GR

ORIGINAL SUBMISSION

Original Submission

POLSINELLI GRN 000538

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August 12, 2014

Peggy Binzer
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RECEIVED
AUG 13 2014
OFFICE OF
FOOD ADDITIVE SAFETY

Antonia Mattia, Ph.D.
Division of Biotechnology and GRAS notice Review (HFS-225)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkway
College Park, MD 20740

Re: GRAS Notification for Cane Juice Electrolyte

Dear Dr. Mattia:

We respectfully submit the attached GRAS Notification on behalf of our client, Nutraceutical & Natural Products (NNP) and the Queensland Department of Agriculture, Fisheries and Forestry (DAFF), for Cane Juice Electrolyte for use as a food ingredient for fruit juice and flavored water. We are submitting three (3) hard copies of the GRAS Notification and Form FDA 3667.

We look forward to the Agency's review of this submission and we would be happy to provide you with any further information you ~~may~~ need.

(b) (6)

Sincerely,

(b) (6)

Peggy Binzer

(b) (6)

Enclosure

GRN 538

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statemen

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE (GRAS) NOTICE

FDA USE ONLY

GRN NUMBER 000538	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

RECEIVED AUG 13 2014 OFFICE OF FOOD ADDITIVE SAFETY

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: 2013-04-01

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier	Name of Contact Person Mike Lehman / David Poulsen	Position CEO / Science Leader	
	Company *(if applicable)* Nutraceutical & Natural Products AG (NNP) / Department of Agriculture, Fisheries and Forestry (DAFF)		
	Mailing Address *(number and street)* Bahnhofstrosse 27 6300 ZUG		
City Zug	State or Province n/a	Zip Code/Postal Code	Country Switzerland
Telephone Number +41 41 71 10 25 0/ 0428-536-579	Fax Number	E-Mail Address mike.lehman@nnp.ch / david.poulsen@daff.gov.au	
1b. Agent or Attorney *(if applicable)*	Name of Contact Person Margaret C. Binzer	Position Attorney	
	Company *(if applicable)* Polsinelli, PC		
	Mailing Address *(number and street)* 1401 Eye Street, N.W.		
City Washington	State or Province D.C.	Zip Code/Postal Code 20005	Country United States of America
Telephone Number 202-626-8362	Fax Number	E-Mail Address pbinzer@polsinelli.com	

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PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

Cane Juice Electrolytes

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

☐ Electronic Submission Gateway

☒ Paper

☐ Electronic files on physical media with paper signature page

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes _____

Total number of pages _____

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

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

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

☐ a) GRAS Notice No. GRN _____

☐ b) GRAS Affirmation Petition No. GRP _____

☐ c) Food Additive Petition No. FAP _____

☐ d) Food Master File No. FMF _____

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

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

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

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 8)*

☒ No *(Proceed to Part IV)*

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

☐ Yes, see attached Designation of Confidential Information

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

☐ No

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

☐ Yes, a redacted copy of the complete submission

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

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).*

The cane juice electrolyte will be used as a food ingredient in fruit juice (excluding baby juice) and flavored waters.

The cane juice electrolyte is intended to be added to 100% fruit juice (excluding baby juices) and flavored waters at a maximum use level of 7.5% by weight in the beverages as consumed.

The cane juice electrolyte is intended to serve as a source of potassium.

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

☐ Yes ☒ No

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PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
1	Cane Juice Electrolytes				
2					
3					

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (1 - 3) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)* and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), no carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s))*, and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source)*, and include any known toxicants that could be in the source.

Cane juice electrolytes are substances obtained by removal of the majority of sugar and other constituents from purified sugar cane juice and contains 95% by weight of sugar cane juice minerals, mainly potassium and 90% by weight less sugar when compared to purified sugar cane juice. Cane juice electrolytes are produced by filtration by which most of the sugar is removed.

3. Synonyms

Provide as available or relevant:

1	
2	
3	

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PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- ☒ Any additional information about identity not covered in Part V of this form
- ☒ Method of Manufacture
- ☒ Specifications for food-grade material
- ☒ Information about dietary exposure
- ☒ Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- ☐ Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- ☒ Comprehensive discussion of the basis for the determination of GRAS status
- ☐ Bibliography

Other Information

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

☐ Yes ☒ No

[illegible]

☐ [illegible] ☐ [illegible]

PART VII – SIGNATURE

1. The undersigned is informing FDA that NNP and DAFF *(name of notifier)* has concluded that the intended use*(s)* of Cane Juice Electrolytes *(name of notified substance)* described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. ☒ NNP and DAFF *(name of notifier)* agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

NNP and DAFF *(name of notifier)* agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

Polsinelli PC, 1041 Eye Street, N.W., Suite 800, Washington, D.C. 20005
(address of notifier or other location)

NNP and DAFF *(name of notifier)* agrees to send these data and information to FDA if FDA asks to do so.

OR

☐ The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No. ---------- *(GRAS Affirmation Petition No.)*

(b) (6)

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
(b) (6)	Margaret C. Binzer	08/12/2014

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(b) (6)

PART VIII – LIST OF ATTACHMENTS

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

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Cover Letter to Anotonia Mattia, Ph.D.	N/A
	GRAS Notification for Cane Juice Electrolyte	27 pages

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OMB Statement: Public reporting burden for this collection of information is estimated to average 150 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Health and Human Services,Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, Room 400, Rockville, MD 20850. (Please do NOT return the form to this address.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

GRAS NOTIFICATION FOR CANE JUICE ELECTROLYTE

Prepared for:

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

Prepared by:

Polsinelli, PC
1401 Eye Street, N.W.
Suite 800
Washington, D.C. 20005

Date:

August 12, 2014

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I. Introduction

Polsinelli, PC submits the enclosed information on behalf of our client, Nutraceutical & Natural Products AG, in support of this notification that cane juice electrolyte is generally recognized as safe (GRAS) for use in several food applications.

The cane juice electrolytes are intended for use as a food ingredient for nutritional purposes in fruit juice (excluding baby juice) and flavored water.

We submit information in the following areas:

- The identity and specifications for the cane juice electrolyte;
- The manufacturing process for the cane juice electrolyte;
- The intended uses and an estimate of consumption of the cane juice electrolyte;
- Supportive evidence of the long history of safe use of electrolytes and sugar cane juice.

It is our expectation that FDA will concur that the information presented fully supports the determination that the cane juice electrolyte as produced by Natural Nutritional Products are GRAS for use in several food applications.

II. Administrative Information

A. Claim Regarding GRAS Status

Nutraceutical & Natural Products AG (NNP) and the Queensland Department of Agriculture, Fisheries and Forestry (DAFF) have determined that cane juice electrolyte is GRAS for use in fruit juice and flavored water based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and in conformance with the guidance issued by FDA under proposed 21 C.F.R. § 170.36 Fed. Reg. 18938 (Apr. 17, 1997). The analytical data, published studies, and information that are the basis for this GRAS determination are available for FDA review and copying at reasonable times at Polsinelli PC, 1401 Eye Street, NW, Suite 800, Washington DC 20005, or will be sent to FDA upon request.

B. Name and Address of the Notifiers

Nutraceutical & Natural Products AG
Bahnhofstrasse 27
6300 Zug Switzerland

Department of Agriculture, Fisheries and Forestry (DAFF)
Queensland Austrailia

All communication on this matter are to be sent to Counsel for the Notifiers:

Peggy Binzer
Polsinelli PC
1401 Eye Street, NW
Suite 800
Washington DC 20005
Telephone: 202.626.8962
Email: pbinzer@polsinelli.com

C. Common or Usual Name of GRAS Substance

The common and usual names for the GRAS ingredient is "cane juice electrolyte."

D. Intended Use of GRAS Substance

The cane juice electrolyte will be used as a food ingredient in fruit juice (excluding baby juices) and flavored waters.

The cane juice electrolyte is intended to be added to 100% fruit juice (excluding baby juices) and flavored waters at a maximum use level of 7.5% by weight in the beverages as consumed.

Cane juice electrolyte is intended to serve as a source of potassium.

E. Self-Limiting Levels of Use

The use of the cane juice electrolyte is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability.

III. Product Identity and Specifications

A. Product Identification

Cane Juice electrolytes are substances obtained by removal of majority of sugar and other constituents such as colorants from purified sugar cane juice and contain 95% by weight of sugarcane juice minerals mainly potassium and 90% by weight less sugar when compared to purified sugar cane juice. Cane Juice electrolytes contain negligible amounts of fat and proteins.

Table 1. Cane Juice Electrolyte per 100ml Serving (Batch Production)

	Sample 1	Sample 2
Energy (kJ)	33	37
Cal	8	9
Protein	<0.06g	<0.06g
Fat	<1g	<1g
Trans Fat	<0.01g	<0.01g

Sodium	7.3 mg	5.5 mg
Potassium	100 mg	100 mg
Magnesium	4.4. mg	3.8 mg

B. Product Specifications

Table 2 provides the typical composition and microbiological and lead specifications for various cane juice electrolytes and their test methods. The product is standardized to potassium level. The cane juice electrolytes are produced in single strength, ready to drink (RTD) composition similar to the one shown in Table 1 above. However, these electrolytes are normally concentrated into a liquid concentrate or dried and are made available as a light yellow powder due to advantages with logistics and storage.

See Appendix 1. Representative Composition of Cane Juice Electrolytes

Table 2. Cane Juice Electrolytes Product Characterization Data

	ID Description of Data	**Certificate No**	**Issue Date**	**Sample Description**
1	Microbial analysis	222677-A	March 5, 2013	12255-201 (200 g); 12283-101 (300 g)
2	Heavy metals analysis	222677-B	March 4, 2013	12255-201 (200 g); 12283-101 (300 g)
3	Multi-residue analysis	222677-C	March 4, 2013	12255-201 (200 g); 12283-101 (300 g)
4	Nutritional composition	222677-D	March 8, 2013	12255-201 (200 g); 12283-101 (300 g)
5	Method breakdown summary	Method Details Breakdown 010313.pdf	March 1, 2013	not applicable

Heavy metals limits of reporting - not applicable

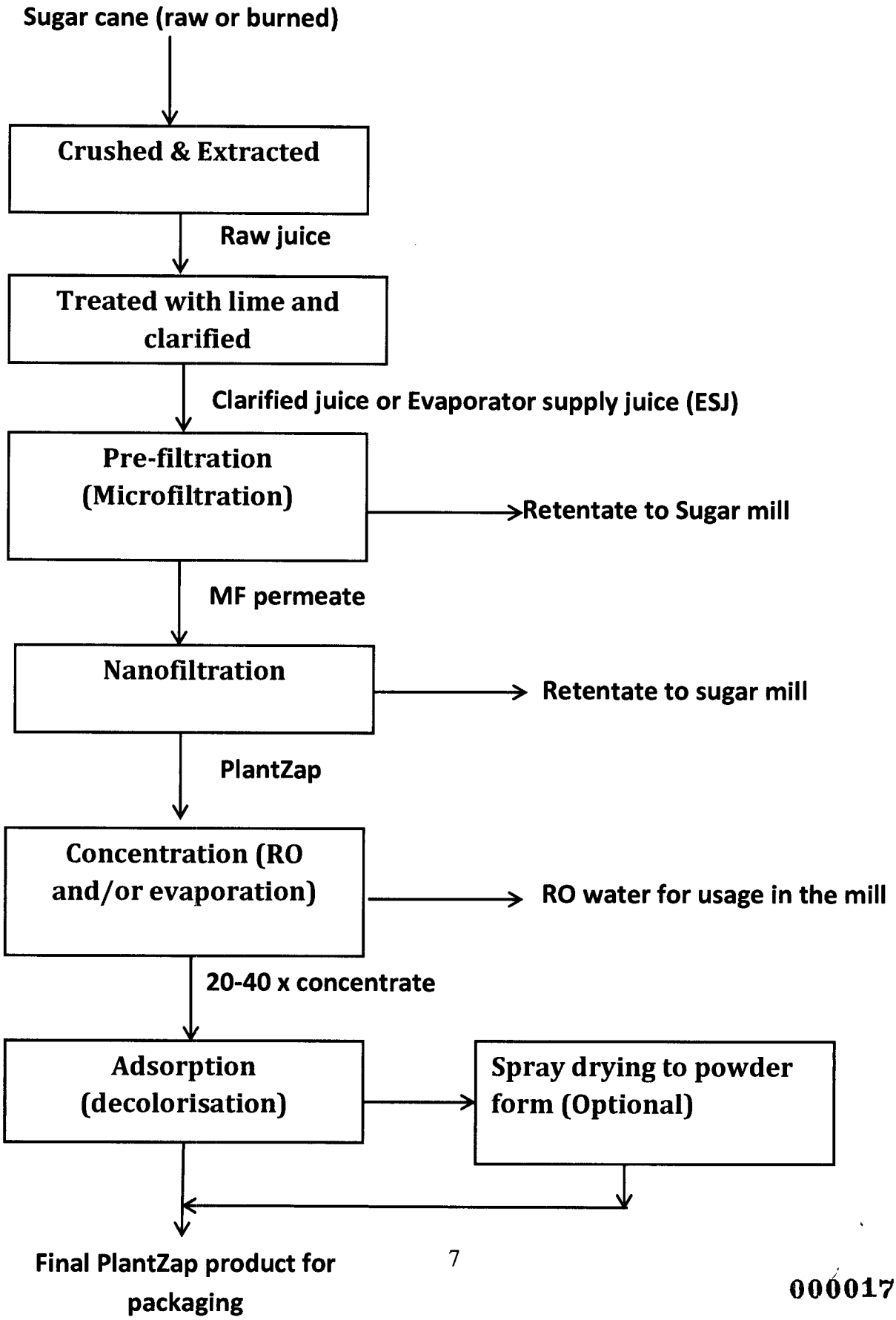
IV. Manufacturing Process

Figure 1 below provides a step-by-step illustration of the manufacturing process, which we also describe below.

The cane juice electrolytes are manufactured from clarified cane juice (ESJ) in accordance with Good Manufacturing Practices (cGMP) for food (21 C.F.R. Part 110).

The manufacturing techniques employed to produce the electrolytes and remove sugar and other constituents from sugar cane juice are based primarily on the use of membrane filtration technologies, as listed in 21 C.F.R. § 177.2910 (" Micro, nano and reverse osmosis (RO)-filtration membranes").

Figure 1. Manufacturing Process Flow Chart



All membrane materials employed in the production of cane juice electrolytes comply with applicable food-contact regulations, and the use of such technologies complies with cGMP for food (21 C.F.R. Part 110).

Two distinct semi-permeable membrane processes are employed as core technologies in the manufacture of cane juice electrolytes: microfiltration (MF) and nanofiltration(NF). The raw material (clarified cane juice) is first sent through a microfiltration membrane which basically helps to remove all the particulate material and microbes from the juice. Permeate stream of MF membrane circulated along a semi-permeable NF membrane in a pressure-driven process. The membrane is permeable to low molecular weight constituents (electrolytes, some sugars, and other low molecular weight components) that pass through and form a permeate stream. High molecular weight constituents are preferentially retained by the membrane (sugar) and become components of the retentate stream which is sent back to mill for sugar manufacture. The permeate stream of NF membrane is considered as single strength cane juice electrolytes. These electrolytes are concentrated by RO membranes and by evaporation to have logistic and storage (longer-shelf-life) advantages. The electrolyte concentrate is finally passed through an adsorption column to standardize colour and taste and packed. An optional spray drying technique is employed if the product is required in powder form.

V. Consideration of Potential Contaminating Materials

A. Heavy Metals

Cane juice electrolyte is tested regularly for the presence of heavy metals. The elemental metals analyses measured levels of 15 metals in the samples using inductively coupled plasma mass spectrometry (ICPMS). Levels of antimony, cadmium, lead, mercury, and silver were below the limit of reporting (LOR) of 0.01 mg/kg, or < 0.01 ppm. The level of tin was below the LOR of 0.025 mg/kg, or < 0.025 ppm, and the level of molybdenum was below the LOR of 0.2 mg/kg, or < 0.2 ppm. For six of the eight metals detected at levels above the LOR (chromium, copper, manganese, nickel, selenium, zinc), an RDA/AI and/or a UL was established by the IOM (see Table 3). The EDI of each of these six metals from the proposed use of cane juice electrolyte is below the UL and the recommended intake for the nutrients (for all nutrients other than nickel, which does not have and AI or RDA), and therefore does not indicate a need for toxicity testing.

The IOM did not establish DRIs for arsenic or cobalt. Arsenic was reviewed by the IOM, but there were insufficient data to set a UL (IOM 2006). The mean level of arsenic in the concentrate in the two analyzed samples was 0.15 mg/kg, or 150 ppb. Assuming a maximum use of 7.5% cane juice electrolyte by weight in fruit juices and flavored water as consumed, the mean concentration of arsenic in the cane juice electrolyte samples as consumed is 11 ppb ([150 ppb arsenic in concentrate] x [7.5 g concentration/100 g beverage as consumed]; however, this value of 11 ppb excludes any arsenic contributions from the juice or water. The concentration of arsenic in water (or juice) can conservatively be assumed to be no more than 10 ppb in the remaining 92.5% of the product since any water used in the production of a food must comply with the federal drinking water standard of no more than 10 ppb arsenic, therefore the total

concentration is the beverages as consumed is no more than approximately10 ppb ([0.075 x 11 ppb] + [0.925 x 10 ppb]).

The US Food and Drug Administration (FDA) has analyzed levels of arsenic in juice and juice concentrates from apple and pear (FDA 2011, 2012). These products have been determined to be safe, therefore levels of arsenic in the apple and pear juice and juice concentrate samples provide a reference for levels that are not a public health risk in juice and juice concentrates.

A total of 142 pear juice and concentrate samples were analyzed by the FDA between 2005 and 2011 (FDA 2012); total arsenic concentrations were converted to levels in a single-strength juice. In the 118 samples with inorganic levels of no concern (below 23 ppb), mean and median total arsenic concentrations were 21.4 and 10.0 ppb, respectively, with total mean arsenic concentrations ranging from 0 to 124 ppb. The level of arsenic was measured in a total of 94 samples of single strength apple juice by the FDA in 2011 (FDA 2011); the mean and median total arsenic concentrations were 6.2 and 6.1 ppb, respectively, with the concentration ranging from 0.4 to 36.0 ppb. In both the pear and apple juice samples, values reported as ND were assigned a value of ½ the lowest Limit of Detection (LOD) (i.e., 0.5 x 0.2 = 0.1), and values reported as Trace were assigned a value of ½ of the difference between the lowest LOD and Limit of Quantification (LOQ) (i.e., ½ x [1-0.2] = 0.4). The mean concentration of total arsenic in the cane juice electrolyte as consumed, no more than approximately10 ppb, is therefore within the level of arsenic found in juices determined to be of no public health risk.

The IOM did not establish Dietary Reference Intakes for cobalt. The UK Expert Group on Vitamins and Minerals (EVM), however, recently reviewed information on cobalt and identified 23 mcg/kg total cobalt as a Guidance Level of exposure that would not be expected to result in any adverse effects; for a 60 kg adult, this is equivalent to 1400 mcg cobalt/day (FSA 2003). Intake of cane juice electrolyte at the 90th percentile level per user is estimated to result in an exposure to cobalt of approximately 1 mcg, which is below the Guidance Level for cobalt and therefore unlikely to be a public health risk.

B. Pesticide Residues

The analysis of pesticide residues completed on the two cane juice electrolyte samples was a broad residue screen that included 134 chemicals. For each analyte, the measured value was below the limit of reporting, which was 0.01 mg/kg for most analytes, and 0.02, 0.05 or 0.1 mg/kg for the remaining analytes. A preliminary review conducted by Exponent Inc.,[1] of the pesticides allowed for use on sugar cane in the United States and the pesticides included in the multi-residue battery indicate that only a fraction of pesticides permitted for use on sugar cane were examined.

C. Microbiological Contaminants

The analysis of microbiological contaminants included a Standard Plate Count, and enumeration of yeast, mold, coliforms, and presumptive Escherichia coli. In both tested samples

[1] Exponent Inc., 1150 Connecticut Avenue, N.W., Suite 1150, Washington, D.C. 200036. Memorandum Dated April 15, 2013

of cane juice electrolyte, the measured levels of the microbiological contaminants were at or below the apparent LOD and therefore raise no safety concerns under the intended conditions of use.

VI. Nutrition – Electrolytes

The cane juice electrolytes manufacturing process utilizes physical separation processes that simply concentrate the electrolytes in the juice and do not result in any substantive alteration to the chemical character of the cane juice constituents. Each 100 gram portion of cane juice electrolyte provides approximately 105 mg sodium, 1645 mg potassium, and 66 mg magnesium. Nutritional value includes a source of potassium, very low in sugar/carbohydrates and a favorable ratio of potassium to sodium.

Results of the analyses indicate that the product is approximately 63-64% water and approximately 32% carbohydrate in the form of sucrose. Ash accounts for 3.2 to 3.9% of the concentrate by weight in the two samples, with the balance of the concentrate present as protein (0.7-0.9%) and fat (0.1-0.2%). Each 100 g portion of cane juice electrolyte provides approximately 105 mg sodium, 1645 mg potassium, and 66 mg magnesium; these three minerals therefore account for approximately 50% of the ash in the concentrate.

The Institute of Medicine has established recommended dietary intakes for potassium, sodium, and magnesium (IOM 2006). The Daily Recommended Intakes (DRIs) include recommendations for daily intake referred to as a Recommended Dietary Allowance (RDA) or Adequate Intake (AI) level, and when possible, a Tolerable Upper Intake Level (UL). Definitions of these terms are as follows:

- RDA: The average daily dietary nutrient intake level that is sufficient to meet the nutrient requirements of nearly all (97-98 percent) healthy individuals in a particular life stage and gender group.
- AI: The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate; an AI is used when an RDA cannot be determined.
- UL: The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase. In some cases a UL was not determinable due to lack of data of adverse effects in an age group and concern with regard to lack of ability to handle excess amounts.

The DRIs were established for specific life stage groups defined by age, sex, and pregnancy/lactation status. The life stage groups correspond to subpopulations of children, adolescents, and adults. The DRIs for the youngest group of children, namely children age 1-3 y, are typically the lowest due to their small body size. The DRIs for the subpopulation of children age 1-3 y therefore provide the lowest and therefore most conservative estimates of recommended intakes or ULs for comparison with intakes by the general population ages 2 years

and older. Nutrient intakes below the corresponding DRI (either RDA/AI or UL) can be considered to be of no safety concern.

VII. Basis for GRAS Determination

A. Regulatory Status of Electrolytes

All of the substances contained in cane juice electrolyte are GRAS. Potassium chloride, and magnesium sulfate are generally recognized as safe under the intended use (21 CFR 582.5622; magnesium sulfate 582.5443). Sodium chloride and sucrose are found at low levels in cane juice electrolyte and at such levels are GRAS.

B. Safety Overview

1. Human Consumption of Electrolytes from Juice

The raw material used in the manufacture of cane juice electrolytes is clarified sugar cane juice. Cane juice electrolytes is manufactured using safe and well-characterized physical separation techniques. Such physical separation processes do not cause substantive alterations to the chemical character and safety-related properties of the constituents. The food additives that may be utilized in the manufacturing process for cane juice electrolytes are all either approved food additives or GRAS food ingredients for these applications and are used in accordance with food cGMP (21 C.F.R. Part 110). The manufacturing process does not generate, concentrate, or introduce any potential toxicants. As a result, the cane juice electrolytes are as safe as the cane juice itself.

2. Safety Studies on Cane Juice Electrolytes

Given the long history of human consumption of electrolytes, cane juice electrolytes are of little toxicological concern to humans. We are not aware of adverse effects associated with the consumption of electrolytes in juice or water. In addition, a literature search does not yield any reported adverse effects.

3. Allergenicity

The presence of protein in cane juice electrolyte presents the possibility of allergic reaction in some individuals. A literature search of PubMed for studies and case reports of allergy to components of sugar cane was performed using the search terms "(allergy OR allergen OR allergenicity OR allergic) AND (sugarcane or "sugar cane" or "cane sugar" OR "Saccharum officinarum")"; a total of 31 papers were identified in the search. Based on a screening of the titles and abstracts, there were no case reports or studies of allergy following consumption of sugar cane except for a single publication, Randolph and Rollins (1950), reporting on allergic reactions from the ingestion or intravenous injection of cane sugar (sucrose). Evidence from a more recent study indicated that fatty acids from sugar cane wax oil may be allergenic (Ledon et al. 2005).

The literature demonstrates that raw sugar cane contains potentially allergenic protein contaminants including, but not limited to, fungi and mycotoxins, bacteria, pest residues, and pollen (Agata et al. 1994; Atluri and Murthy 2002; Barbieri et al. 2005; Boral et al. 2004; Chakraborty et al. 2001; Gascon et al. 2012; Mehta and Sandhu 1983; Richter et al. 1976; Romeo et al. 2009). The existence of dermal and inhalation allergies, including those documented in occupational situations, does not necessarily indicate that consumption of sugar cane as a component of food would experience similar reactions, however the possibility of allergic response cannot be completely eliminated.

A search of resources available from the Food Allergy Research and Resource Program (FARRP) indicates that proteins from sugar cane itself are not allergenic upon consumption, which again does not rule out the possibility that protein contaminants present in the cane juice electrolyte concentrate could be allergenic.

However, sugarcane juice electrolytes are obtained after passing clarified cane juce through a NF membrane with very small pore sizes. Proteins including sugarcane juice proteins are high molecular weight compounds and are retained by NF membranes as evidenced from the results of analysis (Table 1). Hence, allergenicity due to any sugarcane proteins in the electrolytes is ruled out.

C. Estimated Consumption[2]

1. Consumption Data and Study Population

Data collected as part of the National Health and Nutrition Examination Surveys (NHANES) conducted in the combined periods 2003-2004, 2005-2006, 2007-2008, and 2009-2010 were used to complete this assessment (CDC 2007, 2008, 2010, 2012).

The NHANES datasets provide nationally representative nutrition and health data and prevalence estimates for nutrition and health status measures in the United States. Information on food consumption was collected in the dietary interview component of NHANES, also known as What We Eat in America (WWEIA). As part of the examination, trained dietary interviewers collected detailed information on all foods and beverages consumed by respondents in the previous 24 hour time period (midnight to midnight). A second dietary recall was administered by telephone three to ten days after the first dietary interview, but not on the same day of the week as the first interview. The dietary component of the survey is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). DHHS is responsible for the sample design and data collection, and USDA is responsible for the survey's dietary data collection methodology, maintenance of the databases used to code and process the data, and data review and processing.

[2] The Estimated Consumption Analysis was prepared by Exponent, Inc., 1150 Connecticut Avenue, NW, Suite 1150, Washington DC 20036, April 1, 2013.

This analysis was limited to the 30,407 individuals ages 2 years and older in NHANES 2003-2010 who provided two complete dietary recalls as determined by the National Center for Health Statistics (NCHS).

Each reported intake of 100% fruit juice or flavored water was multiplied by the maximum intended use of cane juice electrolyte (7.5% by weight). For each respondent, the cumulative sum of cane juice electrolyte intake over the two dietary recalls was divided by two to derive an estimate of the 2-day average intake. Using these values, Exponent estimated the 2-day average daily mean and 90th percentile intake of cane juice electrolyte in units of grams on a "*per capita*" and "*per user*" basis for the U.S. population ages 2 years and older and six subpopulations including subpopulations of children (2-5 years, 6-10 years), adolescents (males 11-19 years, females 11-19 years), and adults (males 20 years and older, females 20 years and older). In this analysis, a "user" is anyone who reported consuming a food on either of the survey days. This approach is consistent with the definition of "user" followed by the USDA.

The estimates of intake were generated using Exponent's Foods and Residues Evaluation Program (FARE® version 9.89) software using statistical weights provided by NCHS. The statistical weights compensate for variable probabilities of selection, adjust for non-response, and provide intake estimates that are representative of the U.S. population.

2. Results

The 2-day average estimated intakes of cane juice electrolyte assuming the maximum intended use in 100% fruit juice and flavored water are shown in Table 3 below. Thirty eight percent (38%) of the U.S. population ages 2 years and older reported intake of 100% fruit juice or flavored water at least once during the two days of dietary recall.

The estimated *per user* mean and 90th percentile intakes of cane juice electrolyte by the population ages 2 years and older were 18 and 36 g/day, respectively. Among the subpopulations included in this analysis, children ages 2-5 years were most likely to report consumption of 100% fruit juice or flavored water; 71% of children consumed a juice or flavored water at least once during the period of dietary recall. Adolescent males were estimated to have the highest daily intake of cane juice electrolyte under the intended conditions of use; the estimated *per user* mean and 90th percentile intakes by males ages 11-19 years were 21 and 41 g/day, respectively.

Table 3. Estimated 2-day average intake of cane juice electrolyte (g/day) by the U.S. population assuming the maximum proposed use in 100% fruit juice and flavored water, NHANES 2003-2010

Population Group	Population Count	Users (n)	% Users	*Per Capita* (g/day)		*Per User* (g/day)	
				Mean	90th Percen-tile	Mean	90th Percen-tile
Total 2+ y	30,407	13,274	38	7	22	18	36
Children 2-5 y	2,863	2,051	71	12	30	17	35
Children 6-10 y	2,989	1,734	54	8	21	14	26
Males 11-19 y	3,321	1,517	40	9	27	21	41
Females 11-19 y	3,332	1,519	41	8	23	19	35
Males 20+y	8,500	2,985	34	7	23	21	37
Females 20+y	9,402	3,468	34	6	19	17	34

Maximum proposed use of cane juice electrolyte is 7.5% by weight in beverages as consumed. Population count and user sample sizes represent unweighted values.

VIII. Summary of Basis for GRAS Determination

NNP and DAFF have determined that cane juice electrolytes are Generally Recognized as Safe (GRAS) based on the following:

- The fact that the electrolytes found in cane juice electrolytes are GRAS at the proposed levels of consumption.
- The fact that cane juice electrolytes are manufactured under current good manufacturing practices (cGMP) for food (21 C.F.R. Part 110) and meet appropriate food grade specifications.
- The potential contamination at such as pesticides and heavy metals are either absent (not detected) or below toxicological and regulatory limits.
- The nutritional quality of the cane juice electrolytes.
- The intended uses and the estimated consumption for the cane juice electrolytes; and
- Supportive evidence from the long history of safe use as juice as food and electrolytes in food.

IX. Conclusion

Based on the documentation provided in this GRAS Notification, and as discussed above, NNP have concluded that cane juice electrolyte is GRAS via scientific procedures for use in fruit juice (except baby juice) and flavored water.

X. References

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XI. Appendices

Appendix 1 Representative Composition of Purified Cane Juice Concentrate

Component	Sample			Method of Analysis		
	12255-201	12283-101	Average	LOR	Internal Code	Method Reference/Name
Macronutrients						
Moisture, %w/w	63.0	64.0	63.5	---	CF005.2	AOAC 934.01
Protein, %w/w	0.9	0.7	0.8	---	CF003.1	AOAC 990.03, 992.15
Fat, %w/w	0.1	0.2	0.2	---	CF004.1	AOAC 960.39
Total Carbohydrate, %	32.1	31.9	32.0	---	CF029.2	by calculation
Total sugar (sucrose), %w/w	32.0	31.8	31.9	---	CF047	Pearson's Chem Analysis Foods
Ash, %w/w	3.9	3.2	3.6	---	CF007	AOAC 923.03, 920.153
Total	***100.0***	***100.0***	***100.0***			
Micronutrients						
Sodium, mg/100 g	126	84	105	---	ESI-2	ICP-AES, in-house method
Potassium, mg/100 g	1790	1500	1645	---	ESI-2	ICP-AES, in-house method
Magnesium, mg/100 g	76	56	66	---	ESI-2	ICP-AES, in-house method
Total	***1992***	***1640***	***1816***			
Specific Gravity (20 °C)	1.160	1.135	1.148	---	CF078	AOAC 950.20
Other Components and Impurities						
Metals						
Antimony, mg/kg	<0.01	<0.01	<0.01	0.01	ESMO2	ICP-MS, in-house method
Arsenic, mg/kg	0.17	0.12	0.15	0.025	ESMO2	ICP-MS, in-house method
Cadmium, mg/kg	<0.01	<0.01	<0.01	0.01	ESMO2	ICP-MS, in-house method
Chromium, mg/kg	0.1	0.09	0.10	0.025	ESMO2	ICP-MS, in-house method
Cobalt, mg/kg	0.04	0.03	0.04	0.01	ESMO2	ICP-MS, in-house method
Copper, mg/kg	0.61	0.89	0.75	0.025	ESMO2	ICP-MS, in-house method
Lead, mg/kg	<0.01	<0.01	<0.01	0.01	ESMO2	ICP-MS, in-house method
Manganese, mg/kg		1.94	2.32	0.025	ESMO2	ICP-MS, in-house method
Mercury, mg/kg	<0.01			0.01	ESMO2	ICP-MS, in-house method
Molybdenum, mg/kg	<0.2	<0.2	<0.2	0.2	ESMO2	ICP-MS, in-house method
Nickel, mg/kg	0.18	0.15	0.17	0.01	ESMO2	ICP-MS, in-house method
Selenium, mg/kg	0.07	0.06	0.07	0.025	ESMO2	ICP-MS, in-house method
Silver, mg/kg	<0.01	<0.01	<0.01	0.01	ESMO2	ICP-MS, in-house method
Tin, mg/kg	<0.025	<0.025	<0.025	0.025	ESMO2	ICP-MS, in-house method
Zinc, mg/kg	0.25	0.17	0.21	0.025	ESMO2	ICP-MS, in-house method
Pesticide residues	< LOR	< LOR		variable*	CR006	GCMS & LCMS, in-house methods
Microbiological Components						
Standard Plate Count, CFU/g	100	<100		---	M2.5	AOAC 990.12
Yeast, CFU/g	<100	<100		---	M3.2	AS 5013.29-2009
Mold, CFU/g	<100	<100		---	M3.2	AS 5013.29-2009
Coliforms, MPN/g	<3.0	<3.0		---	M8.3.1	AS 5013.3-2009
Presumptive Escherichia coli, MPN/g	<3.0	<3.0		---	M8.3.3	AS 5013.15-2006

* typical LOR = 0.01 mg/kg; LOR for some chemicals = 0.02, 0.05 or 0.1 mg/kg

ABBREVIATIONS:

AOAC = Association of Official Agricultural Chemists; AS = Australian Standard; CFU = colony forming unit; GCMS = gas chromatography mass spectrometry; ICP-AES = Inductively Coupled Plasma Atomic Emission Spectrometry; ICP-MS = Inductively Coupled Plasma Mass Spectrometry; LCMS = liquid chromatography mass spectrometry; LOR = limit of reporting; MPN = most probable number

Appendix 2 Micronutrient and Metal Intakes from Proposed Use of Cane Juice Electrolyte vs. Dietary Reference Intakes

Component	Average	Analytical Value	Intake for 90th Percentile User of Cane Juice Electrolyte*		Dietary Reference Intakes: RDA/AI (1-3 Y)	Dietary Reference Intakes: UL (1-3 y)
Micronutrients						
Sodium	105	mg/100 g	38	mg	1000	1500 mg/day
Potassium	1645	mg/100 g	592	mg	3000	ND mg/day
Magnesium	66	mg/100 g	24	mg	80	NA mg/day
Metals						
Antimony	< LOR	mg/kg	**	-	-	-
Arsenic	0.15	mg/kg	5	mcg	-	ND -
Cadmium	< LOR	mg/kg	**	-	-	-
Chromium	0.10	mg/kg	4	mcg	11	ND mcg/day
Cobalt	0.04	mg/kg	1	mcg	-	-
Copper	0.75	mg/kg	27	mcg	340	1000 mcg/day
Lead	< LOR	mg/kg	**	-	-	-
Manganese	2.32	mg/kg	0.1	mg	1.2	2 mg/day
Mercury	< LOR	mg/kg	**	-	-	-
Molybdenum	< LOR	mg/kg	**	-	17	300 mcg/day
Nickel	0.17	mg/kg	0.01	mg	-	0.2 mg/day
Selenium	0.07	mg/kg	3	mcg	20	90 mcg/day
Silver	< LOR	mg/kg	**	-	-	-
Tin	< LOR	mg/kg	**	-	-	-
Zinc	0.21	mg/kg	0.01	mg	3.0	7.0 mg/day

* assume intake of 36 g cane juice electrolyte/day (see EDI report, Exponent, Inc. 2013)
** exposure not estimated; concentration of component < LOR
\- no Dietary Reference Intake established

ABBREVIATIONS:
AI = Adequate Intake; LOR = level of reporting; NA = not applicable; ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water; ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts; RDA = Recommended Dietary Allowance; UL = tolerable upper intake level.

Appendix 3 Food Codes Included in Consumption Analysis

Food Code	Food Description
100% Fruit Juice	
61201010	Grapefruit juice, freshly squeezed
61201020	Grapefruit juice, NS as to form
61201220	Grapefruit juice, canned, bottled or in a carton
61201620	Grapefruit juice, frozen (reconstituted with water)
61210000	Orange juice, NFS
61210010	Orange juice, freshly squeezed
61210220	Orange juice, canned, bottled or in a carton
61210250	Orange juice, with calcium added, canned, bottled or in a carton
61210620	Orange juice, frozen (reconstituted with water)
61210720	Orange juice, frozen, not reconstituted*
61210820	Orange juice, frozen, with calcium added (reconstituted with water)
61213000	Tangerine juice, NFS
61213220	Tangerine juice, canned
61213800	Fruit juice blend, including citrus, 100% juice
61213900	Fruit juice blend, including citrus, 100% juice, with calcium added
61214000	Grape-tangerine-lemon juice
61216010	Grapefruit and orange juice, fresh
61219000	Orange and banana juice
61219100	Pineapple-orange-banana juice
61219150	Orange-white grape-peach juice
61222000	Pineapple-grapefruit juice, NFS
61225000	Pineapple-orange juice, NFS
61225200	Pineapple-orange juice, canned, NS as to sweetened or unsweetened; sweetened, NS as to type of sweetener
61225220	Pineapple-orange juice, canned, bottled or in a carton
61226000	Strawberry-banana-orange juice
64100100	Fruit juice, NFS
64100110	Fruit juice blend, 100% juice, with added Vitamin C
64100200	Fruit juice blend, with cranberry, 100% juice
64101010	Apple cider
64104010	Apple juice
64104150	Apple-cherry juice
64104200	Apple-pear juice
64104450	Apple-raspberry juice
64104500	Apple-grape juice
64104600	Blackberry juice
64105400	Cranberry juice, unsweetened
64105500	Cranberry-white grape juice mixture, unsweetened
64116020	Grape juice
64120010	Papaya juice
64121000	Passion fruit juice

Food Code	Food Description
64124020	Pineapple juice
64124200	Pineapple-apple-guava juice, with added vitamin C
64125000	Pineapple juice-non-citrus juice blend, unsweetened, with added vitamin C
64126000	Pomegranate juice
64132010	Prune juice
64132020	Prune juice, unsweetened
64132500	Strawberry juice
64133100	Watermelon juice
Flavored Water	
92410110	Carbonated water, sweetened
94100200	Water, bottled, sweetened, with low or no calorie sweetener
94100300	Water, fruit flavored, sweetened, with high fructose corn syrup and low calorie sweetener
94210100	Propel Fitness Water
94210200	Vitamin Water

*Adjusted to reconstituted amount

Appendix 4 D-1 Nutritional Panel

LABORATORY BATCH NO. (b) (6)

Symbio ALLIANCE

12255-201, 200g

NUTRITION INFORMATION			
Servings per package:	1.0		
Serving size:	200 mL		
	Quantity per Serving	% Daily Intake* (per serving)	Quantity per 100 mL
Energy	1310 kJ 313 (Cal)	15 %	655 kJ 156 (Cal)
Protein	2.1 g	4 %	1.0 g
Fat - total	less than 1 g	<1 %	less than 1 g
- saturated	less than 1 g	<1 %	less than 1 g
- monounsaturated	less than 1 g		less than 1 g
- polyunsaturated	less than 1 g		less than 1 g
- trans	0.03 g		0.01 g
Carbohydrate, total	74.5 g	24 %	37.2 g
-sugars	74.2 g	82 %	37.1 g
Sodium	292 mg 14.7 (mmol)	13 %	146 mg 6.4 (mmol)
Potassium	4146 mg 123.0 (mmol)	118 %	2073 mg 53.0 (mmol)
Magnesium	176 mg 8.5 (mmol)	55 %	88 mg 3.7 (mmol)

* Percentage Daily intakes are based on an average adult diet of 8700kJ. Your daily intakes may be higher or lower depending on your energy needs.

PLEASE NOTE: The above nutrition panel is only a presentation to show all the results in the general format and it is the customer's responsibility to ensure that the label conforms to regulatory requirements.

Appendix 5 D-2 Nutritional Panel

LABORATORY BATCH NO. (b) (6)

Symbio ALLIANCE

12283-101, 300g

NUTRITION INFORMATION			
Servings per package:	1.0		
Serving size:	300 mL		
	Quantity per Serving	% Daily Intake* (per serving)	Quantity per 100 mL
Energy	1912 kJ 457 (Cal)	22 %	637 kJ 152 (Cal)
Protein	2.4 g	5 %	less than 1 g
Fat - total	less than 1 g	<1 %	less than 1 g
- saturated	less than 1 g	2 %	less than 1 g
- monounsaturated	less than 1 g		less than 1 g
- polyunsaturated	less than 1 g		less than 1 g
- trans	0.12 g		0.04 g
Carbohydrate, total	108.6 g	35 %	36.2 g
-sugars	108.3 g	120 %	36.1 g
Sodium	286 mg 14.1 (mmol)	12 %	95 mg 4.1 (mmol)
Potassium	5108 mg 148.3 (mmol)	146 %	1703 mg 43.5 (mmol)
Magnesium	191 mg 9.0 (mmol)	60 %	64 mg 2.6 (mmol)

* Percentage Daily intakes are based on an average adult diet of 8700kJ. Your daily intakes may be higher or lower depending on your energy needs.

PLEASE NOTE: The above nutrition panel is only a presentation to show all the results in the general format and it is the customer's responsibility to ensure that the label conforms to regulatory requirements.

Appendix 6 GRAS Nutritional Information

Symbio ALLIANCE

CERTIFICATE NO.: 222677-D **REVISION NO.:** 00
ISSUE DATE: 7/03/13 This certificate supersedes any previous revisions

CLIENT DETAILS: Ram Mereddy
DEEDI - Health & Food Science Prescint
PO Box 156
Archerfield QLD 4108

CLIENT REF:
DATE RECEIVED: 26/02/2013
TEST DATE: Sample tested between date received and reported.

CONDITIONS OF SAMPLE: Receipt Temperature: Room Temperature
Storage Temperature: Refrigerated

RESULTS OF ANALYSIS:

Sample Description Test	Method Code	Unit	222677-D-1 12255-201, 200g
Protein	CF003.1	% w/w	0.9
Fat	CF004.1	% w/w	0.1
Saturated Fat	CFH056.2	% w/w	0.1
Mono-unsat Fat	CFH056.2	% w/w	<0.1
Poly-unsat Fat	CFH056.2	% w/w	<0.1
Trans Fat	CFH056.2	% w/w	0.01
Moisture (vacuum)	CF005.2	% w/w	63.0
Ash	CF007	% w/w	3.9
Sodium (Na)	ES02	mg/100g	126
Potassium (K)	ES02	mg/100g	1,790
Magnesium (Mg)	ES02	mg/100g	76.0
Total sugar (Sucrose)	CF047	% w/w	32.0
Total Carbohydrate#	CF029.2	%	32.1
Energy#	CF030.2	kJ/100g	565

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NATA

Appendix 7 GRAS Chemical Residue

Symbio ALLIANCE

CERTIFICATE NO.: 222677-C **REVISION NO.:** 00
ISSUE DATE: 4/03/13 This certificate supersedes any previous revisions

CLIENT DETAILS: Ram Mereddy
DEEDI - Health & Food Science Prescint
PO Box 156
Archerfield QLD 4108

CLIENT REF:
DATE RECEIVED: 26/02/2013
TEST DATE: Sample tested between date received and reported

CONDITIONS OF SAMPLE: Receipt Temperature: Room Temperature
Storage Temperature: Refrigerated

TEST REQUESTED: Multi-residue in Plant Product
METHOD CODE: CR006

RESULTS OF ANALYSIS

Lab Ref	Sample Description	Chemical Detected	Result (mg/kg)	MRL (mg/kg)
222677-C-1	12255-201, 200g	Multi-Pesticide Residues	<LOR	

Lab Ref	Sample Description	Chemical Detected	Result (mg/kg)	MRL (mg/kg)
222677-C-2	12283-101, 300g	Multi-Pesticide Residues	<LOR	

* This test is not covered by the scope of our NATA accreditation.
<LOR: less than Level of Reporting
A result of "<LOR" indicates no chemical on the attached list was detected at a concentration equal to or exceeding the LOR.
If a chemical is detected at a concentration equal to or exceeding the LOR, it will be detailed in the "Result of Analysis".

MRL: Maximum Residue Limit as defined by the latest edition of the Australian New Zealand Food Standards Code.
MRL information is only provided in the event of a chemical detection.

Disclaimer: All reasonable measures have been taken to ensure the MRL information provided is accurate and current.
However no liability is accepted by Symbio Laboratories for any occurence arising from the adoption of any of the information.

Sample preparation was in accordance with Food Standards Australia New Zealand, Standard 1.4.2, Schedule 4.
Results are reported on an "as received" basis and pertain only to the samples submitted.

(b) (6)

Glenn Barlow, Analyst
For Bruce Chen CEO of Symbio Alliance

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NATA

CERTIFICATE NO.: 222677-C

Symbio ALLIANCE

METHOD CR006 CHEMICAL LIST

CHEMICAL	LOR (mg/kg)
Organochlorines:	
Aldrin	0.01
alpha-BHC	0.01
beta-BHC	0.01
delta-BHC	0.01
Dieldrin	0.05
Dieldrin	0.01
alpha-Endosulfan	0.01
beta-Endosulfan	0.01
Endosulfan sulfate	0.01
Total endosulfan	0.01
HCB	0.01
Endrin	0.01
Heptachlor	0.01
Heptachlor epoxide	0.01
Lindane	0.01
p,p-DDD	0.01
p,p-DDE	0.01
p,p-DDT	0.01
Trichlorfon	0.02
Organophosphates:	
Acephate	0.01
Azinphos methyl	0.01
Chlorpyrifos	0.01
Chlorpyrifos methyl	0.01
Diazinon	0.01
Dichlorvos	0.01
Dimethoate	0.01
Fenamiphos	0.01
Fenitrothion	0.01
Fenthion	0.01
Malathion	0.02
Methamidophos	0.01
Methidathion	0.02
Mevinphos	0.01
Monocrotophos	0.05
Omethoate	0.01
Parathion ethyl	0.05
Parathion methyl	0.01
Phorate	0.01
Phosmet	0.01
Pirimiphos methyl	0.01
Profenofos	0.01
Prothiofos	0.01
Terbufos	0.01
Vamidothion	0.01
Strobilurins:	
Azoxystrobin	0.05
Trifloxystrobin	0.02
Pyraclostrobin	0.02

CHEMICAL	LOR (mg/kg)
Synthetic Pyrethroids:	
Bioresmethrin	0.01
Bifenthrin	0.01
Cyfluthrin	0.02
beta-Cyfluthrin	0.02
Cyhalothrin	0.01
lambda-Cyhalothrin	0.01
Cypermethrin	0.02
alpha-Cypermethrin	0.02
Deltamethrin	0.01
Esfenvalerate	0.01
Fenvalerate	0.01
Phenothrin	0.01
tau-Fluvalinate	0.01
Permethrin	0.01
Phenothrin	0.02
Acaricides:	
Bifenazate *	0.01
Chlorfenapyr	0.05
Clofentezine	0.01
Etoxazole *	0.01
Hexythiazox	0.01
Mitex	0.01
Propargite	0.01
Tebufenpyrad	0.01
Tetradifon	0.01
Carbamates :	
Carbaryl	0.01
Methomyl	0.01
Methomyl oxime	0.01
Pirimicarb	0.01
Herbicides	
Chlorthal dimethyl	0.01
Diuron	0.01
Linuron	0.01
Metribuzin	0.01
Oxyfluorfen	0.05
Pendimethalin	0.01
IGRs:	
Buprofezin	0.01
Fenoxycarb	0.01
Fipronil	0.01
Indoxacarb	0.01
Pyriproxyfen	0.01
Nicotinamide:	
Imidacloprid	0.01
Thiacloprid	0.01
Thiamethoxam *	0.01

CHEMICAL	LOR (mg/kg)
Benzimidazoles:	
Benomyl	0.01
Carbendazim	0.01
Thiabendazole	0.01
Fungicides:	
Benalaxyl	0.01
Bitertanol	0.01
Captan	0.1
Chlorothalonil	0.05
Cyproconazole	0.01
Cyprodinil	0.01
Dichloran	0.05
Difenoconazole	0.01
Dimethomorph	0.01
Diphenylamine	0.05
Fenarimol	0.01
Flutriafol	0.01
Fludioxonil	0.01
Hexaconazole	0.01
Imazalil	0.01
Kresoxim methyl	0.01
Iprodione	0.05
Metalaxyl	0.01
Myclobutanil	0.01
o-phenylphenol	0.01
Paclobutrazol	0.01
Penconazole	0.01
Piperonyl butoxide	0.01
Procloraz	0.01
Procymidone	0.01
Propiconazole	0.01
Pyrimethanil	0.01
Quinoxyfen	0.01
Tebuconazole	0.01
Tetraconazole	0.01
Triadimefon	0.01
Triadimenol	0.01
Vinclozolin	0.01
Other Compounds:	
Boscalid	0.01
Chlorantraniliprole *	0.01
Fenhexamid	0.01
Fenpyroximate	0.01
Pyrimethanil	0.01
Spirotetramat *	0.01
Tebufenozide	0.01
Spinosyns:	
Spinosad	0.01
Spinetoram *	0.01

* Does not fall within the scope of our NATA accreditation

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Appendix 8 GRAS Heavy Metal

Symbio ALLIANCE

CERTIFICATE NO.: 222677-B **REVISION NO.:** 00
ISSUE DATE: 4/03/13 This certificate supersedes any previous revisions

CLIENT DETAILS: Ram Mereddy
DEEDI - Health & Food Science Prescint
PO Box 156
Archerfield QLD 4108
CLIENT REF:
DATE RECEIVED: 26/02/2013
TEST DATE: Sample tested between date received and reported.

CONDITIONS OF SAMPLE: Receipt Temperature: Room Temperature
Storage Temperature: Refrigerated

RESULTS OF ANALYSIS:

Sample Description Test	Method Code	Unit	222677-B-1 12255-201, 200g	222677-B-2 12283-101, 300g
Chromium (Cr)	ESM02	mg/kg	0.10	0.09
Manganese (Mn)	ESM02	mg/kg	2.70	1.94
Cobalt (Co)	ESM02	mg/kg	0.04	0.03
Nickel (Ni)	ESM02	mg/kg	0.16	0.15
Copper (Cu)	ESM02	mg/kg	0.61	0.69
Zinc (Zn)	ESM02	mg/kg	0.26	0.17
Arsenic (As)	ESM02	mg/kg	0.17	0.12
Selenium (Se)	ESM02	mg/kg	0.07	0.05
Silver (Ag)	ESM02	mg/kg	<0.01	<0.01
Cadmium (Cd)	ESM02	mg/kg	<0.01	<0.01
Antimony (Sb)	ESM02	mg/kg	<0.01	<0.01
Mercury (Hg)	ESM02	mg/kg	<0.01	<0.01
Lead (Pb)	ESM02	mg/kg	<0.01	<0.01
Tin (Sn)	ESM02	mg/kg	<0.025	<0.025
Molybdenum (Mo)	ESI02	mg/kg	<0.2	<0.2
Moisture (vacuum)	CF005.2	% w/w	66.7	71.2
Ash	CF007	% w/w	4.0	3.2

DEFINITIONS: < = Less than, > = Greater than, - = Not Tested, DWB = Dry Weight Basis.
* This test is not covered by the scope of our NATA accreditation.
# = The result is derived from calculation.

Results were reported on an "as received" basis unless otherwise indicated.
Sampling was carried out by the customer and results reported pertain only to the samples submitted, responsibility for representative sampling rests with the customer.

(b) (6)

Arthur Zang, Chemist
For Bruce Chen CEO of Symbio Alliance

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Appendix 9 GRAS Micro

CERTIFICATE OF ANALYSIS

Symbio ALLIANCE

ANALYSIS PERFORMED FOR
Ram Mereddy
DEEDI - Health & Food Science Prescint
PO Box 156
Archerfield QLD 4108

CERTIFICATE NO.: 222677-A
ISSUE DATE: 5/03/13
REVISION NO.: 00
This certificate supercedes any previous revisions

SAMPLE INFORMATION
Description: Beverage
Date Received: 26/02/2013 9:00
Testing Commenced: 26/02/2013

CONDITIONS OF SAMPLE ON RECEIPT
Receipt Temperature: -0.4°C (Surface Temperature taken by infra-red)
Storage Temperature: Less than -10 °C
Order No.:

RESULTS OF ANALYSIS *Results pertain only to sample(s) analysed.*

Beverages

LAB CODE	SAMPLE DESCRIPTION	Standard Plate Count (CFU/g)	Yeast (CFU/g)	Mould (CFU/g)
222677-A-1	12255-201, 200g	100	<100	<100
222677-A-2	12283-101, 300g	<100	<100	<100

LAB CODE	SAMPLE DESCRIPTION	Coliforms (MPN/g)	Presumptive Escherichia coli (MPN/g)
222677-A-1	12255-201, 200g	<3.0	<3.0
222677-A-2	12283-101, 300g	<3.0	<3.0

> = Greater than ~ = Estimated ND = Not detected MPN = Most probable number CFU = Colony forming units
< = Less than - = Not tested TBA = To be advised * = Test not covered by scope of NATA accreditation

TEST PERFORMED

Test No.	TEST	Method	REFERENCE
1	Standard Plate Count	M2.5	AOAC 990.12
2	Yeast	M3.2	AS 5013.29-2009
3	Mould	M3.2	AS 5013.29-2009
4	Coliforms	M8.3.1	AS 5013.3-2009
5	Presumptive Escherichia coli	M8.3.3	AS 5013.15-2006

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Submission End