Pyure Trio

Enclosed in this data packet are the following documents for Pyure Brands products:

Product Specification
Material Safety Data Sheet (MSDS)
Shelf-life, Storage, Expiry
Allergen Status
California Prop 65 Statement
Certificate of Origin
Continuing Guarantee/ GMO Position
Regulatory Status
U.S. Food and Drug Administration No Objection Letter

Quality Control Department
Pyure Brands, LLC

Pyure

pyure trio

STEVIA EXTRACT

Ingredients: Rebaudioside D, C, A (Stevia Extract)

Product Description: A high purity (white to slightly off-white) fine powder extracted from the Stevia rebaudiana Bertoni plant.

Identification: Freely soluble to slightly soluble in water.

Chromatogram Statement: The main peak in the chromatogram obtained following the procedure in Method of Assay corresponds to either stevioside or rebaudioside A.

Functionality: PyureTrio is a natural, plant-derived, high intensity sweetener that is engineered for mid-calorie beverage formulation. Pyure Trio is useful in formulating products with low/reduced calorie, carbohydrate and sugar content.

Allergens: Does not contain wheat, soy, eggs, milk products, peanuts, tree nuts (and derivatives), fish (any type), and shellfish (any type).

Packaging: Two, 3-mil polyethylene bags-in-box at 10kg each

ANALYTICAL STANDARDS:

Chemical Data:

Rebaudioside A (% wt/wt, dry basis)	≥ 80.0
Rebaudioside D (% wt/wt, dry basis)	≥ 5.0
Rebaudioside C (% wt/wt, dry basis)	≤ 3.0
Total Steviol Glycosides (% wt/wt)	≥ 95.0
Moisture (%)	≤ 6.0
Ethanol Residual	≤ 200 mg/kg
Methanol Residual	≤ 200 mg/kg
Ash (%)	≤ 1.0
pH	4.5 - 7.0
Specific Rotation (degrees)	-30.0 - -38.0
Lead (ppm)	< 1.0
Arsenic (ppm)	< 1.0

Microbiological Data:

Standard Plate Count (CFU/g)	< 1000
Total Yeast & Mold (CFU/g)	< 100
Total Coliforms (MPN/g)	Negative
E. Coli	Negative
Salmonella	Negative

NUTRITIONAL INFORMATION:

Nutritional Content ("as is" basis):

Calories:	0.0 Cal/100g
Calories from Fat:	0.0 Cal/100g
Total Fat:	0.0 g/100g
Saturated Fat:	0.0 g/100g
Trans Fat:	0.0 g/100g
Cholesterol:	0.0 mg/100g
Sodium:	1.0mg/100g
Potassium:	0.0 mg/100g
Total Carbohydrates:	1.0 g/100g
Dietary Fiber:	0.0 g/100g
Sugars:	< 1.0 g/100g
Protein:	0.0 g/100g
Calcium:	0.0 mg/100g
Iron:	0.0 mg/100g

Not a significant source of calories from fat, saturated fat, trans fat, cholesterol, dietary fiber, vitamin A, vitamin C, calcium and iron.

SHELF LIFE/STORAGE:

The recommended shelf life of this product is 2 years (24 months) if sealed and stored properly in a cool, dry place.

SHIPPING:

Ship only in clean, dry, transport containers that meet all applicable federal, state, and local regulations at temperatures (<86°F) necessary to maintain the integrity of the product.

Shelf Life
(Stevia Extract)

Storage conditions

The above mentioned products should be sealed and stored in original packaging or tight containers in a cool, well ventilated, dry place, away from chemicals and odors.

Shelf life

Pyure Brands guarantees a shelf life of 2 years for the above mentioned products (based on manufacture date) if the products are stored in their original packaging under the recommended conditions.

Physical properties may change on prolonged storage; a retest is recommended after 2 years.

Expiry date

The expiry date is consequently 2 years after the production date. Both, the expiry date and production date are indicated on the certificate of analysis and packaging label.

Pyure

Allergen Statement

Effective January 1st, 2015

Product Name: Stevia Extract
Botanical Name: *Stevia rebaudiani* Bertoni
Plant Source: Stevia

Allergen List: Pyure Brands stevia extract does not contain any of the allergens listed below:

ITEM:	
Tree Nuts (i.e. walnuts, hazelnuts, pecans)	NO
Sesame Seeds (and derivatives)	NO
Peanuts (and derivatives i.e. peanut oil)	NO
Fish (any type)	NO
Shellfish (any type)	NO
Sulphites	NO
Dairy Products (i.e. milk, lactose, whey, caeseinates)	NO
Eggs	NO
Soy Products	NO
Wheat (Gluten)	NO

Quality Control Department
Pyure Brands, LLC

Pyure

California Proposition 65

To the best of our knowledge the following Pyure Brands products

PyureElite	Rebaudioside A 98-99% Rebaudioside A 95%
Pyure Trio	Rebaudioside 80%, Rebaudioside D 5%
PyurePremium	Rebaudioside A 80% Rebaudioside A 60% Rebaudioside A 55% Rebaudioside A 40% Stevioside 98% Stevioside 95% Stevioside 90%
PyureOrganic	Rebaudioside A 98% Rebaudioside A 95% Rebaudioside A 80% Rebaudioside A 60% Rebaudioside A 40% Stevioside 95% Stevioside 90%
PyureBlends	SE SM SOA

do not contain any contaminants of by-products known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act.

Quality Control Department
Pyure Brands

Pyure

Certificate of Origin

Pyure Brands products are manufactured by a proprietary extraction process. The products undergo several purification steps and are finally obtained in their highly pure form.

Please find below an explanation in which country our products are manufactured:

UNITED STATES
PyureBlend SE
PyureBlend SM
PyureBlend SOA

Pyure Brands retail tabletop
Pyure Brands retail tabletop (organic)

CHINA
PyureElite Rebaudioside A 98-99%
PyureElite Rebaudioside A 95%
Pyure Trio Rebaudioside A 80%, Rebaudioside D 5%

PyurePremium Rebaudioside A 80%
PyurePremium Rebaudioside A 60%
PyurePremium Rebaudioside A 55%
PyurePremium Rebaudioside A 40%

PyurePremium Stevioside S98%
PyurePremium Stevioside S95%
PyurePremium Stevioside S90%

PyureOrganic Rebaudioside A 98%
PyureOrganic Rebaudioside A 95%
PyureOrganic Rebaudioside A 80%
PyureOrganic Rebaudioside A 60%
PyureOrganic Rebaudioside A 40%
PyureOrganic Stevioside S95%
PyureOrganic Stevioside S90%

Pyure

Continuing Guarantee / GMO Position

January 1st, 2015

CONTINUING FOOD GUARANTEE, NATURAL and GMO-FREE CERTIFICATE:

Pyure Brands, LLC hereby certifies our stevia extract, derived from the Stevia Rebaudiana plant, is an all-natural product and contains no artificial additives, flavorings, coloring or preservatives. It is produced without any synthetic or chemical modification of compounds and is both gluten and GMO-free. Our GMO status can be viewed and verified at www.**nongmoproject**.org.

Any extract sold or distributed in the United States by or for Pyure Brands, LLC is certified and third-party tested & analyzed by an independent laboratory in the United States that specializes in Rebaudioside A and steviol glycoside analytics.

Pyure Brands, LLC guarantees its stevia extract will meet the specifications outlined in the company's Product Specifications Sheet. Should any modifications or alterations be made to the Product Specifications Sheet, Pyure Brands, LLC will provide customers appropriate notice of such modifications or alterations.

Pyure Brands, LLC guarantees supply to its customers in accordance with executed Purchase Orders and Agreements.

Signed:

Ben Fleischer
CEO & Founder
Pyure Brands, LLC

Regulatory Status:
High purity Rebaudioside A (Reb A), and steviol glycosides are generally recognized as safe (GRAS).

The FDA issued letters of no objection to GRAS (generally recognized as safe) status for stevia-based Reb A, at a 95% purity level or above in December 2008.

Pyure Brands submitted a GRAS notification to the FDA on January 10, 2010. It is listed on the U.S. FDA website as GRN No. 000318.

> Subject: Rebaudioside A purified from the leaves of *Stevia rebaudiana* (Bertoni) Bertoni
> GRAS Notice No. GRN 000318

European Union:
Pyure Brands' Reb A, stevioside and blend products with a total steviol glycoside content of 95% or higher meet Commission Regulation (EU) No. 1131/2011, set forth November 11th, 2011. Pyure Brands' products meeting the requirement set forth by Commission Regulation (EU) No. 1131/2011 are accepted as food ingredients listed as E960.

Explanation of GRAS Specifications:
FDA: Rebaudioside A, produced consistent with good manufacturing practice and meeting appropriate purity and food grade specifications, is GRAS, by scientific procedures, under the conditions of its intended use. The rebaudioside A that is the subject of GRAS Notice No. GRN 000318 is a highly purified component of the stevia plant.[1]

JECFA: The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated the safety of steviol glycosides. In 2008, a permanent acceptable daily intake (ADI) was established for steviol glycosides, including rebaudioside A. [2]

Regulatory Guideline & Uses:
The notices inform that rebaudioside A is GRAS, through scientific procedures, for use as a table top sweetener and general-purpose sweetener in foods, excluding meat and poultry products, provided that food standards of identity do not preclude such use, at levels determined by current good manufacturing practices (cGMP).[3]

Pyure Brands LLC and its products:
The following products follow current FDA requirements & regulations, per GRAS Notice No. GRN 000252 and GRN 000253.

- PyureElite (Rebaudioside A 95-99%)
- PyurePremium (Stevioside 90-95% - Rebaudioside 40-80%)
- PyureOrganic (Stevioside 90-95% - Rebaudioside 40-98%+)
- PyureBlends (Rebaudioside A 97%+)
- Pyure Brands TT Products (Rebaudioside A 98%+ Organic and Non)
- Pyure Trio (Rebaudioside A 80%, Rebaudioside D 5%)

Pyure Brands LLC guarantees its stevia extract is tested & analyzed to meet the specifications outlined by the FDA GRAS responses by Certificate of Analysis and a certified, third-party independent laboratory in the United States that specializes in Rebaudioside A and steviol glycoside analytics.

---

[1] Section 21 CFR 101.4 and 21 CFR 102.5 of The Food and Drug Administration (FDA)
[2] At its 69th meeting in June 2008, JECFA reviewed new data on the effects of steviol glycosides on blood glucose and blood pressure in humans. JECFA concluded that the results of the new studies showed no adverse effects of steviol glycosides at the levels tested. Source: GRAS Notice No. GRN 000318
[3] Section 301 (II) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 15 2010

Robert S. McQuate, Ph.D.
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

Re: GRAS Notice No. GRN 000318

Dear Dr. McQuate:

The Food and Drug Administration (FDA) is responding to the notice, dated January 13, 2010, that you submitted on behalf of Pyure Brands, LLC (Pyure) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received this notice on January 20, 2010, filed it on January 20, 2010, and designated it as GRN No. 000318.

The subject of the notice is rebaudioside A purified from the leaves of *Stevia rebaudiana* (Bertoni) Bertoni (rebaudioside A). The notice informs FDA of the view of Pyure that rebaudioside A is GRAS, through scientific procedures, for use as a general-purpose sweetener in foods, excluding meat and poultry products and infant formulas, at levels determined by good manufacturing practice, as well as use as a table top sweetener. Pyure notes that rebaudioside A has recently been the subject of other GRAS notices and that FDA responded to these GRAS notices informing the notifiers that, at the time of its response, the agency had no questions regarding their conclusion that the rebaudioside A that is the subject of their respective notices is GRAS for its intended use as a sweetener in food.

The rebaudioside A that is the subject of GRN 000318 is a highly purified component of the leaves of the stevia plant. As such, FDA notes that a GRAS notice for the use of a specific purified component of stevia, such as rebaudioside A, and FDA's response do not necessarily apply to the uses of other stevia products.

Title 21 CFR 101.4 states that all ingredients must be declared by their common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Our use of "rebaudioside A" or "rebaudioside A purified from the leaves of *Stevia rebaudiana* (Bertoni) Bertoni" in this letter should not be considered an endorsement or recommendation of any of these terms as an appropriate common or usual name for the purpose of declaring the substance in the ingredient statement of foods that contain that ingredient. Issues associated with labeling and the appropriate common or usual name of a food are the responsibility of the Office of Nutrition, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition.

As part of its notice, Pyure includes the report of a panel of individuals (Pyure's GRAS panel) who evaluated the data and information that are the basis for Pyure's GRAS determination. Pyure considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Pyure's GRAS panel evaluated the identity, method of manufacture, product specifications, and the potential exposure resulting from the intended uses of rebaudioside A as well as published and unpublished studies on rebaudioside A and related substances. Based on this review, Pyure's GRAS panel concluded that rebaudioside A, produced

consistent with good manufacturing practice and meeting appropriate purity and food grade specifications, is GRAS, by scientific procedures, under the conditions of its intended use.

Pyure provides information about the identity, method of manufacture, and specifications for its rebaudioside A. Rebaudioside A (CAS Reg. No. 58543-16-1), a glycoside of steviol, is identified as 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. Rebaudioside A is one of a group of known steviol glycosides, which differ by the number of glycoside moieties and bonding order. Rebaudioside A is obtained from the leaves of *S. rebaudiana* (Bertoni) Bertoni through extraction and multiple purification steps. The leaves are dried and extracted with water. An adsorption resin is used to trap the steviol glycosides of the leaf extract. The resin is then washed with ethanol to release the glycosides. The resulting solution is filtered, desalinated, and concentrated. The concentrate is then decolorized with activated carbon and dried. The resulting material is dissolved in a water/ethanol solution, crystallized and dried to yield the final rebaudioside A product. Pyure provides specifications for rebaudioside A that include the content of rebaudioside A (≥95% by weight (w/w)) and limits for moisture (≤6% w/w), lead (≤1 milligrams per kilogram (mg/kg)), arsenic (≤1 mg/kg), residual ethanol (<5000 mg/kg) and microbial contaminants (within specified limits). Pyure states that the rebaudioside A product meets or exceeds the specifications for steviol glycosides established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 69th meeting in June 2008.

Pyure estimates the intake of rebaudioside A resulting from its intended use in foods. Pyure largely relies on the consumer intake estimates provided by JECFA. In addition to the JECFA intake estimates, Pyure considered the anticipated human exposure levels as determined in both GRN 000252 and GRN 000253. Pyure notes that the multiple approaches tend to converge to yield estimated daily intakes (EDIs) for rebaudioside A in the range of 0.4 – 1.6 mg/kg body weight per day (mg/kg bw/d), expressed as steviol equivalents. Furthermore, Pyure reports that if adjustments are made for the 400-fold increased sweetness of rebaudioside A alone compared to the mixed steviol glycosides sweetness factor of 200-fold relative to sucrose (JECFA), the EDI of rebaudioside A, based on the JECFA determined EDIs for steviol glycosides, would likely be about 0.5 to 0.8 mg/kg bw/d (expressed as steviol). Pyure states that the use of rebaudioside A in food is self-limiting due to organoleptic factors and consumer taste considerations.

Pyure discusses published and unpublished studies pertaining to the safety evaluation of rebaudioside A, including studies on rebaudioside A, stevioside, steviol, and crude stevia extracts. Among the published studies considered were acute toxicity studies in rats, mice, and hamsters; subchronic toxicity studies in rats; chronic toxicity/carcinogenicity studies in rats; and reproductive/developmental toxicity studies in rats and hamsters. Pyure also considers published clinical studies and published and unpublished absorption, distribution, metabolism and excretion studies in animals and humans. Additional studies that Pyure discusses include published *in vitro* and *in vivo* mutagenicity/genotoxicity studies. Based on its consideration of all these studies, Pyure concludes that rebaudioside A is safe for its intended use in foods.

To further support its view that rebaudioside A is safe for the intended use, Pyure describes recent decisions by JECFA and the Food Standards Australia New Zealand (FSANZ) on the safety of steviol glycosides, one of which is rebaudioside A, for use in food as sweeteners. Pyure notes that in 2008, JECFA established an acceptable daily intake (ADI) for steviol glycosides of 0-4 mg/kg bw/d (expressed as steviol) and FSANZ established an ADI for steviol glycosides of 4 mg/kg bw/d (expressed as steviol).

Standards of Identity

In the notice, Pyure states its intention to use rebaudioside A in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

The Food and Drug Administration Amendments Act of 2007, that was signed into law on September 27, 2007, amends the FFDCA to, among other things, add section 301(ll). Section 301(ll) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In its review of Pyure's notice that rebaudioside A is GRAS for use as a general-purpose sweetener in foods, excluding meat and poultry products and infant formulas, as well as use as a table top sweetener, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing rebaudioside A. Accordingly, this response should not be construed to be a statement that foods that contain rebaudioside A, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information provided by Pyure, as well as other information available to FDA, the agency has no questions at this time regarding Pyure's conclusion that rebaudioside A is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of rebaudioside A. As always, it is the continuing responsibility of Pyure to ensure that food ingredients the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to GRN 000318, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying via the FDA home page at http://www.fda.gov. To view or obtain an electronic copy of the text of the letter, follow the hyperlinks from the "Food" topic to the "Food Ingredients and Packaging" section to the "Generally Recognized as Safe (GRAS)" page where the GRAS Inventory is listed.

Sincerely,

Mitchell A. Cheeseman, Ph.D.
Acting Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

Certificate of Analysis

Product Name: Stevia Extract
Genus/Species: *Stevia rebaudiana Bertoni*

Lot #:	Date of Production:	Date of Analysis:	Shelf Life:	Date of Expiry:
20151205	2015.12.05	2015.12.05	Two years	2017.12.04

ATTRIBUTES	SPECIFICATIONS	RESULTS
Description		
Appearance	Free-flowing powder	Complies
Color	White to slightly off-white	Complies
Odor	None	Complies
Taste	Sweet	Complies
Purity Data		
Rebaudioside A%	≥ 80	80.3%
Rebaudioside D%	≥ 5	5.8%
Rebaudioside C%	≤ 3	0.5%
Total Content %	≥ 95	95.2%
Chemical Data		
pH	4.5-7.0	5.60
Sweetness	300-400	350
Specific-Optical Rotation	-30.0 to -38.0	-35.0
Loss Of Drying	NMT 6.0%	2.39%
Residue On Ignition	NMT 0.2%	0.090%
Total Heavy Metals (as Pb)	NMT 10PPM	Complies
Gluten-Wheat,Rye,Barley	<3.0ppm	Complies
Ash (%)	<1.0	Complies
Lead and Arsenic	<1.0	Complies
Ethanol Residual	<200 mg/kg	Complies
Micro Data		
Total Plate Count	NMT 1000CFU/G	<100cfu/g
Yeast and Mold	NMT 100CFU/G	<10cfu/g
E.Coli	Negative	Complies
Pathogenic Bacteria	Negative	Complies
Salmonella	Negative	Complies
Total Colifoms (MPN/g)	Negative	Complies

Country of Origin: China

First in Organic & Non-GMO Stevia

2277 Trade Center Way, Naples, FL 34109 • Ofc: 305.509.5096 • Fax: 888.226.2490

PYURESWEET.COM