

GRAS Notice (GRN) No. 365

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>

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ORIGINAL SUBMISSION

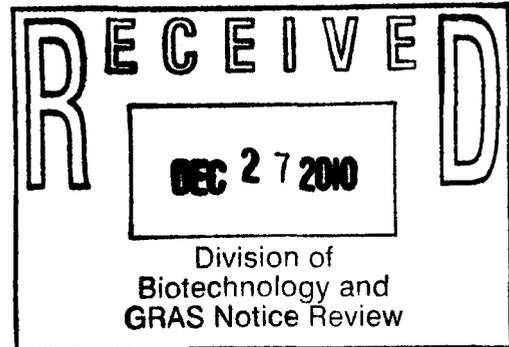
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December 21, 2010

Ms. Moraima Ramos-Valle
Food and Drug Administration
University Station (HFS-200)
4300 River Road
College Park MD 20740
T: 301-436-1248
E: moraima.ramos-valle@fda.hhs.gov



Dear Ms. Ramos,

Please find enclosed a revised copy of the RioSweet™ 97% Reb-A GRAS Notification. This Notification document replaces the RioSweet™ 97% Reb-A GRAS Notification dated December 6, 2010, and received at your office on December 8, 2010. Appropriate changes have been made *per* your request during our phone call on December 16, 2010.

The first paragraph on page 2 of 11, section 1.A. of the original submission stated: “RioSweet™ 97% Reb-A (Rebaudioside A) has been determined to be generally recognized as safe (GRAS) under the conditions of its intended use as described below and is therefore, exempt from the requirement of premarket approval.” This statement has been revised to “BrazTech International (d/b/a RioNatural) has, on the basis of advice from its Expert Panel, determined RioSweet™ 97% Reb-A (Rebaudioside A) to be generally recognized as safe (GRAS) under the conditions of its intended use as described below and is therefore, exempt from the requirement of premarket approval.”

Additionally, on page 4 of 11, section 1.A.(v)- Availability of Information, the following statement has been added: “Data and information in support of this determination are available for review and/or copying during conventional office hours at the offices of the Notifier (see address above).”

If you have any questions please feel free to contact me.

Best regards,

(b) (6)

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

Enclosure

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December 16, 2010

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

RE: RioSweet™ 97% Reb-A GRAS Notification

Dear Dr. Martin:

In accordance with proposed 21 CFR § 170.36 (a notice of a claim for exemption based on a GRAS determination) published in the Federal Register (62 FR 18937-18964), I am submitting in triplicate, as the agent of the notifier, Braz-Tech (d/b/a Rio Natural), 5050 Robert J. Mathews Pkwy., Suite #200, El Dorado Hills, CA 95762, a GRAS notification for the use of RioSweet™ 97% Reb-A for use as a food ingredient. RioSweet™ 97% Reb-A is substantially equivalent to the rebaudioside A product specified in GRN 000253 and will be in competition with another substantially similar rebaudioside A sweeteners and would therefore, not be additive to the total daily consumption of rebaudioside A. Rio Natural, on the basis of the advice of its GRAS expert panel, has determined RioSweet™ 97% Reb-A to be generally recognized as safe on the basis of scientific procedure. A GRAS expert panel determination describing the basis for the finding of GRAS and the *curriculum vitae* of the members of the GRAS expert panel are enclosed, and references are available upon request for review or copying during conventional office hours.

Best regards,

(b) (6)

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

1. GRAS Exemption Claim

A. Claim of Exemption from the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)

BrazTech International (d/b/a RioNatural) has, on the basis of advice from its Expert Panel, determined RioSweet™ 97% Reb-A (Rebaudioside A) to be generally recognized as safe (GRAS) under the conditions of its intended use as described below and is therefore, exempt from the requirement of premarket approval. The basis for this finding is described in the notification.

Signed,

(b) (6)

16 December 2010

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
801 N. Orange Avenue Suite 710
Orlando, FL 32801

Date

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(i) Name and Address of the Notifier

BrazTek International, Inc.
d/b/a Rio Natural
5050 Robert J. Mathews Pkwy.
Suite #200
El Dorado Hills, CA 95762

Agent of the Notifier:

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
Burdock Group
801 N. Orange Ave. Suite 710
Orlando, FL 32801
Telephone: 407-802-1400
Facsimile: 407-802-1405
Email: gburdock@burdockgroup.com

(ii) Common Name of the Notified Substance

The common name of RioSweet™ 97% Reb-A for the purposes of this GRAS Notification is:

Rebaudioside A

(iii) Conditions of Use

RioSweet™ 97% Reb-A is to be used as a non-nutritive sweetener¹ as a table top sweetener and for incorporation into various food categories as a general purpose sweetener. The use of RioSweet™ 97% Reb-A is limited by intense sweetness at high levels. RioSweet™ 97% Reb-A is to be added to foods at an amount that, under good manufacturing practice (GMP), will accomplish its intended technical effect.² The conditions of use will be the same as those of comparable high purity rebaudioside A products that have been notified GRAS^{3,4,5,6} without objection from FDA (2008, 2009, 2010a, 2010b).

¹ 21 CFR 170.3(o)(19). Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.

² 21CFR 182.1 Substances that are generally recognized as safe.

³ GRN 000253. GRAS Notice for Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni, dated May 20, 2008, available at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=253>, site visited 22 November, 2010.

⁴ GRN 000278. GRAS Notice for Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni, dated January 22, 2009, available at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=278>, site visited 22 November, 2010.

⁵ GRN 000318. GRAS Notice for Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni, dated January 20, 2010, available at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=318>, site visited 22 November, 2010.

⁶ GRN 000329. GRAS Notice for Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni, dated March 12, 2010, available at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=329>, site visited 22 November, 2010.

(iv) Basis of GRAS Determination

Pursuant to 21 CFR § 170.3, RioSweet™ 97% Reb-A has been determined GRAS by scientific procedures for its intended conditions of use. The safety of RioSweet™ 97% Reb-A is supported by the fact that it is substantially equivalent to Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni (Rebaudioside A) which was notified as GRAS to FDA on May 20, 2008 (GRN 000253)³ and received a no objection letter from FDA on December 17, 2008 (FDA, 2008). The data and information provided in GRN 000253 including, but not limited to, the safety and consumption information, are incorporated by reference in this notification. The GRAS determination for RioSweet™ 97% Reb-A is based on the views of experts who are qualified by scientific training and experience to evaluate the safety of substances used as ingredients in food.

(v) Availability of Information

The data and information that serve as a basis for this GRAS determination are manufacturing information from the notifier as well as the GRAS determination for Rebaudioside A (GRN 000253)³ which is incorporated herein by reference. Data and information in support of this determination are available for review and/or copying during conventional office hours at the offices of the Notifier (see address above).

2. Detailed Information about the Identity of the Notified Substance

A. Identity

RioSweet™ 97% Reb-A is a white crystalline powder produced from *Stevia rebaudiana* Bertoni leaves. The general descriptive characteristics of RioSweet™ 97% Reb-A are presented in Table 1

Table 1. General description of RioSweet™ 97% Reb-A

Source	<i>Stevia rebaudiana</i> Bertoni
Appearance	White, crystalline powder
Solubility	40.0% in water at 25°C
Packaging	Packaged in plastic bags
Storage	Store at 25°C
Labeling	Reb A, Rebaudioside A
Functionality in Food	Non-nutritive sweetener

Common or Usual Name:

The common name of RioSweet™ 97% Reb-A is “Rebaudioside A”.

B. Composition

0 0 0 0 0 6

Steviol glycosides are *ent*-kaurene diterpene glycosides obtained from the *Stevia rebaudiana* Bertoni perennial herb that is a member of the Asteraceae family from the genus *Stevia* (Kinghorn, 2002). The leaves of the *S. rebaudiana* Bertoni plant contain at least eight different steviol glycosides, all of which contain a common backbone termed the steviol backbone, and

differ only in the glycosidic constituents attached at carbon-13 and/or carbon-14 (Kennelly, 2002). The steviol glycosides stevioside and rebaudioside A are the most abundant in the *S. rebaudiana* Bertoni leaves, with rebaudioside A being the sweetest of the steviol glycosides. Rebaudioside A is approximately 250-450 times sweeter than sucrose and is non-caloric (Kinghorn, 2002).

RioSweet™ 97% Reb-A is predominantly composed of rebaudioside A ($\geq 97\%$), with a total steviol glycoside content (rebaudiosides A, B, C, D and F, steviolbioside, and dulcoside A) of 98-99%. The structure of rebaudioside A (CAS No. 58543-16-1; 13-[(2-O- β -D-glucopyranosyl-3-O- β -D-glucopyranosyl- β -D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β -D-glucopyranosyl ester) (JECFA, 2007) is shown in Figure 1.

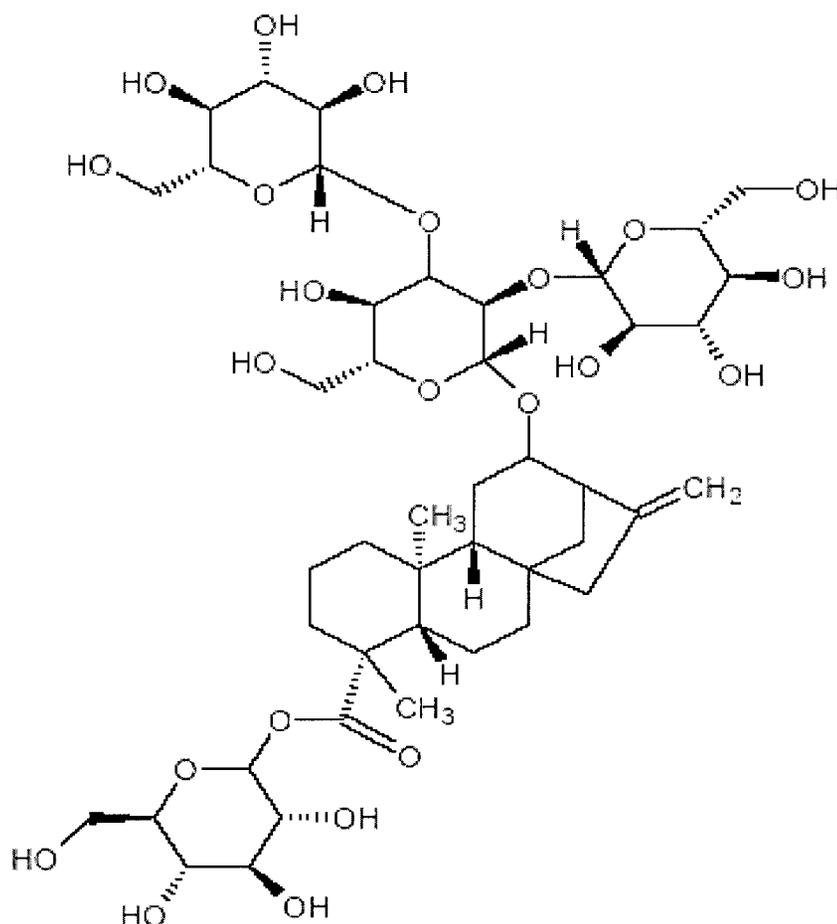


Figure 1. Structure of rebaudioside A

C. Method of Manufacture of RioSweet™ 97% Reb-A

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RioSweet™ 97% Reb-A is manufactured according to Good Manufacturing Practice (GMP). Leaves of the *S. rebaudiana* Bertoni plant are extracted with hot water and the extract is passed

through an ion exchange resin, concentrated, and then spray dried to yield the steviol glycoside primary extract (crude stevia). The crude stevia is crystallized/re-crystallized three times with 100% methanol, concentrated, filtered, sterilized, and spray dried, to obtain the 97% rebaudioside A product. The bulk product will be sold in 1 kg or 10 kg, plastic, sealed bags. A graphical depiction of the manufacturing process is offered in Figure 2.

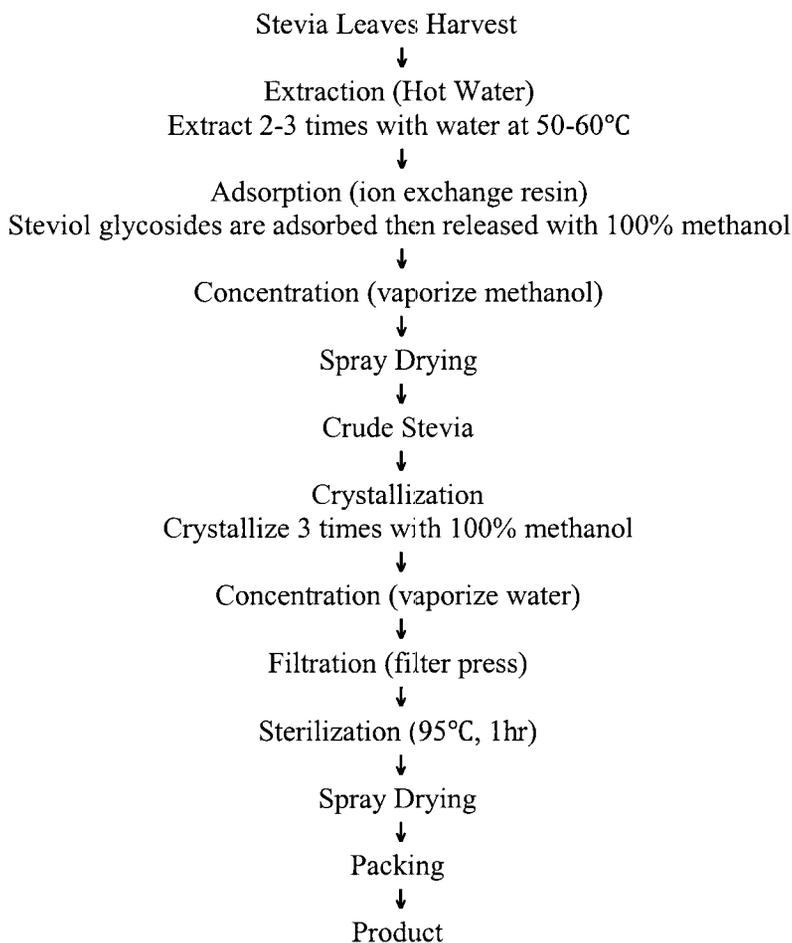


Figure 2. Schematic of the RioSweet™ 97% Reb-A manufacturing process

D. Specifications for Food Grade RioSweet™ 97% Reb-A

Specifications provided in Table 2 for bulk RioSweet™ 97% Reb-A include total steviol glycosides (rebaudiosides A, B, C, D and F, steviolbioside, and dulcoside A), rebaudioside A, lead, arsenic, bacteria, yeast and mold, and the absence of *Escherichia coli*, *Salmonella* and pesticides.

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Table 2. Specifications for RioSweet™ 97% Reb-A

Analysis	Method	Specification	Batch Analysis Results (n = 5)	
			Range	Average
Appearance	Visual	A white crystalline powder	Passed	Passed
Total Steviol Glycosides ¹ (% dry weight)	HPLC	≥97	98.6 – 99.0	98.7
Rebaudioside A (% dry weight)	HPLC	≥97	97.3 – 97.5	97.4
Residual Methanol (ppm)	FCC (2003)	≤200	Passed	Passed
pH	FCC (2003)	4.5 – 7.0	5.3 – 5.8	5.6
Total Ash (%)	FCC (2003)	≤1	0.2	0.2
Loss on drying (%)	FCC (2003)	≤6	2.9 – 3.5	3.2
Arsenic (ppm)	EPA SW6010B	≤1	Passed	Passed
Lead (ppm)	EPA SW6010B	≤1	Passed	Passed
Microbiological				
Total Viable Bacteria (cfu/g)	AOAC (1998) Chapter 4	< 1000	Passed	Passed
Total <i>Escherichia coli</i> (mpn/g)	AOAC (1998) Chapter 4	< 10	Passed	Passed
Fecal <i>Escherichia coli</i> (mpn/g)	AOAC (1998) Chapter 4	< 3	Passed	Passed
<i>Salmonella</i> (in 25 g)	AOAC (2001) Chapter 36	Negative	Passed	Passed
Mold (cfu/g)	AOAC (2001) Chapter 36	Negative (< 100)	Passed	Passed
Yeast (cfu/g)	AOAC (2001) Chapter 20	Negative (< 100)	Passed	Passed
Coliform (cfu/g)	AOAC (1998) Chapter 4	Negative (< 3)	Passed	Passed
Pesticides	FDA (2004)	None Detected	Passed	Passed

AOAC= Association of Official Analytical Chemists, Inc.; cfu = colony forming units; EPA = Environmental Protection Agency; FCC = Food Chemicals Codex; FDA = Food and Drug Administration; HPLC = High Performance Liquid Chromatography; mpn = most probable number; n = number of batches analyzed; ppm = parts *per* million; Reb = Rebaudioside.

¹Reb A, Reb B, Reb C, Reb D, Reb F, Steviolbioside, Dulcoside A

3. Self Limiting Levels of Use

The use of RioSweet™ 97% Reb-A is limited by intense sweetness at high levels. The amounts of RioSweet™ 97% Reb-A to be added to foods under good GMP will accomplish its intended technical effect in foods.⁷ The conditions of use (particular foods and concentrations of addition) will be the same as comparable high purity rebaudioside A products that have been determined GRAS and notified^{3,4,5,6} without objection from FDA (2008, 2009, 2010a, 2010b).

4. Basis of GRAS Determination

The determination that RioSweet™ 97% Reb-A is GRAS is on the basis of scientific procedures. The US FDA has issued ten “no objection” letters in response to GRAS determinations concerning the use of rebaudioside A and steviol glycosides for use in food that have been

⁷ 21CFR 182.1 Substances that are generally recognized as safe.
fusing science and compliance

notified. The safety of RioSweet™ 97% Reb-A is supported by the fact that it is substantially equivalent to Rebaudioside A, which was notified as GRAS to FDA on May 20, 2008 (GRN 000253)³ and received a no objection letter from FDA on December 17, 2008 (FDA, 2008).

RioSweet™ 97% Reb-A meets specifications for steviol glycosides established by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in its 68th meeting in June 2007 (JECFA, 2007) (Table 3). RioSweet™ 97% Reb-A also meets the Rebaudioside A (GRN 000253) specifications for rebaudioside A content (>97%), pH (4.5 – 7.0), lead (≤1 ppm), loss on drying (≤6.0%), ash (≤1.0%), methanol (200 ppm), solubility, and common microbiota (total microbes, coliforms, yeast, mold, *Salmonella* and *Escherichia coli*). Although not specified, analyses of RioSweet™ 97% Reb-A show that additional steviol glycosides (1-2%) are within the ≤3.0% specification for Rebaudioside A defined in GRN 000253. While additional specifications were established for Rebaudioside A defined in GRN 000253 (e.g. identity by IR and specific rotation and limits for *Listeria* and *Staphylococcus*), this should not preclude RioSweet™ 97% Reb-A from meeting the substantial equivalence standard because the FDA did not object to the GRAS notification for Rebpure™ (GRN 000329)⁶, which was based on substantial equivalence to Rebaudioside A defined in GRN 000253 but did not include a specification for identity by Infrared Spectroscopy (IR) or specific rotation and did not specify limits for *Listeria* (FDA, 2010b).

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Table 3. Specifications for RioSweet™ 97% Reb-A and Rebpure™

Analysis	RioSweet 97% Reb-A	JECFA (2007)	Reb A (GRN 000253)	Rebpure™ (GRN 000329)
Appearance/Identity	A white crystalline powder	White to light yellow powder	Conforms to IR standard	NS
Total Steviol Glycosides ^a (% dry weight)	≥97	≥95	NS ^b	NS
Rebaudioside A (% dry weight)	≥97	NS	≥97 and ≤ 102.0	> 97
Specific rotation	NS	NS	-29 to -31°	NS
pH	4.5 – 7.0	4.5 – 7.0	4.5 – 7.0	4.5 – 7.0
Total Ash (%)	≤1	≤1	≤1	< 0.2
Loss on drying (%)	≤6	≤6	≤6	< 5
Solubility	40.0% in water at 25°C ^c	Freely soluble in water and ethanol	Freely soluble in water	Freely soluble in water
Residual Methanol (ppm)	≤200	≤200	≤200	≤200
Residual Ethanol (ppm)	NR	NS	≤5000	≤5000
Arsenic (ppm)	≤1	≤1	NS	≤1
Lead (ppm)	≤1	≤1	≤1	≤1
Microbiological				
Total Viable Bacteria (cfu/g)	< 1000	NS	≤1000	<10000
Total <i>Escherichia coli</i> (mpn/g)	< 10	NS	≤10	Negative
Fecal <i>Escherichia coli</i> (mpn/g)	< 3	NS	≤3 ^d	NS
<i>Salmonella</i> (in 25 g)	Negative	NS	Negative	NS
Mold (cfu/g)	Negative	NS	≤100	< 1000
Yeast (cfu/g)	Negative	NS	≤100	< 1000
Coliform (cfu/g)	Negative	NS	≤3	NS
<i>Listeria</i> (in 11 g)	NS	NS	Negative	NS
<i>Staphylococcus</i>	NS	NS	≤10	Negative
Pesticides	None Detected	NS	NS	NS

cfu = colony forming units; JECFA = FAO/WHO Joint Expert Committee on Food Additives; mpn = most probable number; n = number of batches analyzed; NR = not relevant; NS = not specified; ppm = parts per million; Reb = Rebaudioside

^a Reb A, Reb B, Reb C, Reb D, Reb F, Steviolbioside, Dulcoside A

^b Stated that other related steviol glycosides should be ≤3%.

^c Water solubility is not included in the specification for RioSweet 97% Reb-A. Information was obtained from a written communication from Rio Natural.

^d This is the specified limit for fecal or total coliforms in GRN 000253.

5. Conclusion

On the basis of the data and information described in this notification and other publicly available information, there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food (see ATTACHMENT 1) that RioSweet 97% Reb-A is generally recognized as safe (GRAS) such that the total daily consumption of rebaudioside A would not exceed, and would partially replace the current consumption of comparable rebaudioside A products.

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6. References:

- FDA (2008) Agency Response Letter GRAS Notice No. GRN 000253. CFSAN/Office of Food Additive Safety. December 17, 2008. Food and Drug Administration (FDA).
- FDA (2009) Agency Response Letter GRAS Notice No. GRN 000278. CFSAN/Office of Food Additive Safety. July 20, 2009. Food and Drug Administration (FDA).
- FDA (2010a) Agency Response Letter GRAS Notice No. 000318. CFSAN/Office of Food Additive Safety. May 15, 2010. Food and Drug Administration (FDA).
- FDA (2010b) Agency Response Letter GRAS Notice No. GRN 000329. CFSAN/Office of Food Additive Safety. September 9, 2010. Food and Drug Administration (FDA).
- JECFA (2007) Steviol Glycosides. Prepared at the 68th JECFA (2007) and published in FAO JECFA Monographs 4 (2007). The Joint FAO/WHO Committee on Food Additives (JECFA).
- Kennelly, E. J. (2002) Sweet and non-sweet constituents of *Stevia rebaudiana*. In *Stevia: The Genus Stevia*. (A. D. Kinghorn, Ed.) Taylor and Francis, Inc., London, England. p. 68-85.
- Kinghorn, A. D. (2002) Overview. In *Stevia: The Genus Stevia*. (A. D. Kinghorn, Ed.) Taylor and Francis, Inc., London, England. p. 1-17.

ATTACHMENT 1

DOSSIER IN SUPPORT OF THE GENERALLY RECOGNIZED AS SAFE (GRAS)
STATUS OF RIOSWEET™ 97% REB-A AS A FOOD INGREDIENT

The undersigned, an independent panel of recognized experts (hereinafter referred to as the Expert Panel)⁸, qualified by their scientific training and relevant national and international experience to evaluate the safety of food ingredients, was requested by Rio Natural to determine the Generally Recognized As Safe (GRAS) status of RioSweet™ 97% Reb-A, based on scientific procedures. RioSweet™ 97% Reb-A is substantially equivalent to Rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni (Rebaudioside A), which has been determined GRAS by an expert panel, notified to FDA (GRN 000253), and acknowledged by FDA with a letter of no objection (FDA, 2008). In addition, the Expert Panel members independently evaluated materials deemed appropriate and necessary for their determination. Following an independent, critical evaluation, the Expert Panel conferred and unanimously agreed that RioSweet™ 97% Reb-A is substantially equivalent to Rebaudioside A determined GRAS in GRN 000253.

The Expert Panel has determined that, based on common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food, there is reasonable certainty that RioSweet™ 97% Reb-A, produced in accordance with Good Manufacturing Practice (GMP), is safe under the intended conditions of use, and is therefore Generally Recognized As Safe (GRAS), by scientific procedures, when used as a food ingredient so that total daily consumption of rebaudioside A will not exceed the amount determined safe outlined in GRN 000253.⁹

It is our opinion that other experts qualified by scientific training and experience to evaluate the safety of food and food ingredients would agree with these conclusions.

(b) (6)

Ray A. Matulka, Ph.D.
Director of Toxicology, Burdock Group

December 21, 2010
Date

(b) (6)

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition
President, Burdock Group

16 December 2010
Date

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⁸ Modeled after that described in Section 201(s) of the Federal Food, Drug, and Cosmetic Act, as amended. See also attachments (*curriculum vitae*) documenting the expertise of the Panel members.

⁹ Predicted intakes for heavy intake consumers ranged from 3.4 mg/kg body weight/day (1.12 mg/kg body weight/day as steviol equivalents) for non-diabetic adults to 5.0 mg/kg body weight/day (1.64 mg/kg body weight/day as steviol equivalents) for non-diabetic children.

Pages 000014-00036 removed under Freedom of Information exemption
6.

SUBMISSION END

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May 18, 2011

Gladys V. Erives, Ph.D.
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RE: Questions concerning GRN 000365

Dear Dr. Erives:

Burdock Group received a request for clarification by FDA concerning GRN 000365 (Notification of Rebaudioside A purified from the leaves of *Stevia rebaudiana* (Bertoni) Bertoni as a food ingredient) via a conference call on May 13, 2011. The trade name for the substance is RioSweet™ 97% Reb-A. This letter is provided in response to your request for clarification:

1. Clarification that the manufacturing process utilizes food grade materials.

RESPONSE: The manufacturer has provided the attached letter indicating the manufacturing process for RioSweet™ 97% Reb-A uses only food grade materials.

2. Clarification that the specifications for the substance in GRN 000365 meet JECFA specifications, albeit there are certain discrepancies (e.g. solubility).

RESPONSE: The specifications for RioSweet™ 97% Reb-A are substantially equivalent to the specifications for steviol glycosides established by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) in its 68th meeting in June 2007 (JECFA, 2007). The specification for water solubility (40.0 %) meets the "freely soluble in water" JECFA specification, because it meets the JECFA definition of freely soluble (1 part solute per 1 to less than 10 parts solvent¹). The fact that a specification for solubility in ethanol has not been established for RioSweet™ 97% Reb-A (and has for steviol glycosides) does not have an impact on the safety of the product. The expert panel gave due consideration to all JECFA specifications and determined that any differences would not impact a determination of safety.

¹ FAO JECFA Monographs 1: Combined Compendium of Food Additive Specifications-General Methods, Appearance and Physical Properties (2006). <http://www.fao.org/docrep/009/a0691e/A0691E06.htm#6.1.6> <site accessed May 16, 2010>

3. Request for clarification by FDA that no information has been published since GRN 000253 that would negatively impact the conclusion of safety.

RESPONSE: As noted by FDA, the safety of RioSweet™ 97% Reb-A is based on substantial equivalence to Reb A (GRN 000253), which was notified as GRAS to FDA on May 20, 2008 and received a letter of no objection from FDA on December 17, 2008. A comprehensive search of literature published from 2008 to the time of submission had been performed and the Expert Panel had found nothing that would impact the conclusion of safety of a substance that is substantially equivalent to the Reb A substance notified in GRN 000253.

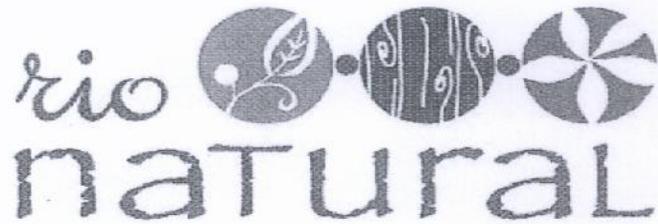
Thank you for the opportunity to respond with these clarifications and please let me know if you have any additional questions concerning this GRAS notification (GRN 000365).

Sincerely,

(b) (6)

George A. Burdock, Ph.D.

*Diplomate, American Board of Toxicology
Fellow, American College of Nutrition*



RioSweet™ 97% REB A Stevia Sweetener

Letter of Guarantee

Our manufacturing process contains only food grade materials in the production of our RioSweet 97% REB A. All our products are sold for human consumption and is guaranteed to be clean, sound, healthful, and wholesome in compliance with the US FDA.

DAVID J. Borba

(b) (6)

CEO. 5/18/2011

Rio Natural 5050 Robert J. Mathews Pkwy, Suite #200 * El Dorado Hills, CA 95762
Phone: 916-941-8059 Fax: 916-941-3690

Belay, Negash

From: George Burdock [gburdock@burdockgroup.com]
Sent: Friday, March 04, 2011 1:51 PM
To: Belay, Negash
Cc: Ray Matulka; Amy Mozingo
Subject: GRN 365 BrazTek Int'l Clarification

Dear Dr. Belay:

As discussed during our phone call this afternoon, the product (Rebaudioside A purified from the leaves of Stevia rebaudiana (Bertoni) Bertoni) is intended as a general-purpose sweetener in foods, excluding meat and poultry products, at levels described in the Notification.

Best regards,
George A. Burdock

George A. Burdock, Ph.D.
Diplomate, American Board of Toxicology
Fellow, American College of Nutrition

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Belay, Negash

From: Amy Mazingo [amazingo@burdockgroup.com]
Sent: Friday, April 29, 2011 10:47 AM
To: Belay, Negash
Cc: gburdock@burdockgroup.com
Subject: GRN 000365

Dear Dr. Belay,

In reference to GRN No. 365, we would like to request that correspondence related to this GRN include the company name as "**BrazTek International Inc. d/b/a Rio Natural.**" In the letter that we received from you dated March 9, 2011 the company was referenced only as BrazTeck International Inc. (BrazTek). We appreciate your consideration of this request.
Best Regards,

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