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FOOD ADDITIVE SAFETY

GRAS Notice for Steviol Glycosides

Prepared for:

Office of Food Additive Safety (FHS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Campus Drive
College Park, MD
20740

Submitted by:

Summit Life Science, Inc.
255 Oser Avenue
Hauppauge, New York
11788

April 17, 2017

GRAS Notice for Steviol Glycosides

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GRAS Notice for Steviol Glycosides

Part 1 §170.225 Signed Statements and Certification

In accordance with 21 CFR §170 Subpart E consisting of §170.203 through 170.285, Xinghua GL Stevia Co., Ltd. hereby informs the U.S. Food and Drug Administration (FDA) of its view that steviol glycosides, manufactured by Xinghua GL Stevia Co., Ltd, are not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on its conclusion that the notified substances are Generally Recognized as Safe (GRAS) under the conditions of its intended use described in Part 1.3 below. In addition, as agent for Xinghua GL Stevia Co., Ltd, Jimmy Wang, hereby certifies that all data and information presented in this notice constitute a complete, representative, and balanced submission, and which considered all unfavorable as well as favorable information known to Xinghua GL Stevia Co., Ltd.'s and pertinent to the evaluation of the safety and GRAS status of steviol glycosides as ingredients for addition to food, as described herein.

Signed,

(b) (6)

4/24/2017

Jimmy Wang
Chief Scientific Officer
jimmy@summit-life-science.com
Summit Life Science, Inc. on behalf of
Xinghua GL Stevia Co., Ltd

Date

1.1 Name and Address of Notifier

Xinghua GL Stevia Co., Ltd.
No.26 Kaifu Road,
Xinghua Economic Development Zone
Xinghua City, Jiangsu Province
China

1.2 Common Name of Notified Substance

The common name of the notified substances is steviol glycosides. Xinghua GL Stevia Co., Ltd.'s GRAS Notified products include Rebaudioside 95 (RA95), Rebaudioside 97 (RA97), Rebaudioside 98 (RA98), and Steviol Glycosides 95-Rebaudioside A 60 (SG95—RA 60). Each of these products contains at least 95% total glycosides, of which rebaudioside A is the primary component.

1.3 Conditions of Use

Xinghua GL Stevia Co., Ltd.'s 4 steviol glycoside products are intended for use as table top and general purpose sweeteners when used as a general purpose sweetener in a variety of food products at levels determined by cGMP. These uses are the same as those proposed for several purified steviol glycosides (≥95% purity) or enzyme-modified steviol glycosides that have been determined to be GRAS and have been the subject of GRAS Notifications to FDA. These Notices have received a "no questions" letter from FDA. Use in infant formula and USDA-regulated products is excluded.

1.4 Basis for GRAS

Pursuant to 21 CFR § 170.30 (a) and (b) of the *Code of Federal Regulations* (CFR), steviol glycosides, manufactured by Xinghua GL Stevia Co., Ltd. have been concluded to have GRAS status for use as an ingredient for addition to specified conventional food and beverage products, as described in Part 1.3, on the basis of scientific procedures.

1.5 Availability of Information

The data and information that serve as the basis for this GRAS Notification will be made available to the United States (U.S.) Food and Drug Administration (FDA) for review and copying upon request during business hours at the offices of:

Summit Life Science, Inc.
255 Oser Avenue
Hauppauge, New York
11788

In addition, should the FDA have any questions or additional information requests regarding this notification during or after the Agency`s review of the notice, Summit Life Science, Inc. will supply these data and information on behalf of Xinghua GL Stevia Co., Ltd.

1.6 Freedom of Information Act, 5 U.S.C. Section 552

It is Xinghua GL Stevia Co., Ltd.'s view that all data and information presented in parts 2 through 7 of this notice do not contain any trade secret, commercial, or financial information that is privileged or confidential, and therefore all data and information presented herein are not exempt from the Freedom of Information Act, 5 U.S.C. Section 552.

Part 2. §170.230 Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

2.1 Identity

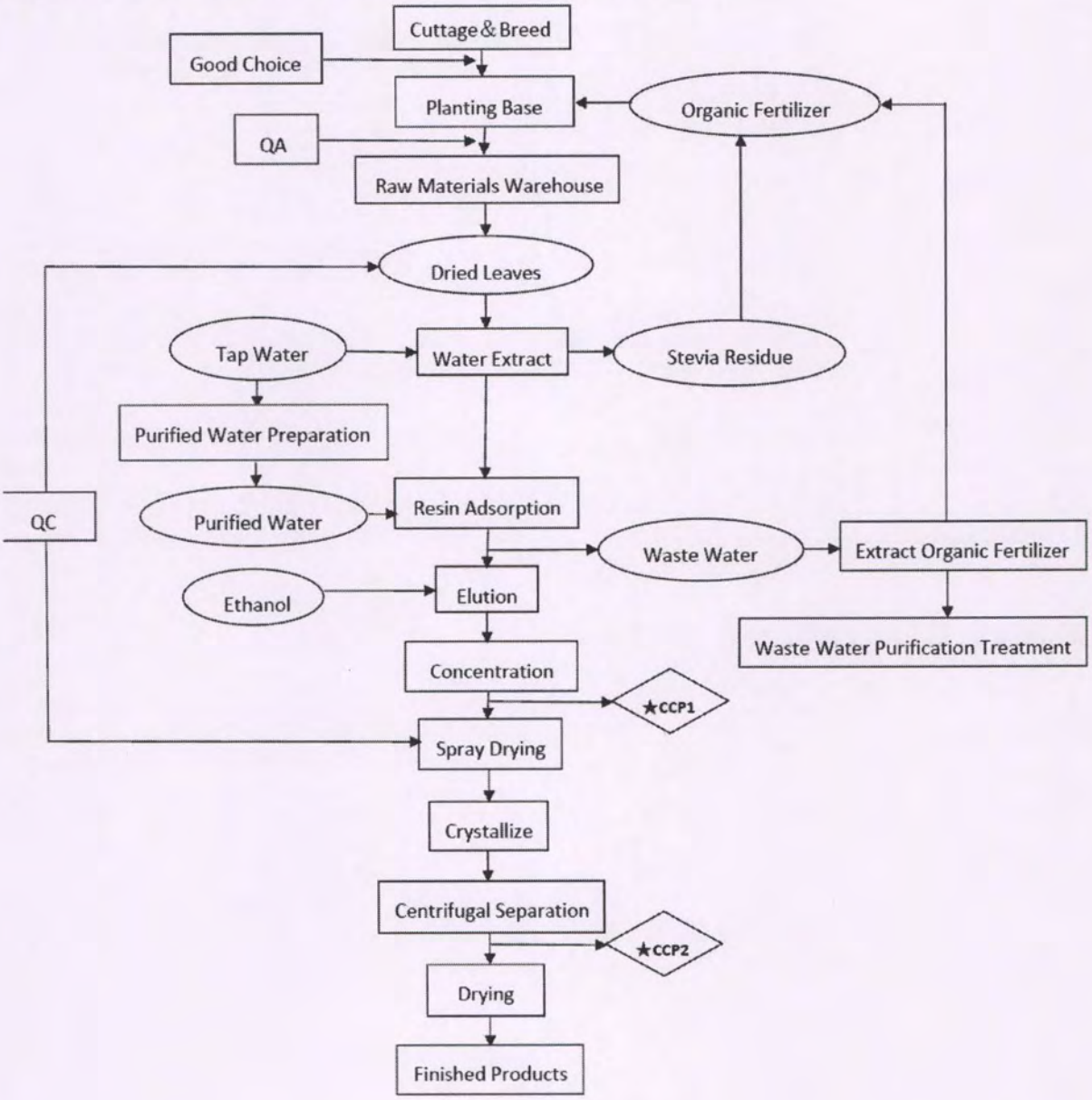
The *Stevia rebaudiana* Bertoni (*S. rebaudiana*) plant is a perennial shrub of the Compositae family, native to Northeastern Paraguay, Brazil, and other South American regions for over 1,500 years (Geuns, 2003; Ferlow, 2005). Approximately 40 steviol glycosides have been isolated from S. rebaudiana, which share a common steviol backbone and are conjugated with various numbers of glucose, xylose, rhamnose, fructose, and/or deoxyglucose moieties (Ihrahim *et al.*, 2016; Purkayastha *et al.*, 2016). The glycosides can be obtained by extracting stevia leaves with hot water, followed by solvent purification of the water-soluble extract. The water extracts, obtained from the crushed stevia leaves, have a long history of use primarily for their sweetening properties. Rebaudioside A comprises the principal constituents of Xinghua GL Stevia Co., Ltd.'s (Xinghua GL) stevia products and is accompanied by smaller amounts of other steviol glycosides. Consistent with the established purity criteria for steviol glycosides as set by JECFA and the Committee's recent review of steviol glycosides.

2.2 Method of Manufacturing

2.2.1 Overview

An overview of the manufacturing process for Xinghua GL steviol glycoside products is provided in Figure 2.1-1. All chemical solvents and reagents used in the process (*i.e.*, ethanol, used as a solvent, ferric chloride used in precipitation, and hydrochloric acid used in resin regeneration) are food grade. The steviol glycoside products are prepared in accordance with cGMP using a Hazard Analysis and Critical Control Points (HACCP)-controlled manufacturing process.

Figure 2.1-1 Process Flow Diagram for Steviol Glycosides



2.3 Product Specifications

2.3.1 Overview

The product specifications for Xinghua GL's 4 steviol glycoside products are summarized in Table 3.2.1-1. All of Xinghua GL's products meet JECFA's purity criteria for total steviol glycoside content, with a minimum concentration of ≥ 95%. Appropriate limits for heavy metals, microbial impurities, and residual solvents have been established.

Table 2.3.1-1 Product Specifications

Parameter	Specifications			
	RA95	**RA97**	**RA98**	**SG95-RA60**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥95.0%	≥97.0%	≥98.0%	≥95.0%
Rebaudioside A (Reb a)	≥95.0%	≥97.0%	≥98.0%	≥60.0%
Odor	Characteristic	Characteristic	Characteristic	Characteristic
Solubility	Soluble in water and alcohol	Soluble in water and alcohol	Soluble in water and alcohol	Soluble in water and alcohol
Loss on Drying	<5.0%	<5.0%	<5.0%	<5.0%
Total Ash	<1%	<1%	<1%	<1%
Methanol Residue	<200 ppm	<200 ppm	<200 ppm	<200 ppm
Ethanol Residue	<5,000 ppm	<5,000 ppm	<5,000 ppm	<5,000 ppm
Lead (Pb)	≤1 ppm	≤1 ppm	≤1 ppm	≤1 ppm
Arsenic (As)	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm
Cadmium (Cd)	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm
Mercury (Hg)	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm	≤0.1 ppm
Pesticides	Negative	Negative	Negative	Negative
Total Plate Count	≤1,000 cfu/g	≤1,000 cfu/g	≤1,000 cfu/g	≤1,000 cfu/g
Yeast & Mold	≤100 cfu/g	≤100 cfu/g	≤100 cfu/g	≤100 cfu/g
Escherichia coli	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Total Coliforms (MPN/g)	<3 MPN/g	<3 MPN/g	<3 MPN/g	<3 MPN/g
Salmonella	Negative	Negative	Negative	Negative
Staphylococcus	Negative	Negative	Negative	Negative

cfu = colony forming units; MPN = most probable number

In Sections 2.3.1-2 through 2.3.1-3, specifications and analysis of 5 non-consecutive batches of each product are provided for Xinghua GL Stevia Co., Ltd.'s RA95, RA97, RA98, and SG95—RA 60 steviol glycoside. Products are rigorously tested in final production batches to verify adherence to quality control specifications. Certificates of analysis are provided in Appendix 1.

2.3.2 RA95

Table 2.3.2-1 Product Specifications for RA95		
Parameter	**Specifications**	**Method**
Appearance	Pure white granule or powder	Visual
Steviol Glycosides	≥95.00%	on the dried basis; HPLC
Rebaudioside A (Reb a)	≥95.00%	HPLC
Odor	Characteristic	Gustation
Solubility	Free soluble in water and ethanol	Visual
pH	Between 4.5 and 7.0	1 in 100 solution
Loss on Drying	<5.0%	105 °C, 2h
Total Ash	<1%	AOAC
Methanol Residue	<200 ppm	HS-GC-MS
Ethanol Residue	<5,000 ppm	HS-GC-MS
Lead (Pb)	≤1 ppm	AOAC
Arsenic (As)	≤0.1 ppm	AOAC
Cadmium (Cd)	≤0.1 ppm	AOAC
Mercury (Hg)	≤0.1 ppm	AOAC
Pesticides	Negative	AOAC
Total Plate Count	≤1,000 cfu/g	USP 2021
Yeast & Mold	≤100 cfu/g	USP 2021
Escherichia coli	<10 cfu/g	USP 2022
Total Coliforms (MPN/g)	<3 MPN/g	FDA-BAM
Salmonella	Negative	USP 2022
Staphylococcus	Negative	USP 2022

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN =most probable number ; NR = not reported; USP = United States Pharmacopoeia

Table 2.3.2-2 Summary of the Chemical Product Analysis for 5 Lots of RA95						
Parameter	**Specification**	**Batch**				
		SR20160811	**SR20160812**	**SR20161014**	**SR20160821**	**SR20160826**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥95.00% (on the dried basis; HPLC)	96.35%	95.87%	96.15%	96.15%	97.46%
Rebaudioside A (Reb a)	≥95.00% (HPLC)	95.56%	95.00%	95.42%	95.42%	96.89%
Odor	Characteristic (Gustation)	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	4.14%	4.89%	3.88%	3.88%	4.77%
Total Ash	<1% (AOAC)	<0.02%	<0.02%	<0.02%	<0.02%	<0.03%
Methanol Residue	<200 ppm (HS-GS-MS)	98 ppm	34 ppm	98 ppm	98 ppm	61 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	234 ppm	477 ppm	286 ppm	286 ppm	182 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Yeast & Mold	≤100 cfu/g (USP 2021)	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Escherichia coli	<10 cfu/g (USP 2022)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g

Table 2.3.2-2 Summary of the Chemical Product Analysis for 5 Lots of RA95						
Parameter	**Specification**	**Batch**				
		SR20160811	**SR20160812**	**SR20161014**	**SR20160821**	**SR20160826**
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g
Salmonella	Negative (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected
Staphylococcus	<10 cfu/g (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

2.3.3 RA97

Table 2.3.3-1 Product Specifications for RA97

Parameter	Specifications	Method
Appearance	Pure white granule or powder	Visual
Steviol Glycosides	≥97.00% (on the dried basis; HPLC)	on the dried basis; HPLC
Rebaudioside A (Reb a)	≥97.00% (HPLC)	HPLC
Odor	Characteristic (Gustation)	Gustation
Solubility	Free soluble in water and ethanol	Visual
pH	Between 4.5 and 7.0 (1 in 100 solution)	1 in 100 solution
Loss on Drying	<5.0% (105 °C, 2h)	105 °C, 2h
Total Ash	<1% (AOAC)	AOAC
Methanol Residue	<200 ppm (HS-GC-MS)	HS-GC-MS
Ethanol Residue	<5,000 ppm (HS-GC-MS)	HS-GC-MS
Lead (Pb)	≤1 ppm (AOAC)	AOAC
Arsenic (As)	≤0.1 ppm (AOAC)	AOAC
Cadmium (Cd)	≤0.1 ppm (AOAC)	AOAC
Mercury (Hg)	≤0.1 ppm (AOAC)	AOAC
Pesticides	Negative (AOAC)	AOAC
Total Plate Count	≤1,000 cfu/g (USP 2021)	USP 2021
Yeast & Mold	≤100 cfu/g (USP 2021)	USP 2021
Escherichia coli	<10 cfu/g (USP 2022)	USP 2022
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	FDA-BAM
Salmonella	Negative (USP 2022)	USP 2022
Staphylococcus	Negative (USP 2022)	USP 2022

AOAC = Association of Official Analytical Chemists ; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; NR = not reported; USP = United States Pharmacopoeia

Table 2.3.3-2 Summary of the Chemical Product Analysis for 5 Lots of RA97						
Parameter	**Specification**	**Batch**				
		SR20160419	**SR20160807**	**SR20160824**	**SR20160911**	**SR20160929**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥97.00% (on the dried basis; HPLC)	97.76%	97.75%	98.24%	97.48%	97.91%
Rebaudioside A (Reb a)	≥97.00% (HPLC)	97.41%	97.21%	97.59%	97.05%	97.59%
Odor	Characteristic (Gustation)	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	2.15%	4.13%	4.90%	2.89%	4.02%
Total Ash	<1% (AOAC)	<0.03%	<0.02%	<0.03%	<0.01%	<0.02%
Methanol Residue	<200 ppm (HS-GS-MS)	187 ppm	52 ppm	117 ppm	60 ppm	47 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	152 ppm	20 ppm	10 ppm	86 ppm	57 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Yeast & Mold	≤100 cfu/g (USP 2021)	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Escherichia coli	<10 cfu/g (USP 2022)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g
Salmonella	Negative (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected
Staphylococcus	<10 cfu/g (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

2.3.4 RA98

Table 2.3.4-1 Product Specifications for RA98		
Parameter	**Specifications**	**Method**
Appearance	Pure white granule or powder	Visual
Steviol Glycosides	≥98.00% (on the dried basis; HPLC)	on the dried basis; HPLC
Rebaudioside A (Reb a)	≥98.00% (HPLC)	HPLC
Odor	Characteristic (Gustation)	Gustation
Solubility	Free soluble in water and ethanol	Visual
pH	Between 4.5 and 7.0 (1 in 100 solution)	1 in 100 solution
Loss on Drying	<5.0% (105 °C, 2h)	105 °C, 2h
Total Ash	<1% (AOAC)	AOAC
Methanol Residue	<200 ppm (HS-GC-MS)	HS-GC-MS
Ethanol Residue	<5,000 ppm (HS-GC-MS)	HS-GC-MS
Lead (Pb)	≤1 ppm (AOAC)	AOAC
Arsenic (As)	≤0.1 ppm (AOAC)	AOAC
Cadmium (Cd)	≤0.1 ppm (AOAC)	AOAC
Mercury (Hg)	≤0.1 ppm (AOAC)	AOAC
Pesticides	Negative (AOAC)	AOAC
Total Plate Count	≤1,000 cfu/g (USP 2021)	USP 2021
Yeast & Mold	≤100 cfu/g (USP 2021)	USP 2021
Escherichia coli	<10 cfu/g (USP 2022)	USP 2022
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	FDA-BAM
Salmonella	Negative (USP 2022)	USP 2022
Staphylococcus	Negative (USP 2022)	USP 2022

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

Table 2.3.4-2 Summary of the Chemical Product Analysis for 5 Lots of RA98						
Parameter	**Specification**	**Batch**				
		SR20160604	**SR20160719**	**SR20160925**	**SR20161008**	**SR20161018**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥98.00% (on the dried basis; HPLC)	98.87%	98.42%	98.68%	98.93%	98.84%
Rebaudioside A (Reb a)	≥98.00% (HPLC)	98.57%	98.25%	98.22%	98.44%	98.59%
Odor	Characteristic (Gustation)	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	4.18%	4.14%	2.90%	1.41%	2.02%
Total Ash	<1% (AOAC)	<0.02%	<0.02%	<0.01%	<0.02%	<0.01%
Methanol Residue	<200 ppm (HS-GS-MS)	57 ppm	30 ppm	79 ppm	13 ppm	138 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	98 ppm	16 ppm	81 ppm	42 ppm	171 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Yeast & Mold	≤100 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Escherichia coli	<10 cfu/g (USP 2022)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g
Salmonella	Negative (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected
Staphylococcus	<10 cfu/g (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

2.3.5 SG95-RA60

Table 2.3.5-1 Product Specifications for SG95-RA60

Parameter	Specifications	Method
Appearance	Pure white granule or powder	Visual
Steviol Glycosides	≥95.00% (on the dried basis; HPLC)	on the dried basis; HPLC
Rebaudioside A (Reb A)	≥60.00% (HPLC)*	HPLC
Odor	Characteristic (Gustation)	Gustation
Solubility	Free soluble in water and ethanol	Visual
pH	Between 4.5 and 7.0 (1 in 100 solution)	1 in 100 solution
Loss on Drying	<5.0% (105 °C, 2h)	105 °C, 2h
Total Ash	<1% (AOAC)	AOAC
Methanol Residue	<200 ppm (HS-GC-MS)	HS-GC-MS
Ethanol Residue	<5,000 ppm (HS-GCS-MS)	HS-GC-MS
Lead (Pb)	≤1 ppm (AOAC)	AOAC
Arsenic (As)	≤0.1 ppm (AOAC)	AOAC
Cadmium (Cd)	≤0.1 ppm (AOAC)	AOAC
Mercury (Hg)	≤0.1 ppm (AOAC)	AOAC
Pesticides	Negative (AOAC)	AOAC
Total Plate Count	≤1,000 cfu/g (USP 2021)	USP 2021
Yeast & Mold	≤100 cfu/g (USP 2021)	USP 2021
Escherichia coli	<10 cfu/g (USP 2022)	USP 2022
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	FDA-BAM
Salmonella	Negative (USP 2022)	USP 2022
Staphylococcus	Negative (USP 2022)	USP 2022

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

*The remaining 35% is comprised of ducloside A, rebaudioside D, rebaudioside B, rebaudioside C, rebaudioside F, stevioside, rubusoside, steviobioside

Table 2.3.5-2 Summary of the Chemical Product Analysis for 5 Lots of SG95-RA60						
Parameter	**Specification**	**Batch**				
		RA20160509	**RA20160811**	**RA20160914**	**RA20161014**	**RA20161102**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥95.00% (on the dried basis; HPLC)	95.59%	96.88%	95.70%	95.88%	96.46%
Rebaudioside A (Reb a)	≥60.00% (HPLC)	60.56%	60.74%	61.59%	61.98%	61.83%
Odor	CHARCS (Gustation)	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	3.77%	4.75%	4.60%	4.63%	4.77%
Total Ash	<1% (AOAC)	<0.03%	<0.03%	<0.01%	<0.01%	<0.01%
Methanol Residue	<200 ppm (HS-GS-MS)	82 ppm	77 ppm	50 ppm	53 ppm	65 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	14 ppm	12 ppm	63 ppm	66 ppm	11 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Yeast & Mold	≤100 cfu/g (USP 2021)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Escherichia coli	<10 cfu/g (USP 2022)	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g	<10 cfu/g
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g	<0.3 MPN/g

Table 2.3.5-2 Summary of the Chemical Product Analysis for 5 Lots of SG95-RA60						
Parameter	**Specification**	**Batch**				
		RA20160509	**RA20160811**	**RA20160914**	**RA20161014**	**RA20161102**
Salmonella	Negative (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected
Staphylococcus	Negative (USP 2022)	Not detected	Not detected	Not detected	Not detected	Not detected

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; CHARCS = Characteristic; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; USP = United States Pharmacopoeia

2.4 Stability

Xinghua GL evaluated the stability of each of its four steviol glycoside products for 24 months at room temperature. Data are summarized in Tables 2.4-1 through 2.4-4.

In addition to these data, the stability of steviol glycosides has been previously reviewed by JECFA. JECFA concluded that steviol glycosides are thermally and hydrolytically stable for use in foods and acidic beverages under normal processing and storage conditions (JECFA, 2007a). Steviol glycosides do not undergo browning or caramelization when heated, and are reasonably stable under elevated temperatures used in food processing. High-purity steviol glycosides (90 to 94%) are stable for at least 180 days when stored at temperatures up to 24°C in acidic solutions (pH 2 to 4). However, when solutions of steviol glycosides were exposed to elevated temperatures (80°C in water, 8 hours) at pH 4.0 and 3.0, 4 and 8% decomposition, respectively, was observed, indicating that the stability is pH and temperature dependent. Higher rates of steviol glycoside decomposition (10 and 40% at pH 4.0 and 3.0, respectively) were observed with temperatures of 100°C.

Table 2.4-1 Long-Term Stability Analysis for RA95 – Batch No. SR20140122										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥95.00% (on the dried basis; HPLC)	97.56%	97.56%	97.55%	97.55%	97.54%	97.54%	97.54%	97.53%	97.53%
Rebaudioside A (Reb a)	≥95.00% (HPLC)	96.27%	96.27%	96.26%	96.26%	96.25%	96.25%	96.25%	96.24%	96.24%
Odor	CHARCS (Gustation)	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	3.43%	3.42%	3.42%	3.41%	3.41%	3.40%	3.39%	3.38%	3.38%
Total Ash	<1% (AOAC)	<0.02%	<0.02%	<0.02%	<0.03%	<0.03%	<0.03%	<0.03%	<0.03%	<0.04%
Methanol Residue	<200 mg/kg (HS-GS-MS)	189 mg/kg	189 ppm	189 ppm	187 ppm	186 ppm	185 ppm	185 ppm	184 ppm	184 ppm
Ethanol Residue	<5,000 mg/kg (HS-GS-MS)	225 mg/kg	225 ppm	224 ppm	224 ppm	223 ppm	223 ppm	222 ppm	221 ppm	220 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm

Table 2.4-1 Long-Term Stability Analysis for RA95 – Batch No. SR20140122										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Yeast & Mold	≤100 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Escherichia coli	<10 cfu/g (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Coliforms (MPN/g)	≤1,000 cfu/g (USP 2021)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Salmonella	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Staphylococcus	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; CHARCS = characteristic; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; NR not reported; Spec. = Specifications; USP = United States Pharmacopoeia

Table 2.4-2 Long-Term Stability Analysis for RA97 – Batch No. SR20140101										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥97.00% (on the dried basis; HPLC)	98.23%	98.23%	98.22%	98.22%	98.21%	98.21%	98.19%	98.19%	98.18%
Rebaudioside A (Reb a)	≥97.00% (HPLC)	97.10%	97.10%	97.10%	97.09%	97.09%	97.09%	97.08%	97.08%	97.07%
Odor	CHARCS (Gustation)	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	3.13%	3.14%	3.14%	3.15%	3.15%	3.16%	3.16%	3.17%	3.17%
Total Ash	<1% (AOAC)	<0.02%	<0.02%	<0.02%	<0.03%	<0.03%	<0.03%	<0.03%	<0.04%	<0.04%
Methanol Residue	<200 ppm (HS-GS-MS)	138 ppm	138 ppm	136 ppm	136 ppm	136 ppm	135 ppm	135 ppm	135 ppm	135 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	99 ppm	98 ppm	97 ppm	97 ppm	97 ppm	96 ppm	96 ppm	96 ppm	96 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm

Table 2.4-2 Long-Term Stability Analysis for RA97 – Batch No. SR20140101										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Yeast & Mold	≤100 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Escherichia coli	<10 cfu/g (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Salmonella	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Staphylococcus	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; CHARCS = characteristic; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; Spec. = Specifications; USP = United States Pharmacopoeia

Table 2.4-3 Long-Term Stability Analysis for RA98 – Batch No. SR20140116										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥98.00% (on the dried basis; HPLC)	98.87%	98.86%	98.86%	98.85%	98.83%	98.81%	98.81%	98.81%	98.80%
Rebaudioside A (Reb a)	≥98.00% (HPLC)	98.57%	98.57%	98.57%	98.55%	98.54%	98.54%	98.53%	98.53%	98.52%
Odor	CHARCS (Gustation)	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	4.18%	4.19%	4.19%	4.19%	4.21%	4.21%	4.22%	4.23%	4.23%
Total Ash	<1% (AOAC)	<0.02%	<0.02%	<0.02%	<0.03%	<0.03%	<0.03%	<0.03%	<0.04%	<0.04%
Methanol Residue	<200 ppm (HS-GS-MS)	57 ppm	57 ppm	57 ppm	56 ppm	55 ppm	55 ppm	54 ppm	54 ppm	54 ppm
Ethanol Residue	<5,000 ppm (HS-GS-MS)	98 ppm	98 ppm	97 ppm	97 ppm	97 ppm	96 ppm	96 ppm	95 ppm	95 ppm
Lead (Pb)	≤1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm	<0.1 ppm
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm

Table 2.4-3 Long-Term Stability Analysis for RA98 – Batch No. SR20140116										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan 2016**
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm	<0.01 ppm
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Yeast & Mold	≤100 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Escherichia coli	<10 cfu/g (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Salmonella	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Staphylococcus	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; CHARCS = characteristic; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; Spec. = Specifications; USP = United States Pharmacopoeia

Table 2.4-4 Long-Term Stability Analysis for SG95-RA60 – Batch No. SR20140102										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan2016**
Appearance	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder	Pure white granule or powder
Steviol Glycosides	≥95.00% (on the dried basis; HPLC)	96.77%	96.77%	96.78%	96.79%	96.79%	96.79%	96.78%	96.78%	96.78%
Rebaudioside A (Reb a)	≥60.00% (HPLC)	60.73%	60.74%	60.75%	60.73%	60.75%	60.75%	60.73%	60.73%	60.72%
Odor	CHARCS (Gustation)	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS	CHARCS
Solubility	Free soluble in water and ethanol	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Loss on Drying	<5.0% (105 °C, 2h)	4.55%	4.55%	4.54%	4.56%	4.54%	4.54%	4.56%	4.56%	4.56%
Total Ash	<1% (AOAC)	<0.04%	<0.04%	<0.04%	<0.04%	<0.03%	<0.03%	<0.04%	<0.04%	<0.04%
Methanol Residue	<200 mg/kg (HS-GS-MS)	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg	141 mg/kg
Ethanol Residue	<5,000 mg/kg (HS-GS-MS)	78 mg/kg	78 mg/kg	78 mg/kg	78 mg/kg	77 mg/kg	77 mg/kg	77 mg/kg	78 mg/kg	78 mg/kg
Lead (Pb)	≤1 ppm (AOAC)	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg
Arsenic (As)	≤0.1 ppm (AOAC)	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg	<0.1 mg/kg

Table 2.4-4 Long-Term Stability Analysis for SG95-RA60 – Batch No. SR20140102										
Parameter	**Spec.**	**Time from Manufacturing Date**								
		Initial	**3 months**	**6 months**	**9 months**	**12 months**	**15 months**	**18 months**	**21 months**	**24 months**
		Jan 2014	**Apr 2014**	**July 2014**	**Oct 2014**	**Jan 2015**	**Apr 2015**	**July 2015**	**Oct 2015**	**Jan2016**
Cadmium (Cd)	≤0.1 ppm (AOAC)	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg
Mercury (Hg)	≤0.1 ppm (AOAC)	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg	<0.01 mg/kg
Pesticides	Negative (AOAC)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Plate Count	≤1,000 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Yeast & Mold	≤100 cfu/g (USP 2021)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Escherichia coli	<10 cfu/g (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Total Coliforms (MPN/g)	<3 MPN/g (FDA-BAM)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Salmonella	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Staphylococcus	Negative (USP 2022)	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform

AOAC = Association of Official Analytical Chemists; cfu = colony forming units; CHARCS = characteristic; HPLC = high performance liquid chromatography; FDA-BAM = Food and Drug Administration Bacteriological Analytical Manual; HS-GC-MS = Headspace gas chromatography mass spectrometry; MPN = most probable number; Spec. = Specifications; USP = United States Pharmacopoeia

Part 3. §170.235 Dietary Exposure

3.1 Probable Consumption

Background Dietary Intakes to Stevia

Steviol glycosides are naturally occurring constituents of the stevia plant, *S. rebaudiana* (Bertoni). As a result of their characteristically sweet taste, extracts of the stevia plant have a long history of human consumption. Furthermore, the use of steviol glycosides has been the approved in multiple jurisdictions; authoritative bodies in the U.S., EU, Australia and New Zealand, and Canada have concluded that preparations containing at least 95% steviol glycosides are safe when used in accordance with cGMP.

Intake from Proposed Conditions of Use

As in previous GRAS Notifications for steviol glycoside products, Xinghua GL Stevia Co., Ltd. used the data of Renwick (2008) to estimate consumer exposure to steviol glycosides. Using published data available for other high intensity sweeteners Renwick (2008) estimated rebaudioside A exposure in various population subgroups. Rebaudioside A was assumed to have relative sweetness 200 times that of sucrose. Table 3.1-1 shows the projected intakes of rebaudioside A (also expressed in terms of steviol equivalents) by average and high consumers in different population groups.

Table 3.1-1 Estimated Intake of Rebaudioside A by Population Group (mg/kg body weigh/day)

Population Group	Intake of Intense Sweeteners[a]		Projected Intakes of Rebaudioside A		Steviol Equivalents[b]	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	1.3	3.4	0.4	1.1
Diabetic adults	280	897	1.4	4.5	0.5	1.5
Non-diabetic children	425	990	2.1	5.0	0.7	1.7
Diabetic children	672	908	3.4	4.5	1.1	1.5

[a] Expressed as sucrose equivalents.
[b] Values are estimated as one-third of rebaudioside A values since the molecular weight of rebaudioside A is about three times that of steviol (*i.e.*, 967 *vs.* 318)

As shown in the table above, the predicted rebaudioside A exposure is 1.3 mg/kg body weight/day for average consumers and 3.4 mg/kg body weight/day for high consumers. Children and individuals with diabetes would be expected to have the highest exposures. These intakes are below the acceptable daily intake (ADI) of 0 to 4 mg/kg body weight/day established by JECFA for steviol glycosides (JECFA, 2007b).

JECFA has also considered different intake models for the estimation of dietary exposure to steviol glycosides. Although higher intake estimates than those presented by Renwick (2008) were identified using other methodologies, including ones considering replacement of all sweeteners used in food (up to approximately 6 mg/kg body weight/day, expressed as steviol equivalents), it was noted by JECFA that such replacement estimates were highly conservative and that actual exposures to steviol glycosides (expressed as steviol equivalents) would be 20 to 30% of these values (1 to 2 mg/kg body weight/day, expressed as steviol equivalents). Furthermore, JECFA noted that the intake estimates based on post-market surveillance further confirmed the lower range.

Part 4. §170.240 Self-Limiting Levels of Use

The use of steviol glycosides in food is largely limited by the desired sweetness intended for a particular food or beverage product; therefore, the use of steviol glycosides as table top sweeteners and general purpose sweeteners in foods is self-limiting based on their organoleptic properties.

Part 5. §170.245 Experience Based on Common Use in Food Before 1958

Not applicable.

Part 6. §170.250 Narrative

6.1 Overview

As Xinghua GL Stevia Co., Ltd. 's stevia glycosides meet current specifications established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemical Codex (FCC) and may be considered substantially equivalent to other commercial available stevia products, Xinghua GL Stevia Co., Ltd. utilized information related to the estimated intake and safety of stevia glycosides contained in previous scientific opinions published by these international scientific bodies and regulatory authorities.

Data to support the safety of Xinghua GL's steviol glycoside products include publically available toxicity studies, as well as the conclusions from several scientific bodies and regulatory agencies, including FDA, EFSA, Food Standards Australia New Zealand (FSANZ), and JECFA. These data uniformly demonstrated that the safety of steviol glycosides was related to steviol content (JECFA, 2009), the common metabolite of steviol glycosides which is formed prior to systemic uptake. Consequently, safety studies available for one steviol glycoside have been used to support the safety of another steviol glycoside.

6.2 Absorption, Distribution, Metabolism, and Excretion

As demonstrated in *in vitro* studies, steviol glycosides are not hydrolyzed by digestive enzymes of the upper gastrointestinal tract and are not absorbed through the upper portion of the gastrointestinal tract (Hutapea *et al.*, 1997; Geuns *et al.*, 2003, 2007; Koyama *et al.*, 2003a). Therefore, steviol glycosides enter the colon intact, where they are subject to microbial degradation by members of the *Bacteroidaceae* family, resulting in the release of the aglycone steviol (Renwick and Tarka, 2008). Several *in vitro* studies mimicking the anaerobic conditions of the colon have confirmed the ability of gut microflora from mice, rats, hamsters, and humans to hydrolyze steviol glycosides completely to steviol and thus share a common metabolic fate (Wingard *et al.*, 1980; Hutapea *et al.*, 1997; Gardana *et al.*, 2003; Koyama *et al.*, 2003b; Purkayastha *et al.,* 2014, 2015, 2016).

Microbes hydrolyze steviol glycosides sequentially by removing one glucose molecule at a time. As a result, the hydrolysis of rebaudioside A to steviol appears to be slower than that of stevioside to steviol, partly due to the presence of one additional glucose moiety. Although the degradation rate of different steviol glycosides varies slightly depending on the complexities of the steviol glycoside structure (Wingard *et al.*, 1980; Koyama *et al.*, 2003b), a stevia mixture containing rebaudioside A, stevioside, rebaudioside C, and dulcoside A (purities not reported) in the presence of human fecal homogenates under anaerobic condition was degraded completely to steviol within 24 hours of incubation. Similarly, Purkayastha *et al.* (2014, 2015, 2016) compared that the degradation rates of individual steviol glycosides (rebaudioside A, B, C, D, E, F, M, steviolbioside, and dulcoside A; 0.2 or 2.0 mg/mL, depending on solubility) to steviol (48 hours incubation in the presence of fecal homogenates from male and female volunteers). No significant differences, especially during the first 24 hours of incubation, were noted. Furthermore, no significant differences in the rate of hydrolysis or amount of steviol formed were observed with respect to the source of human fecal homogenate (male *vs.* female, Asian *vs.* Caucasian) were seen.

Once steviol is formed, it is absorbed systemically by the portal vein and distributed to a number of organs and tissues, including the liver, spleen, adrenal glands, and fat (Nakayama *et al.*, 1986; Sung, 2002; Koyama *et al.*, 2003a; Wang *et al.*, 2004; Roberts and Renwick, 2008; Roberts *et al.*, 2016). Following administration of steviol to Sprague-Dawley rats, peak concentrations were detected in the plasma within 15 to 30 minutes. In contrast, when steviol glycosides (a mixture of rebaudioside A (28.8%), rebaudioside C (25.2%), stevioside (17.0%), and dulcoside A (10.2%) are administered, maximum levels of steviol are attained within 8 hours (Nakayama *et al.*, 1986; Koyama *et al.*, 2003a; Roberts and Renwick, 2008; Roberts *et al.*, 2016). This delay is attributed to the fact that glycosides are first cleaved to steviol before absorption and that this hydrolysis takes place by the gut microflora within the large intestine (Koyama *et al.*, 2003a).

Following absorption, steviol primarily undergoes conjugation with glucuronic acid to steviol glucuronide in the liver. In rats, free steviol (82 to 86% of chromatographed radioactivity), steviol glucuronide (10 to 12% of chromatographed radioactivity), and 2 unidentified metabolites (5 to 6% of chromatographed radioactivity) were identified in the plasma 8 hours after oral administration of radiolabeled rebaudioside A or stevioside (Roberts and Renwick, 2008). Similarly, steviol glucuronide was detected in the plasma following ingestion of stevioside or rebaudioside A in humans, with maximal concentrations detected 8 and 12 hours after administration, respectively (Geuns and Pietta, 2004; Simonetti *et al.*, 2004; Geuns *et al.*, 2007; Wheeler *et al.*, 2008). Significant inter-individual variability in maximum plasma steviol glucuronide levels, and in the time required to reach peak plasma levels, was noted in study participants following stevioside ingestion (Geuns *et al.*, 2007), with these variations attributed to differences in the time required to release steviol from the glycoside in the gut as a result of inter-individual variability in the microflora composition and/or gastric emptying.

Roberts *et al.* (2016) recently compared the toxicokinetic/pharmacokinetic differences of steviol and steviol glucuronide in the plasma of rats and humans. Following oral administration of a single 40 mg/kg body weight dose of stevioside to male and female Sprague-Dawley rats and healthy male human volunteers, plasma samples taken over the subsequent 72 hours were analyzed using a validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) method. Peak plasma concentrations (C_{max}) of steviol and steviol glucuronide occurred slightly later in humans in comparison to rats. C_{max} values of plasma steviol were similar, however corresponding values for steviol glucuronide in the plasma were approximately 25-fold higher in humans than in rats (approximately 4,400 ng/mL *vs.* 180 ng/mL). Systemic exposure to steviol, assessed by the area under the curve ($AUC_{0.75\text{-}72h}$) were approximately 2.8-fold higher in humans than in rats (approximately 1,650 ng*h/mL *vs.* 590 ng*h/mL). Similarly, concentrations of steviol glucuronide were approximately 57-fold higher in humans than rats (approximately 136,000 ng*h/mL *vs.* 2,400 ng*h/mL) when assessed by AUC. These results confirmed that the extent of glucuronidation in humans is greater than in rats.

Species differences in elimination exist. In rats, free and conjugated steviol, as well as any unhydrolyzed fraction of the administered glycosides, are excreted primarily in the feces *via* the bile (generally within 48 hours), with smaller amounts appearing in the urine (less than 3%) (Wingard *et al.,* 1980; Nakayama *et al.,* 1986; Sung, 2002; Roberts and Renwick, 2008). In contrast, elimination of steviol glycosides in humans, primarily as steviol glucuronide with very small amounts of the unchanged glycoside or steviol, occurs *via* the urine (Kraemer and Maurer, 1994; Geuns and Pietta, 2004; Simonetti *et al.,* 2004; Geuns *et al.,* 2006, 2007; Wheeler *et al.,* 2008). Unabsorbed steviol (released from steviol glycosides in the colon or from small amounts of steviol glucuronide secreted back into the gut *via* the bile) also were eliminated in the feces of humans (Geuns and Pietta, 2004; Simonetti *et al.*, 2004; Geuns *et al.*, 2007; Wheeler *et al.*, 2008).

The difference in the route of elimination of systemically absorbed steviol as steviol glucuronide in rats and humans (*via* the bile and in the urine, respectively) occurs as a result of the lower molecular weight threshold for biliary excretion in rats (325 Da) as compared to humans (500 to 600 Da; molecular weight of steviol glucuronide is 495 Da) (Renwick, 2007). Although the primary routes of elimination of steviol glucuronide differ between rats and humans, the similar metabolism and pharmacokinetics of steviol glycosides confirm the rat as an acceptable model for risk assessment in humans. The difference in the route of elimination is considered to be of no toxicological significance due to the fact that the water soluble phase II metabolites are rapidly cleared in both species. Therefore, toxicology data generated in rats are applicable to assess the safety of steviol glycosides in humans given the similarities in metabolic fate.

Furthermore, with the exception of having different numbers and types of sugar moieties, steviol glycosides share the same structural backbone, steviol. As such, all steviol glycosides are expected to follow the same metabolic pathway and the results of toxicology studies on either stevioside or rebaudioside A are applicable to the safety of steviol glycosides, in general.

6.3 Safety Evaluations on Steviol Glycosides

JECFA has conducted numerous safety evaluations on steviol glycosides (JECFA, 2006a,b, 2007a,b, 2008, 2009). Similarly, an adequate daily intake (ADI) of 0 to 4 mg/kg body weight, as steviol equivalents has been established by the European Food Safety Authority (EFSA), Food Standards Australia New Zealand (FSANZ), Health Canada, and JECFA (JECFA, 2007; FSANZ, 2008; EFSA, 2010; Health Canada, 2012). In addition to the evaluations conducted by international authorities, numerous GRAS notices regarding the use of steviol glycosides in foods have been submitted and reviewed by the FDA, with the majority of i these GRAS Notices pertaining to steviol glycoside products with rebaudioside A and/or stevioside as the principal component(s).

These evaluations were based on the safety information available in the published scientific literature. Acute gavage administration of 2 g/kg rebaudioside A produced no toxic effect in male Swiss-Webster (Medon *et al.*, 1982), while stevioside (96% purity) was not associated with any adverse effects following intragastric administration at dose levels of up to 15 g/kg body weight in mice, rats, and hamsters (Medon *et al.*, 1982; Toskulkao *et al.*, 1997). The acute oral median lethal dose (LD_{50}) of steviol in male and female hamsters was 5.20 and 6.10 g/kg body weight, respectively. The no-observed-adverse-effect levels of 4,161 mg/kg and 4,645 mg/kg body weight/day have been reported following 13-week dietary administration in rats and noted that no reproductive or developmental toxicity was seen in multi-generational reproductive and developmental studies conducted with rebaudioside A (Curry and Roberts, 2008; Curry *et al.*, 2008). Steviol glycosides and stevia extract did not produce any carcinogenicity or adverse effects following prolonged high-dose exposure, with a no-observed-adverse-effect level (NOAEL) of 970 mg/kg body weight/day established for stevioside in a 2-year study (Toyoda *et*

al., 1997). Likewise, no mutagenic or genotoxic effects have been seen in various *in vivo* and *in vitro* assays with rebaudioside A.

6.4 Updated Safety Discussion

Subsequent to the EFSA and JECFA evaluations of steviol glycoside safety (EFSA, 2010; JECFA, 2010), 4 additional repeated-dose studies were identified in the published scientific literature, as were 2 genotoxicity studies that provide further support for the safety of steviol glycosides.

The potential toxicity of rebaudioside D was assessed in a 28-day repeat dose toxicity study (Nikiforov *et al.* 2013). Sprague-Dawley rats (10 animals/sex/group) received rebaudioside D in the diet at target exposure levels of 500, 1,000, and 2,000 mg/kg body weight (body weight)/day. The control group received the basal diet (PMI Nutrition International, LLC Certified Rodent Lab-Diet 5002) while a comparator group received Reb A at a target dosage level of 2,000 mg/kg/day. No treatment-related effects on the general condition and behavior of the animals and no toxicologically relevant, treatment-related effects on hematology, serum chemistry, or urinalysis were observed. Likewise, macroscopic and microscopic findings revealed no treatment-related effects on any organ evaluated. Results were comparable between the group administered 2000 mg/kg/d Reb D and the group administered 2,000 mg/kg/day Reb A.

Rumelhard *et al.* (2016) evaluated the potential toxicity of rebaudioside A produced *via* fermentation by a genetically engineered yeast (*Yarrowia lipolytica; Y. lipolytica*) expressing the *S. rebaudiana* metabolic pathway. Oral administration of fermentative Reb A to Sprague-Dawley rats for at least 91 days produced no adverse effects at consumption levels up to 2,057 mg/kg body weight/day for males and 2,023 mg/kg body weight/day for females.

In the 28-day study conducted by Ramanathan and Sellappan (2010), male albino Wistar rats (6/group) were orally administered 0, 500 (low-dose), 1,000 (mid-dose), or 2,000 (high-dose) mg/kg body weight/day of a *S. rebaudiana* leaf extract of unspecified purity. Some inconsistent changes in serum liver enzymes and histological lesions in the liver were reportedly observed in the test groups as compared to the control group.

In the study by Awney *et al.* (2011), male Sprague-Dawley rats (8/group; aged 21 days) were administered high-purity stevioside (purity >97%) at dose levels of 0, 15 (low-dose), or 1,500 (high-dose) mg/kg body weight in drinking water for 12 weeks. At the low-dose, a further group of rats was co-administered stevioside with inulin (dose not reported). In comparison to the control group, within the high-dose test group significant variations were noted in several parameters, including body weights, food intakes, hematological and clinical chemistry indices, and organ weights. Based on the results of their study, the authors concluded that administration of stevioside at the high-dose level was associated with toxicity in rats, and that

the reductions observed in serum tartrate-resistant acid phosphatase (TRAP) activity in all stevioside groups was suggestive of a potential effect of stevioside on bone metabolism and warranted further investigation.

However, the validity of these studies has been questioned. Specifically, the purity of the *S. rebaudiana* leaf extract in the study by Ramanathan and Sellappan (2010) calls into question the relevance of the results to the safety assessment of steviol glycosides. Similarly, the findings and conclusions of Awney *et al.* (2011) have been challenged through several published 'Letters to the Editor' (Waddell, 2011; Carakostas, 2012). Carakostas (2012) criticized the study's analytical methods and errors in sample handling, as well as the authors' over-interpretation of results, particularly in relation to the variability observed in TRAP activity considering the use of non-specific and outdated methodology. Waddell (2011) noted that the findings observed in the study have not been previously reported, that there is adequate background research on safety thresholds set by JECFA, and suggested that the animal sample size used in the study were inadequate. In response, Awney (2011a,b) acknowledged that theirs was an exploratory study to which further studies would need to be conducted to confirm the results, but refuted the claims of analytical and sampling errors. In a recent GRAS Notice for enzyme-modified steviol glycosides that received no objections from the agency (GRN No. 000448, U.S. FDA, 2013a), the short-comings of this study's experimental design and implementation were discussed and differences in the hematological and chemistry data were considered likely to be random, non-specific, and not toxicologically significant.

Urban *et al.* (2013) reviewed the available data pertaining to the potential genotoxicity of steviol glycosides concluded that the available data set provides no indication of steviol glycoside genotoxicity. These conclusions are consistent with those of JECFA, who concluded in 2010 that steviol glycosides do not show any evidence of genotoxicity (JECFA, 2010).

Rebaudioside A (>95% purity) produced *via* fermentation by a genetically engineered yeast (*Y. lipolytica*) to express the *S. rebaudiana* metabolic pathway was not mutagenic in the Ames reverse mutation assay when tested at concentrations of up to 5,000 µg/plate in the presence or absence of metabolic activation (Rumelhard *et al.*, 2016). Additionally, fermentative rebaudioside A was not cytotoxic and did not induce micronuclei formation in cultured peripheral human lymphocytes when incubated for up to 3 hours in the presence or absence of metabolic activation or up to 24 hours in the absence of metabolic activation at concentrations of up to 5,000 µg/plate as part of an *in vitro* micronucleus assay.

As mentioned previously, the ADI for steviol glycosides is calculated using the NOAEL of 970 mg stevioside/kg body weight/day (equivalent to 383 mg steviol equivalents/kg body weight/day) determined from the carcinogenicity study by Toyoda *et al.* (1997) and the standard 100-fold safety factor for inter-and intra-species differences (10-fold, each) to be 4 mg/kg body weight, as steviol equivalents (FSANZ, 2008; JECFA, 2009; EFSA, 2010; Health Canada, 2012). The standard safety factor value of 100 can further be refined by using a chemical-

specific adjustment factor (CSAF) as defined by the World Health Organization (JECFA, 2005) using suitable toxicokinetic/toxicodynamic data. Specifically, the 10-fold safety factor to account for inter-species differences can be further defined as a 4-fold value to account for toxicokinetic differences and a 2.5-fold value accounting for toxicodynamic differences for a particular chemical. On this basis, Roberts *et al.* (2016) concluded that the CSAF for toxicokinetic differences between rats and humans can be estimated to range between 1 based on C_{max} values (ratio of free plasma steviol between humans and rats) and 2.8 based on AUC values (ratio of AUC for steviol between humans and rats). As a result, he safety factor for determining the ADI for steviol glycosides can be revised to 25 [*i.e.*, 1 x 2.5 x 10 (human variability)] or 70 [*i.e.*, 2.8 x 2.5 x 10 (human variability)], providing an ADI between 6 and 16 mg/kg body weight, as steviol equivalents.

6.5 Expert Panel Evaluation

Xinghua GL Stevia Co., Ltd has concluded that its steviol glycoside products, extracted and purified from the leaves of *S. rebaudiana* Bertoni and manufactured consistent with cGMP and meeting food-grade specifications established by JECFA, are GRAS for use as table-top sweeteners and as ingredients in specified conventional food and beverage products, as described in Part 1.3, on the basis of scientific procedures. Xinghua GL Stevia Co., Ltd.'s conclusion on the GRAS status of steviol glycosides under the conditions of their intended use is based on data generally available in the public domain and include a series of toxicology studies on steviol glycoside, as well as reviews by JECFA and FDA's response of no questions related to safety to several previous GRAS Notifications for steviol glycoside products.

A Panel of Experts (the Expert Panel) who are qualified by scientific training and experience to evaluate the safety of food ingredients unanimously concluded on the GRAS status of the steviol glycosides under conditions of their intended use. The Expert Panel consisted of the following qualified scientific experts: Dr. John Thomas (Adjunct Professor, Indiana University School of Medicine), Dr. Robert Nicolosi (Professor Emeritus, University of Massachusetts Lowell) and Dr. David Bechtel (Bechtel Consulting, Inc.).[1]

The Expert Panel, convened by Xinghua GL Stevia Ltd., independently and critically evaluated all data and information presented herein and concluded that steviol glycosides meeting appropriate food-grade specifications and manufactured consistent with current Good Manufacturing Practice, are safe and suitable for use as an ingredient as table-top sweeteners and in specified conventional food and beverage products, as described in Part 1.3, and are GRAS based on scientific procedures. A summary of data and information reviewed by the

[1] The panelists participated in their individual capacities. Institutional affiliations are provided for identification purposes only.

Expert Panel, and evaluation of such data as it pertains to the proposed GRAS uses of the steviol glycosides is presented in Appendix 2.

6.6 Conclusion

Based on the above data and information presented herein, Xinghua GL Stevia Co., Ltd. has concluded that the intended uses of steviol glycosides as table-top sweeteners and in specified conventional food and beverage products, as described in Part 1.3, are GRAS based on scientific procedures using publically available data from toxicology studies and substantial equivalence to other GRAS-notified steviol glycoside products. The GRAS status of steviol glycosides is further supported by the unanimous consensus rendered by an independent Panel of Experts, qualified by experience and scientific training to evaluate the safety of food ingredients, who concluded that the intended use of steviol glycosides as table-top sweeteners and in conventional food and beverage products, as described herein, is GRAS.

The steviol glycosides, therefore, may be marketed and sold for their intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21, Section 170.3 of the Code of Federal Regulations.

Part 7. §170.255 List of Supporting Data and Information

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Part	**§**	**Section Title**
170—Food additives	170.3	Definitions
	170.30	Eligibility for classification as generally recognized as safe (GRAS)

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Appendix 1

Certificates of Analysis

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Certificate of Analysis

Stevia Grade	Reb-A 95(RA95)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20161014	**Test Date**	2016.10.14

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	96.15%
Rebaudioside A(Reb a)	≥95.00%(HPLC)	95.42%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	3.88%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	98ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	286ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>95, RA95-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20161014 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	14.10.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 95(RA95)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160811	**Test Date**	2016.08.11

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	96.35%
Rebaudioside A(Reb a)	≥95.00%(HPLC)	95.56%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.14%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	98ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	234ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>95, RA95-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160811 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	11.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 95(RA95)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160812	**Test Date**	2016.08.12

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	95.87%
Rebaudioside A(Reb a)	≥95.00%(HPLC)	95.00%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.89%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	34ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	477ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>95, RA95-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160812 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	12.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 95(RA95)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160821	**Test Date**	2016.08.21

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	96.15%
Rebaudioside A(Reb a)	≥95.00%(HPLC)	95.42%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	3.88%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	98ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	286ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>95, RA95-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160821 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	21.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 95(RA95)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160826	**Test Date**	2016.08.26

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	97.46%
Rebaudioside A(Reb a)	≥95.00%(HPLC)	96.89%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.77%
Total Ash	<1%(AOAC)	<0.03%
Methanol Residue	<200 ppm(HS-GS-MS)	61ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	182ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>95, RA95-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160826 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	26.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 97(RA97)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160419	**Test Date**	2016.05.02

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥97.00%(on the dried basis HPLC)	97.76%
Rebaudioside A(Reb a)	≥97.00%(HPLC)	97.41%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	2.15%
Total Ash	<1%(AOAC)	<0.03%
Methanol Residue	<200 ppm(HS-GS-MS)	187ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	152ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>97, RA97-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160419 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	02.05.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 97(RA97)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160807	**Test Date**	2016.08.07

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥97.00%(on the dried basis HPLC)	97.75%
Rebaudioside A(Reb a)	≥97.00%(HPLC)	97.21%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.13%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	52ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	20ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>97, RA97-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160807 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	07.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 97(RA97)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160824	**Test Date**	2016.08.24

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥97.00%(on the dried basis HPLC)	98.24%
Rebaudioside A(Reb a)	≥97.00%(HPLC)	97.59%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.90%
Total Ash	<1%(AOAC)	<0.03%
Methanol Residue	<200 ppm(HS-GS-MS)	117ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	10ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>97, RA97-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160824 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	24.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 97(RA97)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160911	**Test Date**	2016.09.11

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥97.00%(on the dried basis HPLC)	97.48%
Rebaudioside A(Reb a)	≥97.00%(HPLC)	97.05%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	2.89%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	60ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	86ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>97, RA97-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160911 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	11.09.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 97(RA97)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160929	**Test Date**	2016.09.29

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥97.00%(on the dried basis HPLC)	97.91%
Rebaudioside A(Reb a)	≥97.00%(HPLC)	97.59%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.02%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	47ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	57ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>97, RA97-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160929 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	29.09.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 98(RA98)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160604	**Test Date**	2016.06.04

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥98.00%(on the dried basis HPLC)	98.87%
Rebaudioside A(Reb a)	≥98.00%(HPLC)	98.57%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.18%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	57ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	98ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>98, RA98-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160604 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	04.06.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 98(RA98)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160719	**Test Date**	2016.07.19

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥98.00%(on the dried basis HPLC)	98.42%
Rebaudioside A(Reb a)	≥98.00%(HPLC)	98.25%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.14%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	30ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	16ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>98, RA98-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160719 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	19.07.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 98(RA98)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20160925	**Test Date**	2016.09.26

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥98.00%(on the dried basis HPLC)	98.68%
Rebaudioside A(Reb a)	≥98.00%(HPLC)	98.22%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	2.90%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	79ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	81ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>98, RA98-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20160925 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	29.09.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 98(RA98)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20161008	**Test Date**	2016.10.08

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥98.00%(on the dried basis HPLC)	98.93%
Rebaudioside A(Reb a)	≥98.00%(HPLC)	98.44%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	1.41%
Total Ash	<1%(AOAC)	<0.02%
Methanol Residue	<200 ppm(HS-GS-MS)	13ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	42ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>98, RA98-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20161008 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	08.10.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	Reb-A 98(RA98)	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	SR20161018	**Test Date**	2016.10.18

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 58543-16-1 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥98.00%(on the dried basis HPLC)	98.84%
Rebaudioside A(Reb a)	≥98.00%(HPLC)	98.59%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	2.02%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	138ppm
Ethanol Residue	<500 ppm(HS-GS-MS)	171ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>98, RA98-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The SR20161018 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	18.10.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	SG95-RA60	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	RA20160509	**Test Date**	2016.05.09

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 57817-89-7 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		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	95.59%
Rebaudioside A(Reb a)	≥60.00%(HPLC)	60.56%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	3.77%
Total Ash	<1%(AOAC)	<0.03%
Methanol Residue	<200 ppm(HS-GS-MS)	82 ppm
Ethanol Residue	<200 ppm(HS-GS-MS)	14 ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>60, RA60-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The RA20160509 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Yan Lv	
verified by:	QingHai Yu	
Latest Update	09.05.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	SG95-RA60	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	RA20160811	**Test Date**	2016.08.12

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 57817-89-7 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		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	96.88%
Rebaudioside A(Reb a)	≥60.00%(HPLC)	60.74%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.75%
Total Ash	<1%(AOAC)	<0.03%
Methanol Residue	<200 ppm(HS-GS-MS)	77ppm
Ethanol Residue	<200 ppm(HS-GS-MS)	12 ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>60, RA60-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The RA20160811 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	12.08.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	SG95-RA60	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	RA20160914	**Test Date**	2016.09.16

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 57817-89-7 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		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	95.70%
Rebaudioside A(Reb a)	≥60.00%(HPLC)	61.59%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.60%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	50ppm
Ethanol Residue	<200 ppm(HS-GS-MS)	63 ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>60, RA60-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The RA20160914 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	16.09.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	SG95-RA60	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	RA20161014	**Test Date**	2016.10.14

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 57817-89-7 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		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	95.88%
Rebaudioside A(Reb a)	≥60.00%(HPLC)	61.98%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.63%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	53ppm
Ethanol Residue	<200 ppm(HS-GS-MS)	66 ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>60, RA60-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The RA20161014 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	14.10.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Stevia Grade	SG95-RA60	**Plant Latin Name**	*S. rebaudiana* Bertoni
Type of Product	Food Ingredient Non-GMO, Non-Allergen	**Plant Part Used**	Dry leaf (100% natural)
		Origin of Product	P. R. China-by GL Stevia
Batch No.	RA20161102	**Test Date**	2016.11.02

Parameter	GL Stevia Specification	Test Result
CAS Reg. No. 57817-89-7 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		
Appearance	White Powder form	White Powder form
Steviol Glycosides[1]	≥95.00%(on the dried basis HPLC)	96.46%
Rebaudioside A(Reb a)	≥60.00%(HPLC)	61.83%
Odor	Characteristic(Gustation)	Characteristic
Solubility	Free soluble in water and ethanol	Conform
pH	Between 4.5 and 7.0 (1 in 100 solution)	Conform
Loss on Drying	<5.0% (105 °c, 2h)	4.77%
Total Ash	<1%(AOAC)	<0.01%
Methanol Residue	<200 ppm(HS-GS-MS)	65 ppm
Ethanol Residue	<200 ppm(HS-GS-MS)	11 ppm
Lead (Pb)	≤1 ppm(AOAC)	<0.1 ppm
Arsenic (As)	≤0.1 ppm(AOAC)	<0.1 ppm
Cadmium(Cd)	≤0.1 ppm(AOAC)	<0.01 ppm
Mercury(Hg)	≤0.1 ppm(AOAC)	<0.01ppm
Pesticides	Negative(AOAC)	Conform
Total Plate Count	≤1,000cfu/g (USP 2021)	<10 cfu/g
Yeast & Mold	≤100cfu/g (USP 2021)	<10 cfu/g
E. Coli.	<10 cfu/g(USP 2022)	<10 cfu/g
Total Coliforms, MPN/g	<3 MPN/g(FDA-BAM)	<0.3 MPN/g
Salmonella	Negative(USP 2022)	Not Detected
Staphylococcus	Negative(USP 2022)	Not Detected
Packing: 20 kg fiber drum with double liner polyethylene bag inside.		
Labeling: Stevia Reb-A>60, RA60-White Powder		
Storage:Keep sealed, in dry,cool place		
Shelf Life:2 years		
Conclusion	*----The RA20161102 batch sample pass the QC test. Parameter conforms with in-house Standard, JECFA Standard, EFSA Standard.*	
tested checked by:	Lu Gao	
verified by:	QingHai Yu	
Latest Update	02.11.2016	

1 Stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B,rebaudioside D and rebaudioside F.

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Appendix 2

Expert Panel Consensus Statement

Expert Panel Report Concerning the Generally Recognized as Safe (GRAS) Status of Four Steviol Glycoside Preparations (RA98, RA97, RA95, and SG95-RA60) as Generally Recognized as Safe (GRAS) for Use as Table Top and General Purpose Sweeteners

February 27, 2017

INTRODUCTION

At the request of Xinghua GL Stevia Co., Ltd.'s (Xinghua GL), an Expert Panel (the "Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of human and animal food ingredients, was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and information on steviol glycosides. The Panel was asked to determine whether 4 steviol glycoside preparations (*i.e.*, RA98, RA97, RA95, and SG95-RA60) would be Generally Recognized as Safe (GRAS) for use in the United States (U.S.) as table top and general purpose sweeteners. The Panel consisted of the below-signed qualified scientific experts: Dr. David H. Bechtel (Bechtel Consulting, Inc.), Robert J. Nicolosi (RJ Nicolosi, LLC), and Dr. John A. Thomas (Tom-Tox, LLC).

The Panel, independently and collectively, critically examined a comprehensive package of scientific information and data compiled from the publicly available literature and other sources based on searches of the published scientific literature conducted through December of 2016. As Xinghua GL's steviol glycoside preparations meet the specifications established by The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and may be considered substantially equivalent to other stevia products, the Panel reviewed information related to the safety of steviol glycosides contained in numerous previous GRAS Notices submitted to the U.S. Food and Drug Administration (U.S. FDA, 2008a,b, 2009a,b,c,d, 2010a,b,c,d,e, 2011a,b,c,d,e,f,g,h,i, 2012a,b,c,d,e, 2013a,b,c,d,e,f, 2014; a,b,c, 2015a,b,c,d, 2016a,b,c,d,e,f,g,h). In addition, the Panel considered other information deemed appropriate or necessary, including data and information provided by Xinghua GL. The data evaluated by the Panel included information pertaining to the method of manufacture and product specifications, analytical data, intended use levels in specified food products, consumption estimates for all intended uses, and comprehensive literature on the safety of steviol glycosides.

Following independent, critical evaluation of such data and information, the Panel unanimously concluded that the intended uses described herein of Xinghua GL's steviol glycoside products, manufactured consistent with current Good Manufacturing Practice (cGMP) and meeting appropriate food-grade specifications, including those established by JECFA, are GRAS based on scientific procedures. A summary of the basis for the Panel's conclusion is provided below.

SUMMARY AND BASIS FOR GRAS

Xinghua GL's steviol glycoside products are manufactured using a cGMP-compliant and Hazard Analysis and Critical Control Point-controlled process consistent with other commercial methods used to manufacture steviol glycosides. *Stevia rebaudiana* Bertoni leaves undergo a hot-water extraction process followed by purification techniques and crystallization steps to produce highly-purified products that comply with JECFA specifications. Appropriate limits for heavy metals, microbial impurities, and residual solvents have been established. During the review of steviol glycosides at their 63rd meeting, JECFA concluded that steviol glycosides are thermally and hydrolytically stable for use in foods and acidic beverages under normal processing and storage conditions (JECFA, 2007). Long-term stability analyses conducted on Xinghua GL's products have corroborated JECFA's conclusions.

The panel noted that steviol glycosides are naturally occurring constituents of the stevia plant, *S. rebaudiana* (Bertoni) with a long history of human consumption. The panel also considered that the safety of steviol glycosides has been the subject of numerous reviews over the last couple of decades by authoritative bodies in numerous jurisdictions, including the U.S., European Union, Australia and New Zealand, and Canada, and have concluded that preparations containing at least 95% steviol glycosides are safe when used in accordance with cGMP.

The Panel reviewed the available toxicity data on steviol glycosides and noted that steviol glycosides possess low acute toxicity. Acute gavage administration of 2 g/kg rebaudioside A produced no toxic effect in male Swiss-Webster (Medon *et al.,* 1982), while stevioside (96% purity) was not associated with any adverse effects following intragastric administration at dose levels of up to 15 g/kg body weight in mice, rats, and hamsters (Medon *et al.,* 1982; Toskulkao *et al.,* 1997). The acute oral median lethal dose (LD_{50}) of steviol in male and female hamsters was 5.20 and 6.10 g/kg body weight, respectively. The Panel also considered that no-observed-adverse-effect levels of 4,161 mg/kg and 4,645 mg/kg body weight/day have been reported following 13-week dietary administration in rats and noted that no reproductive or developmental toxicity was seen in multi-generational reproductive and developmental studies conducted with rebaudioside A (Curry and Roberts, 2008; Curry *et al.*, 2008). The Panel noted that steviol glycosides and stevia extract did not produce any carcinogenicity or adverse effects following prolonged high-dose exposure, with a no-observed-adverse-effect level (NOAEL) of 970 mg/kg body weight/day established for stevioside in a 2-year study (Toyoda *et al.,* 1997). Likewise, the panel noted that no mutagenic or genotoxic effects have been seen in various *in vivo* and *in vitro* assays with rebaudioside A.

Finally, the Panel considered that the proposed use of XInghua GL's steviol glycoside products result in intakes within the adequate daily intake (ADI) of 0 to 4 mg/kg body weight, as steviol equivalents established by the European Food Safety Authority (EFSA), Food Standards Australia New Zealand (FSANZ), Health Canada, and JECFA (JECFA, 2007; FSANZ, 2008; EFSA, 2010;

Health Canada, 2012). This ADI was derived from the NOAEL of 970 mg/kg body weight/day (equivalent to 383 mg steviol equivalents/kg body weight/day) from a 2-year study in rats (Toyoda *et al.*, 1997), and a safety factor of 100, to account for intra- and inter-species differences. The Panel noted that a recent investigation into the toxicokinetic differences of steviol and steviol glucuronide in the plasma of rats and humans suggest application of a chemical-specific adjustment factor derived from maximal plasma concentrations and systemic exposure of free steviol support a higher ADI for steviol glycosides between 6 and 16 mg/kg body weight, as steviol equivalents (Roberts *et al.*, 2016).

CONCLUSION

Having considered all the relevant information, it is our opinion as qualified experts that there is reasonable certainty that no harm will result from the intended use of XInghua GL's 4 steviol glycoside preparations (*i.e.*, RA98, RA97 RA95, and SG95-RA60), meeting JECFA specifications and manufactured in accordance with current Good Manufacturing Practices (cGMP), for use in the U.S. as table top and general purpose sweeteners. Such use would be considered Generally Recognized as Safe (GRAS) through scientific procedures, making Xinghua GL's products exempt from the premarket approval requirements outlined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (U.S. FDA, 2015d).

(b) (6)

03/10/2017

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Professor Emeritus, Department of Clinical Laboratory and Nutritional Sciences
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Date

(b) (6)

3/7/17

John A. Thomas, Ph.D., F.A.T.S., D.A.T.S
Adjunct Professor, Department of Pharmacology & Toxicology
Indiana University School of Medicine
Indianapolis, IN

Date

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3/16/17

David H. Bechtel, Ph.D., DABT
President,
Bechtel Consulting, Inc.
Monroe, NJ

Date

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U.S. FDA (2009a). *Agency Response Letter GRAS Notice No. GRN 000275 [Purified steviol glycosides with Rebaudioside A as the principal component, Fort Washington (PA): McNeil Nutritionals, LLC].* College Park (MD): U.S. Food and Drug Administration (U.S. FDA), Center for Food Safety & Applied Nutrition (CFSAN), Office of Food Additive Safety. Available at: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=grasListing&id=275 [June 11, 2009].

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