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#769

By FedEx

March 16, 2018

Office of Food Additive Safety (HFS–200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

Re: GRAS Notice for Ascorbic Acid (Vitamin C)

Dear Sir or Madam:

We hereby submit the enclosed GRAS notice for the ascorbic acid (vitamin C), an underconsumed nutrient in the U.S., to be used as a substitute for other commercially available forms of ascorbic acid that are added to foods. While typical use levels will vary depending on the manufacturer and the product, the maximum use levels in foods for children four and over and adults is 90 mg/serving (i.e., 100% of the Reference Daily Intake (RDI or DV) of vitamin C). The maximum use levels in foods for infants six month and older is 25 mg/serving (i.e., 50% of the RDI or DV) for children one through three years old is 7.5 mg/serving (i.e., 50% of the RDI or DV). The statutory basis of the GRAS conclusion is scientific procedures.

The NutriFusion product can be included in baby foods (excluding use as a supplement to breast milk or infant formula) for infants from six to 12 months and children from one to four years old. Examples of these products include baby and toddler pureed fruits and vegetables, dinners, dairy-based foods intended for children six months up to four years, and toddler meals. The NutriFusion product is intended to be used only as a substitute for the existing commercially available forms of ascorbic acid on the market. In other words, the NutriFusion vitamin C extract is intended to be used in food categories that currently are formulated with other forms of ascorbic acid.

The GRAS notice does not contain any designated confidential business information. In accordance with the Agency's guidelines, we have enclosed one original copy of the GRAS notice, and one complete electronic copy of the GRAS notice on a compact disk (CD).

The notified substance was also the subject of GRAS Notice No. 690, which we requested the agency to cease its review on June 20, 2017. NutriFusion submitted the GRN No. 690 to FDA through the voluntary GRAS notice program following a pre-submission meeting on April 26, 2016. During the meeting, the agency encouraged NutriFusion to submit a single GRAS notice for the vitamin blends extracted from fruits and vegetables. We understand that when FDA received the GRAS notice, it ran into difficulty completing its review given the variability in the composition of the vitamin blends. We also understand FDA has since determined that GRAS notifications should be limited to single ingredients rather than blends. We agreed to withdraw the GRAS notice and to submit separate GRAS notices.

We are confident that the current GRAS notice, which only covers a single vitamin extract, addresses the questions FDA had regarding the identity and composition of the notified substance. We plan to submit GRAS notices for other single vitamin extracts in the future.

We are committed to cooperating with the Agency and believe an open dialog is one of the most effective ways to accomplish that objective. If any questions arise in the course of your review, please contact us, preferably by telephone or e-mail, so that we can provide a prompt response.

Sincerely,

(b) (6)

Martin J. Hahn
Partner
Hogan Lovells US LLP
martin.hahn@hoganlovells.com
202 637 5926

Cc:

Lauren Viebrock, Ph.D.
Consumer Safety Officer/Microbiology Reviewer
Office of Food Additive Safety
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HOGAN LOVELLS US LLP

GRAS Notice for Ascorbic Acid (Vitamin C) Extracted from Fruit and Vegetable Sources

March 16, 2018

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1.0 GRAS Statement and Certification

1.1 Claim of Exemption

On behalf of NutriFusion LLC (NutriFusion), Hogan Lovells US LLP (Hogan) is submitting this generally recognized as safe (GRAS) notice summarizing the data and information supporting NutriFusion's conclusion that its intended use of ascorbic acid (vitamin C) extracted from edible portions of commonly consumed fruits and vegetables using conventional extraction procedures is GRAS for use in foods intended for infants from six to 12 months of age, toddlers and young children from one to four, and the general population four and over, when used as a substitute for other commercially available sources of vitamin C.

1.2 Name and Address of the Notifier

NutriFusion LLC

1.3 Name of the Notified Substance

Ascorbic acid (vitamin C) from edible fruits and vegetables.

1.4 Intended Conditions of Use

The NutriFusion ascorbic acid will be used as a substitute for other commercially available forms of ascorbic acid that are added to foods. The NutriFusion product can be included in baby foods (excluding use as a supplement to breast milk or infant formula) for infants from six to 12 months and children from one to four years old. Examples of these products include baby and toddler pureed fruits and vegetables, dinners, dairy-based foods intended for children six months up to four years, and toddler meals. The NutriFusion product is intended to be used only as a substitute for the existing commercially available forms of ascorbic acid on the market. In other words, the NutriFusion vitamin C extract is intended to be used in food categories that currently are formulated with other forms of ascorbic acid.

While typical use levels will vary depending on the manufacturer and the product, the maximum use levels in foods for children four and over and adults is 90 mg/serving (i.e., 100% of the Reference Daily Intake (RDI or DV) of vitamin C). The maximum use levels in foods for infants six month and older is 25 mg/serving (i.e., 50% of the RDI or DV) for children one through three years old is 7.5 mg/serving (i.e., 50% of the RDI or DV).

1.5 Statutory Basis of GRAS Conclusion

Through scientific procedures in accordance with 21 CFR § 170.30(a) and (b).

1.6 GRAS Statement

The notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on the NutriFusion's conclusion that the notified substance is GRAS under the conditions of the intended use.

1.7 Availability of Information

A complete copy of the data and information that was used as a basis for this GRAS conclusion can be provided to the FDA upon request, and is also available for FDA's copying and reviewing during customary business hours at:

Martin J. Hahn
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

1.8 Trade Secret and Confidential Information

Certain information regarding the manufacturing section of this GRAS notice is exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552.

1.9 GRAS Certification

To the best of our knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to us and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

1.10 Signature

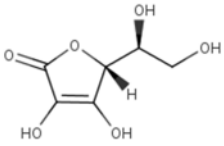
(b) (6)

_____
Martin J. Hahn
Hogan Lovells US LLP
martin.hahn@hoganlovells.com
202 637 5926

2.0 Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

2.1 Identity

Chemical identity information for ascorbic acid can be summarized in **Table 1**, below.

Table 1. Identity of Vitamin C Extracted from Fruits and Vegetables				
Name	**CAS Number**	**Molecular Formula**	**Molecular Weight**	**Synonyms**
Vitamin C	50-81-7		176	L- (+) - Ascorbic acid

The vitamin C extract also contains maltodextrin that encapsulates the vitamin C portion.

2.2 Characteristic Properties

Appearance: Free-flowing Powder

2.3 Quantitative Composition

The quantitative composition analysis of four non-consecutive product lots of NutriFusion vitamin C extract is summarized in **Table 2**, below.

Table 2. Quantitative Composition of Four Non-Consecutive Product Lots of NutriFusion Vitamin C Extract					
Constituent	**Range**	**Lot#-17-10-006-117**	**Lot#-17-10-007-117**	**Lot#-17-10-008-118**	**Lot#-17-10-010-118**
Vitamin C	25 - 30	27.41	28.15	27.9	28.36
Starch	67 - 72	69	70	68	68
Moisture	2 - 5	4.1	2.2	3.7	3.4

The results demonstrate the company is able to offer a standardized extract that meets the specification established for vitamin C extract in the product. *See also* **Attachment 1**.

2.4 Manufacturing Process

The nutrient blend is manufactured from edible portions of fruits and vegetables following good manufacturing practices for food (21 CFR Part 110 and 21 CFR Part 117, Subpart B, when it

becomes effective). All the starting materials have a long history of safe consumption. **Table 3** provides examples of the fruit or vegetable that can be used as a source for the ascorbic acid.

Table 3. Fruits and Vegetables Sources of Vitamin C	
Fruit/Vegetable Used as the Source (Edible Portions Only)	**Specie Names**
Plums	*Prunus domestica*, *Prunus salicina* and hybrids)
Black currant	*Ribes nigrum*
Broccoli	*Brassica oleracea*
Orange	*Citrus sinensis*
Beet	*Beta vulgaris*
Apple	*Malus pumila*
Strawberry	*Fragaria × ananassa*
Blueberry	*Vaccinium corymbosum*
Cranberry	*Vaccinium macrocarpon, Vaccinium oxycoccos*

NutriFusion uses various conventional extraction methods to extract the vitamins and will select the method that is most effective depending on the fruit or vegetable matrix and the nutrient(s) that are extracted. The solvents most commonly used are water, ethanol or critical $CO_{2.}$ Solid phase extraction is also used. The solvent extraction process can be described as follows:

1. Food grade fruits and vegetables are harvested, sorted, garbled (i.e., the desired part of the plant (the edible portion) is separated from other parts of the plant), and dried.
2. The dried plants are prepared for extraction by grinding into a fine powder to maximize the surface area available for extraction.
3. An Individual dried plant, or a blend of dried fruits and vegetables with naturally occurring ascorbic acid, will then be immersed in solvents commonly used in food processing (e.g., water, alcohol, or critical CO_2).
4. The extraction process can take several days.
5. Once the extraction process is complete the solvent and plant solids are separated by centrifugation.
6. The liquid portion is decanted and stored in a container for later processing (see step 9).
7. The extraction can be repeated with the solid materials separated by centrifugation as needed (for example, the plant material could first be exposed to an aqueous extraction and after centrifugation, the remaining solids could then be subjected to an ethanol extraction to isolate those remaining vitamins that are soluble in ethanol but not in water).
8. The ascorbic acid rich liquid is then freeze dried and encapsulated with food grade GRAS ingredients such as maltodextrin to protect them from oxidation.

The solid phase extraction can be described as follows:

1. Food grade fruits and vegetables are harvested, sorted, garbled, and dried.

2. The dried plants are prepared for extraction by grinding into a fine powder to maximize the surface area available for extraction.
3. An individual dried plant, or a blend of dried fruits and vegetables with naturally occurring ascorbic acid will be blended together, will then be immersed in solvents commonly used in food processing (e.g., water, alcohol, or critical CO_2).
4. The solution will then pass through a single-use cartridge containing a chromatographic sorbent (e.g., silica particles that have been functionalized on their surface) using appropriate food grade food contact substances that are authorized by FDA for this type of use;
5. Another common food-grade solvent will be used as elute to remove the nutrients retained on the stationary phase.
6. The collected liquid will be stored in a container.
7. The extracted ascorbic acid is removed from the container, freeze dried, and then encapsulated with food grade GRAS ingredients such as maltodextrin to protect the ascorbic acid from oxidation.

2.5 Specifications

We are attaching the analytical reports on four non-consecutive production lots that demonstrate the products meet the heavy metal and microbiological specifications. We also include vitamin C levels from four non-consecutive production lots.

Table 5. Impurity Specification

Item	Limit	Method	Lot#-17-10-006-117	Lot#-17-10-007-117	Lot#-17-10-008-117	Lot#-17-10-010-117
Vitamin C	25% - 30% 1/	CFIA LCAQ 001-09	27.41%	28.15%	-	-
Arsenic	< 1.0 ppm	USEPA-6010C	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
Cadmium	< 0.5 ppm	USEPA-6010C	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
Lead	< 1.5 ppm	USEPA-6010C	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
Mercury	< 0.2 ppm	USEPA-7471B	< 0.01 ppm	< 0.01 ppm	< 0.01 ppm	< 0.01 ppm
Bismuth	< 0.2 ppm	USEPA-6010C	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm
Antimony	< 0.2 ppm	USEPA-6010C	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm	< 0.1 ppm

1/ Vitamin C levels in Lot#-17-10-008-118 and Lot#-17-10-010-118 also meet the specifications. *See* **Table 2**. As reported in Table 2, starch and water are also parts of the vitamin C blend. These two excipients are used to encapsulate the vitamin C to protect it from oxidation. The Company views their levels immaterial to the safety assessment of the vitamin C blend, and, thus, has not established specifications for starch or moisture levels.

Table 5. Impurity Specification						
Item	**Limit**	**Method**	**Lot#-17-10-006-117**	**Lot#-17-10-007-117**	**Lot#-17-10-008-117**	**Lot#-17-10-010-117**
Total Aerobic Plate Count	< 3,000 CFU/g	AOAC-966.23	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g
Total Yeast/Mold Count	< 300 CFU/g	FDA BAM 7th Ed.	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g
E. coli Count	< 3 MPN/g	AOAC-966.24	< 3 MPN/g	< 3 MPN/g	< 3 MPN/g	< 3 MPN/g
Salmonella Count	Negative	AOAC-2004.03	Negative	Negative	Negative	Negative
Total Coliforms	< 10 MPN/g	AOAC-966.24	< 1 MPN/g	< 1 MPN/g	< 1 MPN/g	< 1 MPN/g
Staphylococcus Aureus	< 1 CFU/g	AOAC-975.55	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g	< 1 CFU/g

See also **Attachment 2**.

2.6 Stability Data

NutriFusion created this innovative source of ascorbic acid extracted from fruits and vegetables and is merely a supplier of this extract to companies that will then formulate the vitamin C extract into various foods. As such, the customer ultimately is responsible for deciding the level of the vitamin C extract that will be added as well as the data supporting any claims that are made on their finished product throughout the shelf life of the product. The customer, therefore, has the responsibility to determine the level of overages, if any, which will need to be added to the product at time of formulation to meet the level of vitamin C declared on the label throughout the shelf life of the product.

NutriFusion, nonetheless, is aware of customers that have formulated its vitamin C into foods and dietary supplements and has collected products from commerce to evaluate the level of its vitamin C that can be detected in these commercially available foods. For the stability data, NutriFusion analyzed a dietary supplement containing the NutriFusion vitamin C extract. NutriFusion supplied this dietary supplement company with a nutrient blend that contains vitamin C extract in 2013. NutriFusion collected two commercially available samples of the dietary supplement from commerce in 2015 and analyzed the product for the levels of vitamins in the product. The analytical report can be found in **Attachment 3**. The data demonstrate the vitamin C extract used to formulate the dietary supplement remained stable throughout this two year period of time. We note the manufacturer of this dietary supplement has established an expiration date of May 2017, demonstrating the manufacturer expects the vitamins to remain stable for at least four years.

NutriFusion also wanted to assess the stability of its nutrient blend including vitamin C extract in a food matrix. NutriFusion supplies a pasta company with one its nutrient blends. The pasta goes through various stages and exposures to heat from the time of manufacture until it is consumed. The pasta company will formulate the flour, vitamin blend, and other ingredients into dough, extrude the pasta in the proper shape, and then subject the extruded pasta to a drying oven to dry the pasta to the desired moisture level. The pasta will be transported and held at retail and by consumers at ambient conditions. When preparing the pasta, the labeled directions for use instruct the consumers to cook the pasta in boiling water for 11-13 minutes.

NutriFusion collected from commerce a 10-month old pasta made by a pasta company. NutriFusion instructed the laboratory to prepare the pasta according to the labeled directions for use and to analyze the cooked pasta to assess the level of vitamins in the product compared to those declared on the label. The laboratory results and copy of the declared nutrient values are found in **Attachment 4** and summarized in the table below. As the data indicate, the level of vitamin C in the cooked 10-month old pasta is in line with the declared nutritional claims.

Table 6: Stability of Vitamin Blend in Cooked Pasta

Vitamin	Label Declared Value (%DV)	Analytical Value #1 (% DV)	Analytical Value #2 (% DV)	Analytical Value #3 (% DV)
Vitamin C	25	26	24	25

2.7 Detailed Information on Intended Use

The NutriFusion vitamin C extract product is intended for use by infants from six to 12 months of age, toddlers and young children from one to four, and the general population four and over, when used as a substitute for commercially available vitamin blends, most of which are synthetic. For infants from six to 12 months and children from one to four, the NutriFusion product will be used in baby foods purees (e.g., fruits, veggies, dinners, dairy), toddler meals, and other foods specifically formulated and positioned for children under four. The uses of the NutriFusion vitamin C extract will be substitutional with the currently authorized commercially available vitamin C. Under 21 CFR §182.3013 (“Ascorbic acid”), there are currently no limits other than cGMPs for vitamin C.

The typical use levels will vary depending on the manufacturer and the product. The maximum recommended use levels in foods for children four and over and adults is 90 mg/serving. The maximum recommended use levels in foods for infants six month and older is 25 mg/serving for children one through three years old is 7.5 mg/serving.

3.0 Dietary Exposure

The intended use of the NutriFusion product will be a substitutional use with the ascorbic acid extracted from fruits and vegetables replacing other currently authorized commercially available sources of ascorbic acid and would not increase dietary exposures. According to the Scientific

Report of the 2015 Dietary Guideline Advisory Committee and reviews conducted by the Institute of Medicine (IOM), the current 90th percentile intake of vitamin C from foods and beverages among children 1 through 3 years old and all individuals four and over can be summarized with the table below.

Table 7. Common Vitamins 90th Percentile Intake		
Nutrient	**90th Percentile Intake (≥4) 2/**	**90th Percentile Intake (1 - 3)**
Vitamin C	177.1 mg/day	164.7 mg/d

2/ We adopt the highest 90th percentile intake data reported for different age groups. Also, when there are different 90th percentile intake values reported for male and female, we adopt the higher number for the purpose of conservatism.

4.0 Self-limiting Levels of Use

The use of NutriFusion product will be controlled closely through the product formulation. The self-limiting levels of use are not known.

5.0 Experience Based on Common Use in Food before 1958

The NutriFusion blend was not marketed prior to 1958. The fruit and vegetables used to extract the vitamin C extract, however, have an extensive history of use prior to 1958. Infants, toddlers, young children, and humans four and over have been consuming the fruit and vegetables used as the sources of the vitamins in most instances, for over a millennia. Moreover, in general, the quantity of whole fruit and vegetable used to extract the ascorbic acid is comparable to typical consumption levels of that fruit or vegetable. *See* **Table 8**. While the history of use of these fruits and vegetables prior to 1958 is supportive of the GRAS status, this notification is based on scientific procedures and not common use in foods.

6.0 GRAS Narrative

6.1 Overview

The fruit and vegetables used for the extraction have a long safe consumption history and their GRAS status is well-established. NutriFusion uses process methods that are commonly used such as solvent extraction and solid phase extraction in food processing to extract and isolate the vitamins commonly found in various fruits and vegetables. In many instances, the quantity of the fruit or vegetable that is needed to deliver 100 percent of the RDI is comparable to the quantity of the fruit or vegetable consumed in a normal eating occasion. **Table 8** identifies the fruit or vegetable that could be used as a source for the ascorbic acid, the maximum use level (which is set at 100 percent of the RDI for children over four and adults), and the quantity of the whole fruit or vegetable that, if consumed, would provide 100 percent of the RDI.

Table 8. Comparison of Fruit and Vegetable Source Consumption

Source	Maximum Use Level	Vitamin C Source of Fruits/Vegetables	Comparable Quantity of Fruit/Vegetable
Plums	90 mg/serving	9.5 mg/ 100g 3/	947.4 g of plums
Black currant	90 mg/serving	181 mg/100 g 4/	49.7 g of black currant
Broccoli	90 mg/serving	89.2 mg/ 100g 5/	100.9 g of broccoli
Orange	90 mg/serving	53.2 mg/100g 6/	169.2 g of orange

According to 21 CFR §170.30(d), "[a] food of natural biological origin that has been widely consumed for its nutrient properties . . . without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS." As the above table indicates, the intended use of the NutriFusion vitamin C extract is roughly equivalent in all instances with the

3/ *See* USDA National Nutrient Database for Standard Reference Release 28: Report 09279 "Plums, raw."
4/ *See* USDA National Nutrient Database for Standard Reference Release 28: Report 09083 "Currants, european black, raw."
5/ *See* USDA National Nutrient Database for Standard Reference Release 28: Report 11090 "Broccoli, raw."
6/ *See* USDA National Nutrient Database for Standard Reference Release 28: Report 09200 "Oranges, raw, all commercial varieties."

consumption of five or more servings of fruits and vegetables per day – the existing dietary recommendation. We, therefore, would not expect the NutriFusion vitamin C extract product to contain levels of any unintended soluble constituents from the plant that would present a health or safety concern. We recognize the manufacturing process will result in the extraction of the vitamins as well as any other soluble constituents that may be present in the plant material. Even if there are incidental constituents concentrated in the finished NutriFusion products along with the vitamins, the level of potential dietary intake of these constituents would be comparable or less than what a consumer would otherwise be exposed to when consuming a comparable level of the plant material used to extract the vitamin.

We also recognize it is possible the manufacturing process could extract the constituent in the fruit or vegetable that may be linked to an allergy or sensitivity. Allergic reactions are triggered by proteins while sensitivities can be triggered by other constituents in a food. In addition, individuals with oral allergy syndrome are usually sensitized to one or more pollens and could react to proteins in specific fresh fruits and vegetables that cross-react with the pollen allergens.7/ We also recognize some consumers experience reactions that can be triggered by constituents in certain fruits and vegetables other than proteins.

As reported in Table 2, the GRAS substance is not expected to contain protein. We recognize it is possible one of the allergenic proteins found in the source plant could be present in the extracted vitamin C. To the extent a consumer has an allergy or sensitivity to one of the fruits or vegetables used as the source materials, final blend could contain that particular substance. Any concerns with allergies and sensitivities are handled through labeling. The labels of the foods bearing the NutriFusion vitamin C extract will identify each fruit or vegetable used in the extraction process. Individuals with a food allergy or sensitivity to one of the fruits or vegetables used in the extraction process, therefore, will be able to identify the possible presence of the plant material and can avoid the product.

We, therefore, view the long history of consumption of fruits and vegetables and the use of conventional food processing extractions methods as supporting the GRAS status of the NutriFusion vitamin C extract. The GRAS status is further demonstrated by a review of the scientific literature. For example, several authoritative bodies including the IOM and the European Food Safety Authority (EFSA) have conducted comprehensive reviews of the safety data related to the vitamins including vitamin C. When comparing the current 90th percentile intake of vitamin C to the safety levels identified by various expert groups, the intended use of the NutriFusion vitamin C extract product can be reasonably expected to be safe.

7/ Taylor, Steve L., and Susan L. Hefle. *Food allergies and other food sensitivities* Food Technology 55.9 (2001): 68-84.

6.2 Safety Assessment

6.2.1 Vitamin C

Vitamin C, also known as ascorbic acid, is a water-soluble vitamin. The biological functions of vitamin C are based on its ability to provide reducing equivalents for a variety of biochemical reactions. Because of its ability to donate electrons, vitamin C is also an effective anti-oxidant. The Scientific Report of the 2015 Dietary Guidelines Advisory Committee concluded vitamin C is underconsumed among the U.S. population ages 2 years and older. Vitamin C has very low toxicity and is not believed to cause serious adverse effects even at high intakes. There is no scientific evidence suggesting that vitamin C is carcinogenic or teratogenic, or that it causes adverse reproductive effects. The adverse effects have been reported primarily after very large doses (greater than 3 g/day) and these effects include symptoms such as diarrhea and other gastrointestinal disturbances, increased oxalate excretion, and kidney stone formation. 8/

Vitamin C is listed as GRAS under 21 CFR §182.3013 ("Ascorbic acid"), there are no limits other than cGMP.

- **IOM (2000) 9/**

After reviewing extensive safety data related to vitamin C, the IOM selected osmotic diarrhea and related gastrointestinal disturbances as the critical endpoints on which to base a UL. Specifically, the UL for children 1-3 years old is set at 400 mg/day and the UL for adults is set at 2,000 mg/day. The IOM also noted that the *in vivo* data did not show a causal relationship between excess vitamin C intake by apparently healthy individuals and other adverse effects. Overall, the IOM found the risk of adverse effects resulting from excess intake of vitamin C from food and supplements to be very low even at the highest intake levels.

- **EFSA (2004) 10/**

EFSA reviewed the vitamin C safety data in 2004. The agency noted that despite the extensive use of high doses of vitamin C in some vitamin supplements, there have been few controlled studies that specifically investigated the adverse effects and the acute gastrointestinal intolerance is the mostly clearly defined effect. EFSA concluded that the available human data suggested that supplemental daily doses of vitamin C up to about 1 g, in addition to normal dietary intakes, are not associated with adverse gastrointestinal effects.

Vitamin C is affirmed with GRAS with no limitations other than GMPs. The vitamin C extracted from fruits and vegetables is a substitutional use and would not increase vitamin C dietary exposure. Based on the safety reviews conducted by the IOM and EFSA, even very

8/ *See* Institute of Medicine. *Food and Nutrition Board. DRI, Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids.* National Academy Press, 2000.
9/ *See id*.
10/ EFSA Journal (2004) 59, 1-21.

conservatively assuming the intended use of vitamin C in the NutriFusion product will replace all the existing uses, the 90th percentile dietary intake of 177.1 mg/day can reasonably be considered as safe.

6.3 Safety Conclusion

Several expert panels organized by reputable scientific and regulatory agencies including the IOM and EFSA have reviewed the available safety data on the various vitamins and established safety levels when appropriate. The intended use of the NutriFusion vitamin C extract is a substitutional use given that the synthetic vitamin C is currently authorized for use with no limits other than GMPs. The current cumulative intake of vitamin C in children one to three years old, children above four, and adults are all well below the ULs set by the IOM.

Table 9. Vitamins 90th Percentile Intake and UL Among Different Age Groups

Age Groups	90th Percentile Intake (Male) 11/	90th Percentile Intake (Female)	UL 12/
1-3	161.4 mg/day	164.7 mg/d	400 mg/d
4-8	134.4 mg/day	124.5 mg/d	650 mg/d
9-13	130.1 mg/day	122.5 mg/d	1,200 mg/d
14-18	157.8 mg/day	121.0 mg/d	1,800 mg/d
19-30	176.3 mg/day	135.2 mg/d	2,000 mg/d
31-50	177.1 mg/day	140.1 mg/d	2,000 mg/d
50 and over	156.9 mg/day	144.5 mg/d	2,000 mg/d

Vitamin C is also considered an underconsumed nutrient in the U.S. by the 2015 Dietary Guidelines Advisory Committee. The long history of consumption of fruits and vegetables as a source of vitamin C also supports its safety. In addition, the underlying safety reviews establish the safety of including the plant-based vitamin C in the diet.

Overall, the existing dietary intake from the proposed use can be considered safe. We, therefore, are of the view that there is a consensus among experts qualified by scientific training and experience to evaluate the safety that there is reasonable certainty the intended use of the NutriFusion vitamin C extract product is not harmful.

In summary, due to the demonstrated safe consumption history of the fruits and vegetables that are used to make the NutriFusion vitamin C extract product, as well as the expert panels opinions, we concluded that the intended use of NutriFusion vitamin C extract product in foods that are otherwise authorized for the addition of vitamins can be considered GRAS through scientific procedures.

11/ Millen, B. E., A. H. Lichtenstein, and S. Abrams. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee." *Washington (DC): Department of Health and Human Services* (2015).
12/ *See supra* note 7.

7.0 List of Supporting Data and Information

All of the following data and information are publicly available.

- USDA National Nutrient Database for Standard Reference Release 28
- Taylor, Steve L., and Susan L. Hefle. *Food allergies and other food sensitivities* Food Technology 55.9 (2001): 68-84.
- Institute of Medicine. Food and Nutrition Board. *DRI, Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids*. National Academy Press, 2000.
- EFSA Journal (2004) 59, 1-21.
- Millen, B. E., A. H. Lichtenstein, and S. Abrams. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee." *Washington (DC): Department of Health and Human Services* (2015).

Attachment 1

CORNERSTONE LABORATORIES, LLC

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001

Cornerstone Report#: 300-17-006
Attn: William Grand, NutriFusion, LLC.
Address; 10641 Airport Pulling Road North, Ste 31, Naples, FL 34109.
Cornerstone Reference #(s): 140689-140692.

Date Sampled: None Given
Date Received: 10/27/17
Date of Report: 11/14/17

Quality Conformance Results

Vitamin C Powder on Maltodextrin Lot#-17-10-006-117

Analysis	Results	Units	Method	Specification Range
Water Soluble Vitamins				
Vitamin C (Ascorbic Acid)	27.41	%, w/w	CFIA LCAQ 001-09	25-30
Physical				
Total Starch	69	%, w/w	AOAC-925.38	-
Moisture	4.1	% w/w	Vac Oven	-
Total	100.51%			

Vitamin C Powder on Maltodextrin Lot#-17-10-007-117

Analysis	Results	Units	Method	Specification Range
Water Soluble Vitamins				
Vitamin C (Ascorbic Acid)	28.15	%, w/w	CFIA LCAQ 001-09	25-30
Physical				
Total Starch	70	%, w/w	AOAC-925.38	-
Moisture	2.2	% w/w	Vac Oven	-
Total	100.35%			

Vitamin C Powder on Maltodextrin Lot#-17-10-008-118

Analysis	Results	Units	Method	Specification Range
Water Soluble Vitamins				
Vitamin C (Ascorbic Acid)	27.90	%, w/w	CFIA LCAQ 001-09	25-30
Physical				
Total Starch	68	%, w/w	AOAC-925.38	-
Moisture	3.7	% w/w	Vac Oven	-
Total	99.60%			

Vitamin C Powder on Maltodextrin Lot#-17-10-010-118

Analysis	Results	Units	Method	Specification Range
Water Soluble Vitamins				
Vitamin C (Ascorbic Acid)	28.36	%, w/w	CFIA LCAQ 001-09	25-30
Physical				
Total Starch	68	%, w/w	AOAC-925.38	-
Moisture	3.4	% w/w	Vac Oven	-
Total	99.76%			

Attachment 2

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001

Cornerstone Report#: 334-17-003
Attn: William Grand, NutriFusion, LLC.
Address; 10641 Airport Pulling Road North, Ste 31, Naples, FL 34109.
Cornerstone Reference #(s): 141285.

Date Sampled: None Given
Date Received: 11/30/17
Date of Report: 12/11/17

Quality Conformance Results

Vitamin C Powder on Maltodextrin Lot#-17-10-006-117

Analysis	Results	Units	Method	Threshold Limit
Heavy Metals				
Arsenic	<0.1	ppm, w/w	USEPA-6010C	1.0
Cadmium	<0.1	ppm, w/w	USEPA-6010C	0.5
Lead	<0.1	ppm, w/w	USEPA-6010C	1.5
Mercury	<0.01	ppm, w/w	USEPA-7471B	0.2
Bismuth	<0.1	ppm, w/w	USEPA-6010C	0.2
Antimony	<0.1	ppm, w/w	USEPA-6010C	0.2
Microbiology				
E. coli Count (3 Tube MPN)	<3	MPN/G	AOAC-966.24	<3
Total Aerobic Bacteria Count	<1	CFU/G	AOAC-966.23	<3,000
Total Yeast/Mold Count	<1	CFU/G	FDA BAM 7th Ed.	<300
Total Coliforms Count (3 Tube MPN)	<1	MPN/G	AOAC-966.24	<10
Salmonella Count	Negative	-	AOAC-2004.03	Negative
Staphylococcus Count	<1	CFU/G	AOAC-975.55	<1

(b) (6)

Samuel J. LaBonia
President and Technical Director

CORNERSTONE LABORATORIES, LLC

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001

Cornerstone Report#: 334-17-003
Attn: William Grand, NutriFusion, LLC.
Address; 10641 Airport Pulling Road North, Ste 31, Naples, FL 34109.
Cornerstone Reference #(s): 141286.

Date Sampled: None Given
Date Received: 11/30/17
Date of Report: 12/11/17

Quality Conformance Results

Vitamin C Powder on Maltodextrin Lot#-17-10-007-117

Analysis	Results	Units	Method	Threshold Limit
Heavy Metals				
Arsenic	<0.1	ppm, w/w	USEPA-6010C	1.0
Cadmium	<0.1	ppm, w/w	USEPA-6010C	0.5
Lead	<0.1	ppm, w/w	USEPA-6010C	1.5
Mercury	<0.01	ppm, w/w	USEPA-7471B	0.2
Bismuth	<0.1	ppm, w/w	USEPA-6010C	0.2
Antimony	<0.1	ppm, w/w	USEPA-6010C	0.2
Microbiology				
E. coli Count (3 Tube MPN)	<3	MPN/G	AOAC-966.24	<3
Total Aerobic Bacteria Count	<1	CFU/G	AOAC-966.23	<3,000
Total Yeast/Mold Count	<1	CFU/G	FDA BAM 7th Ed.	<300
Total Coliforms Count (3 Tube MPN)	<1	MPN/G	AOAC-966.24	<10
Salmonella Count	Negative	-	AOAC-2004.03	Negative
Staphylococcus Count	<1	CFU/G	AOAC-975.55	<1

(b) (6)

Samuel J. LaBonia
President and Technical Director

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001

Cornerstone Report#: 334-17-003
Attn: William Grand, NutriFusion, LLC.
Address; 10641 Airport Pulling Road North, Ste 31, Naples, FL 34109.
Cornerstone Reference #(s): 141287.

Date Sampled: None Given
Date Received: 11/30/17
Date of Report: 12/11/17

Quality Conformance Results

Vitamin C Powder on Maltodextrin Lot#-17-10-008-117

Analysis	Results	Units	Method	Threshold Limit
Heavy Metals				
Arsenic	<0.1	ppm, w/w	USEPA-6010C	1.0
Cadmium	<0.1	ppm, w/w	USEPA-6010C	0.5
Lead	<0.1	ppm, w/w	USEPA-6010C	1.5
Mercury	<0.01	ppm, w/w	USEPA-7471B	0.2
Bismuth	<0.1	ppm, w/w	USEPA-6010C	0.2
Antimony	<0.1	ppm, w/w	USEPA-6010C	0.2
Microbiology				
E. coli Count (3 Tube MPN)	<3	MPN/G	AOAC-966.24	<3
Total Aerobic Bacteria Count	<1	CFU/G	AOAC-966.23	<3,000
Total Yeast/Mold Count	<1	CFU/G	FDA BAM 7th Ed.	<300
Total Coliforms Count (3 Tube MPN)	<1	MPN/G	AOAC-966.24	<10
Salmonella Count	Negative	-	AOAC-2004.03	Negative
Staphylococcus Count	<1	CFU/G	AOAC-975.55	<1

(b) (6)

Samuel J. LaBonia
President and Technical Director

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001

Cornerstone Report#: 334-17-003
Attn: William Grand, NutriFusion, LLC.
Address; 10641 Airport Pulling Road North, Ste 31, Naples, FL 34109.
Cornerstone Reference #(s): 141288.

Date Sampled: None Given
Date Received: 11/30/17
Date of Report: 12/11/17

Quality Conformance Results

Vitamin C Powder on Maltodextrin Lot#-17-10-010-117

Analysis	Results	Units	Method	Threshold Limit
Heavy Metals				
Arsenic	<0.1	ppm, w/w	USEPA-6010C	1.0
Cadmium	<0.1	ppm, w/w	USEPA-6010C	0.5
Lead	<0.1	ppm, w/w	USEPA-6010C	1.5
Mercury	<0.01	ppm, w/w	USEPA-7471B	0.2
Bismuth	<0.1	ppm, w/w	USEPA-6010C	0.2
Antimony	<0.1	ppm, w/w	USEPA-6010C	0.2
Microbiology				
E. coli Count (3 Tube MPN)	<3	MPN/G	AOAC-966.24	<3
Total Aerobic Bacteria Count	<1	CFU/G	AOAC-966.23	<3,000
Total Yeast/Mold Count	<1	CFU/G	FDA BAM 7th Ed.	<300
Total Coliforms Count (3 Tube MPN)	<1	MPN/G	AOAC-966.24	<10
Salmonella Count	Negative	-	AOAC-2004.03	Negative
Staphylococcus Count	<1	CFU/G	AOAC-975.55	<1

(b) (6)

Samuel J. LaBonia
President and Technical Director

Attachment 3

CORNERSTONE LABORATORIES LLC

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001 Fax: (901) 398-4223

Cornerstone Report#: 033-15-004
Attn: Brad Young, AddisonField, Inc.
Address; 2 Townsend Street, 2-808, San Francisco, CA 94107.
Cornerstone Reference #(s): 117210-117211.

Date Sampled: 01/15/15
Date Received: 02/02/15
Date of Report: 02/13/15

Quality Conformance Results

RDA-12 Dietary Supplement Powder Lot#1304048 MFG:05/2013

Analysis	Results	Units	Method	Specification Range
Physical				
Moisture	1.6	% w/w	Vac Oven	5.0
Fat Soluble Vitamins				
Vitamin A	2,680	IU/225mg	AOAC-974.29M	2,514
Vitamin E	18.3	IU/225mg	AOAC-974.29M	15
Vitamin D	279	IU/225mg	AOAC-982.29M	257
Phylloquinone K_1	52	mcg/225mg	JOFCA#42M	42
Water Soluble Vitamins				
Vitamin C	39	mcg/225mg	JOFCA#94M	31
Thiamin B_1	745	mcg/225mg	JOCA-A1007M	756
Riboflavin B_2	910	mcg/225mg	JOCA-A1007M	869
Niacin B_3	10,115	mcg/225mg	JOCA-A1007M	9,946
Pantothenic Acid	5,020	mcg/225mg	JOCA-A1007M	5,172
Pyridoxine-B_6	811	mcg/225mg	JOCA-A1007M	970
Biotin B_7	174	mcg/225mg	JOCA-A1007M	157
Folic Acid B_9	206	mcg/225mg	JOCA-A1007M	186

Comments

Sample was received in its original packaging.

EPA#TN01074
AOCS#485183
ADEQ#88-0859

AOAC#93939
APHA#9798654
ASTA LISTED

CORNERSTONE LABORATORIES LLC

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001 Fax: (901) 398-4223

Cornerstone Report#: 033-15-004
Attn: Brad Young, AddisonField, Inc.
Address; 2 Townsend Street, 2-808, San Francisco, CA 94107.
Cornerstone Reference #(s): 117210-117211.

Date Sampled: 01/15/15
Date Received: 02/02/15
Date of Report: 02/13/15

Quality Conformance Results

RDA-12 Dietary Supplement Capsules Lot#1304047 MFG:05/2013 Capsule Weight (avg) 410mg

Analysis	Results	Units	Method	Specification Range
Physical				
Moisture	5.1	% w/w	Vac Oven	5.0
Fat Soluble Vitamins				
Vitamin A	2,440	IU/capsule	AOAC-974.29M	2,514
Vitamin E	14.8	IU/capsule	AOAC-974.29M	15
Vitamin D	261	IU/capsule	AOAC-982.29M	257
Phylloquinone K_1	40	mcg/capsule	JOFCA#42M	42
Water Soluble Vitamins				
Vitamin C	30	mcg/capsule	JOFCA#94M	31
Thiamin B_1	759	mcg/capsule	JOCA-A1007M	756
Riboflavin B_2	881	mcg/capsule	JOCA-A1007M	869
Niacin B_3	9,960	mcg/capsule	JOCA-A1007M	9,946
Pantothenic Acid	5,203	mcg/capsule	JOCA-A1007M	5,172
Pyridoxine-B_6	995	mcg/capsule	JOCA-A1007M	970
Biotin B_7	162	mcg/capsule	JOCA-A1007M	157
Folic Acid B_9	180	mcg/capsule	JOCA-A1007M	186

Comments

Sample was received in its original packaging.

(b) (6)

Samuel J. LaBonia
President and Technical Director

EPA#TN01074
AOCS#485183
ADEQ#88-0859

AOAC#93939
APHA#9798654
ASTA LISTED

Attachment 4

NUTRI FUSION™

Pasta Study

Background:

1. **NutriFusion™ is** a blend of fruits and/or vegetables that can significantly increase the nutritional profile, and therefore the marketability, of food, beverage and supplement products. It does not affect taste or functionality of the products it goes into and is 100% natural.
2. NutriFusion supplies the complex nutrients and phytonutrients from fresh fruits and vegetables.
3. **Three major claims can be made:**
   - % of RDI: Such as 25 % of the recommended daily value for Vitamins A, C, D, E, B1, B2 etc.
   - Source claim: Such as rich in antioxidants, excellent source of Vitamins A, C, D, E, B1, B2 etc.
   - Serving Claims: Such as provides the nutrients from 1 serving of vegetables in each serving of pasta.
4. In certain products, such as baked goods, it can extend shelf life due to the high levels of anti-oxidants (both from vitamins and polyphenols in the fruits & vegetables).

Purpose:

1. The purpose of the study was to see if the pasta prepared at home by the consumer would retain the nutritional value from NutriFusion™ as stated on the nutritional label per the pasta box.
2. The pasta goes through 3 stages of heat in production and consumption:
   a. Initial production: the flour etc is mixed, cooked and turned into wet pasta.
   b. The pasta then goes through a 4-6 hour drying oven at 185-195 degrees F. to dry for cutting and packaging.
   c. Finally, the consumer, at home, cooks the pasta in boiling water for 11-13 minutes.

Methodology:

10 month old pasta was randomly selected for testing.

Background:

- A third-party lab was sent 3 boxes of pasta made with GrandFusion™;
- Finished pasta boxes were randomly selected for testing. Per the box code, the pasta was produced 10 months prior to testing.
- The lab was instructed to cook the pasta per the directions on the box as a normal consumer would at home. [The directions are to boil water, add the pasta, wait for re-boil, and cook for 11 to 13 minutes.]

Results:

1. Attached you will find the nutritional analysis supplied by Cornerstone Labs, Memphis TN.
2. The nutritional results are 100% in line with the original nutritional claims on the box.
3. There was no decline in the nutrients per the nutritional analysis panel on the pasta box.
4. The pasta shows an excellent shelf life; indicating the consumer is benefiting from the bioactive nutrients found in NutriFusion™/GrandFusion™.

Study Completed: July 15, 2013

Why this is important!

Pending Health Crisis:

1. The CDC, the World Health Organization and many other international bodies feel the world is heading to a global health crisis. Heart disease, cancer, and diabetes are assuming epidemic proportions. The number one reason is the lack of protective nutrients in our diets. Why is this happening?

    - Poor diets. We are not getting enough of the protective nutrients in our diets. There's no shortage of calories but the key nutrients that promote health and protect us are missing.
    - Lack of physical activity.

2. Only 6% of individuals achieve their recommended target for vegetables and
3. 8% achieve their recommended target for fruit in an average day per the USDA guidelines.

    Source: **The National Fruit & Vegetable Alliance's** National Action Plan report card. Steering Committee Members include:

- CDC, Centers for Disease Control & Prevention,
- American Cancer Society,
- American Diabetes Association,
- American Dietetic Association,
- American Heart Association,
- National Cancer Institute,
- USDA: (Food, Nutrition and Consumer Services, Research, Education and Economics, Marketing and Regulatory Programs).
- California Department of Public Health,
- National Alliance for Nutrition & Physical Activity,
- Produce for Better Health Foundation,
- American Frozen Food Institute,
- Canned Food Alliance,
- Produce Marketing Association,
- United Fresh Produce Association,
- National Council of Fruit & Vegetable Nutrition Coordinators,

http://www.nfva.org/pdfs/nfva/FINALNAP2010.pdf **The National Fruit & Vegetable Alliance's** National Action Plan report card

CORNERSTONE LABORATORIES LLC

1775 Moriah Woods Blvd., Ste. 12 ▪ Memphis, TN 38117 ▪ (901) 398-4001 Fax: (901) 398-4223

NUTRIFUSION, LLC. **July 15, 2013**
ATTN: WILLIAM J.H. GRAND
3 CLAIRE DRIVE
HILTON HEAD, SC 29928

ACCOUNT #: 10-0623 **REPORT NUMBER: 179-13-013**

Reference: [redacted]

LABORATORY REPORT
CASE NARRATIVE

On June 28, 2013 three samples were submitted to the laboratory for analyses detailed on the chain of custody accompanying the samples. The samples were received sealed and in good condition. Prior to analysis the samples were prepared as per the box label. There were no analytical problems encountered and the results of the analysis are on the following pages.

If you have any questions about this report please do not hesitate to contact me.

Thank you for using Cornerstone Laboratories.

Sincerely,

(b) (6)

Samuel J. LaBonia
President and Technical Director

EPA#TN01074 **AOAC#93939**
AOCS#485183 **APHA#9798654**
ADEQ#88-0859 **ASTA LISTED**

CORNERSTONE LABORATORIES, LLC

NUTRIFUSION, LLC. **July 15, 2013**

ACCOUNT #: 10-0623 **REPORT NUMBER: 179-13-013**

Reference: [redacted]

Report Analysis

Laboratory Number: 104220

Sample ID: Pasta Plus Veggie Rotini
Serving Size: 56g
Samples Taken: 07/09/13

Nutrient	Result/Serving	Units	%DV	100% DV	Analysis Date	Analyst
Vitamin A	1,140	IU	23%	5,000	07/10/13	S. LaBonia
Vitamin E	8.2	IU	27%	30	07/10/13	S. LaBonia
Vitamin D	105	IU	26%	400	07/13/13	S. LaBonia
Vitamin C	15.8	mg	26%	60	07/12/13	K. Shinn
Vitamin B1	0.664	mg	44%	1.50	07/12/13	K. Shinn
Vitamin B6	0.593	mg	30%	2.00	07/12/13	K. Shinn
Vitamin K	0.010	mg	13%	0.080	07/14/13	S. LaBonia

Laboratory Number: 104221

Sample ID: Pasta Plus Veggie Penne Rigate
Serving Size: 56g
Samples Taken: 07/09/13

Nutrient	Result/Serving	Units	%DV	100% DV	Analysis Date	Analyst
Vitamin A	1,290	IU	26%	5,000	07/10/13	S. LaBonia
Vitamin E	8.8	IU	29%	30	07/10/13	S. LaBonia
Vitamin D	113	IU	28%	400	07/13/13	S. LaBonia
Vitamin C	14.2	mg	24%	60	07/12/13	K. Shinn
Vitamin B1	0.627	mg	42%	1.50	07/12/13	K. Shinn
Vitamin B6	0.616	mg	31%	2.00	07/12/13	K. Shinn
Vitamin K	0.011	mg	14%	0.080	07/14/13	S. LaBonia

CORNERSTONE LABORATORIES, LLC

NUTRIFUSION, LLC. **July 15, 2013**

ACCOUNT #: 10-0623 **REPORT NUMBER: 179-13-013**

Reference: [redacted]

Report Analysis

Laboratory Number: 104222

Sample ID: Pasta Plus Veggie Elbows
Serving Size: 56g
Samples Taken: 07/09/13

Nutrient	Result/Serving	Units	%DV	100% DV	Analysis Date	Analyst
Vitamin A	1,206	IU	24%	5,000	07/10/13	S. LaBonia
Vitamin E	7.8	IU	26%	30	07/10/13	S. LaBonia
Vitamin D	96	IU	24%	400	07/13/13	S. LaBonia
Vitamin C	15.0	mg	25%	60	07/12/13	K. Shinn
Vitamin B1	0.651	mg	43%	1.50	07/12/13	K. Shinn
Vitamin B6	0.577	mg	29%	2.00	07/12/13	K. Shinn
Vitamin K	0.015	mg	19%	0.080	07/14/13	S. LaBonia

[redacted]

[redacted]

[redacted]

Nutrition Facts

Serving Size 2 oz dry (56 g)

Amount Per Serving		
Calories	200	Calories From Fat 10
		% Daily Value*
Total Fat 1 g		**2 %**
Saturated Fat	0 g	**0 %**
Trans Fat 0g		
Polyunsaturated Fat	0.5 g	
Monounsaturated Fat	0 g	
Cholesterol	0 mg	**0 %**
Sodium	0 mg	**0 %**
Total Carbohydrate	41 g	**14 %**
Dietary Fiber	2 g	**24 %**
Sugars	2 g	
Protein	7 g	

Vitamin A	20%	Vitamin C	25%
Calcium	0%	Iron	10%
Vitamin D	20%	Vitamin E	25%
Thiamin	40%	Riboflavin	15%
Niacin	20%	Vitamin B6	25%
Folate	30%	Magnesium	15%

* Percent daily values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Saturated Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Ingredients

Durum Wheat Semolina, [enriched with iron (ferrous sulfate) and B vitamins (niacin, thiamin mononitrate, riboflavin, folic acid)], nutrients from whole food concentrates (spinach, broccoli, carrot, tomato, beet, shiitake mushrooms), Color (paprika oleoresin, fruit juice concentrate (watermelon, huito), turmeric oleoresin), maltodextrin, gum arabic, ascorbic acid.

2/2/16

[redacted]