (without Folic Acid) is without any safety concern. The level of B-vitamins enrichment of the PANMOL® B-COMPLEX US100 (without Folic Acid) is less than the safe upper intake levels established by several bodies of experts.

6.2.3.1. Quinoa and Celiac Disease

The available information indicates that quinoa contains low concentrations of prolamins and has a distant phylogenetic link with gluten containing cereals, ranging from chenopodiaceas (quinoa) to grammineas (wheat, barley, and rye). Given this association, there exist a potential that quinoa may adversely affect subjects with celiac disease. Zevallos et al. (2012) analyzed the concentration of celiac-toxic epitopes in quinoa cultivars from different regions of the Andes and to evaluate the ability of quinoa prolamins to stimulate adaptive and innate immune responses in patients with celiac disease. In this study, the concentration of celiac-toxic epitopes was measured by using murine monoclonal antibodies against gliadin and high molecular-weight glutenin subunits. Immune response was assessed by proliferation assays of celiac small intestinal T cells/interferon-g (IFN-g) and production of IFN-g/IL-15 after organ culture of celiac duodenal biopsy samples. Of the 15 quinoa cultivars tested, four cultivars were found to contain quantifiable concentrations of celiac-toxic epitopes, but they were below the maximum permitted for a gluten-free food. Cultivars Ayacuchana and Pasankalla stimulated T cell lines at levels similar to those for gliadin and caused secretion of cytokines from cultured biopsy samples at levels comparable with those for gliadin. The investigators concluded that the majority of quinoa cultivars do not possess quantifiable amounts of celiac-toxic epitopes. However, 2 cultivars had celiac toxic epitopes that could activate the adaptive and innate immune responses in some patients with celiac disease.

These investigators also reported that there is speculation involved in their conclusion and state: "… it is difficult to anticipate the effect of quinoa consumption in patients with CD (celiac disease); therefore, further investigation of quinoa including the amino acid profile (proline and glutamine), prolamin sub-fractions, and quinoa as a composite food within an *in vivo* feeding study will be needed to confirm the suitability of quinoa for patients with CD and to facilitate its full incorporation in the gluten-free market." In a subsequent human study by these authors (described above), Zevallos et al. (2014) investigated the use of quinoa seeds as a safe, gluten-free alternative to cereal grains in celiac patients and concluded that quinoa is safe for consumption by celiac patients. In another study, Penas et al. (2014) characterized 11 quinoa varieties for their suitability for celiac subjects. All the quinoa samples tested showed low binding affinity for both specific anti-gliandin antibodies and IgAs from celiac subjects suggesting that quinoa can be considered as a safe ingredient for celiac disease.

Furthermore, the intended use levels of sprouted quinoa in the specified food categories are very low (150 mg/serving) and the resulting 90^{th} percentile daily intake is only 605 mg/person/day. Therefore, absolute amounts of potential prolamins in the final food products would be far below any levels harmful to celiac disease patients. Sprouted quinoa is marketed by Vis Vitalis in Europe and Canada for the past six years and no adverse effects related to celiac disease has been reported. The quinoa cultivar used in the production of sprouted quinoa powder is commonly consumed in Austria, and no adverse effects of this cultivar related to celiac disease are reported in this region. It is well known that people with celiac disease are typically under the care of health professionals who advise them to follow a strict gluten-free diet and to avoid any other food products that may be contraindicated in causing adverse effects in this disease. Given all this, it is unlikely that the intended uses of sprouted quinoa powder (level of only 150 mg per serving) will 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 16.

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 16. 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 ($p>0.05$).
					Antioxi dant 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 16). In these studies, the 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.

6.2.5. Safety of Saponins and Phytic acid in Quinoa

Quinoa seeds are known to contain saponins and phytic acid that can exert negative effects on bioavailability of dietary nutrients. The seeds are coated with saponins that are responsible for characteristic astringent or bitter taste. To be edible, the saponins from quinoa must be removed. Traditionally, saponins have been removed by scrubbing the quinoa with alkaline water (Arendt and Zannini, 2013). The saponin content is checked by placing the grain in a tube, adding water and vigorously shaking for 30 seconds, if no foam occurs, all saponins are assumed to have been removed. Quinoa can be classified by its saponin content in to sweet or bitter variety. The sweet variety is free from or contains <0.11% free saponins, while the bitter variety contains >0.11% saponin.

Phytic acid is found in most cereals and legumes at concentration ranging from 1-3% dry matter (Arendt and Zannini, 2013). It is also found in some fruits and vegetables. In quinoa phytic acid is found in outer layer of quinoa as well as it is evenly distributed within the endosperm. The phytic acid in five varieties is reported to range from 10.5 to 13.5 mg/g. Phytic acid can bind to minerals such as Fe, Zn, Ca and Mg. Germination of quinoa has been reported to reduce the phytate and its degradation product by 35-39%.

For production of sprouted quinoa powder, the subject of present GRAS, Vis Vitalis uses food-grade quinoa. The legal requirements for food safety are respected. As mentioned above, the sprouted seeds are washed intensively with water after the germination process, whereby potentially contained saponins are removed and the phytic acid content is reduced. The phytic acid content of quinoa is on the one hand reduced by the germination process (Azeke et al., 2011; Gupta et al., 2015), and on the other hand it can be considered as insignificant due to the small amounts of intended use of quinoa powder (150 mg/serving). It should be noted that the intended use is as a food ingredient with resulting estimated 90th percentile intake of 605 mg/person/day. This intake of quinoa powder is very small as compared to the intake of quinoa as a food (consumption of about 50 g per portion can be assumed).

Given the low uses of sprouted quinoa powder, exposure to potential saponin or phytic acid content is far below any harmful amounts. Also as indicated earlier, saponins are water soluble and the sprouted seeds are rinsed with copious amounts of water thus removing the saponins. Similarly, the washing process with water also removes phytic acid. It has been well accepted that high-phytate foods, including grains, can raise the risk of iron and zinc deficiency and as a countermeasure, strategies such as soaking, sprouting and fermentation are often employed. Given the low use levels of sprouted quinoa powder and the use of water for washing is likely to further reduce the levels of saponins and phytic acid, any presence of saponins and phytic acid in the final product is unlikely to cause any adverse effects.

6.3. Summary and Discussion

Vis Vitalis intends to use sprouted quinoa preparation enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) as a nutrient source at use levels up to 150 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in various food products such as Baked Goods and Ready-to-eat cereals (not restricted by a Standard of identity). The product is 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 (without folic acid). The product concentrations of the B vitamins in the germination solution have been calibrated to produce the desired B vitamin (B1, B2, B3, B5, B6, B7, and B12) concentration in the sprouted quinoa. The intended use of sprouted quinoa enriched with B-vitamins in the specified foods will result in mean and 90th percentile intake of 327.27 and 605.46 mg/person/day, respectively. For safety assessment purposes intake at high levels of 605 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 are widely consumed in many countries, including the United States, as a food product. Sprouted quinoa enriched with B-vitamins is approved by Health Canada as source of B-vitamins. In European countries, quinoa sprouts enriched with 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.

There have been no modern scientific safety studies related to vitamin B enriched sprouted quinoa (PANMOL® B-COMPLEX US100 [without Folic Acid]); however the safety of PANMOL® B-COMPLEX US100 (without Folic Acid) can be extrapolated from the safe use of (1) B vitamins as ingredients used for nutrient fortification of foods, and (2) quinoa and quinoa sprouts as articles used as food. 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 (without Folic Acid) 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 (without Folic Acid) in selected foods resulting in a daily intake of 605 mg PANMOL® B-COMPLEX US100 (without Folic Acid)/person/day.

There is sufficient qualitative and quantitative scientific information to determine the safety-in-use of PANMOL® B-COMPLEX US100 (without Folic Acid) for its proposed uses. The GRAS status of PANMOL® B-COMPLEX US100 (without Folic Acid) 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 is well recognized that commonly consumed quinoa contains high amounts of vitamins, minerals and plant compounds, and is especially high in antioxidants.
- There is recognition that diets of many individuals are deficient in the B-vitamins.
- The B-vitamins are water soluble with no known significant adverse effects.
- PANMOL® B-COMPLEX US100 (without Folic Acid) 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 (without Folic Acid) for the intended use in food at levels resulting in daily intake of 605 mg/person/day is supported by current use levels in which no adverse effects have been reported in the published literature;
- PANMOL® B-COMPLEX US100 (without Folic Acid) is approved by Health Canada as a source ingredient for B vitamins and is marketed in European countries as a food ingredient.
- There is adequate data supporting the safety of PANMOL® B-COMPLEX US100 (without Folic Acid) available in the published literature.

In summary, the cumulative scientific information on PANMOL® B-COMPLEX US100 (without Folic Acid) --- 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 (without Folic Acid) at levels up to 605 mg/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 (without Folic Acid) at use levels of 150 mg/serving in food is considered as safe. The proposed uses are compatible with current regulations, *i.e.*, PANMOL® B-COMPLEX US100 (without Folic Acid) is used as a food nutrient in selected foods when not otherwise precluded by a Standard of Identity, and is produced at facility operating according to the principles of GMP.

[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.

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 sprouted quinoa preparation enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) as a nutrient source [21 CFR 170.3(o)(20)] at use levels up to 150 mg/serving (reference amounts customarily consumed, 21 CFR 101.12) in food products such as Baked Goods and Ready-to-eat cereals (not restricted by a Standard of identity). A comprehensive search of the scientific literature for safety and toxicity information on sprouted quinoa enriched with B-vitamins and its constituents was conducted through February 2018 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. The Expert Panel was selected and convened in accordance with the Food and Drug Administration (FDA)'s guidance for industry on "Best Practices for Convening a GRAS Panel"[6]. Vis Vitalis ensured that all reasonable efforts were made to identify and select a balanced Expert Panel with expertise in food safety, toxicology, and nutrition. Efforts were made to identify conflicts of interest or relevant "appearance issues" that could potentially bias the outcome of the deliberations of the Expert Panel. No such conflicts of interest or "appearance issues" were identified. The Expert Panel received a reasonable honorarium as compensation for their time; the honoraria provided to the Expert Panel were not contingent upon the outcome of their deliberations.

In arriving at this decision that sprouted quinoa enriched with 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 food, without any known safety concerns, as well as the published articles relating to the use of sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]) and the safety of other food products from sprouted quinoa enriched with B-vitamins. The Panel also relied upon reports from deliberative review by expert panels on safe upper levels for vitamins.

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 sprouted quinoa enriched with B-vitamins (PANMOL® B-COMPLEX US100 [without Folic Acid]), meeting the specifications cited above, and when used as a nutrient [21 CFR 170.3(o)(20)] at maximum use levels of up to 150 mg/serving in selected foods such as Baked Goods and Ready-to-eat cereals, when not otherwise precluded by a Standard of Identity, and resulting in the 90th percentile all-user estimated intake of 605 mg/person/day is safe and GRAS.

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[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] Available at:
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm583856.htm

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 (without Folic Acid), when used as described, is GRAS based on scientific procedures.

Signatures

[redacted]

Robert L. Martin, Ph.D.

April 23, 2018

Date

[redacted]

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

April 27, 2018

Date

[redacted]

James Hoadley, Ph.D.

April 26, 2018

Date

Adviser to Expert Panel

[redacted]

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

April 30, 2018

Date

7. Part VII – SUPPORTING DATA AND INFORMATION

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8. APPENDIX I

Certificate of analysis from different manufacturing lots

Batch 1 / page 1:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.1	

Specification release by production manager / Date: 30.01.2018	
Name: DI (FH) Harald Paril	**Sign:**

Certificate of Analysis release by quality assurance / Date: 06.03.2018	
Name: DI Denise-Silvia Pop	**Sign:**

Definition
PANMOL® B-COMPLEX US100 (without Folic Acid)
(Quinoa sprouts rich in biologically active vitamins)

Characteristics	**Reference**	**Requirements**	**Results**
Appearance	SOP-02-009	Powder	Complies
Colour	SOP-02-009	Off-white to yellow	Complies
Loss on drying	SOP-02-082	max. 8 %	3.1 %

Assay	**Reference**	**Requirements / 100g**	**Results**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg	186.14 mg
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg	193.14 mg
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2 g	2.91 g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1 g	1.59 g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg	242.65 mg
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg	34.27 mg
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 600 mcg	769 mcg

Microbiology	**Reference**	**Requirements**	**Results**
Total plate count	SOP-02-062	max. 50,000 cfu/g	< 100 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	< 100 cfu/g
Coliform	SOP-02-090	n.d. /g	n.d. /g

Stability and Storage	**Reference**	**Requirements**	**Results**
Shelf life	SOP-02-040	2,5 years	08.2020
Storage	SOP-02-040	Tightly closed, cool, dark and dry	Complies

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Version of the Specification	**Date**	**Par.**	**Reason for change:**
2	30.01.2018	BK	Renaming of the raw material

Druckdatum: 06.03.2018 17:31:00 Seite 1 von 2

Batch 1 / page 2:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.1	

Specification release by production manager / Date: 30.01.2018	
Name: DI (FH) Harald Paril	**Sign:**

Certificate of Analysis release by quality assurance / Date: 06.03.2018	
Name: DI Denise-Silvia Pop	**Sign:**

Heavy metals	Reference	Requirements	Results
Arsenic	SAM07 ***	max. 1 ppm	Not analysed
Cadmium	SAM07 ***	max. 1 ppm	Not analysed
Mercury	SAM07 ***	max. 0.1 ppm	Not analysed
Lead	SAM07 ***	max. 1 ppm	Not analysed

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:
2	30.01.2018	BK	Renaming of the raw material

Batch 2 / page 1:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.2	

Specification release by production manager / Date: 30.01.2018	
Name: DI (FH) Harald Paril	**Sign:** [redacted]

Certificate of Analysis release by quality assurance / Date: 06.03.2018	
Name: DI Denise-Silvia Pop	**Sign:** [redacted]

Definition
PANMOL® B-COMPLEX US100 (without Folic Acid) (Quinoa sprouts rich in biologically active vitamins)

Characteristics	**Reference**	**Requirements**	**Results**
Appearance	SOP-02-009	Powder	Complies
Colour	SOP-02-009	Off-white to yellow	Complies
Loss on drying	SOP-02-082	max. 8 %	3.4 %

Assay	**Reference**	**Requirements / 100g**	**Results**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg	176.15 mg
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg	185.00 mg
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2 g	2.92 g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1 g	1.49 g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg	252.18 mg
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg	35.77 mg
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 600 mcg	749 mcg

Microbiology	**Reference**	**Requirements**	**Results**
Total plate count	SOP-02-062	max. 50,000 cfu/g	< 100 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	< 100 cfu/g
Coliform	SOP-02-090	n.d. /g	n.d. /g

Stability and Storage	**Reference**	**Requirements**	**Results**
Shelf life	SOP-02-040	2,5 years	08.2020
Storage	SOP-02-040	Tightly closed, cool, dark and dry	Complies

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Version of the Specification	**Date**	**Par.**	**Reason for change:**
2	30.01.2018	BK	Renaming of the raw material

Batch 2 / page 2:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.2	

Specification release by production manager / Date: 30.01.2018	
Name: DI (FH) Harald Paril	**Sign:**

Certificate of Analysis release by quality assurance / Date: 06.03.2018	
Name: DI Denise-Silvia Pop	**Sign:**

Heavy metals	Reference	Requirements	Results
Arsenic	SAM07 ***	max. 1 ppm	Not analysed
Cadmium	SAM07 ***	max. 1 ppm	Not analysed
Mercury	SAM07 ***	max. 0.1 ppm	Not analysed
Lead	SAM07 ***	max. 1 ppm	Not analysed

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.

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Version of the Specification	Date	Par.	Reason for change:
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Batch 3 / page 1:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

vis vitalis gmbh

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.3	

Specification release by production manager / Date: 30.01.2018	
Name: DI (FH) Harald Paril	**Sign:** [redacted]

Certificate of Analysis release by quality assurance / Date: 06.03.2018	
Name: DI Denise-Silvia Pop	**Sign:** [redacted]

Definition
PANMOL® B-COMPLEX US100 (without Folic Acid) (Quinoa sprouts rich in biologically active vitamins)

Characteristics	**Reference**	**Requirements**	**Results**
Appearance	SOP-02-009	Powder	Complies
Colour	SOP-02-009	Off-white to yellow	Complies
Loss on drying	SOP-02-082	max. 8 %	3.7 %

Assay	**Reference**	**Requirements / 100g**	**Results**
Vitamin B_1 as thiamine	HPLC-FLD *	≥ 150 mg	181.65 mg
Vitamin B_2 as riboflavin	HPLC-DAD *	≥ 170 mg	191.65 mg
Vitamin B_3 as total niacin	HPLC-DAD *	≥ 2 g	3.01 g
Vitamin B_5 as pantothenic acid	HPLC-DAD *	≥ 1 g	1.54 g
Vitamin B_6 as pyridoxin	HPLC-DAD *	≥ 200 mg	255.90 mg
Vitamin B_7 as biotin	VitaFast® **	≥ 30 mg	35.33 mg
Vitamin B_{12} as cobalamine	VitaFast® **	≥ 600 mcg	706 mcg

Microbiology	**Reference**	**Requirements**	**Results**
Total plate count	SOP-02-062	max. 50,000 cfu/g	< 100 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	< 100 cfu/g
Coliform	SOP-02-090	n.d. /g	n.d. /g

Stability and Storage	**Reference**	**Requirements**	**Results**
Shelf life	SOP-02-040	2,5 years	08.2020
Storage	SOP-02-040	Tightly closed, cool, dark and dry	Complies

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Version of the Specification	**Date**	**Par.**	**Reason for change:**
2	30.01.2018	BK	Renaming of the raw material

Batch 3 / page 2:

FB-02-033V2

Specification / Certificate of Analysis
Raw Material

Raw material: PANMOL® B-COMPLEX US100 (without Folic Acid)	**Supplier:** vis vitalis gmbh
Product code: 911035	**Version:** 2 (GRAS)
Batch Number: L18020113.3	

Specification release by production manager / Date: 30.01.2018
Name: DI (FH) Harald Paril **Sign:**

Certificate of Analysis release by quality assurance / Date: 06.03.2018
Name: DI Denise-Silvia Pop **Sign:**

Heavy metals	Reference	Requirements	Results
Arsenic	SAM07 ***	max. 1 ppm	Not analysed
Cadmium	SAM07 ***	max. 1 ppm	Not analysed
Mercury	SAM07 ***	max. 0.1 ppm	Not analysed
Lead	SAM07 ***	max. 1 ppm	Not analysed

Nutritional values	in 100g	Reference
Energy	~ 1693 kJ / 401 kcal	calculated
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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.
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Version of the Specification	Date	Par.	Reason for change:
2	30.01.2018	BK	Renaming of the raw material

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