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#184

May 15, 2018

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

Subject: GRAS Notice for *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate

Dear Dr. Gaynor:

On behalf of Hunan Huacheng Biotech, Inc., we are submitting a GRAS notification for Luo Han Guo fruit juice concentrate. The attached document contains the specific information that addresses the safe human food uses for the notified substance. We believe that this determination and notification are in compliance with Pursuant to 21 C.F.R. Part 170, subpart E.

We enclose an original copy of this notification for your review. Please feel free to contact me if additional information or clarification is needed as you proceed with the review. We would appreciate your kind attention to this matter.

Sincerely,

(b) (6) 5/15/2018

Susan Cho, Ph.D.
Susanscho1@yahoo.com
Agent for Hunan Huacheng Biotech, Inc.

enclosure

DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF *SIRAITIA GROSVENORII* SWINGLE (LUO HAN GUO) FRUIT JUICE CONCENTRATE AS A FOOD INGREDIENT

Prepared for
Hunan Huacheng Biotech, Inc.
(Hunan Huacheng)

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DETERMINATION OF THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF *SIRAITIA GROSVENORII* SWINGLE (LUO HAN GUO) FRUIT JUICE CONCENTRATE AS A FOOD INGREDIENT

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PART 1. SIGNED STATEMENTS AND A CERTIFICATION

This GRAS conclusion has been reached in accordance with the requirements in 21 CFR 170.220. Pursuant to 21 CFR Part 170, subpart E, Hunan Huacheng Biotech, Inc. (hereinafter referred to as 'Hunan Huacheng') submits a Generally Recognized as Safe (GRAS) notice and claims that the use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrates, as described in Parts 2 through 7 of this GRAS notice, is not subject to premarket approval requirements of the FD&C Act based on its conclusion that the substance is GRAS under the conditions of its intended use.

1.A. Name and Address of the Notifier

Company name: Hunan Huacheng Biotech, Inc.
Address: Apricot Road 8, Changsha National High-Tech Industry Development Zone, Hunan, 410205, China
Telephone number: +86-731 88988 198
E-mail address: sales@huachengbio.com

1.B. Common or Trade Name

The name of the substance is *Siraitia grosvenorii* (Swingle) fruit juice concentrate. It is also commonly known by the following synonyms: Luo Han Guo juice concentrate or Luo Han Guo fruit juice concentrate.

1.C. Applicable Conditions of Use of the Notified Substance

1.C.1. Foods in Which the Substance is to be Used

Siraitia grosvenorii Swingle (Luo Han Guo) fruit juice concentrate is intended to be used in conventional foods and in infant and toddler foods, excluding infant formula.

1.C.2. Levels of Use in Such Food

For conventional foods, the substance will be used as a sugar substitute in the same foods at levels specified in GRNs 301, 359, 522, 556, and 706.

For infant and toddler foods, the use level will be the same as those described in GRN 627. Luo Han Guo juice concentrate is intended to be used as a food ingredient, in a manner similar to many other fruit juices, for its sweetening properties. Also, like other fruit juices and concentrates, the level of addition of Luo Han Guo fruit juice concentrate is limited only by current good manufacturing practices (cGMP). Practically, this results in a maximum addition level of about 1%, more frequently 0.25 to 0.50%.

1.C.3. Purpose for Which the Substance is Used

The substance will be used as a sweetener.

1.C.4. Description of the Population Expected to Consume the Substance

The population expected to consume the substance consists of members of the general population who consume at least one of the products described above.

1.D. Basis for the GRAS Determination

This GRAS conclusion is based on scientific procedures in accordance with 21 CFR 170.30(a) and 170.30(b).

1.E. Availability of Information

The data and information will be made available to FDA in a form in accordance with that requested under 21 CFR 170.225(c)(7)(ii)(A) or 21 CFR 170.225(c)(7)(ii)(B).

1.F. Availability of FOIA Exemption

None of the data and information in Parts 2 through 7 of this GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. §552.

1.G. Certification

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

1.H. Name and Position/Title of Responsible Person Who Signs Dossier:

(b) (6)

Name: Jun Huang Date: May 15, 2018
Title: Quality Man

Address correspondence to
Susan S. Cho, Ph.D., NutraSource, Inc.
Susanscho1@yahoo.com or nutrasource111@gmail.com
Agent for Hunan Huacheng

1.I. FSIS/USDA Statement

Hunan Huacheng does not intend to add *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate to any meat and/or poultry products that come under USDA jurisdiction. Therefore, 21 CFR 170.270 does not apply.

PART 2. IDENTITY, MANUFACTURING, SPECIFICATIONS, AND TECHNICAL EFFECTS

2.A. Scientific Information About the Identity of Notified Substance

2.A.1.1. Common Name

Luo Han Guo fruit juice concentrates

2.A.1.2. Chemical Names of Main Component

Luo Han Guo fruit juice concentrates or *S. grosvenorii* (Swingle) fruit juice concentrates are mixtures of compounds naturally occurring in the Luo Han Guo fruit. Mogroside V is the major sweet component of Luo Han Guo fruit juice concentrates and, thus, will be the focus of this document.

Chemical Name of Mogroside V: mogro-3-O-[beta-D-glucopyranosyl(1-6)-beta –D-glucopyranoside]-24-O-{[beta-D-glucopyranosyl(l-2)]-[beta-D-glucopyranosyl (1 -6)]-beta-D-glucopyranoside

IUPAC Name: (2R,3R,4S,5S,6R)-2-[[(3S,4S,5R,6R)-6-[[(3S,8S,9R,10R,11R,13R,14S,17R)-17-[(2R)-5-[(2S,3R,4S,5S,6R)-4,5-dihydroxy-3-[(2R,3S,4R,5R,6S)-3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-6-[[(2R,3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)oxan-2-yl]oxymethyl]oxan-2-yl]oxy-6-hydroxy-6-methylheptan-2-yl]-11-hydroxy-4,4,9,13,14-pentamethyl-2,3,7,8,10,11,12,15,16,17-decahydro-1H-cyclopenta[a]phenanthren-3-yl]oxy]-3,4,5-trihydroxyoxan-2-yl]methoxy]-6-(hydroxymethyl)oxane-3,4,5-triol

2.A.1.3. Chemical Abstract Service (CAS) Registry Number

Mogroside V CAS Reg. No.: 88901-36-4

2.A.1.4. Molecular Formula

Mogroside V Molecular Formula: $C_{60}H_{102}O_{29}$

2.A.1.5. Structural Formula

The backbone chemical structure is consistent among the mogroside molecules, with differing side chain structures. Figures 1 corresponds to mogroside V.

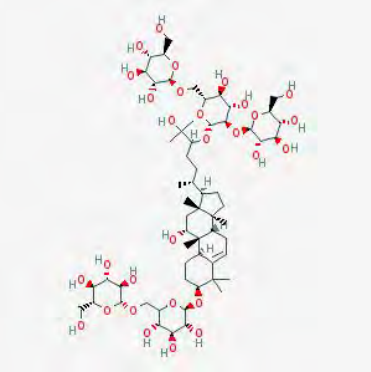

Figure 1. Chemical Structure of Mogroside V

2.A.1.6. Molecular Weight

Molecular Weight of Mogroside V: 1287.447 g/mol

2.A.1.7. Background

Siraitia grosvenorii (Swingle), commonly known as Luo Han Guo or Luo Han Guo fruit, is a plant native to Southern China. Similar to Luo Han Guo fruit extracts, Luo Han Guo fruit juice concentrates contain varying concentrations of mogrosides, which are the non-nutritive constituents of the fruit primarily responsible for the characteristic sweetness of Luo Han Guo fruit juice concentrate (FDA, 2015a). Luo Han Guo fruit extracts, depending on the mogroside V content, are reported to be 100 to 400 times sweeter than sugar (FDA, 2015a, 2015b). They, therefore, can be used as a sugar substitute.

The primary components of Luo Han Guo fruit juice concentrates are cucurbitane glycosides (known as mogrosides, specifically mogrosides II, III, IV, V, and VI) along with flavonoids and melanoidins (Lee, 1975). In particular, mogroside V is the major sweetness component of the fruit. Mogroside V, the most abundant sweet constituent, has been found in whole fruits at concentrations of 0.8-1.3 % w/w (Makapugay et al., 1985; Pawar et al., 2013).

Luo Han Guo fruit juice products (in both powder and liquid forms) have been introduced for use in the U.S. as a table-top sweetener of foods. The subject of this GRAS determination is Luo Han Guo fruit juice concentrates containing 0.6 – 3.9% mogroside V.

2.A.2. Potential Toxicants in the Source of the Notified Substance

Potential toxicants have not been identified. No pesticide residues (organochlorine or organophosphorus) have been detected in Hunan Huacheng's Luo Han Guo fruit juice concentrates (Tables 1 and 2; Certificate of analysis [COA] can be found in the appendix).

Table 1. A List of Organochlorine Pesticides Screened in Luo Han Guo Fruit Juice Concentrate (65°Brix)

Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)
Aclonifen (0.01)	Acrinathrin (0.02)	Aldrin (0.005)
Benfluralin (0.005)	Bifenox (0.02)	Binapacryl (0.02)
Bifenthrin (0.02)	Bromocyclen (0.02)	Bromoxynil-octanoate (0.01)
Butralin (0.02)	Chlordane, cis- (0.005)	Chlordane, oxy- (0.005)
Chlordane, trans- (0.005)	Chlorfenapyr (0.005)	Chlorfenprop-methyl (0.01)
Chlorfenson (0.01)	Chloroneb (0.05)	Chlorothalonil (0.01)
Chlorthal-dimethyl (0.005)	Cyfluthrin (0.02)	Cyhalothrin, lamda- (0.02)
Cypermethrin (0.02)	Cyphenothrin (0.02)	DDD, o,p- (0.005)
DDD, p,p'- (0.005)	DDE, o,p- (0.005)	DDE, p,p'- (0.005)
DDT, o,p'- (0.005)	DDT, p,p'- (0.005)	Deltamethrin (0.02)
Diallate (0.05)	Dichlobenil (0.01)	Dichlone (0.02)
Dicloran (0.005)	Dichlorobenzophenone, o,p-	Dichlorobenzophenone, p,p-

	(0.4)	(0.04)
Dicofol, o,p- (0.04)	Dicofol, p,p- (0.04)	Dieldrin (0.005)
Dienochlor (0.02)	Dinitramine (0.01)	Dinobuton (0.02)
Endosulfan, alpha- (0.005)	Endosulfan sulphate (0.01)	Endosulfan, beta- (0.005)
Endrin (0.01)	Endrin ketone (0.01)	Esfenvalerate (0.02)
Ethalfluralin (0.01)	Etridiazole (0.01)	Fenfluthrin (0.02)
Fenpropathrin (0.02)	Fenson (0.01)	Fenvalerate (RR-/SS-Isomers)
Fenvalerate (RS-/SR-Isomers) (0.01)	Flubenzimine (0.01)	Fluchloralin (0.01)
Flucythrinate (0.02)	Flumetralin (0.01)	Fluorodifen (0.02)
Fluoroimide (0.02)	Genite (0.01)	Halfenprox (0.02)
HCH, alpha- (0.005)	HCH, beta- (0.01)	HCH, delta- (0.005)
HCH, epsilon- (0.005)	Lindane (gamma-HCH) (0.005)	Heptachlor (0.005)
Heptachlor epoxide, cis- (0.005)	Heptachlor epoxide, trans- (0.005)	Hexachlorobenzene (HCB) (0.005)
Ioxynil-octanoate (0.005)	Isobenzan (0.005)	Isodrin (0.005)
Isopropalin (0.01)	Methoxychlor (0.01)	Mirex (0.005)
Nitrapyrin (0.01)	Nitrofen (0.01)	Octachlorstyrene (0.01)
Oxyfluorfen (0.01)	Pendimethalin (0.01)	Pentachloranisole (0.01)
Pentachloroaniline (0.005)	Pentachlorothioanisolte (0.005)	Permethrin (0.02)
Plifenate (0.005)	Polychloroterpene (Camphechlor) (0.2)	Profluralin (0.005)
Propanil (0.02)	Quintozene (0.005)	S 421 (0.005)
Tau-Fluvalinate (0.02)	Tecnazene (0.005)	Tefluthrin (0.02)
Tetradifon (0.01)	Tetrasul (0.01)	Tralomethrin (0.02)
Triallate (0.02)	Trichloronat (0.01)	Trifluralin (0.005)

Table 2. A List of Organophosphorus Pesticides Screened in Luo Han Guo Fruit Juice Concentrate (65°Brix)

Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)
Acephate (0.02)	Amidithion (0.02)	Azamethiophos (0.04)
Azinphos-ethyl (0.05)	Azinphos-methyl (0.05)	Carbophenothion (0.02)
Bromfenvinphos (0.02)	Bromophos-methyl (0.02)	Bromophos-ethyl (0.02)
Butamifos (0.02)	Cadusaphos (0.02)	Carbophenothion (0.02)
Carbophenothion-methyl (0.02)	Chlorfenvinphos (0.02)	Chlormephos (0.02)
Chlorpyrifos (-ethyl) (0.02)	Chlorpyrifos-methyl (0.02)	Chlorthion (0.02)
Chlorthiophos (0.02)	Coumaphos (0.05)	Crotoxyphos (0.02)
Crufomate (0.02)	Cyanofenphos (0.05)	Cyanophos (0.02)
Demeton-S-methyl (0.05)	Demeton-S-methyl-sulfone	Dialifos (0.05)

	(0.05)	
Diazinon (0.02)	Dicapthon (0.01)	Dichlofenthion (0.02)
Dichlorvos (0.01)	Dicrotophos (0.02)	Dimefox (0.02)
Dimethoate (0.02)	Dimethoate/Omethoate (sum)	Dimethylvinphos (002)
Dioxabenzofos (0.02)	Dioxathion (0.02)	Disulfoton (0.02)
Disulfoton-sulfon (0.02)	Disulfoton-sulfoxide (0.04)	Ditalimfos (0.02)
Edifenphos (0.05)	EPN (0.05)	Ethion (0.01)
Ethoprophos (0.02)	Etrimfos (0.02)	Famophos (0.05)
Fenamiphos (0.02)	Fenamiphos (sum)	Fenamiphos-sulfone (0.02)
Fenamiphos-sulfoxide (0.02)	Fenchlorphos (0.02)	Fenchlorphos-oxon-sulfone (0.1)
Fenitrothion (0.01)	Fensulfothion (0.02)	Fensulfothion-oxon-sulfone (0.05)
Fensulfonthion-oxon-sulfoxide (0.02)	Fensulfothion-sulfone (0.02)	Fenthion (0.01)
Fenthion-oxon (0.02)	Fenthion-oxon-sulfone (0.05)	Fenthion-oxon-sulfoxide (0.02)
Fention-sulfone (0.05)	Fenthion-sulfoxide (0.02)	Fonofos (0.02)
Formothion (0.02)	Fosthiazate (0.02)	Fosthietan (0.02)
Heptenophos (0.02)	Iodofenphos (0.02)	Iprobenfos (0.02)
Isazophos (0.02)	Isocarbofos (0.02)	Isofenphos (0.02)
Isofenphos-methyl (0.02)	Isoxathion (0.05)	Leptophos (0.05)
Malaoxon (0.02)	Malathion (0.02)	Mecarbam (0.02)
Mephosfolan (0.02)	Merphos (0.02)	Methacriphos (0.02)
Methamidophos (0.02)	Methidathion (0.02)	Mevinphos (0.02)
Monocrotophos (0.01)	Morphothion (0.05)	Naled (0.02)
N-Desethyl-pirimiphos-methyl (0.02)	Omethoate (0.02)	Oxydemeton-methyl (0.05)
Paraoxon-ethyl (0.02)	Paraoxon-methyl (0.02)	Parathion (0.02)
Parathion-methyl (0.02)	Parathion-methyl/Paraoxon-methyl (sum)	Phenkapton (0.02)
Phenthoate (0.02)	Phorate (0.02)	Phorate (sum)
Phorate-sulfone (0.02)	Phorate-sulfoxide (0.02)	Phosalone (0.04)
Phosfolan (0.02)	Phosmet (0.05)	Phosphamidon (0.02)
Piperophos (0.02)	Pirimiphos-ethyl (0.02)	Pirimiphos-methyl (0.02)
Profenofos (0.02)	Propaphos (0.02)	Propetamphos (0.02)
Prothiofos (0.02)	Prothoate (0.02)	Pyraclofos (0.05)
Pyrazophos (0.05)	Pyridaphenthion (0.02)	Pyrimitate (0.02)
Quinalphos (0.02)	Quintiofos (0.02)	Sulfotep (0.02)
Sulprofos (0.05)	Tebupirimfos (0.02)	TEPP (0.02)
Terbufos (0.02)	Terbufos (sum)	Terbufos-sulfone (0.01)
Tetrachlorvinphos (0.02)	Thiometon (0.02)	Thionazin (0.02)
Tolclofos-methyl (0.02)	Triamiphos (0.05)	Triazophos (0.01)
Tribufos (0.04)	Trichlorfon (0.05)	Vamidothion (0.04)

2.A.3. Particle Size

Not applicable

2.B. Method of Manufacture

Luo Han Guo juice concentrates are manufactured under Current Good Manufacturing Practices (cGMP).

1. Good quality Luo Han Guo fruit is saccharified at room temperature for 15~30 days.
2. Pick out the fruit which has more than 80% yellow surface area. The fresh fruit is mechanically pressed and crushed.
3. The fruit is extracted for 60 minutes at 90℃ with deionized water three times. The extract solution is collected.
4. The extract solution is filtered and subjected to ion exchange column chromatography.
5. The eluate is concentrated to 10°,40°, 50°, or 65°Brix by use of a vacuum system.
6. Concentrated solution is sterilized by using ultra-high temperature (UHT; 121°C, 6 second).
7. The final product is tested and packed.

The ion exchange resins and adsorption polymeric resins used in the manufacturing process comply with 21 CFR 173.25. Food-grade sodium hydroxide and hydrochloric acid are used to regenerate the resin. Both are GRAS substances (21 CFR §184.1763 and 8182.1057, respectively) with use limited only by cGMP. The steps in the production of Luo Han Guo juice are shown schematically in Figure 2.

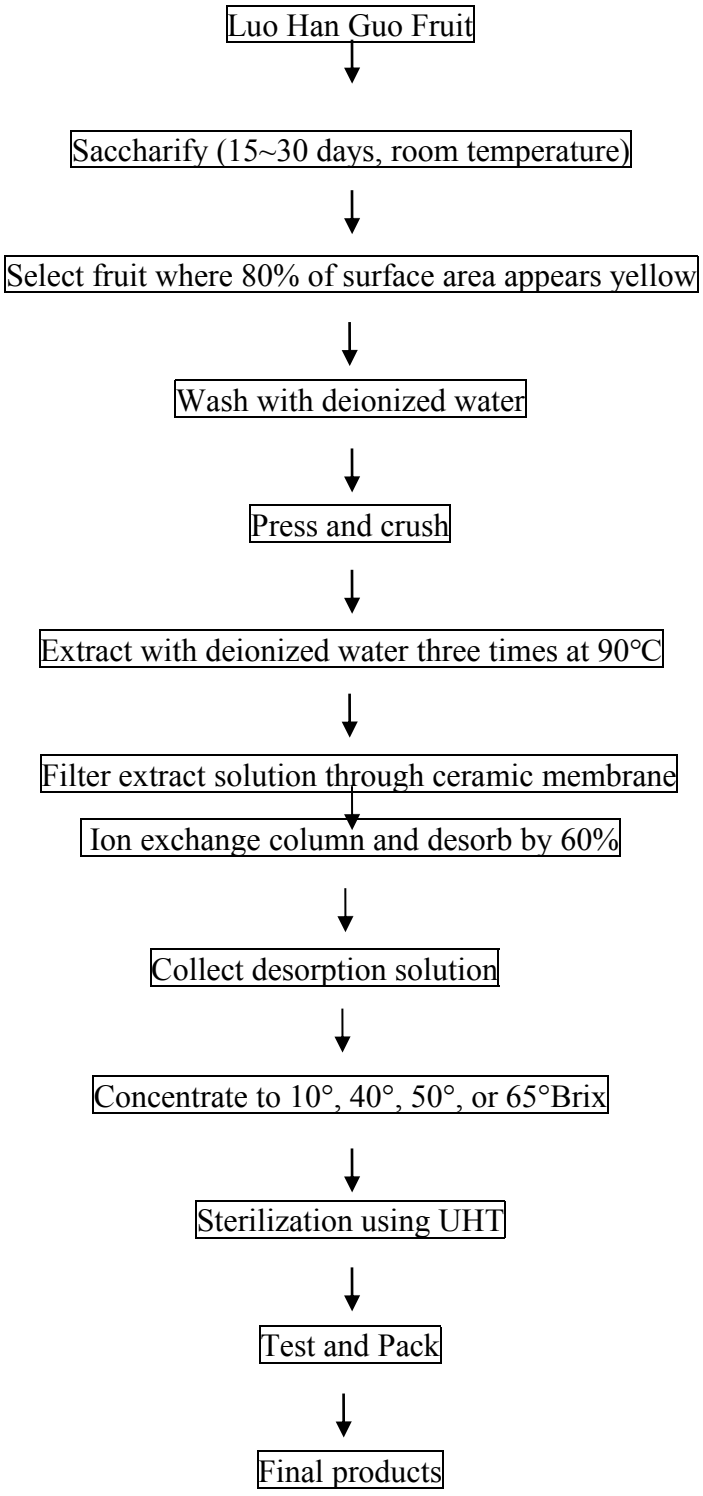

Figure 2. Manufacturing Process of Luo Han Guo Fruit Juice Concentrate

2.C. Composition and Specifications for Luo Han Guo Fruit Juice Concentrates

Luo Han Guo fruit juice concentrates having Brix levels of 10° to 65° Brix are intended for use in conventional foods as well as in infant and toddler foods. The composition and specifications of the four Brix Luo Han Guo fruit juice concentrates are shown in Tables 3 and 4, respectively.

It can be seen that mogroside V constitutes 0.6 to ≥3.9% of the juice concentrate, and most of the remaining materials are sugars, water, and protein. Other substances, including dietary fiber and ash, are each present at less than 1.0%.

Table 3. Composition of Luo Han Guo Juice Concentrates*

Component	Composition				Method of Analysis
	10°Brix	40°Brix	50°Brix	65°Brix	
Mogroside V, % (w/w)	0.63	2.51	3.20	4.11	HPLC
Soluble solids, °Brix	10.43	41.83	51.67	66.93	GB/T 12143
Protein, %	2.59	7.43	5.91	9.63	AOAC984.13
Ash, %	0.24	0.71	0.65	0.76	GB5009.4-2016
Sodium, mg/kg	88.67	159	130.33	155	ICP-MS
Potassium, mg/kg	7.45	44.45	25.21	36.27	ICP-MS
Calcium, mg/kg	8.90	22.84	28.66	27.52	ICP-MS
Glucose, %	1.51	5.29	5.35	7.48	AOAC 995.13, modified
Fructose, %	1.30	2.59	4.32	5.18	AOAC 995.13, modified
Sucrose, %	4.17	12.70	16.57	16.82	AOAC 995.13, modified
Total sugars, %	6.98	20.58	26.24	29.47	AOAC 995.13, modified
Moisture, %	89.03	57.37	48.13	33.80	GB5009.3-2016
Dietary fiber, %	0.09	0.16	< 0.13	0.50	AOAC 991.43
Heavy Metals					
Arsenic, ppm	< 0.2	< 0.2	< 0.2	< 0.2	AOAC 993.14
Lead, ppm	< 0.5	< 0.5	< 0.5	< 0.5	AOAC 993.14
Cadmium, ppm	< 0.15	< 0.15	< 0.15	< 0.15	AOAC 993.14

*Based on the analysis of 3 non-consecutive lots.

Table 4 shows the specifications of Hunan Huacheng's Luo Han Guo fruit juice concentrates. As shown in Table 4, Hunan Huacheng has established the specifications for the minimum mogroside V content as well as the maximum microbiological and heavy metal concentrations for its Luo Han Guo fruit juice concentrates. The specifications for arsenic, cadmium, and lead do not exceed 0.2, 0.15, and 0.5 ppm, respectively.

Tables 5 to 8 present the analytical values supporting the specifications of each product. The subject of this GRAS notice is Luo Han Guo (*Siraitia grosvenorii,* Swingle) fruit juice concentrates (10, 40, 50, and 65°Brix).

Table 4. Specifications for Hunan Huacheng's Luo Han Guo Fruit Juice Concentrates

Parameter	10 °Brix	40 °Brix	50 °Brix	65 °Brix	Method of Analysis
Mogroside V, %	≥ 0.6	≥ 2.4	≥ 3.1	≥ 3.9	HPLC
Soluble solids, °Brix	≥ 10	≥ 40	≥ 50	≥ 65	GB/T 12143
Moisture, %	< 90	< 60	< 50	< 35	GB5009.3-2016
Arsenic, ppm	≤ 0.2	≤ 0.2	≤ 0.2	≤ 0.2	AOAC 993.14
Lead, ppm	≤ 0.5	≤ 0.5	≤ 0.5	≤ 0.5	AOAC 993.14
Cadmium, ppm	≤ 0.15	≤ 0.15	≤ 0.15	≤ 0.15	AOAC 993.14
Aerobic plate count, cfu/g	≤ 1000	≤ 1000	≤ 1000	≤ 1000	CP 2015
Yeast, cfu/g	≤ 20	≤ 20	≤ 20	≤ 20	CP 2015
Molds, cfu/g	≤ 20	≤ 20	≤ 20	≤ 20	CP 2015
E. coli, cfu/g	ND	ND	ND	ND	CP 2015
Salmonella, cfu/25 g	ND	ND	ND	ND	CP 2015
S. aureus, cfu/g	ND	ND	ND	ND	CP 2015

ND = Not Detected; cfu = colony forming unit; CP=Chinese Pharmacopoeia.

Table 5. Analytical Values for Luo Han Guo Fruit Juice Concentrate 10°Brix

	Composition of 10°Brix			
Component	170503	170610	170801	Mean
Mogroside V, % (w/w)	0.63	0.61	0.65	0.63
Soluble solids, °Brix	10.20	10.50	10.60	10.43
Protein, %	2.45	2.56	2.77	2.59
Ash, %	0.32	0.25	0.15	0.24
Sodium, mg/kg	83	87	96	88.67
Potassium, mg/kg	9.26	8.33	4.76	7.45
Calcium, mg/kg	8.46	9.70	8.54	8.90
Glucose, %	1.53	1.67	1.32	1.51
Fructose, %	1.14	1.32	1.45	1.30
Sucrose, %	3.76	4.09	4.67	4.17
Total sugars, %	6.43	7.08	7.44	6.98
Moisture, %	89.40	88.50	89.20	89.03
Dietary fiber, %	0.06	0.12	0.10	0.09
Heavy Metals				
Arsenic, ppm	< 0.2	< 0.2	< 0.2	< 0.2
Lead, ppm	< 0.5	< 0.5	< 0.5	< 0.5
Cadmium, ppm	< 0.15	< 0.15	< 0.15	< 0.15
Microbiology				
Aerobic plate count, cfu/g	Conforms	Conforms	Conforms	Conforms
Yeast, cfu/g	Conforms	Conforms	Conforms	Conforms
Molds, cfu/g	Conforms	Conforms	Conforms	Conforms

E. coli, cfu/g	Conforms	Conforms	Conforms	Conforms
Salmonella, cfu/25 g	Conforms	Conforms	Conforms	Conforms
S. aureus, cfu/g	Conforms	Conforms	Conforms	Conforms

cfu = colony forming unit

Table 6. Analytical Values for Luo Han Guo Fruit Juice Concentrate 40°Brix

	Composition of 40°Brix			
Component	170811	170910	171001	Mean
Mogroside V, % (w/w)	2.52	2.54	2.47	2.51
Soluble solids, °Brix	41.80	42.00	41.70	41.83
Protein, %	7.43	7.54	7.33	7.43
Ash, %	0.75	0.72	0.65	0.71
Sodium, mg/kg	136	164	177	159
Potassium, mg/kg	45.52	43.52	44.32	44.45
Calcium, mg/kg	22.34	24.43	21.76	22.84
Glucose, %	4.32	5.44	6.11	5.29
Fructose, %	2.38	3.23	2.16	2.59
Sucrose, %	13.24	12.43	12.43	12.70
Total sugars, %	19.94	21.10	20.70	20.58
Moisture, %	57.90	57.80	56.40	57.37
Dietary fiber, %	0.22	0.15	0.12	0.16
Heavy Metals				
Arsenic, ppm	< 0.2	< 0.2	< 0.2	< 0.2
Lead, ppm	< 0.5	< 0.5	< 0.5	< 0.5
Cadmium, ppm	< 0.15	< 0.15	< 0.15	< 0.15
Microbiology				
Aerobic plate count, cfu/g	Conforms	Conforms	Conforms	Conforms
Yeast, cfu/g	Conforms	Conforms	Conforms	Conforms
Molds, cfu/g	Conforms	Conforms	Conforms	Conforms
E. coli, cfu/g	Conforms	Conforms	Conforms	Conforms
Salmonella, cfu/25 g	Conforms	Conforms	Conforms	Conforms
S. aureus, cfu/g	Conforms	Conforms	Conforms	Conforms

cfu = colony forming unit

Table 7. Analytical Values for Luo Han Guo Fruit Juice Concentrate 50°Brix

	Composition of 50°Brix			
Component	170814	170918	171015	Mean
Mogroside V, % (w/w)	3.25	3.12	3.22	3.20
Soluble solids, °Brix	51.30	51.60	52.10	51.67
Protein, %	6.54	5.53	5.66	5.91
Ash, %	0.75	0.64	0.57	0.65
Sodium, mg/kg	114	132	145	130.33
Potassium, mg/kg	26.87	24.99	23.76	25.21

Calcium, mg/kg	27.98	28.56	29.43	28.66
Glucose, %	4.25	5.67	6.12	5.35
Fructose, %	3.76	4.88	4.33	4.32
Sucrose, %	19.21	15.17	15.32	16.57
Total sugars, %	27.22	25.72	25.77	26.24
Moisture, %	48.30	48.80	47.30	48.13
Dietary fiber, %	0.10	0.18	<0.1	< 0.13
Heavy Metals				
Arsenic, ppm	< 0.2	< 0.2	< 0.2	< 0.2
Lead, ppm	< 0.5	< 0.5	< 0.5	< 0.5
Cadmium, ppm	< 0.15	< 0.15	< 0.15	< 0.15
Microbiology				
Aerobic plate count, cfu/g	Conforms	Conforms	Conforms	Conforms
Yeast, cfu/g	Conforms	Conforms	Conforms	Conforms
Molds, cfu/g	Conforms	Conforms	Conforms	Conforms
E. coli, cfu/g	Conforms	Conforms	Conforms	Conforms
Salmonella, cfu/25 g	Conforms	Conforms	Conforms	Conforms
S. aureus, cfu/g	Conforms	Conforms	Conforms	Conforms

cfu = colony forming unit

Table 8. Analytical Values for Luo Han Guo Fruit Juice Concentrate 65°Brix

	Composition of 65°Brix			
Component	170927	171018	171122	Mean
Mogroside V, % (w/w)	4.16	4.05	4.11	4.11
Soluble solids, °Brix	67.50	66.20	67.10	66.93
Protein, %	10.33	9.34	9.21	9.63
Ash, %	0.85	0.86	0.56	0.76
Sodium, mg/kg	167	152	146	155
Potassium, mg/kg	36.74	35.75	36.33	36.27
Calcium, mg/kg	28.28	26.54	27.73	27.52
Glucose, %	8.32	7.67	6.44	7.48
Fructose, %	5.37	5.84	4.33	5.18
Sucrose, %	22.14	16.14	12.17	16.82
Total sugars, %	35.83	29.65	22.94	29.47
Moisture, %	33.60	34.20	33.60	33.80
Dietary fiber, %	0.67	0.52	0.32	0.50
Heavy Metals				
Arsenic, ppm	< 0.2	< 0.2	< 0.2	< 0.2
Lead, ppm	< 0.5	< 0.5	< 0.5	< 0.5
Cadmium, ppm	< 0.15	< 0.15	< 0.15	< 0.15
Microbiology				
Aerobic plate count, cfu/g	Conforms	Conforms	Conforms	Conforms
Yeasts, cfu/g	Conforms	Conforms	Conforms	Conforms
Molds, cfu/g	Conforms	Conforms	Conforms	Conforms

E. coli, cfu/g	Conforms	Conforms	Conforms	Conforms
Salmonella, cfu/25 g	Conforms	Conforms	Conforms	Conforms
S. aureus, cfu/g	Conforms	Conforms	Conforms	Conforms

cfu = colony forming unit

2.D. Intended Technical Effects

Siraitia grosvenorii Swingle (Luo Han Guo) fruit juice concentrate can be used as a component of sweetener blends that can be added to food or used as a table-top sweetener. The intended use will be as a high intensity sweetener as defined in 21 CFR 170.3(o)(19). The intended use levels will vary by food category, but the actual levels are self-limiting due to organoleptic characteristics.

PART 3. DIETARY EXPOSURE

3.A. Estimated Dietary Intakes (EDIs) of Mogroside V Under the Intended Use

3.A.1. Applications to Baby Foods with Fruit and Infant Cereals

As noted in GRN 627, the intended use of Luo Han Guo fruit juice concentrates in infant and toddler foods (excluding infant formula and fruit juice) is at a maximum use level of 1% and, more frequently, 0.25 to 0.5%.

The mean and 90th percentile intakes of baby food with fruit and infant cereal are as shown in Table 9. The National Health and Nutrition Examination Survey (NHANES) 2011-2014 dataset was used for calculating EDIs of baby food with fruit and infant cereal.

Table 9. Consumption of Baby Food with Fruit and Infant Cereal*

Age (months)	Median weight (kg)	g/day		g/kg bw/day	
		Mean	90th percentile	Mean	90th percentile
4-7.9	8.0	79.8	189.9	10.0	23.7
8-11.9	9.42	123.9	235.7	13.2	25.0
12.1-17.9	10.76	81.4	216.6	7.6	20.1
18.0-24	12.24	162.2	267.1	13.2	21.8

*Based on the National Health and Nutrition Examination Survey (NHANES) 2011-2014.

Based on the food consumption levels, maximum use level and mogroside V content of each product (10, 40, 50, and 65°Brix products contain 0.6, 2.4, 3.1, and 3.9% mogroside V, respectively), EDIs of mogroside V under the intended use were calculated (Tables 10 and 11). In GRN 627, the maximum self-limiting use level was recognized as 1.0% in foods, although more likely the use levels would be 0.25-0.5%. Thus, in GRN 627, EDI calculations were based on the assumption that juice concentrate will be used at 0.25% or 0.5% in baby food with fruit and infant cereal. Similarly, we calculated EDIs based on the assumption that the use level would be 0.5% in baby food with fruit and infant cereal. For example, the 90th percentile intake of baby food with fruit and infant cereal is estimated to be 189.9 g/day in 4.0 -7.9 month old infants. Assuming the use level of 0.5% and mogroside V content (65°Brix) of 3.9%, mogroside V intake of 4 - 7.9 month old infants would be 37 mg/person/day (189.9 g x 0.005 x 0.039 = 0.037 g) when 65°Brix ingredient is added at a 0.5% level. When 10°Brix ingredient is added at 0.5%, EDI of mogroside V would be 5.7 mg/person/day (189.9 g x 0.005 x 0.006 = 0.0057 g or 5.7 mg/person/day).

As shown in Tables 10 to 11, the highest intake would occur in 18.1 - 24 month old infants with 52.1 mg/person/day when 65°Brix is used. On a body weight basis, 8 - 12 month old babies would have the highest EDI at 4.88 mg/kg bw/day. This is comparable to the 95th percentile EDI of 2.4 mg/kg bw/day for either baby food with fruit or infant cereal reported in GRN 627 (or presumably 4.8 mg/kg bw/day for use in both food categories; Please note: GRN 627 did not report 95th percentile EDIs of mogroside V resulting from the combined use of both baby food with fruit and infant cereal). The safe intake levels of mogroside V are estimated at 17-21 mg/kg bw/day (details are presented in Part 6.B.3).

It is concluded that the use of Luo Han Guo juice concentrate in baby food with fruit and infant cereal would result in 90th percentile of EDI which is within safe intake levels. These estimates are highly amplified since it is not likely that Luo Han Guo fruit juice concentrates would be used at 0.5% levels in all baby foods with fruit and infant cereals.

Table 10. Maximum EDIs of Mogroside V When Used in Baby Food with Fruit and Infant Cereal, mg/person/day

	Mean EDI				90th Percentile EDI			
Age (months)	10°Brix	40°Brix	50°Brix	65°Brix	10°Brix	40°Brix	50°Brix	65°Brix
4-7.9	2.4	9.5	12.3	15.6	5.7	12.8	29.4	37.0
8-12	3.7	14.8	19.2	24.1	7.0	28.3	36.6	46.0
12.1-18	3.2	9.7	12.6	15.8	6.5	26.0	32.8	42.2
18.1-24	3.6	19.4	25.2	31.6	8.0	32.0	41.4	52.1

Assuming baby food with fruit and infant cereal would contain 0.5% of one of Luo Han Guo fruit juice concentrates. Mogroside V contents in 10, 40, 50, and 65°Brix are 0.6, 2.4, 3.1, and 3.9%, respectively.

Table 11. EDIs of Mogroside V When Used in Baby Food with Fruit and Infant Cereal, mg/kg bw/day

	Mean EDI				90th Percentile EDI			
Age (months)	10°Brix	40°Brix	50°Brix	65°Brix	10°Brix	40°Brix	50°Brix	65°Brix
4-7.9	0.30	1.2	1.54	1.94	0.71	2.85	3.68	4.13
8-12	0.39	1.86	2.04	2.06	0.88	3.00	3.78	4.88
12.1-18	0.30	0.91	1.17	1.47	0.60	2.41	3.05	3.92
18.1-24	0.30	1.59	2.06	2.58	0.65	2.62	3.38	4.25

Assuming baby food with fruit and infant cereal would contain 0.5% of one of Luo Han Guo fruit juice concentrates. Mogroside V contents in 10, 40, 50, and 65°Brix are 0.6, 2.4, 3.1, and 3.9%, respectively.

3.A.2. Applications as a General Sweetener

Luo Han Guo fruit juice concentrate can be used as a component of sweetener blends that can be added to foods or used as table-top sweetener.

EDIs of Mogroside V

For children and adults, the exposure to mogroside V is unchanged from that calculated in GRN 556, an exposure that was determined to be GRAS. In GRN 556 (filed by Hunan Huachecng), the EDIs of mogroside V in high consumers were estimated to be approximately 1.05 mg/kg bw/day for healthy population, 1.40 mg/kg bw/day for diabetic adults, 1.55 mg/kg bw/day for healthy children, and 1.42 mg/kg bw/day for diabetic children, when powdered extracts of Luo Han Guo fruit with 25% mogroside V or less (i.e., MV 12.5, MV 20, or MV 25) were assumed to be used as sugar replacements. In other words, EDIs of mogroside V were the same regardless of mogroside V content, when Luo Han Guo fruit extracts contained less than 25% mogroside V. These EDIs are expected to be unchanged when fruit juice concentrates are used as sugar replacements (Table 12). To calculate EDI of mogroside V/person/day under the intended use, we multiplied the mg/kg bw/day value by body weight value.

Table 12. EDIs of Mogroside V for High Consumers When Used as a General Sweetener

	mg/kg bw/day				mg/person/day			
Population	10 °Brix	40 °Brix	50 °Brix	65 °Brix	10 °Brix	40 °Brix	50 °Brix	65 °Brix
Healthy adults	1.05	1.05	1.05	1.05	63.0	63.0	63.0	63.0
Diabetic adults	1.40	1.40	1.40	1.40	84.0	84.0	84.0	84.0
Healthy children	1.55	1.55	1.55	1.55	47.0	47.0	47.0	47.0
Diabetic children	1.42	1.42	1.42	1.42	43.0	43.0	43.0	43.0

Average body weight of adults: 60 kg; Average body weight of children aged 4-12: 30.3 kg.

EDIs of Luo Han Guo Fruit Juice Concentrates When Used as a General Sweetener

We calculated the EDI of fruit juice concentrate by dividing the EDI of mogroside V by the mogroside V content in each Brix preparation. For example, high consumers of healthy adults would have EDI of mogroside V at 1.05 mg/kg bw/day and the mogroside V concentration of 10 °Brix is 0.6%. The EDI of 10 °Brix fruit juice concentrate was calculated to be 175 mg/kg bw/day (or 1.05/0.006 mg/kg bw/day).

These are unrealistically optimistic estimates due to the following facts: 1) the addition level of Luo Han Guo fruit juice concentrate is limited only by cGMP, and 2) most likely uses would occur in a limited market.

Table 13. EDIs of Luo Han Guo Fruit Juice Concentrates for High Consumers When Used as a General Sweetener

	EDI, mg/kg bw/day				EDI, g/person/day			
Population	10 °Brix	40 °Brix	50 °Brix	65 °Brix	10 °Brix	40 °Brix	50 °Brix	65 °Brix
Healthy adults	175.0	43.8	33.9	26.9	10.5	2.6	2.0	1.6
Diabetic adults	233.3	58.4	45.2	35.9	14.0	3.4	2.7	2.2
Healthy children	258.3	64.6	50.0	39.7	7.8	2.0	1.5	1.2
Diabetic children	236.6	59.2	50.0	36.4	7.2	1.8	1.5	1.1

Mogroside V contents in 10, 40, 50, and 65°Brix are 0.6, 2.4, 3.1, and 3.9%, respectively.

3.B. EDIs of Notified Substance from Diet

Not applicable. Mogroside V or Luo Han Guo juice is not present in American's typical diet.

3.C. EDIs of Other Nutrients Under the Intended Use

As described in GRN 627 and the preceding section, Luo Han Guo fruit juice concentrate differs from the powdered extract that was the subject of the GRN 556 by retaining the sugars and water that were removed in producing the powdered extract. Four products (10, 40, 50, and 65°Brix products) contain other nutrients such as total sugars (sucrose, fructose, and glucose) as well as sodium. Total sugar content in 10, 40, 50, and 65°Brix are 7.0, 20.6, 26.2, and 29.5%, respectively, and the corresponding sodium contents are 89, 159, 130, and 155 mg/kg, respectively. Based on the total sugar and sodium contents and EDIs of each juice concentrate, EDIs of total sugars and sodium under the intended use (as a table-top sweetener and general purpose non-nutritive sweetener) were calculated. For example, since high consumers would consume 1.6 g of 65°Brix Luo Han Guo fruit juice concentrate per day and 65°Brix contains 29.5% total sugars, EDIs of total sugars from 65°Brix Luo Han Guo fruit juice concentrate may be estimated as 1.6 g x 0.295 (=0.47 g total sugars/day). As shown in Table 14, daily intakes of total sugars under the intended use are estimated to be less than 1.0 g/person/day and those for sodium are expected to be less than 1.3 ug/person/day in high consumers. These EDIs are negligible compared to Americans' total intakes of these nutrients from the diet. Average Americans' daily intakes were calculated to be 250 g for total sugars and over 3,000 mg for sodium.

Glucose is subjected to 21CFR 184.1277 and 168.120. Fructose (in the form of high fructose corn syrup) and sucrose are subjected to 21CFR 184.1866 and 21CFR 184.1854, respectively.

Table 14. EDIs of Total Sugars and Sodium for High Consumers Under the Intended Use*

	Total sugar intake, g/person/day				Sodium intake, ug/person/day			
Population	10 °Brix	40 °Brix	50 °Brix	65 °Brix	10 °Brix	40 °Brix	50 °Brix	65 °Brix
Healthy adults	0.73	0.54	0.52	0.47	0.93	0.41	0.26	0.25
Diabetic adults	0.98	0.70	0.70	0.65	1.25	0.54	0.35	0.34
Healthy children	0.55	0.41	0.39	0.35	0.69	0.32	0.20	0.19
Diabetic children	0.50	0.37	0.39	0.32	0.64	0.29	0.20	0.17

*Basis of calculations: Other nutrient contents in 10, 40, 50, and 65°Brix: total sugar - 7.0, 20.6, 26.2, and 29.5%, respectively; sodium - 0.089, 0.159, 0.130, and 0.155 ug/kg, respectively. Assumptions for average body weights: adults - 60 kg; children aged 4-12 years - 30.3 kg.

Summary of Exposure Estimates

When Luo Han Guo juice concentrate is used as a table-top sweetener and as a non-nutritive sweetener in foods, the EDI of mogroside V is unchanged from that calculated for 12.5 – 25% mogroside V, an exposure that was determined to be GRAS (details are found on stamped pages 32 to 33 of GRN 556). The EDIs of mogroside V in high consumers were estimated to be

1.05 mg/kg bw/day for healthy population, 1.40 mg/kg bw/day for diabetic adults, 1.55 mg/kg bw/day for healthy children, and 1.42 mg/kg bw/day for diabetic children when Luo Han Guo fruit juice concentrates with 0.6-3.9% mogroside V were assumed to be used as sugar replacements.

The intended use of Luo Han Guo fruit juice concentrates in infant and toddler foods (excluding infant formula) is primarily in baby food with fruit and infant cereal. The highest intake of mogroside V would occur in 18.1 - 24 month old infants (52.1 mg/person/day). On a body weight basis, 8 - 12 month old babies would have the highest EDI of mogroside V (4.88 mg/kg bw/day). This is comparable to the 95th percentile EDI of 2.4 mg/kg bw/day for either baby food with fruit or infant cereal reported in GRN 627 (or approximately 4.8 mg/kg bw/day for the combined use of both foods). The safe intake levels of mogroside V is estimated at 17-21 mg/kg bw/day (details are presented in Part 6.B.3). It is concluded that the use of Luo Han Guo fruit juice concentrate in infant and toddler foods (primarily baby food with fruit and infant cereal) and in general foods would result in 90th percentile EDIs which are within safe intake levels.

The additional exposure of the juice concentrates is due to total sugars (sucrose, glucose, and fructose), sodium, and water. The EDIs of total sugars and sodium under the intended use are negligible; thus, there is no safety issue due to other nutrients present in Luo Han Guo fruit juice concentrates at all Brix levels.

PART 4. SELF LIMITING LEVELS OF USE

The quantity of consumption of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate is self-limiting due to the off-taste that occurs with increasing quantity, similar to any of the natural high intensity sweeteners (such as stevia products) and would be limited in consumer acceptance of products when added as a sugar substitute. The level of addition of Luo Han Guo fruit juice concentrate is limited only by cGMP but, in practice, addition is limited to about 1% and, more frequently, 0.25 to 0.5%, due to adverse organoleptic characteristics at higher levels. The amounts of purified *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate to be added to food will not exceed the amounts reasonably required to accomplish its intended technical effect in foods as required by FDA regulation (21 CFR 182.1[b][1]).

PART 5. HISTORY OF CONSUMPTION

The statutory basis for the conclusion of GRAS status of *S. grosvenorii* (Luo Han Guo) fruit juice concentrates in this document is not based on common use in foods before 1958. The GRAS determination is based on scientific procedures. However, it should be noted that *S. grosvenori* is endemic to China, and principally grows in the Guangxi province, where it has been cultivated for more than 200 years. *S. grosvenorii* fruit (without any extraction and/or purification process) has been safely consumed for centuries in China as a natural sweetener and as a traditional medicine (Li et al., 2014).

PART 6. BASIS FOR GRAS DETERMINATION

6.A. Current Regulatory Status

The FDA has issued 'no question' letters on a GRAS notification related to food use of Luo Han Guo fruit juice concentrate (GRN 627; FDA, 2016). In addition, the FDA has issued 'no question' letters on GRAS notifications related to food uses of Luo Han Guo fruit extract powders (GRN 301, FDA, 2010a; GRN 359, FDA, 2011a; GRN 522, FDA 2014; GRN 556, FDA 2015a; GRN 706, FDA, 2017). The GRAS notices are summarized in Table 15.

Table 15. Summary of GRAS Notices That Passed FDA Review

GRN (year of closure)	Mogroside V content, %	Maximum EDI of mogroside V in high consumers, mg/kg bw/day	Intended use	Company
LHG fruit juice concentrates, liquid				
Present notice	0.6, 2.4, 3.1, or 3.9	1.55 for children and adults as a table-top and as a sweetener in foods; 4.88 for infants and toddlers consuming both baby food with fruit and infant cereal	As a table-top sweetener and as a general purpose sweetener in foods, baby foods with fruit and infant cereals, excluding infant formula, meat, and poultry products	Hunan Huacheng, China
627 (2016)	3.5	4.80 for the combined use of baby foods with fruit and infant cereals (or 2.40 for each category)	As a sweetener and flavor enhancer in foods, baby foods with fruit and infant cereals, excluding infant formula, meat, and poultry products	Guilin GFS Monk Fruit Corporation, China
Dried powder of LHG fruit extracts				
301 (2010)	30	2.97	As a sweetener and flavor enhancer in foods, excluding infant formula, meat, and poultry products	BioVittoria, New Zealand
359 (2011)	25, 45, or 55	2.18	As a sweetener and flavor enhancer in foods, excluding infant formula, meat, and poultry products	Guilin Layn Natural Ingredients Corp., China
522 (2014)	30, 50, or 60	2.12	As a table-top sweetener and as a sweetener in foods, excluding infant formula, meat, and poultry products	GLG Life Tech Corp., Canada
556 (2015a)	12.5, 20, 25, 30, 40, 50, 55, or 90	2.17	As a table-top sweetener and general purpose non-nutritive sweetener, and as a flavor modifier for use in foods other	Hunan Huacheng, China

			than infant formula, meat, and poultry products	
706 (2017)	25, 30, 50, 55, 60, 65, or 95	2.23	As a table-top sweetener and general purpose non-nutritive sweetener in foods, excluding infant formula, meat, and poultry products	Hunan Nutramax, Inc.

EDI=Estimated Dietary Intake; LHG = Luo Han Guo. Max. EDI for mogroside V = 90th percentile intakes of mogroside V.

6.B. Review of Safety Data

As noted above, the FDA has issued 'no question' letters on six GRAS notices related to food uses of Luo Han Guo fruit juice concentrates or fruit extracts. As the *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrates in this GRAS determination are similar in specifications compared to another *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate in the FDA GRAS notices, it is recognized that the information and data in the other GRAS notices are pertinent to the safety of the *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate in this GRAS determination. Therefore, this notice incorporates, by reference, the safety and metabolism studies discussed in the previous GRAS notices (GRN 301 - pages 22-42; GRN 359 - pages 24-30; GRN 522 - pages 19-28; GRN 556 - stamped pages 21-42; GRN 627 - pages 8-14; GRN 706 - pages 31-36) and will not discuss previously reviewed references in detail.

In addition, mutagenicity and acute toxicity studies of Hunan Huacheng's Luo Han Guo fruit juice concentrates (10 and 65°Brix) are included in this notice.

The subject of the present GRAS assessment is *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract (powder form). Our review covers the literature published up to May 12, 2018.

6.B.1. Metabolism

Since the FDA's last review in 2017 (GRN 706 - pages 31-32; GRN 556 - stamped pages 36-37), one new study (Zhou et al., 2018) has been published. Mogroside V's metabolism has been previously reviewed by the FDA (GRN 627, FDA 2016; GRN 556, FDA 2015a; GRN 522, FDA 2014). Mogroside molecules are thought to be relatively inert to degradation during digestion due to their inherent stability with covalent bonds between the triterpene framework and the carbohydrate residues. Thus, the majority of ingested Luo Han Guo is thought to be excreted in the feces. The following summarizes in brief the studies assessing the absorption, distribution, metabolism, or excretion of mogroside V.

Murata et al. (2010) studied the digestion and absorption of mogroside V in 10-week-old Wistar rats orally administered 1 mL of *Siraitia grosvenorii* (Swingle) glycoside powder (containing 72% mogroside V, 117 mg/ml) in solution. The distributions of mogroside V and its metabolites were then analyzed in the small intestine, portal blood, and whole blood. Findings indicated mogroside V was mostly degraded by digestive enzymes and intestinal microflora, with 61% of the administered mogroside V being excreted in the feces as mogrol (aglycone) and

its mono- and diglucosides. None of the *Siraitia grosvenorii* triterpenoids were found excreted in the urine. Most of the orally ingested mogroside V was excreted without absorption as *Siraitia grosvenorii* triterpenoids were not detected in whole blood, and only trace amounts of mogrol and its monoglucoside were found in the portal blood as sulfates and/or glucuronide conjugates. Murata et al. (2010) concluded that "the absorbed amount of [mogroside V] and its metabolites was extremely low" and that "most of the orally ingested mogroside V is excreted without absorption."

Xu et al. (2015) confirmed the previous finding of Murata et al. (2010) that most mogroside metabolites are excreted in the feces. The study reported that mogroside V was mainly excreted in urine, whereas its metabolites were mainly excreted in feces.

Zhou et al. (2018) compared the *in vivo* metabolite profiling of mogroside V in healthy and type 2 diabetic (T2D) model rats (male Sprague–Dawley; SPF). In this paper, the T2D model group was induced with low doses of streptozotocin and high fat diet. Each rat was given a dose of 100 mg/kg of mogroside V through oral administration. Before administration, blank blood, urine, and feces samples were collected. Blood samples were collected from the hepaticportal vein in heparinized tube at 0.5 h, 1 h, 3 h, and 6 h after oral administration of mogroside V. The urine and feces samples were collected at 0–12 h and 12–24 h after a single oral administration of mogroside V. A total of 28 metabolites, most of which were not measured in the study by Murata et al. (2010), were identified. They were formed by a series of metabolic reactions including deglycosylation, dehydrogenation, isomerization + deoxidation, deglycosylation + deoxidation, deglycosylation + oxidation, deglycosylation + dehydrogenation, deglycosylation + oxidation + dehydrogenation, and isomerization. Metabolites include mogroside V-2H, 2 types of V isomers, IVA, IVE, III, IIIE, III A1, III A2, and others. A total of 23 metabolites were observed in healthy rats while 26 metabolites were detected in model rats. The results indicate that the metabolite classes of healthy and type 2 diabetic rats were nearly the same although 2 metabolites (mogrol and 11-O-mogrol) were detected in healthy rats only and 5 metabolites (mogroside III, mogroside IIIE, mogroside I isomer+4O4H, mogroside II-2H, and mogroside III-O) were detected in diabetic rats only. Peak areas of metabolites in T2D rat plasma samples were much larger than those in healthy sample, while in T2D rat urine samples they were remarkably smaller as compared to healthy sample.

6.B.2. Mutagenicity Studies

Since the FDA's last review in 2017 (GRN 706 - pages 32-33; GRN 556 - stamped pages 36-37), no new mutagenicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices.

In addition, the data from a mutagenicity study of Hunan Huacheng's Luo Han Guo Fruit Juice Concentrates (10 and 65°Brix) are included in this notice.

<u>A Study First Reviewed in This GRAS Notice</u>

Gao (2017) evaluated the mutagenic potential of Luo Han Guo juice concentrates (10 and 65 °Brix) in 5 strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535) (Table 16). 4-Nitro-o-phenylenediamine (NPD), daunomycin (DAM), sodium azide (NaN_3), and methyl methanesulfonate (MMS) were used as positive controls in the absence of S9 mix. 2-

aminofluorene (2-AF), 1,8-dihydroxyanthraquinone (1,8-DT), and 2-aminoanthracene (2-AA) were used as positive controls in the presence of S9 mix. The test substance was considered mutagenic if the number of revertant colonies in the test dose levels was more than twofold of that in the control, or if the number of revertant colonies increased in a dose-dependent manner compared to control in at least one strain with or without the metabolic activation. The validity of the study was confirmed by more than twofold increases in the number of revertant colonies in positive control plates compared to the control. Luo Han Guo fruit juice concentrates (10 and 65 °Brix; doses of 5,000, 2,500, and 1,250 ug/plate, respectively) did not increase the number of revertant colonies in any tester strains in the absence or presence of metabolic activation by S9 mix. The data indicated that 10 and 65 °Brix were non-mutagenic under the conditions used in the test.

Unpublished status of this study does not impact the GRAS determination even if experts do not have access to the data from this study since this study confirmed the previous findings that Luo Han Guo fruit products were not mutagenic.

A Study Reviewed in Previous GRAS Notices

In the previous GRAS notices to the FDA, the safety of *Siraitia grosvenorii* Swingle (Luo Han Guo), specifically mogroside V, has been established in mutagenicity and genotoxicity studies. As described in GRN 359, an Ames test (Ames et al., 1975) conducted at Huntingdon Life Sciences (2009a; HLS Study No. HUD0D72) found no mutagenicity of Luo Han Guo fruit extract (30% mogroside V) when *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 as well as in *Escherichia coli* strain WP2*uvr*A were used at a maximum of 5,000 µg of mogroside V per plate with and without S9 activation (Table 16).

Table 16. Studies Showing No Mutagenicity of Luo Han Guo Fruit Juice/ Extract Products

Test concentrations	Test system	Substance	Reference
Studies First Reviewed in This GRAS Notice: Unpublished Studies of Hunan Huacheng's Luo Han Guo Fruit Juice Concentrate (10 and 65°Brix)			
5,000, 2,500, and 1,250 ug/plate	*S. typhimurium* TA97, TA98, TA100, TA102, and TA1535, w/ and w/o S9 activation	Luo Han Guo fruit juice concentrate (10 and 65°Brix)	Gao, 2017a
Studies of Luo Han Guo Fruit Extracts That Were Reviewed in GRN 627 and 556			
Up to 5,000 ug/plate	*S. typhimurium* TA 98, TA 100, TA 1535, TA 1537, and *E. coli* WP2 *uvrA;* w/ and w/o S9 activation	LHG fruit extract powder (30% mogroside V)	Huntington Life Sci., 2009a

6.B.3. Animal Toxicity Studies

Since the FDA's last completed review of 2017 (GRN 706 - pages 33-34; GRN 627 - pages 8-12; GRN 556 - stamped pages 37-39; GRN 522 - pages 19-28; GRN 359 - pages 24-30;

GRN 301 - stamped pages 52-72 or submitter's pages 22-42), no new animal toxicity studies have been published. However, the data from an unpublished, acute toxicity study of Hunan Huacheng's Luo Han Guo fruit juice concentrate (65°Brix) are available (Gao, 2017).

Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices. The notified substance in this notice is *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate at varying concentrations of mogroside V (0.6 to 3.9%); thus, it also includes safety studies of mogroside V as the basis for discussing the safety of Luo Han Guo fruit juice concentrate. Results of animal toxicity studies are summarized in Table 17 (Gao, 2017; Hirose, 1999; Huntingdon Life Science, 2009b; Jin et al., 2007; Lee, 1975; Makapugay et al., 1985; Marone et al., 2008; Qin et al., 2006).

A Study First Reviewed in This GRAS Notice

Acute Toxicity Study of Hunan Huacheng's Luo Han Guo Fruit Juice Concentrate

The acute oral toxicity of Hunan Huacheng's Luo Han Guo fruit juice concentrate (10 and 65°Brix) was studied in 6-week old Sprague-Dawley (SD) rats (n=5 males and females/test substance) (Gao, 2017). Each test substance was administered by oral gavage at a single dose of 0, 15, or 25 g/kg bw. Animals were observed for 14 days to monitor changes in body weight, clinical signs, and food and water consumption. At the end of the study, animals were sacrificed, and major organs were macroscopically and microscopically examined. No animal died during the 14-day observation period, and no abnormal clinical signs were observed at any dose level. No significant differences in mean body weight, food and water intake, and organ weights were found among the groups. No treatment-related abnormalities were observed in macroscopic or microscopic examinations. The lethal doses (LD_{50}) of Luo Han Guo fruit juice concentrates (10 and 65°Brix) were well above 25 g/kg bw on an as-is basis or over 16.2 g/kg bw on a dry weight basis (65°Brix), the highest dose tested. A compound that has a LD_{50} value over 5 g/kg bw in rodents is classified as 'practically nontoxic' and a compound with a LD_{50} value over 15 g/kg bw as 'relatively harmless' (Altug, 2003). This study confirmed the previous findings that Luo Han Guo fruit juice concentrate belongs to the group with the lowest toxicity rating.

Unpublished status of this study does not impact the GRAS determination of Luo Han Guo fruit juice concentrate even if experts do not have access to the data from this study since this study confirmed the previous findings reported in Previous GRAS notices.

Animal Toxicity Studies Reviewed in Previous GRAS Notices

Table 17 summarizes acute toxicity studies (Lee, 1975; Makapugay et al., 1985), subacute toxicity studies (Marone et al., 2008; Qin et al., 2006), and subchronic studies (Hirose, 1999; Huntingdon Life Science, 2009b; Jin et al., 2007; Qin et al., 2006) of Luo Han Guo fruit extracts. As shown in Table 17, studies found that the LD_{50} for a freeze dried extract of *S. grosvenorii* fruit was over 10 g/kg bw in mice (Lee, 1975). Subchronic studies reported that NOAELs for dried powder of Luo Han Guo fruit extract (55% mogroside V) were 3,120 mg/kg bw/day and 3,750 mg/kg bw/day in male and female rats, respectively, and that those of mogroside V were 1,717 and 2,062 mg/kg bw/day in male and female rats, respectively (Huntingdon Life Science, 2009b). After applying for a safety margin of 100, safe intake levels are estimated to be 17-21 mg mogroside V/kg bw/day.

Table 17. Summary of Animal Toxicity Studies of Luo Han Guo Fruit Juice/Extract Products

Species	Dose	Duration	NOAEL	Reference
A Study First Reviewed in This GRAS Notice				
Acute Toxicity Study of Hunan Huacheng's Luo Han Guo Fruit Juice Concentrate (10° and 65°Brix)				
Rat	LHG fruit juice concentrate (0.6 or 3.9% mogroside V; 10 and 65°Brix), up to 25 g/kg bw	Single dose	LD_{50} ≥25 g/kg bw (as-is basis); corresponding to ≥16.2 g/kg bw (65°Brix) on a dry wt basis	Gao, 2017
Studies of Luo Han Guo Fruit Extracts That Were Reviewed in Previous GRAS Notices				
Acute Toxicity				
Mice	LHG fruit extract powder (purity, not specified), up to 2 g/kg bw mogroside V	Single dose	LD_{50} ≥2 g/kg bw mogroside V	Makapu-gay et al., 1985
Mice	LHG fruit extract powder (purity, not specified), up to 10 g/kg bw	Single dose	LD_{50} ≥10 g/kg bw Luo Han Guo fruit extract powder (details of the study are not available)	Lee, 1975
Subacute Toxicity				
6 Dogs; 3M+3F	LHG fruit extract powder (30% mogroside V) at 0 or 3,000 mg/kg/day	28 days	Luo Han Guo fruit extract powder - 3,000 mg/kg/day; or Mogroside V - 900 mg/kg bw/day, the highest level tested	Qin et al., 2006
104 Sprague -Dawley rats	LHG fruit extract powder (30% mogroside V) at 0, 1, 3, or 10% of diet	4 weeks	Luo Han Guo fruit extract powder- M: 7,070 mg/kg/day F: 7,480 mg/kg/day; Mogroside V - M: 2,310 mg/kg bw/day and F: 2,244 mg/kg bw/day, the highest level tested	Marone et al., 2008
Subchronic toxicity				
80 young adult Wistar Hanno-ver rats	LHG fruit extract powder (purity, not specified) at 0, 0.04, 0.2, 1, or 5% of diet	13 weeks	Luo Han Guo fruit extract- M: 2,520 mg/kg bw/day F: 3,200 mg/kg bw/day	Jin et al., 2007
12 dogs	LHG fruit extract powder (30% mogroside V) at 0 or 3,000 mg/kg/day	28 or 90 days	Luo Han Guo fruit extract powder - 3,000 mg/kg/day; or Mogroside V - 900 mg/kg bw/day, the highest level tested	Qin et al., 2006
100 rats	LHG fruit extract powder (30% mogroside V) at	90 days	2.0% Luo Han Guo fruit extract in water	Hirose, 1999

	conc. of 0, 0.25, 0.5, 1.0, or 2.0% in water			
160 rats	LHG fruit extract powder (MV 55% mogroside V), 0, 1.25, 2.5, or 5%	90 days	Luo Han Guo fruit extract- M: 3,120 mg/kg bw/day, F: 3,750 mg/kg bw/day; Mogroside V- M: 1,717 mg/kg bw/day, F: 2,062 mg/kg bw/day	Hunting-don Life Science, 2009b

Expanded from GRN 556 - stamped page 40; M=male; F=female; bw=body weight.

Conclusions of Animal Toxicity Studies

Based on these studies, the NOAELs of 1,717 mg/kg/day for male rats and 2,062 mg/kg/day for female rats were chosen for mogroside V in rats. The lethal dose (LD_{50}) of Luo Han Guo fruit juice concentrate was far above 25 g/kg bw (on an as-is basis), the highest dose tested. Luo Han Guo fruit juice concentrates and mogrosides belong to the group with the lowest toxicity rating.

6.B.4. Animal Efficacy Studies

Since the FDA's last completed review in 2017 (GRN 706 – page 35; GRN 627 - pages 13-14; GRN 556 -stamped page 41), no new animal efficacy studies have been published.

6.B.5. Human Clinical Studies

Since the FDA's last completed review in 2017 (GRN 706 - pages 35-36; GRN 627 -page 13; GRN 556 - stamped page 41), one human clinical studies have been published (Tey et al., 2017a). However, this new study (Tey et al., 2017a) reports the same content previously reported (Tey et al., 2017b) and, thus, it may not be considered as a new study. This GRAS notice briefly summarizes studies already reviewed in previous GRAS notices (Tey et al., 2017b; Xu et al., 2005a and 2005b) (Table 18, expanded from GRN 556-stamped pages 41-42). Our review covers the literature published up to January 2018.

As shown in Table 18, studies reported that a single dose (200 mg/kg bw) of Luo Han Guo fruit concentrate containing up to 30% mogroside V had no adverse effects on blood glucose concentration and five liver enzymes such as alkaline phosphatase, gamma-glutamyl transpeptidase, alanine aminotransferase, aspartate aminotransferase, and lactate dehydrogenase in healthy adults (Xu et al., 2005a and 2005b). In addition, a beverage providing sweetness corresponding to 65 g of sucrose had minimal influence on total daily energy intake and postprandial glucose and insulin concentrations compared to a sucrose-sweetened beverage (Tey et al., 2017a, 2017b). No studies reported adverse effects of Luo Han Guo fruit juice products.

Table 18. Summary of Human Studies of Luo Han Guo Fruit Juice Products

Subjects	Daily dose	Duration	Measurement	Reference
30 healthy men	Beverage providing sweetness corresponding to 65 g	Beverage as a preload in mid-morning	Energy intake, and Area under the curve for glucose and insulin	Tey et al., 2017a

	sucrose	and ad libitum lunch		
Studies included in previous GRAS notices				
30 healthy men	Beverage providing sweetness corresponding to 65 g sucrose	Beverage as a preload in mid-morning and ad libitum lunch	Energy intake, and Area Under the Curve for glucose and insulin	Tey et al., 2017b
5 healthy men and 5 healthy women aged 19-25 years	One dose of 200 mg/kg bw of Luo Han Guo fruit extract concentrate (30% mogroside V) tested over 180 min	Single dose, crossover design	No significant effects on fasting glucose concentrations observed up to 3 h after each dose	Xu et al., 2005a
Six healthy males aged 19-25 years	One dose of 200 mg/kg bw of Luo Han Guo fruit extract concentrate (30% mogroside V) tested over 6 hours	Single dose; crossover design	5 liver enzymes: alkaline phosphatase, gamma-glutamyl transpeptidase, alanine aminotransferase, aspartate aminotransferase, and lactate dehydrogenase	Xu et al., 2005b

Expanded from GRNs 706, 556 and 301. bw=body weight.

6.C. Safety Determination

The following safety evaluation fully considers the composition, intake, and nutritional, microbiological, and toxicological properties of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrates as well as appropriate corroborative data.

1. Hunan Huacheng's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrates are manufactured under cGMP using common food industry materials and processes.

2. Analytical data from multiple lots indicate that the Luo Han Guo fruit juice concentrates comply reliably with established food-grade product specifications and meet all applicable purity standards.

3. *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrates are intended to be used in conventional foods and in infant and toddler foods, excluding infant formula. For infant and toddler foods, the use level will be the same as those specified in GRN 627. Luo Han Guo juice concentrate is intended to be used as a food ingredient, in a manner similar to many other fruit juices, for its sweetening properties. Also, like other fruit juices and concentrates, the level of addition of Luo Han Guo fruit juice concentrate is limited only by cGMP. Practically, this results in a maximum addition level of about 1%, more frequently 0.25 to 0.50%.

4. When used as a general food sweetener, the EDIs under the intended use are estimated to be up to 1.55 mg mogroside V/kg bw/day for high consumers. These levels are far below the reference dose safe for human exposure. When used as a sweetener at the use level of 0.5% in infant and toddler foods (both baby food with fruit or infant cereals), 8 - 12 month old babies would have the highest 90^{th} percentile EDI of mogroside V with 4.88 mg/kg bw/day. This is comparable to the 95^{th} percentile EDI of 2.4 mg/kg bw/day for either baby food with fruit or infant cereal (or presumably 4.8 mg/kg bw/day for the combined use in both food categories) reported in GRN 627. The safe intake levels of mogroside V is estimated at 17 - 21 mg/kg bw/day. Thus, it is concluded that the use of Luo Han Guo juice concentrate in baby food with fruit and infant cereal would result in 90^{th} percentile of EDIs that are within safe intake levels. These estimates are highly amplified since it is not likely to use 65°Brix Luo Han Guo juice concentrate at 0.5% level in all baby food with fruit and infant cereal.

5. The EDI values are based on the assumption that Hunan Huacheng's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice concentrate will replace currently marketed Luo Han Guo fruit juice or fruit extract products. Thus, cumulative exposures are not expected to change.

6. The LD_{50} of Hunan Huacheng's Luo Han Guo fruit juice concentrates (both 10°and 65°Brix) was determined to be higher than 25 g/kg bw in rats, indicating that the substance in this GRAS determination belongs to the groups that have the lowest

toxicity rating. Bacterial reverse mutation assay showed that Hunan Huacheng's Luo Han Guo fruit juice concentrates were not mutagenic. In addition, literature searches did not identify safety or toxicity concerns related to Luo Han Guo fruit extract or juice products. Subchronic studies reported that NOAELs for dried powders of Luo Han Guo fruit extract containing 55% mogroside V were 3,120 mg/kg bw/day and 3,750 mg/kg bw/day in male and female rats, respectively; those of mogroside V were 1,717 mg/kg bw/day for male rats and 2,062 mg/kg bw/day for female rats.

7. In previous GRAS notices (GRNs 301, 359, 522, 556, 627, and 706) to the FDA, the safety of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice and extract products (powdered extract or juice concentrate) was established in toxicological studies in animals and mutagenicity studies and is further supported by clinical studies in humans. Furthermore, historical consumption of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit products (extract or juice concentrate) support the safety of Luo Han Guo fruit juice concentrate.

6.D. Conclusions and General Recognition of the Safety of *Siraitia grosvenorii* Swingle (Luo Han Guo) Fruit Juice Concentrate

Several sources of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit juice products with varying concentrations of mogroside V have been evaluated by the FDA and other global regulatory agencies over the past 10 years for proposed incorporation as a sugar substitute in foods for human consumption. Relevant U.S. GRAS notifications include GRN 627 (FDA, 2017), GRN 301 (FDA, 2010b), GRN 359 (FDA, 2011b), GRN 522 (FDA, 2014), GRN 556 (FDA 2015a), and GRN 706 (FDA, 2017). All the GRAS notices provided summarized human and animal studies supporting the safety of a similar product, Luo Han Guo fruit juice concentrate. This safety evaluation was based on generally available and widely accepted data and information; thus, it satisfies the "common knowledge" element of a GRAS determination.

Hunan Huacheng uses a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications and thus are manufactured consistent with cGMP for food (21 CFR Part 110 and Part 117 Subpart B). The raw materials and processing aids used in the manufacturing process are food grade and/or commonly used in fermentation and food manufacturing processes. Mutagenicity and acute toxicity studies found no adverse effects of Hunan Huacheng's Luo Han Guo fruit juice concentrates. The publicly available scientific literature on the consumption and safety of Luo Han Guo fruit juice products in animal toxicity studies and human clinical studies are sufficient to support the safety and GRAS status of the proposed Luo Han Guo fruit juice concentrates. In addition, the intended uses of Luo Han Guo fruit juice concentrates have been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the "technical" element of the GRAS determination.

Hunan Huacheng concluded that these uses of Luo Han Guo fruit juice concentrates are GRAS based on scientific procedures, and that other experts qualified to assess the safety of foods and food additives would concur with these conclusions. Therefore, it is excluded from the definition of a food additive and may be marketed and sold for its intended purpose in the U.S. without the promulgation of a food additive regulation under Title 21 of the CFR.

Hunan Huacheng is not aware of any information that would be inconsistent with the finding that the proposed use of *Siraitia grosvenorii* (Luo Han Guo) fruit juice concentrate meets appropriate specifications, and its use, according to cGMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concern.

PART 7. REFERENCES

7.A. References That Are Generally Available

Altug T. Introduction to toxicology and food. CRC Press, Boca Raton, FL. 2003.

Ames BN, McCann J, Yamasaki E. Methods for detecting carcinogens and mutagens with the Salmonella/Mammalian-Microsome Mutagenicity test. Mutation Res. 1975;31:347-364.

FDA. 2010a. Agency Response Letter GRAS Notice No. GRN 000301. CFSAN/Office of Food Additive Safety. http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm200326.h.

FDA. 2010b. GRAS Notice No. (GRN) 301. *Siraitia grosvenori* (Luo Han Guo) fruit extracts. Filed by BioVittoria Limited, Hamilton, New Zealand. Date of closure: January 15, 2010. http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn000301.pdf.

FDA. 2011a. Agency Response Letter GRAS Notice No. GRN 000359 CFSAN/Office of Food Additive Safety. http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm253511.h.

FDA. 2011b. GRAS Notification (GRN) 359. *Siraitia grosvenori* (Luo Han Guo) fruit extracts. Filed by Guilin Layn Natural Ingredients Corp., Guanxi, China. Date of closure: April 11, 2011. http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn359.pdf.

FDA. 2014. GRAS Notification (GRN) 522. *Siraitia grosvenori* (Luo Han Guo) fruit extract. Filed by GLG Life Tech Corporation, British Columbia, Canada. Date of closure: December 8, 2014. http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn522.pdf.

FDA. 2015a. GRAS Notification (GRN) 556. *Siraitia grosvenori* (Luo Han Guo) fruit extract. Filed by Hunan Hucheng Biotechnology, Inc., China. Date of closure: June 17, 2015. http://www.accessdata.fda.gov/scripts/fcn/gras_notices/grn556.pdf.

FDA. 2015b. Additional information about high-intensity sweeteners permitted for use in food in the United States. http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm397725.h.

FDA. 2016. GRAS Notification (GRN) 627. *Siraitia grosvenori* (Luo Han Guo) fruit juice concentrate. Filed by Guilin GFS Luo Han Guo Fruit Corporation, China. Date of closure: October 11, 2016.

FDA. 2017. GRAS Notification (GRN) 706. *Siraitia grosvenori* (Luo Han Guo) fruit extract. Filed by Nutramax, China. Date of closure: August 17, 2017.

Hirose I. Test inspection performed to reevaluate the safety of food additives for the year 1999: 90-day oral administration test for the Luo Han Guo (*Momordica Grosvenori* Swingle) extract. 1999. Hiroshima University, Japan. Cited in GRN 522.

Huntingdon Life Sciences. HLS Study No. HUD0072. 2009a. LaynGo: Bacterial Reverse Mutation Test. Huntingdon Life Sciences Eye Research Centre, Eye, Suffolk, IP23 7PX, UK. Cited in GRN 359.

Huntingdon Life Sciences. HLS Study No. 08-2085. 2009b. Go-LuoA: 90-Day Oral (Dietary) Toxicity Study in Rats with a 28-Day Recovery Period. East Millstone, NJ 08875-2360. Cited in GRN 359.

Jin M, Muguruma M, Moto M, Okamura M, Kashida Y, Mitsumori K. Thirteen-week repeated dose toxicity of *Siraitia grosvenori extracts* in Wistar Hannover (GALAS) rats. Food Chem Toxicol. 2007;45:1231-1237.

Lee C. Intense sweetener from Lo Han Kuo (*Momordica grosvenori*). Experientia. 1975;31:533-534.

Li C, Lin LM, Sui F, Wang ZM, Huo HR, Dai L, Jiang TL. Chemistry and pharmacology of *Siraitia grosvenorii*: a review. Chin J Nat Med. 2014; 12:89-102.

Makapugay HC, Nanayakkara NPD, Soejarto DD, Kinghorn AD. High-performance liquid chromatographic analysis of major sweet principle of luo han kuo fruits. J Agric Food Chem. 1985;33:348–350.

Marone PA, Borzelleca JF, Merkel D, Heimbach JT, Kennepohl E. Twenty eight-day dietary toxicity study of Luo Han fruit concentrate in Hsd:SD rats. Food Chem Toxicol. 2008;46:910-919.

Murata Y, Ogawa T, Suzuki YA, Yoshikawa S, Inui H, Sugiura M, Nakano Y. Digestion and absorption of *Siraitia grosvenori* triterpenoids in the rat. Biosci Biotechnol Biochem. 2010;74:673-676.

Pawar RS, Krynitsky AJ, Rader JI. Sweeteners from plants - with emphasis on *Stevia rebaudiana* (Bertoni) and *Siraitia grosvenorii* (Swingle). Anal Bioanal Chem. 2013;405:4397-4407.

Qin X, Xiaojian S, Ronggan L, Yuxian W, Zhunian T, Shouji G, Heimbach J. Subchronic 90-day oral (gavage) toxicity study of a Luo Han Guo mogroside extracts in dogs. Food Chem Toxicol. 2006;44:2106-2109.

Tey SL, Salleh NB, Henry J, Forde CG. Effects of aspartame-, Luo Han Guo fruit-, Stevia-, and sucrose-sweetened beverages on postprandial glucose, insulin and energy intake. Int J Obes (Lond). 2017a;41:450-457.

Tey SL, Salleh NB, Henry CJ, Forde CG. Effects of non-nutritive (artificial vs natural) sweeteners on 24-h glucose profiles. Eur J Clin Nutr. 2017b;71:1129-1132.

Xu Q, Liang R, Li L. 2005a. Experiment report: effect of Luo Han Guo mogroside on human's blood sugar content. Unpublished report, August 19. Cited in GRN 301.

Xu Q, Liang R, Li L. 2005b. Experiment report: effect of PureLo Luo Han Guo mogroside on liver enzymes of human. Unpublished report, September 6. Cited in GRN 301.

Xu F, Li DP, Huang ZC, Lu FL, Wang L, Huang YL, Wang RF, Liu GX, Shang MY, Cai SQ. Exploring in vitro, in vivo metabolism of mogroside V and distribution of its metabolites in rats by HPLC-ESI-IT-TOF-MS(n). J Pharm Biomed Anal. 2015;115:418-430.

Zhou G, Zhang Y, Li Y, Wang M, Li X. The metabolism of a natural product mogroside V, in healthy and type 2 diabetic rats. J Chromatogr B Analyt Technol Biomed Life Sci. 2018;1079:25-33.

7.B. References That Are Not Generally Available

Gao Y. 2017. Safety studies of Luo Han Guo fruit juice concentrate. A report prepared for Hunan Huacheng by Dr. Gao.

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CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 10 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.05.03
Batch No:	LHGE-170503	**Analysis Date**	2017.05.04
Quantity:	600kg	**Report Date**	2017.05.10
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥0.6%	0.63	HPLC
Total mogroside(g/100 g)	/	0.75	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥10 Brix	10.20	GB/T 12143
Protein(g/100 g)	/	2.45	AOAC984.13
Moisture(g/100 g)	<90	89.40	GB5009.3-2016
Ash(g/100 g)	/	0.32	GB5009.4-2016
Sodium(mg/kg)	/	83	ICP-MS
Potassium(mg/kg)	/	9.26	ICP-MS
Calcium(mg/kg)	/	8.46	ICP-MS
Glucose(g/100 g)	/	1.53	AOAC 995.13, modified
Fructose(g/100 g)	/	1.14	AOAC 995.13, modified
Sucrose(g/100 g)	/	3.76	AOAC 995.13, modified
Total sugars(g/100 g)	/	6.43	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.06	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	0.012	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.134	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	Store in a well-closed place with corrosive-proof refrigerant storehous(0℃～-18℃)and no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.05.10

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 10 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.06.10
Batch No:	LHGE-170610	**Analysis Date**	2017.06.10
Quantity:	500kg	**Report Date**	2017.06.17
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥0.6%	0.61	HPLC
Total mogroside(g/100 g)	/	0.72	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥10 Brix	10.50	GB/T 12143
Protein(g/100 g)	/	2.56	AOAC984.13
Moisture(g/100 g)	<90	88.50	GB5009.3-2016
Ash(g/100 g)	/	0.25	GB5009.4-2016
Sodium(mg/kg)	/	87	ICP-MS
Potassium(mg/kg)	/	8.33	ICP-MS
Calcium(mg/kg)	/	9.70	ICP-MS
Glucose(g/100 g)	/	1.67	AOAC 995.13, modified
Fructose(g/100 g)	/	1.32	AOAC 995.13, modified
Sucrose(g/100 g)	/	4.09	AOAC 995.13, modified
Total sugars(g/100 g)	/	7.08	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.12	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.045	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.06.17

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 10 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.08.01
Batch No:	LHGE-170801	**Analysis Date**	2017.08.02
Quantity:	500kg	**Report Date**	2017.08.09
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥0.6%	0.65	HPLC
Total mogroside(g/100 g)	/	0.76	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥10 Brix	10.60	GB/T 12143
Protein(g/100 g)	/	2.77	AOAC984.13
Moisture(g/100 g)	<90	89.20	GB5009.3-2016
Ash(g/100 g)	/	0.15	GB5009.4-2016
Sodium(mg/kg)	/	96	ICP-MS
Potassium(mg/kg)	/	4.76	ICP-MS
Calcium(mg/kg)	/	8.54	ICP-MS
Glucose(g/100 g)	/	1.32	AOAC 995.13, modified
Fructose(g/100 g)	/	1.45	AOAC 995.13, modified
Sucrose(g/100 g)	/	4.67	AOAC 995.13, modified
Total sugars(g/100 g)	/	7.44	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.10	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	Not Detected	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015
Packing and Storage			
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum		
Storage	no direct sun light.		
Shelf Life	2 years .		

Name: (b) (6) Date: 2017.08.09

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 40 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.08.11
Batch No:	LHGE-170811	**Analysis Date**	2017.08.12
Quantity:	600kg	**Report Date**	2017.08.19
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥2.4%	2.52	HPLC
Total mogroside(g/100 g)	/	2.77	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids （Brix）	≥40Brix	41.80	GB/T 12143
Protein(g/100 g)	/	7.43	AOAC984.13
Moisture(g/100 g)	<60	57.90	GB5009.3-2016
Ash(g/100 g)	/	0.75	GB5009.4-2016
Sodium(mg/kg)	/	136	ICP-MS
Potassium(mg/kg)	/	45.52	ICP-MS
Calcium(mg/kg)	/	22.34	ICP-MS
Glucose(g/100 g)	/	4.32	AOAC 995.13, modified
Fructose(g/100 g)	/	2.38	AOAC 995.13, modified
Sucrose(g/100 g)	/	13.24	AOAC 995.13, modified
Total sugars(g/100 g)	/	19.94	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.22	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	0.022	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.045	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	Store in a well-closed place with corrosive-proof refrigerant storehous(0℃～-18℃)and no direct sun light.
Shelf Life	2 years .

Name (b) (6) Date: 2017.08.19

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 40 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.09.10
Batch No:	LHGE-170910	**Analysis Date**	2017.09.10
Quantity:	500kg	**Report Date**	2017.09.17
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥2.4%	2.54	HPLC
Total mogroside(g/100 g)	/	2.79	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids （Brix）	≥40Brix	42.00	GB/T 12143
Protein(g/100 g)	/	7.54	AOAC984.13
Moisture(g/100 g)	<60	57.80	GB5009.3-2016
Ash(g/100 g)	/	0.72	GB5009.4-2016
Sodium(mg/kg)	/	164	ICP-MS
Potassium(mg/kg)	/	43.52	ICP-MS
Calcium(mg/kg)	/	24.43	ICP-MS
Glucose(g/100 g)	/	5.44	AOAC 995.13, modified
Fructose(g/100 g)	/	3.23	AOAC 995.13, modified
Sucrose(g/100 g)	/	12.43	AOAC 995.13, modified
Total sugars(g/100 g)	/	21.10	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.15	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.078	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.09.17

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 40 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.10.01
Batch No:	LHGE-171001	**Analysis Date**	2017.10.02
Quantity:	500kg	**Report Date**	2017.10.09
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥2.4%	2.47	HPLC
Total mogroside(g/100 g)	/	2.68	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥40Brix	41.70	GB/T 12143
Protein(g/100 g)	/	7.33	AOAC984.13
Moisture(g/100 g)	<60	56.40	GB5009.3-2016
Ash(g/100 g)	/	0.65	GB5009.4-2016
Sodium(mg/kg)	/	177	ICP-MS
Potassium(mg/kg)	/	44.32	ICP-MS
Calcium(mg/kg)	/	21.76	ICP-MS
Glucose(g/100 g)	/	6.11	AOAC 995.13, modified
Fructose(g/100 g)	/	2.16	AOAC 995.13, modified
Sucrose(g/100 g)	/	12.43	AOAC 995.13, modified
Total sugars(g/100 g)	/	20.70	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.12	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.131	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015
Packing and Storage			
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum		
Storage	no direct sun light.		
Shelf Life	2 years .		

Name: (b) (6) Date: 2017.10.09

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 50 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.08.14
Batch No:	LHGE-170814	**Analysis Date**	2017.08.14
Quantity:	600kg	**Report Date**	2017.08.21
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.1%	3.25	HPLC
Total mogroside(g/100 g)	/	3.44	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids （Brix）	≥50Brix	51.30	GB/T 12143
Protein(g/100 g)	/	6.54	AOAC984.13
Moisture(g/100 g)	<50	48.30	GB5009.3-2016
Ash(g/100 g)	/	0.75	GB5009.4-2016
Sodium(mg/kg)	/	114	ICP-MS
Potassium(mg/kg)	/	26.87	ICP-MS
Calcium(mg/kg)	/	27.98	ICP-MS
Glucose(g/100 g)	/	4.25	AOAC 995.13, modified
Fructose(g/100 g)	/	3.76	AOAC 995.13, modified
Sucrose(g/100 g)	/	19.21	AOAC 995.13, modified
Total sugars(g/100 g)	/	27.22	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.10	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	0.043	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.172	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	Store in a well-closed place with corrosive-proof refrigerant storehous(0℃～-18℃)and no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.08.21

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 50 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.09.18
Batch No:	LHGE-170918	**Analysis Date**	2017.09.18
Quantity:	500kg	**Report Date**	2017.09.25
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.1%	3.12	HPLC
Total mogroside(g/100 g)	/	3.33	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥50Brix	51.60	GB/T 12143
Protein(g/100 g)	/	5.53	AOAC984.13
Moisture(g/100 g)	<50	48.80	GB5009.3-2016
Ash(g/100 g)	/	0.64	GB5009.4-2016
Sodium(mg/kg)	/	132	ICP-MS
Potassium(mg/kg)	/	24.99	ICP-MS
Calcium(mg/kg)	/	28.56	ICP-MS
Glucose(g/100 g)	/	5.67	AOAC 995.13, modified
Fructose(g/100 g)	/	4.88	AOAC 995.13, modified
Sucrose(g/100 g)	/	15.17	AOAC 995.13, modified
Total sugars(g/100 g)	/	25.72	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.18	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.216	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	no direct sun light.
Shelf Life	2 years .

Name (b) (6) Date: 2017.09.25

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 50 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.10.15
Batch No:	LHGE-171015	**Analysis Date**	2017.10.15
Quantity:	500kg	**Report Date**	2017.10.22
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.1%	3.22	HPLC
Total mogroside(g/100 g)	/	3.45	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥50Brix	52.10	GB/T 12143
Protein(g/100 g)	/	5.66	AOAC984.13
Moisture(g/100 g)	<50	47.30	GB5009.3-2016
Ash(g/100 g)	/	0.57	GB5009.4-2016
Sodium(mg/kg)	/	145	ICP-MS
Potassium(mg/kg)	/	23.76	ICP-MS
Calcium(mg/kg)	/	29.43	ICP-MS
Glucose(g/100 g)	/	6.12	AOAC 995.13, modified
Fructose(g/100 g)	/	4.33	AOAC 995.13, modified
Sucrose(g/100 g)	/	15.32	AOAC 995.13, modified
Total sugars(g/100 g)	/	25.77	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	<0.1	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	0.033	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.191	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015
Packing and Storage			
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum		
Storage	no direct sun light.		
Shelf Life	2 years .		

Name: (b) (6) Date: 2017.10.22

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 65 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.09.27
Batch No:	LHGE-170927	**Analysis Date**	2017.09.27
Quantity:	600kg	**Report Date**	2017.10.08
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.9%	4.16	HPLC
Total mogroside(g/100 g)	/	4.62	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids （Brix）	≥65Brix	67.50	GB/T 12143
Protein(g/100 g)	/	10.33	AOAC984.13
Moisture(g/100 g)	<35	33.60	GB5009.3-2016
Ash(g/100 g)	/	0.85	GB5009.4-2016
Sodium(mg/kg)	/	167	ICP-MS
Potassium(mg/kg)	/	36.74	ICP-MS
Calcium(mg/kg)	/	28.28	ICP-MS
Glucose(g/100 g)	/	8.32	AOAC 995.13, modified
Fructose(g/100 g)	/	5.37	AOAC 995.13, modified
Sucrose(g/100 g)	/	22.14	AOAC 995.13, modified
Total sugars(g/100 g)	/	35.83	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.67	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	0.047	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.232	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	Store in a well-closed place with corrosive-proof refrigerant storehous(0℃～-18℃)and no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.10.08

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 65 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.10.18
Batch No:	LHGE-171018	**Analysis Date**	2017.10.18
Quantity:	500kg	**Report Date**	2017.10.25
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.9%	4.05	HPLC
Total mogroside(g/100 g)	/	4.48	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids (Brix)	≥65Brix	66.20	GB/T 12143
Protein(g/100 g)	/	9.34	AOAC984.13
Moisture(g/100 g)	<35	34.20	GB5009.3-2016
Ash(g/100 g)	/	0.86	GB5009.4-2016
Sodium(mg/kg)	/	152	ICP-MS
Potassium(mg/kg)	/	35.75	ICP-MS
Calcium(mg/kg)	/	26.54	ICP-MS
Glucose(g/100 g)	/	7.67	AOAC 995.13, modified
Fructose(g/100 g)	/	5.84	AOAC 995.13, modified
Sucrose(g/100 g)	/	16.14	AOAC 995.13, modified
Total sugars(g/100 g)	/	29.65	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.52	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.221	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.10.25

Title: Quality manager

HC HUACHENGBIO GreenTech HealthySweet

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Juice Concentrate 65 Brix	**Country of Origin:**	China
Latin Name:	*Siraitia Grosvenorii*	**Active Ingredient:**	Mogroside V
Plant Part Used:	Fruit	**Manufacture Date**	2017.11.22
Batch No:	LHGE-171122	**Analysis Date**	2017.11.22
Quantity:	500kg	**Report Date**	2017.11.29
Extraction solvent:	Pure Water	**Carrier:**	None

Analysis Item	Specification	Result	Test Method
Active Ingredients			
Mogroside V (g/100 g)	Mogroside V ≥3.9%	4.11	HPLC
Total mogroside(g/100 g)	/	4.54	HPLC
Appearance	Brown liquid	Conforms	Visual
Soluble Solids （Brix）	≥65Brix	67.10	GB/T 12143
Protein(g/100 g)	/	9.21	AOAC984.13
Moisture(g/100 g)	<35	33.60	GB5009.3-2016
Ash(g/100 g)	/	0.56	GB5009.4-2016
Sodium(mg/kg)	/	146	ICP-MS
Potassium(mg/kg)	/	36.33	ICP-MS
Calcium(mg/kg)	/	27.73	ICP-MS
Glucose(g/100 g)	/	6.44	AOAC 995.13, modified
Fructose(g/100 g)	/	4.33	AOAC 995.13, modified
Sucrose(g/100 g)	/	12.17	AOAC 995.13, modified
Total sugars(g/100 g)	/	22.94	AOAC 995.13, modified
Dietary fiber(g/100 g)	/	0.32	AOAC 991.43
Chemical Control			
Arsenic (As)	≤0.2 ppm	Not Detected	AOAC 993.14
Cadmium(Cd)	≤0.05 ppm	Not Detected	AOAC 993.14
Lead (Pb)	≤0.5 ppm	0.184	AOAC 993.14
Mercury(Hg)	≤0.1 ppm	Not Detected	AOAC 993.14
Pesticides Residues	Conform to GB2763&USP36	Conforms	GC-MSMS/LC-MSMS
Microbiological Control			
Total Plate Count	≤1000 cfu/g	Conforms	CP2015
Yeast	≤20 cfu/g	Conforms	CP2015
Mold	≤20 cfu/g	Conforms	CP2015
E.Coli	Negative/g	Conforms	CP2015
Salmonella	Negative/25g	Conforms	CP2015
S. aureus	Negative/g	Conforms	CP2015

Packing and Storage	
Packing	Pack in plastic-drums and Aseptic bags inside.Net Weight: 25kg/drum
Storage	no direct sun light.
Shelf Life	2 years .

Name: (b) (6) Date: 2017.11.29

Title: Quality manager

Analytical Report

Sample Code	**502-2017-00060306**	Report date	02-Nov-2017
Certificate No.	**AR-17-SU-056915-02-EN**		

*This analytical report replaces the previous issued analytical report no.: AR-17-SU-056915-01

Hunan Huacheng Biotech,Inc

No 188, Tongzi'po West. Rd., Changsha, China

Our reference:	502-2017-00060306/ AR-17-SU-056915-02-EN
Client Sample Code:	170417
Sample described as:	Monk Fruit Juice Concentrate 65 Brix
Sample Packaging:	Sealed plastic bottle
Sample reception date:	27-Oct-2017
Analysis starting date:	27-Oct-2017
Analysis ending date:	01-Nov-2017

Arrival Temperature (°C)	21.8	Sample Weight	160g
Sample Type	Liquid		

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
Mercury (Hg)		**<0.005**	mg/kg	0.005	
SU05G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Cadmium (Cd)		**<0.01**	mg/kg	0.01	

		Results	Unit	LOQ	LOD
SU355	Pesticides Quechers 100 parameters Method: EN 15662:2008				
Screened pesticides		**Not Detected**	mg/kg		
SU352	Pesticides Quechers (100 parameters) Method: EN 15662:2008				
Screened pesticides		**Not Detected**	mg/kg		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				
Protein		**<0.1 (k=6.25)**	g/100 g	0.1	

List of screened molecules (* = limit of quantification)

SU352 Pesticides Quechers (100 parameters) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.01)	(a) Aldrin (0.01)	(a) Ametryne (0.01)	(a) Anthraquinone (0.01)	(a) Aramite (0.04)
(a) Atrazine (0.01)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Captan (0.01)
(a) Captan/THPI (Sum calculated as Captan) ()	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.01)	(a) Chlorfenvinphos (0.01)
(a) Chlorothalonil (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.02)	(a) Cyhalothrin lambda- (0.01)
(a) Cypermethrin (0.02)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.02)	(a) Dichlofluanid (0.01)	(a) Dicloran (0.01)	(a) Dichlorvos (0.01)
(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.01)	(a) Dicofol, p,p'- (0.01)	(a) Dieldrin (0.01)	(a) Dieldrin (Sum) ()	(a) Diphenylamine (0.01)
(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.01)	(a) Endosulfan, beta- (0.01)	(a) Endosulfan, sulfat- (0.01)	(a) Endrin (0.01)	(a) EPN (0.01)
(a) Ethion (0.01)	(a) Etrimfos (0.01)	(a) Famoxadone (0.01)	(a) Fenamiphos (0.01)	(a) Fenitrothion (0.01)	(a) Fenpropathrin (0.01)
(a) Fenthion (0.01)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR isomers) (0.01)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()	(a) Fenvalerate & Esfenvalerate(Sum of RR&SS isomers) (0.01)	(a) Flucythrinate (0.01)	(a) Fluvalinate-tau (0.01)
(a) Folpet (0.01)	(a) Folpet/PI (Sum calculated as Folpet) ()	(a) Fonofos (0.01)	(a) HCB (0.01)	(a) HCH (Sum, without Lindan) ()	(a) HCH gamma(Lindan) (0.01)
(a) HCH, alpha- (0.01)	(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()
(a) Heptenophos (0.01)	(a) Iprobenfos (0.01)	(a) Isazofos (0.01)	(a) Isocarbophos (0.01)	(a) Isofenphos (0.01)	(a) Isofenphos-methyl (0.01)
(a) Isoprothiolane (0.01)	(a) Kresoxim-methyl (0.01)	(a) Malaoxon (0.01)	(a) Malathion (Sum) ()	(a) Methidathion (0.01)	(a) Methoxychlor (0.01)
(a) Mevinphos (0.01)	(a) Mirex (0.01)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.01)	(a) Paclobutrazol (0.01)	(a) Parathion (0.02)
(a) Parathion-methyl (0.02)	(a) Parathion-methyl (Sum) ()	(a) Permethrin (0.01)	(a) Phenthoate (0.01)	(a) Phorate (0.01)	(a) Phorate (Sum) ()
(a) Phthalimid (PI) (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Prometryn (0.01)	(a) Propanil (0.01)
(a) Pyrazophos (0.01)	(a) Pyridaphenthion (0.01)	(a) Pyrifenox (0.01)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)
(a) Quintozene (Sum) ()	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.01)	(a) Tefluthrin (0.01)	(a) Terbufos (0.01)	(a) Tetrachlorvinphos (0.01)
(a) Tetradifon (0.01)	(a) Tetrahydrophthalimide (THPI) (0.01)	(a) Tolylfluanid (0.01)	(a) Triazophos (0.01)	(a) Vinclozolin (0.01)	

SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) 2,4-D (0.01)	(a) 2,4-D, total (0.01)	(a) Abamectin (Sum) ()	(a) Acephate (0.01)	(a) Acetamiprid (0.01)	(a) Alachlor (0.01)
(a) Aldicarb (0.01)	(a) Aldicarb (Sum) ()	(a) Aldicarb-sulfone (0.01)	(a) Aldicarb-sulfoxide (0.01)	(a) Amitraz (0.01)	(a) Avermectin B1a (0.01)
(a) Avermectin B1b (0.01)	(a) Azinphos-methyl (0.01)	(a) Azoxystrobin (0.01)	(a) Benalaxyl (0.01)	(a) Bendiocarb (0.01)	(a) Benoxacor (0.01)
(a) Bensulfuron methyl (0.01)	(a) Bentazone (0.01)	(a) Bitertanol (0.01)	(a) Boscalid (0.01)	(a) Bupirimate (0.01)	(a) Buprofezin (0.01)
(a) Carbaryl (0.01)	(a) Carbendazim/Benomyl (sum) (0.005)	(a) Carbofuran (0.01)	(a) Carbofuran (Sum) ()	(a) Carbosulfan (0.01)	(a) Carfentrazone-ethyl (0.01)

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SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) Chlorantraniliprole (0.01)	(a) Chlorobenzuron (0.01)	(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chromafenoziod (0.01)	(a) Clethodim (0.01)
(a) Clofentezine (0.01)	(a) Clothianidin (0.002)	(a) Cymoxanil (0.01)	(a) Cyproconazole (0.01)	(a) Cyromazine (0.01)	(a) Demeton-S-methyl (0.01)
(a) Demeton-S-methyl-sulfone (0.01)	(a) Diazinon (0.01)	(a) Diethofencarb (0.01)	(a) Difenoconazole (0.01)	(a) Diflubenzuron (0.01)	(a) Diflufenican (0.01)
(a) Dimethoate (0.01)	(a) Dimethoate/Omethoate (sum) ()	(a) Dimethomorph (0.01)	(a) Diniconazole (0.01)	(a) Dinotefuran (0.01)	(a) Epoxiconazole (0.01)
(a) Etofenprox (0.01)	(a) Ethoprophos (0.01)	(a) Ethoxyquin (0.01)	(a) Fenarimol (0.01)	(a) Fenazaquin (0.01)	(a) Fenhexamid (0.01)
(a) Fenobucarb (0.01)	(a) Fipronil (0.002)	(a) Fipronil (sum) ()	(a) Fipronil-sulfide (0.002)	(a) Fipronil-sulfone (0.002)	(a) Fluazifop-P-butyl (0.01)
(a) Fludioxonil (0.01)	(a) Flusilazole (0.01)	(a) Formetanate (0.01)	(a) Hexaconazole (0.01)	(a) Hexythiazox (0.01)	(a) Imazalil (0.01)
(a) Imidacloprid (0.01)	(a) Indoxacarb (0.01)	(a) Iprodione (0.01)	(a) Iprovalicarb (0.01)	(a) Isoprocarb (0.01)	(a) Linuron (0.01)
(a) Malathion (0.01)	(a) Metalaxyl (0.01)	(a) Methamidophos (0.01)	(a) Methidathion (0.01)	(a) Methomyl (0.01)	(a) Metolachlor (0.01)
(a) Monocrotophos (0.01)	(a) Myclobutanil (0.01)	(a) Napropamide (0.01)	(a) Neburon (0.01)	(a) Omethoate (0.01)	(a) Oxadixyl (0.01)
(a) Oxydemeton-methyl (0.01)	(a) Oxydemeton-methyl (sum) ()	(a) Penconazole (0.01)	(a) Pendimethalin (0.01)	(a) Phorate (Sum) ()	(a) Phorate Sulfoxide (0.01)
(a) Phorate-sulfone (0.01)	(a) Phosalone (0.01)	(a) Phosmet (0.01)	(a) Phoxim (0.01)	(a) Piperonyl butoxide (0.01)	(a) Pirimicarb (0.01)
(a) Pirimiphos-methyl (0.01)	(a) Prochloraz (0.01)	(a) Procymidone (0.01)	(a) Propamocarb (0.01)	(a) Propargite (0.01)	(a) Propham (0.01)
(a) Propiconazole (0.01)	(a) Propoxur (0.01)	(a) Propyzamide (0.01)	(a) Pyrethrins (0.01)	(a) Pyridaben (0.01)	(a) Pyrimethanil (0.01)
(a) Quinoxyfen (0.01)	(a) Simazine (0.01)	(a) Spiromesifen (0.01)	(a) Tebuconazole (0.01)	(a) Tebufenozide (0.01)	(a) Tetraconazole (0.01)
(a) Thiabendazole (0.01)	(a) Thiacloprid (0.01)	(a) Thiamethoxam (0.01)	(a) Thiophanate-methyl (0.01)	(a) Tolclofos-methyl (0.01)	(a) Triadimenol (0.01)
(a) Trichlorfon (0.01)	(a) Tridemorph (0.01)	(a) Triflumizol/FM-6-1 (Sum) ()	(a) Triflumizole (0.01)	(a) Zoxamide (0.01)	

SIGNATURE (b) (6)

Shine Xie
Food Chemistry Manager

EXPLANATORY NOTE

≥ Greater than or equal to
< Less than
≤ Less than or equal to
N/A means Not applicable

☆ means the test is subcontracted within Eurofins group
▫ means the test is subcontracted outside Eurofins group

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END OF REPORT

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Analytical Report

Sample Code	**502-2017-00060307**	Report date	02-Nov-2017
Certificate No.	**AR-17-SU-056916-02-EN**		

*This analytical report replaces the previous issued analytical report no.: AR-17-SU-056916-01

Hunan Huacheng Biotech,Inc

No 188, Tongzi'po West. Rd., Changsha, China

Our reference:	502-2017-00060307/ AR-17-SU-056916-02-EN
Client Sample Code:	170610
Sample described as:	Monk Fruit Juice Concentrate 65 Brix
Sample Packaging:	Sealed plastic bottle
Sample reception date:	27-Oct-2017
Analysis starting date:	27-Oct-2017
Analysis ending date:	01-Nov-2017
Arrival Temperature (°C)	21.8
Sample Weight	170g
Sample Type	Liquid

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
	Mercury (Hg)	**<0.005**	mg/kg	0.005	
SU05G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
	Cadmium (Cd)	**<0.01**	mg/kg	0.01	

		Results	Unit	LOQ	LOD
SU355	Pesticides Quechers 100 parameters Method: EN 15662:2008				
	Screened pesticides	**Not Detected**	mg/kg		
SU352	Pesticides Quechers (100 parameters) Method: EN 15662:2008				
	Screened pesticides	**Not Detected**	mg/kg		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				
	Protein	**<0.1 (k=6.25)**	g/100 g	0.1	

List of screened molecules (* = limit of quantification)

SU352 Pesticides Quechers (100 parameters) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.01)	(a) Aldrin (0.01)	(a) Ametryne (0.01)	(a) Anthraquinone (0.01)	(a) Aramite (0.04)
(a) Atrazine (0.01)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Captan (0.01)
(a) Captan/THPI (Sum calculated as Captan) ()	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.01)	(a) Chlorfenvinphos (0.01)
(a) Chlorothalonil (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.02)	(a) Cyhalothrin lambda- (0.01)
(a) Cypermethrin (0.02)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.02)	(a) Dichlofluanid (0.01)	(a) Dicloran (0.01)	(a) Dichlorvos (0.01)
(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.01)	(a) Dicofol, p,p'- (0.01)	(a) Dieldrin (0.01)	(a) Dieldrin (Sum) ()	(a) Diphenylamine (0.01)
(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.01)	(a) Endosulfan, beta- (0.01)	(a) Endosulfan, sulfat- (0.01)	(a) Endrin (0.01)	(a) EPN (0.01)
(a) Ethion (0.01)	(a) Etrimfos (0.01)	(a) Famoxadone (0.01)	(a) Fenamiphos (0.01)	(a) Fenitrothion (0.01)	(a) Fenpropathrin (0.01)
(a) Fenthion (0.01)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR Isomers) (0.01)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()	(a) Fenvalerate & Esfenvalerate(Sum of RR&SS Isomers) (0.01)	(a) Flucythrinate (0.01)	(a) Fluvalinate-tau (0.01)
(a) Folpet (0.01)	(a) Folpet/PI (Sum calculated as Folpet) ()	(a) Fonofos (0.01)	(a) HCB (0.01)	(a) HCH (Sum, without Lindan) ()	(a) HCH gamma(Lindan) (0.01)
(a) HCH, alpha- (0.01)	(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()
(a) Heptenophos (0.01)	(a) Iprobenfos (0.01)	(a) Isazofos (0.01)	(a) Isocarbophos (0.01)	(a) Isofenphos (0.01)	(a) Isofenphos-methyl (0.01)
(a) Isoprothiolane (0.01)	(a) Kresoxim-methyl (0.01)	(a) Malaoxon (0.01)	(a) Malathion (Sum) ()	(a) Methidathion (0.01)	(a) Methoxychlor (0.01)
(a) Mevinphos (0.01)	(a) Mirex (0.01)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.01)	(a) Paclobutrazol (0.01)	(a) Parathion (0.02)
(a) Parathion-methyl (0.02)	(a) Parathion-methyl (Sum) ()	(a) Permethrin (0.01)	(a) Phenthoate (0.01)	(a) Phorate (0.01)	(a) Phorate (Sum) ()
(a) Phthalimid (PI) (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Prometryn (0.01)	(a) Propanil (0.01)
(a) Pyrazophos (0.01)	(a) Pyridaphenthion (0.01)	(a) Pyrifenox (0.01)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)
(a) Quintozene (Sum) ()	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.01)	(a) Tefluthrin (0.01)	(a) Terbufos (0.01)	(a) Tetrachlorvinphos (0.01)
(a) Tetradifon (0.01)	(a) Tetrahydrophthalimide (THPI) (0.01)	(a) Tolylfluanid (0.01)	(a) Triazophos (0.01)	(a) Vinclozolin (0.01)	

SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) 2,4-D (0.01)	(a) 2,4-D, total (0.01)	(a) Abamectin (Sum) ()	(a) Acephate (0.01)	(a) Acetamiprid (0.01)	(a) Alachlor (0.01)
(a) Aldicarb (0.01)	(a) Aldicarb (Sum) ()	(a) Aldicarb-sulfone (0.01)	(a) Aldicarb-sulfoxide (0.01)	(a) Amitraz (0.01)	(a) Avermectin B1a (0.01)
(a) Avermectin B1b (0.01)	(a) Azinphos-methyl (0.01)	(a) Azoxystrobin (0.01)	(a) Benalaxyl (0.01)	(a) Bendiocarb (0.01)	(a) Benoxacor (0.01)
(a) Bensulfuron methyl (0.01)	(a) Bentazone (0.01)	(a) Bitertanol (0.01)	(a) Boscalid (0.01)	(a) Bupirimate (0.01)	(a) Buprofezin (0.01)
(a) Carbaryl (0.01)	(a) Carbendazim/Benomyl (sum) (0.005)	(a) Carbofuran (0.01)	(a) Carbofuran (Sum) ()	(a) Carbosulfan (0.01)	(a) Carfentrazone-ethyl (0.01)

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SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) Chlorantraniliprole (0.01)	(a) Chlorobenzuron (0.01)	(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chromafenoziod (0.01)	(a) Clethodim (0.01)
(a) Clofentazine (0.01)	(a) Clothianidin (0.002)	(a) Cymoxanil (0.01)	(a) Cyproconazole (0.01)	(a) Cyromazine (0.01)	(a) Demeton-S-methyl (0.01)
(a) Demeton-S-methyl-sulfone (0.01)	(a) Diazinon (0.01)	(a) Diethofencarb (0.01)	(a) Difenoconazole (0.01)	(a) Diflubenzuron (0.01)	(a) Diflufenican (0.01)
(a) Dimethoate (0.01)	(a) Dimethoate/Omethoate (sum) ()	(a) Dimethomorph (0.01)	(a) Diniconazole (0.01)	(a) Dinotefuran (0.01)	(a) Epoxiconazole (0.01)
(a) Etofenprox (0.01)	(a) Ethoprophos (0.01)	(a) Ethoxyquin (0.01)	(a) Fenarimol (0.01)	(a) Fenazaquin (0.01)	(a) Fenhexamid (0.01)
(a) Fenobucarb (0.01)	(a) Fipronil (0.002)	(a) Fipronil (sum) ()	(a) Fipronil-sulfide (0.002)	(a) Fipronil-sulfone (0.002)	(a) Fluazifop-P-butyl (0.01)
(a) Fludioxonil (0.01)	(a) Flusilazole (0.01)	(a) Formetanate (0.01)	(a) Hexaconazole (0.01)	(a) Hexythiazox (0.01)	(a) Imazalil (0.01)
(a) Imidacloprid (0.01)	(a) Indoxacarb (0.01)	(a) Iprodione (0.01)	(a) Iprovalicarb (0.01)	(a) Isoprocarb (0.01)	(a) Linuron (0.01)
(a) Malathion (0.01)	(a) Metalaxyl (0.01)	(a) Methamidophos (0.01)	(a) Methidathion (0.01)	(a) Methomyl (0.01)	(a) Metolachlor (0.01)
(a) Monocrotophos (0.01)	(a) Myclobutanil (0.01)	(a) Napropamide (0.01)	(a) Neburon (0.01)	(a) Omethoate (0.01)	(a) Oxadixyl (0.01)
(a) Oxydemeton-methyl (0.01)	(a) Oxydemeton-methyl (sum) ()	(a) Penconazole (0.01)	(a) Pendimethalin (0.01)	(a) Phorate (Sum) ()	(a) Phorate Sulfoxide (0.01)
(a) Phorate-sulfone (0.01)	(a) Phosalone (0.01)	(a) Phosmet (0.01)	(a) Phoxim (0.01)	(a) Piperonyl butoxide (0.01)	(a) Pirimicarb (0.01)
(a) Pirimiphos-methyl (0.01)	(a) Prochloraz (0.01)	(a) Procymidone (0.01)	(a) Propamocarb (0.01)	(a) Propargite (0.01)	(a) Propham (0.01)
(a) Propiconazole (0.01)	(a) Propoxur (0.01)	(a) Propyzamide (0.01)	(a) Pyrethrins (0.01)	(a) Pyridaben (0.01)	(a) Pyrimethanil (0.01)
(a) Quinoxyfen (0.01)	(a) Simazine (0.01)	(a) Spiromesifen (0.01)	(a) Tebuconazole (0.01)	(a) Tebufenozide (0.01)	(a) Tetraconazole (0.01)
(a) Thiabendazole (0.01)	(a) Thiacloprid (0.01)	(a) Thiamethoxam (0.01)	(a) Thiophanate-methyl (0.01)	(a) Tolclofos-methyl (0.01)	(a) Triadimenol (0.01)
(a) Trichlorfon (0.01)	(a) Tridemorph (0.01)	(a) Triflumizol/FM-6-1 (Sum) ()	(a) Triflumizole (0.01)	(a) Zoxamide (0.01)	

SIGNATURE

(b) (6)

Shine Xie
Food Chemistry Manager

EXPLANATORY NOTE

≥ Greater than or equal to
< Less than
≤ Less than or equal to
N/A means Not applicable

☆ means the test is subcontracted within Eurofins group
▪ means the test is subcontracted outside Eurofins group

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Analytical Report

Sample Code	502-2017-00060308	Report date	02-Nov-2017
Certificate No.	AR-17-SU-056917-02-EN		

*This analytical report replaces the previous issued analytical report no.: AR-17-SU-056917-01

Hunan Huacheng Biotech,Inc

No 188, Tongzi'po West. Rd., Changsha, China

Our reference:	502-2017-00060308/ AR-17-SU-056917-02-EN		
Client Sample Code:	170622		
Sample described as:	Monk Fruit Juice Concentrate 65 Brix		
Sample Packaging:	Sealed plastic bottle		
Sample reception date:	27-Oct-2017		
Analysis starting date:	27-Oct-2017		
Analysis ending date:	01-Nov-2017		
Arrival Temperature (°C)	21.8	Sample Weight	150g
Sample Type	Liquid		

		Results	Unit	LOQ	LOD
SU007	Mercury (AAS) Method: BS EN 13806:2002				
Mercury (Hg)		<0.005	mg/kg	0.005	
SU05G	Cadmium (ICP-MS) Method: BS EN ISO 17294-2 2016 mod.				
Cadmium (Cd)		<0.01	mg/kg	0.01	

		Results	Unit	LOQ	LOD
SU355	Pesticides Quechers 100 parameters Method: EN 15662:2008				
Screened pesticides		Not Detected	mg/kg		
SU352	Pesticides Quechers (100 parameters) Method: EN 15662:2008				
Screened pesticides		Not Detected	mg/kg		

		Results	Unit	LOQ	LOD
SU20L	Protein Method: AOAC 984.13				
Protein		<0.1 (k=6.25)	g/100 g	0.1	

List of screened molecules (* = limit of quantification)

SU352 Pesticides Quechers (100 parameters) (LOQ* mg/kg)

(a) 2-Phenylphenol (0.01)	(a) Acetochlor (0.01)	(a) Aldrin (0.01)	(a) Ametryne (0.01)	(a) Anthraquinone (0.01)	(a) Aramite (0.04)
(a) Atrazine (0.01)	(a) Bifenthrin (0.01)	(a) Biphenyl (0.01)	(a) Bromopropylate (0.01)	(a) Butachlor (0.01)	(a) Captan (0.01)
(a) Captan/THPI (Sum calculated as Captan) ()	(a) Chlordane (Sum) ()	(a) Chlordane, alpha (0.01)	(a) Chlordane, gamma (0.01)	(a) Chlorfenapyr (0.01)	(a) Chlorfenvinphos (0.01)
(a) Chlorothalonil (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chlorthal-dimethyl (0.01)	(a) Cyanophos (0.02)	(a) Cyfluthrin (0.02)	(a) Cyhalothrin lambda- (0.01)
(a) Cypermethrin (0.02)	(a) DDD, o,p'- (0.01)	(a) DDD, p,p'- (0.01)	(a) DDE, o,p'- (0.01)	(a) DDE, p,p'- (0.01)	(a) DDT (Sum) ()
(a) DDT, o,p'- (0.01)	(a) DDT, p,p'- (0.01)	(a) Deltamethrin (0.02)	(a) Dichlofluanid (0.01)	(a) Dicloran (0.01)	(a) Dichlorvos (0.01)
(a) Dicofol (Sum) ()	(a) Dicofol, o,p'- (0.01)	(a) Dicofol, p,p'- (0.01)	(a) Dieldrin (0.01)	(a) Dieldrin (Sum) ()	(a) Diphenylamine (0.01)
(a) Endosulfan (Sum) ()	(a) Endosulfan, alpha- (0.01)	(a) Endosulfan, beta- (0.01)	(a) Endosulfan, sulfat- (0.01)	(a) Endrin (0.01)	(a) EPN (0.01)
(a) Ethion (0.01)	(a) Etrimfos (0.01)	(a) Famoxadone (0.01)	(a) Fenamiphos (0.01)	(a) Fenitrothion (0.01)	(a) Fenpropathrin (0.01)
(a) Fenthion (0.01)	(a) Fenvalerate & Esfenvalerate (Sum of RS&SR Isomers) (0.01)	(a) Fenvalerate & Esfenvalerate(sum of RR,SS,RS,SR) ()	(a) Fenvalerate & Esfenvalerate(Sum of RR&SS Isomers) (0.01)	(a) Flucythrinate (0.01)	(a) Fluvalinate-tau (0.01)
(a) Folpet (0.01)	(a) Folpet/PI (Sum calculated as Folpet) ()	(a) Fonofos (0.01)	(a) HCB (0.01)	(a) HCH (Sum, without Lindan) ()	(a) HCH gamma(Lindan) (0.01)
(a) HCH, alpha- (0.01)	(a) HCH, beta- (0.01)	(a) HCH, delta- (0.01)	(a) HCH, epsilon- (0.01)	(a) Heptachlor (0.01)	(a) Heptachlor (Sum) ()
(a) Heptenophos (0.01)	(a) Iprobenfos (0.01)	(a) Isazofos (0.01)	(a) Isocarbophos (0.01)	(a) Isofenphos (0.01)	(a) Isofenphos-methyl (0.01)
(a) Isoprothiolane (0.01)	(a) Kresoxim-methyl (0.01)	(a) Malaoxon (0.01)	(a) Malathion (Sum) ()	(a) Methidathion (0.01)	(a) Methoxychlor (0.01)
(a) Mevinphos (0.01)	(a) Mirex (0.01)	(a) Nitrothal-isopropyl (0.01)	(a) Octachlorodipropyl ether (S-421) (0.01)	(a) Paclobutrazol (0.01)	(a) Parathion (0.02)
(a) Parathion-methyl (0.02)	(a) Parathion-methyl (Sum) ()	(a) Permethrin (0.01)	(a) Phenthoate (0.01)	(a) Phorate (0.01)	(a) Phorate (Sum) ()
(a) Phthalimid (PI) (0.01)	(a) Pirimiphos-ethyl (0.01)	(a) Procymidone (0.01)	(a) Profenofos (0.01)	(a) Prometryn (0.01)	(a) Propanil (0.01)
(a) Pyrazophos (0.01)	(a) Pyridaphenthion (0.01)	(a) Pyrifenox (0.01)	(a) Pyrimethanil (0.01)	(a) Quinalphos (0.01)	(a) Quintozene (0.01)
(a) Quintozene (Sum) ()	(a) Tebufenpyrad (0.01)	(a) Tecnazene (0.01)	(a) Tefluthrin (0.01)	(a) Terbufos (0.01)	(a) Tetrachlorvinphos (0.01)
(a) Tetradifon (0.01)	(a) Tetrahydrophthalimide (THPI) (0.01)	(a) Tolylfluanid (0.01)	(a) Triazophos (0.01)	(a) Vinclozolin (0.01)	

SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) 2,4-D (0.01)	(a) 2,4-D, total (0.01)	(a) Abamectin (Sum) ()	(a) Acephate (0.01)	(a) Acetamiprid (0.01)	(a) Alachlor (0.01)
(a) Aldicarb (0.01)	(a) Aldicarb (Sum) ()	(a) Aldicarb-sulfone (0.01)	(a) Aldicarb-sulfoxide (0.01)	(a) Amitraz (0.01)	(a) Avermectin B1a (0.01)
(a) Avermectin B1b (0.01)	(a) Azinphos-methyl (0.01)	(a) Azoxystrobin (0.01)	(a) Benalaxyl (0.01)	(a) Bendiocarb (0.01)	(a) Benoxacor (0.01)
(a) Bensulfuron methyl (0.01)	(a) Bentazone (0.01)	(a) Bitertanol (0.01)	(a) Boscalid (0.01)	(a) Bupirimate (0.01)	(a) Buprofezin (0.01)
(a) Carbaryl (0.01)	(a) Carbendazim/Benomyl (sum) (0.005)	(a) Carbofuran (0.01)	(a) Carbofuran (Sum) ()	(a) Carbosulfan (0.01)	(a) Carfentrazone-ethyl (0.01)

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SU355 Pesticides Quechers 100 parameters (LOQ* mg/kg)

(a) Chlorantraniliprole (0.01)	(a) Chlorobenzuron (0.01)	(a) Chlorpyrifos (-ethyl) (0.01)	(a) Chlorpyrifos-methyl (0.01)	(a) Chromafenoziod (0.01)	(a) Clethodim (0.01)
(a) Clofentazine (0.01)	(a) Clothianidin (0.002)	(a) Cymoxanil (0.01)	(a) Cyproconazole (0.01)	(a) Cyromazine (0.01)	(a) Demeton-S-methyl (0.01)
(a) Demeton-S-methyl-sulfone (0.01)	(a) Diazinon (0.01)	(a) Diethofencarb (0.01)	(a) Difenoconazole (0.01)	(a) Diflubenzuron (0.01)	(a) Diflufenican (0.01)
(a) Dimethoate (0.01)	(a) Dimethoate/Omethoate (sum) ()	(a) Dimethomorph (0.01)	(a) Diniconazole (0.01)	(a) Dinotefuran (0.01)	(a) Epoxiconazole (0.01)
(a) Etofenprox (0.01)	(a) Ethoprophos (0.01)	(a) Ethoxyquin (0.01)	(a) Fenarimol (0.01)	(a) Fenazaquin (0.01)	(a) Fenhexamid (0.01)
(a) Fenobucarb (0.01)	(a) Fipronil (0.002)	(a) Fipronil (sum) ()	(a) Fipronil-sulfide (0.002)	(a) Fipronil-sulfone (0.002)	(a) Fluazifop-P-butyl (0.01)
(a) Fludioxonil (0.01)	(a) Flusilazole (0.01)	(a) Formetanate (0.01)	(a) Hexaconazole (0.01)	(a) Hexythiazox (0.01)	(a) Imazalil (0.01)
(a) Imidacloprid (0.01)	(a) Indoxacarb (0.01)	(a) Iprodione (0.01)	(a) Iprovalicarb (0.01)	(a) Isoprocarb (0.01)	(a) Linuron (0.01)
(a) Malathion (0.01)	(a) Metalaxyl (0.01)	(a) Methamidophos (0.01)	(a) Methidathion (0.01)	(a) Methomyl (0.01)	(a) Metolachlor (0.01)
(a) Monocrotophos (0.01)	(a) Myclobutanil (0.01)	(a) Napropamide (0.01)	(a) Neburon (0.01)	(a) Omethoate (0.01)	(a) Oxadixyl (0.01)
(a) Oxydemeton-methyl (0.01)	(a) Oxydemeton-methyl (sum) ()	(a) Penconazole (0.01)	(a) Pendimethalin (0.01)	(a) Phorate (Sum) ()	(a) Phorate Sulfoxide (0.01)
(a) Phorate-sulfone (0.01)	(a) Phosalone (0.01)	(a) Phosmet (0.01)	(a) Phoxim (0.01)	(a) Piperonyl butoxide (0.01)	(a) Pirimicarb (0.01)
(a) Pirimiphos-methyl (0.01)	(a) Prochloraz (0.01)	(a) Procymidone (0.01)	(a) Propamocarb (0.01)	(a) Propargite (0.01)	(a) Propham (0.01)
(a) Propiconazole (0.01)	(a) Propoxur (0.01)	(a) Propyzamide (0.01)	(a) Pyrethrins (0.01)	(a) Pyridaben (0.01)	(a) Pyrimethanil (0.01)
(a) Quinoxyfen (0.01)	(a) Simazine (0.01)	(a) Spiromesifen (0.01)	(a) Tebuconazole (0.01)	(a) Tebufenozide (0.01)	(a) Tetraconazole (0.01)
(a) Thiabendazole (0.01)	(a) Thiacloprid (0.01)	(a) Thiamethoxam (0.01)	(a) Thiophanate-methyl (0.01)	(a) Tolclofos-methyl (0.01)	(a) Triadimenol (0.01)
(a) Trichlorfon (0.01)	(a) Tridemorph (0.01)	(a) Triflumizol/FM-6-1 (Sum) ()	(a) Triflumizole (0.01)	(a) Zoxamide (0.01)	

SIGNATURE

(b) (6)

Shine Xie
Food Chemistry Manager

EXPLANATORY NOTE

≥ Greater than or equal to
< Less than
≤ Less than or equal to
N/A means Not applicable

☆ means the test is subcontracted within Eurofins group
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TOXICOLOGY STUDY REPORT

Part A

Title of Study	Oral Acute Toxicity Study of Luo Han Guo Extract in Rats
Study Number	A2017-T012
Entrustment Company	Huan Huacheng Biotech, Inc
Address of Entrustment Company	No. 188, Tongzi'po West. Rd., Changsha, China
Contact Person	Jun Huang
Contact Tel. and E-mail	86-18907956933;qm@huachengbio.com
Primary Test Facility	School of Life Sciences, Yantai University
Address of Research Institute	30, Qingquan RD, Laishan District, Yantai, China
Contact Person	Yonglin Gao (b) (6)
Contact Tel. and E-mail	86-15854569558; gylbill@163.com;gaoyonglin@ytu.edu.cn.
Study Director	Yonglin Gao
Study Participants	YonglinGao *Operator* Yunzhi Wang *Test products management* Yiran Wang *Animal management*
Study Start and End Dates	October 2017 –November 2017

Table of Content

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Oral Acute Toxicity Study of Luo Han Guo Extract in Rats

ABSTRACT

The aim of this study was to evaluate the acute toxicity of Luo Han Guo Extract (10 brix and 65 brix) after a single oral administration in rats. Test substances were administered to young rats by oral gavage at a single dose of 0, 15 g/kg body weight (BW) 10 brix, 25 g/kg BW 10 brix, 15 g/kg BW 65 brix, and 25 g/kg BW 65 brix (5 males and 5 females per group). Animals were observed for 14 days to monitor changes in body weight and clinical signs, as well as food and water consumption. At the end of the study, animals were sacrificed and major organs were examined macroscopically and microscopically. No animal died during the 14-day observation period and no clinical signs of abnormality were observed at any dose level. Furthermore, no significant differences in mean body weight, food consumption and water intake, and organ weights were found among the four test and control groups. No treatment-related abnormalities were observed in macroscopic examinations. In summary, the present study found that the lethal dose (LD_{50}) of 10 brix and 65 brix was far above 25 g/kg BW, the highest dose tested. According to the acute toxicity classification (World Health Organization), Luo Han Guo Extract (10 brix and 65 brix) was relatively non-toxic.

Key words: Luo Han Guo Extract; 10 brix; 65 brix; Acute Toxicity Study; Rat

1. Study design

The study was performed in accordance with the Food and Drug Administration (FDA) Redbook 2000: chapter IV.C.3.a Short-Term Toxicity Studies with Rodents. Luo Han Guo Extract (10 brix and 65 brix) was administered by oral gavage to rats (0, 15 g/kg BW 10 brix, 25 g/kg BW 10 brix, 15 g/kg BW 65 brix, and 25 g/kg BW 65 brix; 5 males and 5 females for each group) and observed for 2 weeks. Clinical signs, body weight, food and water consumption, and death rates were observed. On day 15, all surviving animals were sacrificed and organs were weighed, including brain, lung, heart, kidney, liver, and spleen. The study was performed in accordance with Good Laboratory Practices (GLP) regulations.

2. Animals

Sprague-Dawley rats, 7 weeks of age, were housed in cages under hygienic conditions and placed in a controlled environment with a 12-h light/dark cycle at 23±3 °C and 40-60% humidity. Animals were allowed a commercial standard rat cube diet and water *ad libitum*. All procedures involving the use of laboratory animals were in accordance with the Guidelines of the Animal Care.

3. Treatment

Rats were divided into five groups (each group of 10 rats consisted of 5 male and 5 female rats) based on stratified randomization by using body weights taken before treatment: control (purified water), 15 g/kg BW 10 brix, 25 g/kg BW 10 brix, 15 g/kg BW 65 brix, and 25 g/kg BW 65 brix (a single orally administered dose by gavage). Group assignments are outlined in Table 1.

Table 1. Experimental design of a 14-day rat acute toxicity study.

Groups	Test substance (g/kg BW)	Number of animals
1	0 (Control)	**10（♀:5+♂:5）**
2	25 g/kg BW 10 brix	**10（♀:5+♂:5）**
3	15 g/kg BW 10 brix	**10（♀:5+♂:5）**
4	25 g/kg BW 65 brix	**10（♀:5+♂:5）**
5	15 g/kg BW 65 brix	**10（♀:5+♂:5）**

Abbreviations: BW =Body weight.

4. Observations and clinical tests

All animals were observed twice daily for clinical signs of toxicity, mortality, and morbidity. The body weight of each rat was measured pre-test, weekly thereafter, and at sacrifice. Food consumption and water intake also were noted.

5. Organ weights, gross necropsy, and histopathological examination

At the end of treatment, all surviving animals were fasted overnight. The body weight and the main organ weights (including liver, kidneys, spleen, heart, brain, and lung) were measured. Moreover, the coefficient was reported as the organ weight/body weight ratio. These tissues were examined, with gross lesions examined microscopically. If treatment-related effects were noted in certain tissues, they were examined microscopically.

6. Statistical analysis

We used SPSS 11.5 software for Windows to perform all analyses. One-way ANOVA with Dunnet's post-hoc test was used to compare treatment and control group data. A P-value less than 0.05 was considered statistically significant.

7. Results

7.1 General clinical signs and mortality

Rats from all dose groups survived to the end of the experiment and appeared healthy throughout the study periods. No obvious abnormal clinical signs (i.e., changes in skin color, eyes, mucous membranes, or behavior patterns; loss of fur or scabbing) were observed in any of 10 brix and 65 brix groups. As shown in Tables 2,3 and Figures 1,2, there were no significant treatment-related changes in body weight for male and female rats in test substance treated groups compared with the control group.

7.2 Feed consumption and water intake

In the experiment, feed consumption or water intake were studied in rats during a 14-day study. The results showed that all data were within historic controls obtained in our facility, and there were also no significant differences in water intake (Tables 4,5; Figures 3,4) or feed consumption (Tables 6,7; Figures 5,6) between 10 brix, 65 brix, and control group.

7.3 The organ/body weight ratio (the organ coefficient)

The organ/body weight ratios (the organ coefficient) are shown in Tables 8,9 and Figures 7,8. No consistent, statistically significant, or dose-dependent, adverse effects were observed

in all groups. On macroscopic examination, there are no treatment-related effects were noted in these tissues.

8. Conclusion

Under our test conditions, the present study found that the lethal dose (LD_{50}) of 10 brix and 65 brix was far above 25 g/kg BW, the highest dose tested. According to the acute toxicity classification (World Health Organization), Luo Han Guo Extract (10 brix and 65 brix) was relatively non-toxic.

Table 2. Body weight change of female rats during a 14-day study (g)

Groups	Test substance (g/kg BW)	Before	1st week	2nd week
1	0 (Control)	137.80±7.53	169.60±14.77	192.20±14.70
2	25 g/kg BW 10 brix	137.40±6.73	172.80±10.52	195.40±17.52
3	15 g/kg BW 10 brix	136.40±9.56	173.60±10.31	192.60±21.55
4	25 g/kg BW 65 brix	137.80±6.69	169.40±6.58	194.20±14.22
5	15 g/kg BW 65 brix	139.80±8.64	175.20±14.65	195.20±19.28

Abbreviations: BW =Body weight.

Table 3. Body weight change of male rats during a 14-day study (g)

Groups	Test substance (g/kg BW)	Before	1st week	2nd week
1	0 (Control)	150.60±10.69	198.80±14.96	243.40±11.10
2	25 g/kg BW 10 brix	150.60±11.46	198.60±15.47	240.00±17.03
3	15 g/kg BW 10 brix	154.80±6.30	204.00±11.81	238.60±11.30
4	25 g/kg BW 65 brix	153.60±7.33	214.00±10.98	243.00±20.62
5	15 g/kg BW 65 brix	154.40±8.17	213.80±10.43	242.00±16.48

Abbreviations: BW =Body weight.

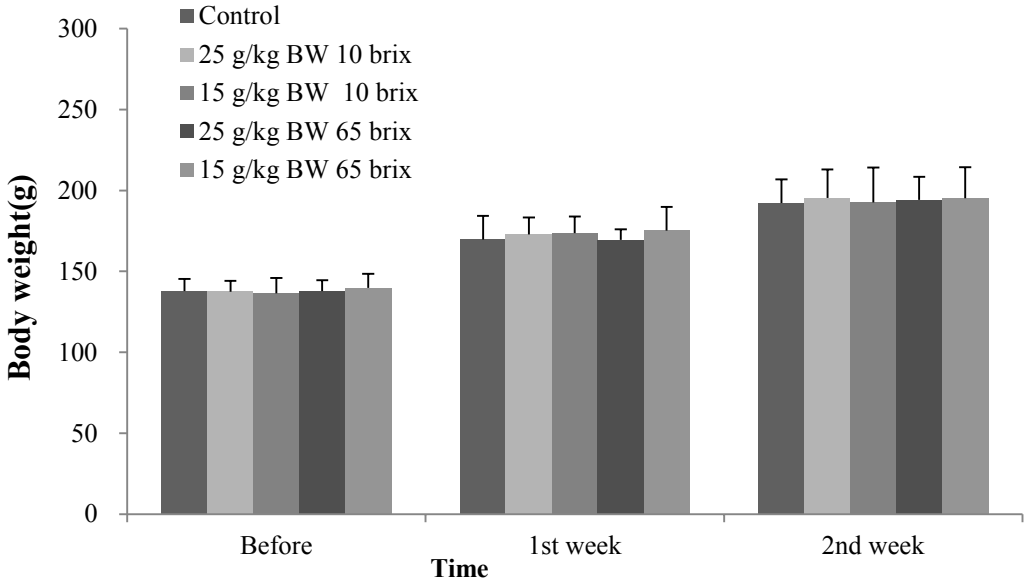

Figure 1. Body weight change of female rats during a 14-day study

Abbreviations: BW =Body weight.

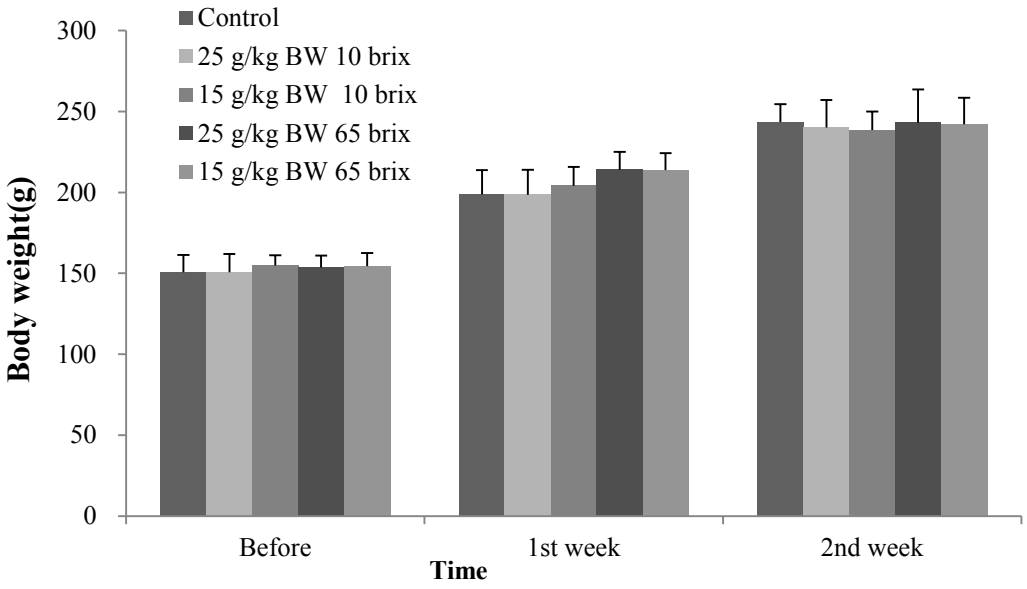

Figure 2. Body weight change of male rats during a 14-day study

Abbreviations: BW =Body weight.

Table 4. Water intake of female rats during a 14-day study (mL/100 g BW/day)

Groups	Test substance (g/kg BW)	1st week	2nd week
1	0 (Control)	14.27±2.22	13.68±2.03
2	25 g/kg BW 10 brix	13.02±2.78	12.80±1.50
3	15 g/kg BW 10 brix	14.19±3.05	13.24±2.84
4	25 g/kg BW 65 brix	13.76±2.26	13.43±2.47
5	15 g/kg BW 65 brix	14.62±2.60	13.27±2.24

Abbreviations: BW =Body weight.

Table 5. Water intake of male rats during a 14-day study (mL/100 g BW/day)

Groups	Test substance (g/kg BW)	1st week	2nd week
1	0 (Control)	11.50±2.14	10.66±1.02
2	25 g/kg BW 10 brix	12.04±2.75	9.55±2.77
3	15 g/kg BW 10 brix	11.59±1.87	10.73±2.00
4	25 g/kg BW 65 brix	10.59±2.64	11.17±1.42
5	15 g/kg BW 65 brix	11.62±1.74	10.70±1.53

Abbreviations: BW =Body weight.

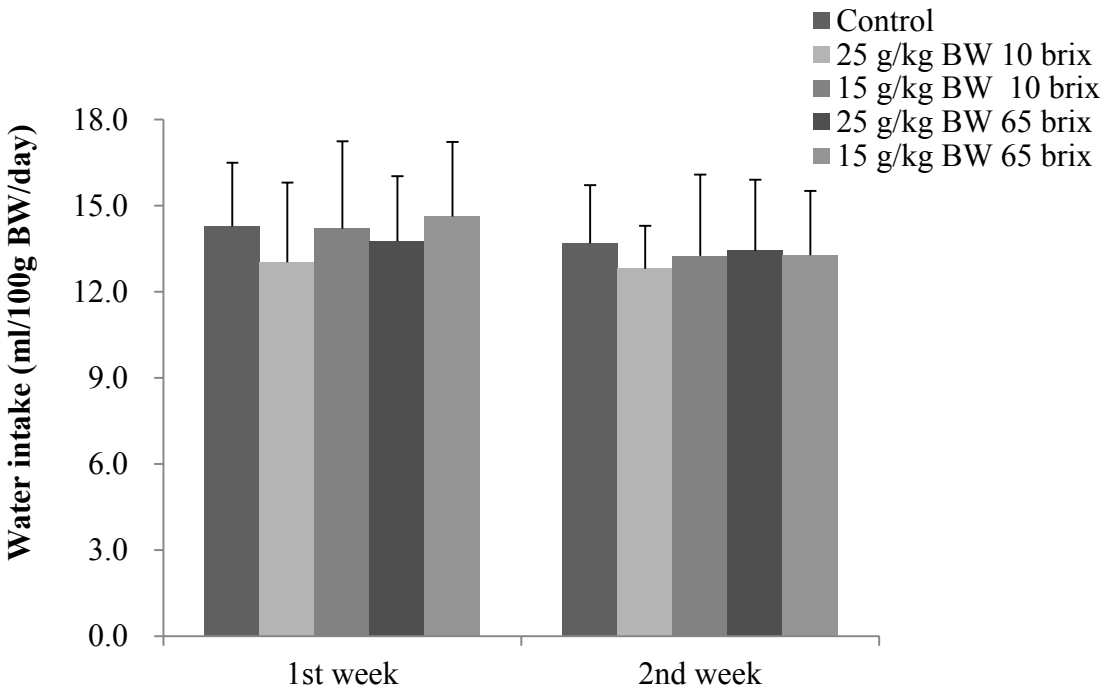

Figure 3. Water intake of female rats during a 14-day study

Abbreviations: BW =Body weight.

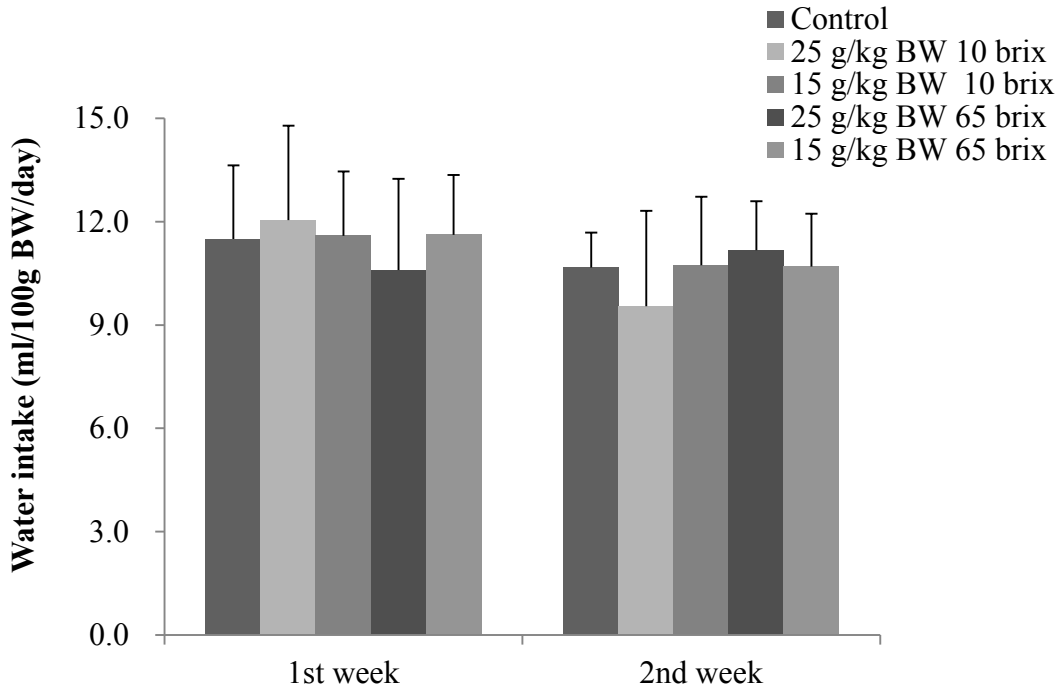

Figure 4. Water intake of male rats during a 14-day study

Abbreviations: BW =Body weight.

Table 6. Food consumption of female rats during a 14-day study (g/100 g BW/day)

Groups	Test substance (g/kg BW)	1st week	2nd week
1	0 (Control)	10.15±0.97	9.95±1.44
2	25 g/kg BW 10 brix	9.92±1.08	10.44±1.50
3	15 g/kg BW 10 brix	10.62±1.83	10.29±2.05
4	25 g/kg BW 65 brix	10.27±1.42	10.42±2.13
5	15 g/kg BW 65 brix	9.65±1.32	10.06±0.76

Abbreviations: BW =Body weight.

Table 7. Food consumption of male rats during a 14-day study (g/100 g BW/day)

Groups	Test substance (g/kg BW)	1st week	2nd week
1	0 (Control)	10.38±1.26	11.50±1.61
2	25 g/kg BW 10 brix	10.36±2.04	11.29±1.19
3	15 g/kg BW 10 brix	10.26±2.12	10.87±1.19
4	25 g/kg BW 65 brix	11.05±1.94	11.04±1.86
5	15 g/kg BW 65 brix	11.06±1.17	11.15±1.69

Abbreviations: BW =Body weight.

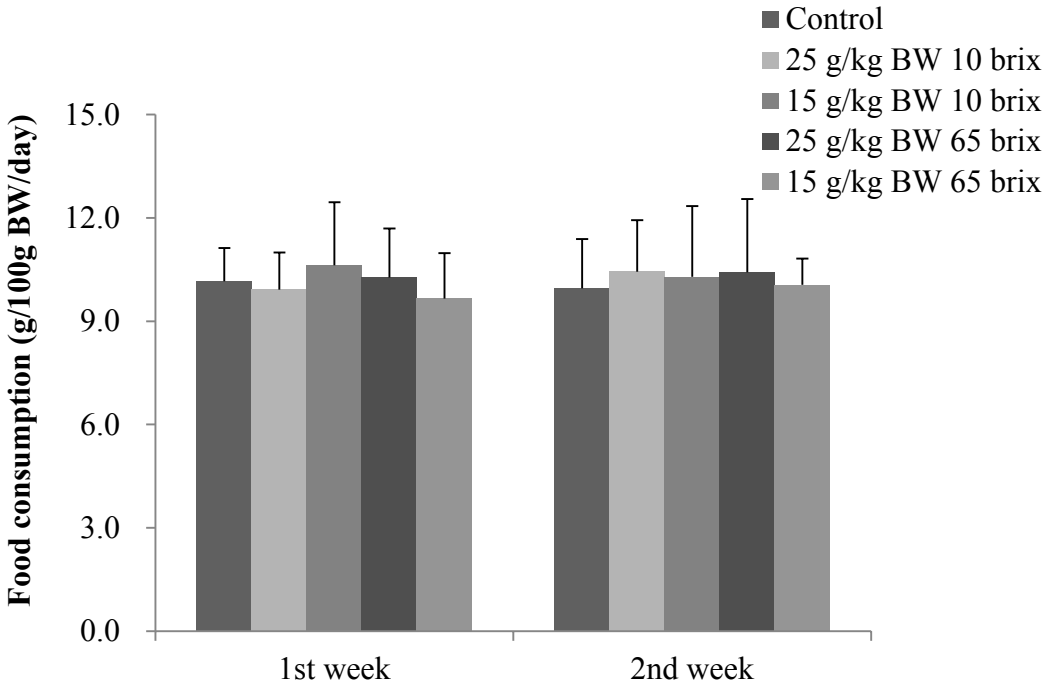

Figure 5. Food consumption of female rats during a 14-day study

Abbreviations: BW =Body weight.

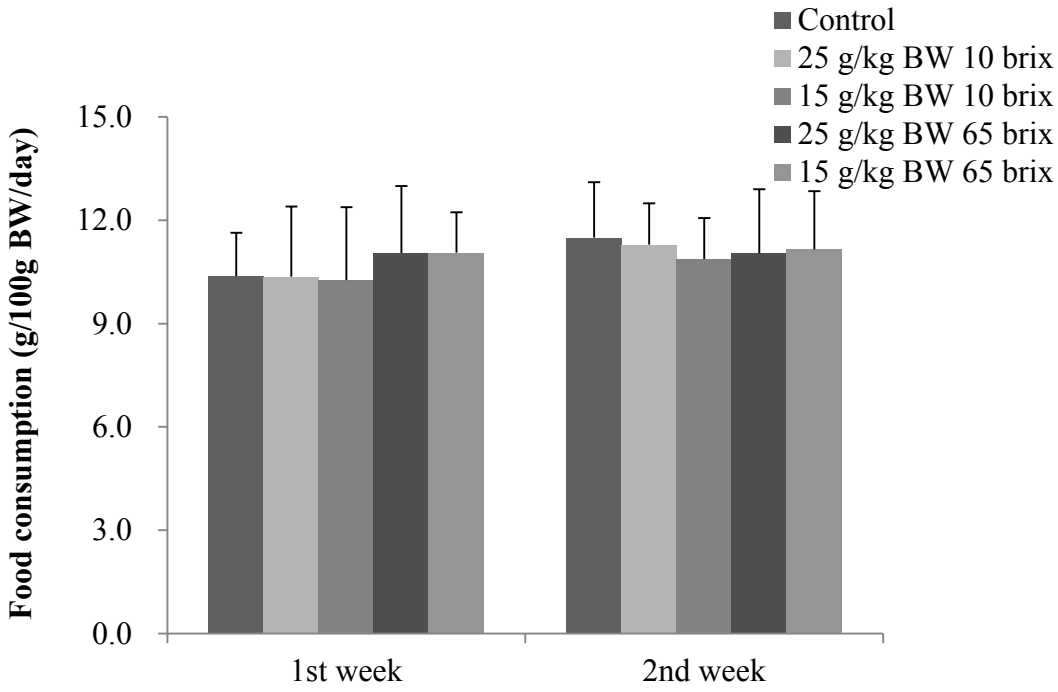

Figure 6. Food consumption of male rats during a 14-day study

Abbreviations: BW =Body weight.

Table 8. The organ coefficient of female rats after a 14-day study (% BW).

Test substance	0	25 g/kg BW 10 brix	15 g/kg BW 10 brix	25 g/kg BW 65 brix	15 g/kg BW 65 brix
Heart	0.38±0.09	0.37±0.08	0.36±0.05	0.42±0.09	0.39±0.06
Liver	3.78±0.33	3.62±0.57	3.81±0.68	3.74±0.59	4.11±0.91
Spleen	0.28±0.05	0.31±0.05	0.29±0.06	0.26±0.05	0.28±0.08
Lung	0.46±0.06	0.43±0.08	0.53±0.11	0.51±0.21	0.43±0.09
Kidney	0.66±0.11	0.64±0.10	0.68±0.11	0.70±0.11	0.64±0.11
Brain	0.76±0.14	0.83±0.13	0.76±0.17	0.82±0.06	0.78±0.14

Abbreviations: BW =Body weight.

Table 9. The organ coefficient of male rats after a 14-day study (% BW).

Test substance	0	25 g/kg BW 10 brix	15 g/kg BW 10 brix	25 g/kg BW 65 brix	15 g/kg BW 65 brix
Heart	0.48±0.08	0.50±0.08	0.48±0.07	0.50±0.11	0.46±0.06
Liver	3.95±0.31	3.97±0.45	3.96±0.37	3.85±0.36	4.05±0.49
Spleen	0.32±0.03	0.36±0.04	0.36±0.04	0.36±0.05	0.37±0.06
Lung	0.49±0.12	0.51±0.09	0.51±0.06	0.54±0.13	0.51±0.08
Kidney	0.68±0.04	0.64±0.07	0.60±0.06	0.65±0.09	0.61±0.07
Brain	0.77±0.07	0.79±0.06	0.76±0.09	0.74±0.06	0.76±0.08

Abbreviations: BW =Body weight.

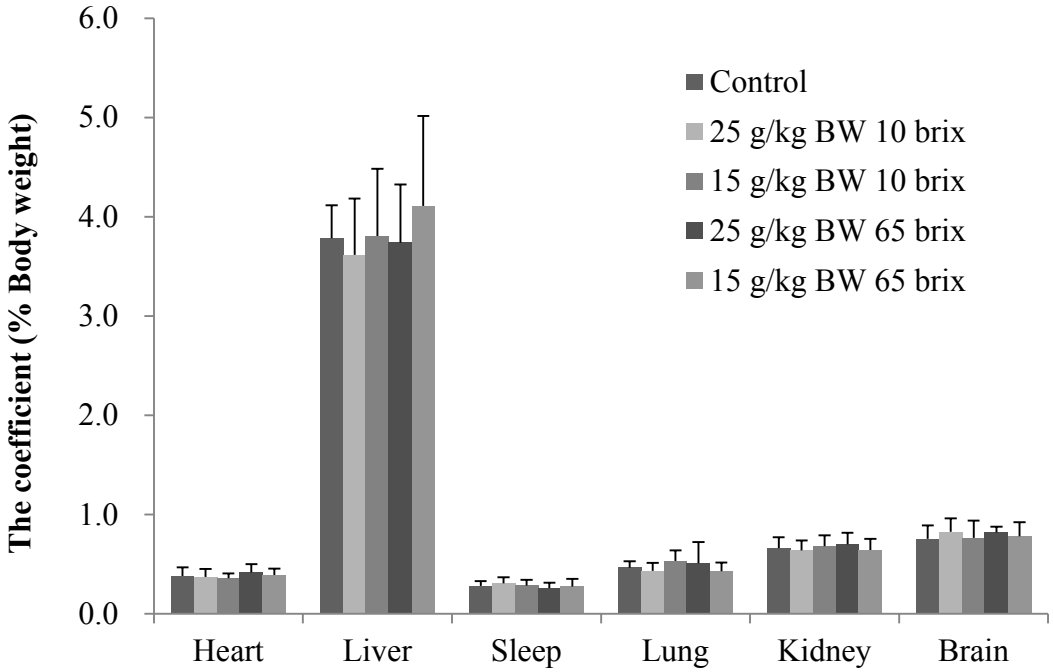

Figure 7. The organ coefficient of female rats after a 14-day study

Abbreviations: BW =Body weight.

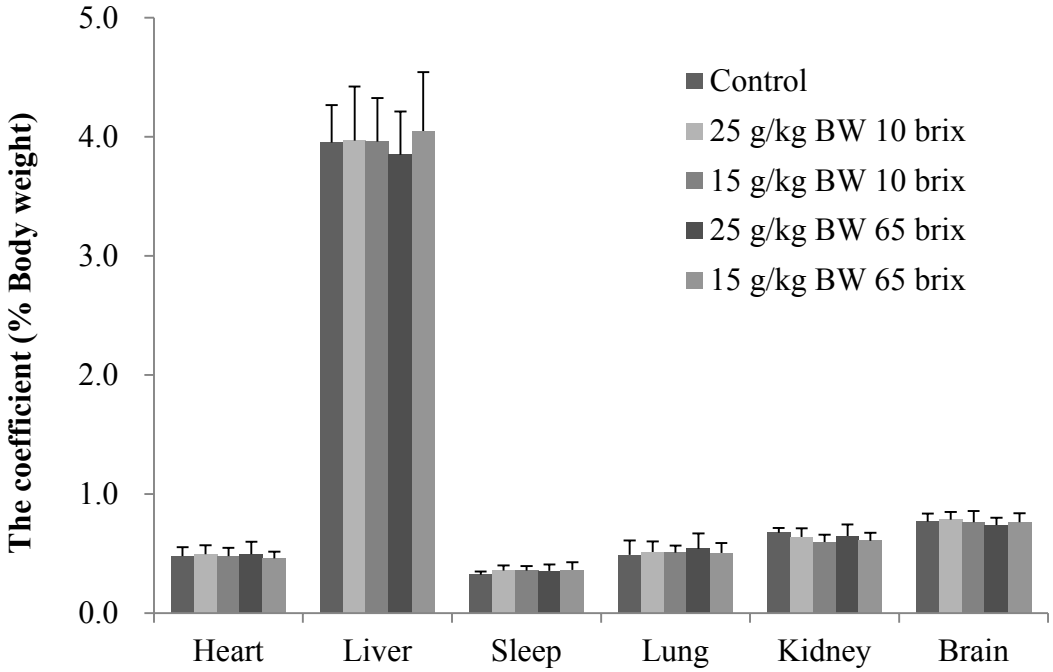

Figure 8. The organ coefficient of male rats after a 14-day study

Abbreviations: BW =Body weight.

Part B

Title of Study	Mutagenicity study of Luo Han Guo Extract
Study Number	A2017-T013
Entrustment Company	Huan Huacheng Biotech, Inc
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Study Director	Yonglin Gao
Study Participants	YonglinGao *Operator* Meina, Bing Han *Test products management* Yiran Wang, Yudong Lv *Animal management*
Study Start and End Dates	October 2017 –November 2017

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Mutagenicity study of Luo Han Guo Extract

ABSTRACT

As part of a safety evaluation, we evaluated the potential mutagenicity of Luo Han Guo Extract (10 brix and 65 brix) using a bacterial reverse mutation assay. In a reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), Luo Han Guo Extract (10 brix and 65 brix) at doses of 5,000, 2,500, 1250 μg/plate, respectively, did not increase the number of revertant colonies in any tester strains regardless of metabolic activation by S9 mix. The data indicated that 10 brix and 65 brix were non-mutagenic under the conditions used in this test.

Keywords: Luo Han Guo Extract; 10 brix; 65 brix; Bacterial reverse mutation assay

2. Study design

As part of a safety evaluation, we evaluated the potential mutagenicity of Luo Han Guo Extract (10 brix and 65 brix) using a bacterial reverse mutation assay. The study was performed in accordance with Good Laboratory Practices (GLP) regulations.

3. Materials and methods

Five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535) were treatment with the plate incorporation method. We selected test concentrations based on a preliminary study, and the results indicated that 10 brix and 65 brix did not show any antibacterial activity up to 5,000 μg/plate. TA97, TA98, TA100, TA102, and TA1535 were treated with 10 brix and 65 brix at concentrations of 0 (solvent control), 5,000, 2,500, and 1,250 μg/plate in the presence and absence of an exogenous metabolic activation system (S9) by the plate incorporation method. We prepared triplicate plates for each concentration.

4-Nitro-o-phenylenediamine (NPD), daunomycin (DAM), sodium azide (NaN_3), and methyl methanesulfonate (MMS) were used as positive controls in conditions without S9 mix, and 2-aminofluorene (2-AF), 1,8-Dihydroxyanthraquinone (1,8-DT), and 2-aminoanthracene (2-AA) were used as positive controls in conditions with S9 mix. All plates were incubated at 37 °C for 72 h, and the number of revertant colonies was counted.

We declared the test substance mutagenic if the number of revertant colonies in the test dose levels was more than twofold that in the control, or the number of revertant colonies increased in a dose-dependent manner compared to control in at least one strain with or without the metabolic activation system. The validity of the study was confirmed by more than twofold increases in the number of revertant colonies in positive control plates compared to the control.

3. Statistical analysis

We used SPSS 11.5 software for Windows to perform all analyses. One-way ANOVA with Dunnet's post-hoc test was used to compare treatment and control group data. A P-value less than 0.05 was considered statistically significant.

4. Results

The mutagenicity of 10 brix and 65 brix in bacteria was evaluated up to a maximum dose

of 5,000 μg/plate using the plate incorporation method (Tables 1, 2). We found no increases in revertant frequencies at any test article doses in any of the tester strains with or without S9 compared to those in the vehicle control cultures. The positive control chemicals for each tester strain induced obvious increases in the number of revertant colonies compared to the vehicle control. The data indicated that 10 brix and 65 brix were non-mutagenic under the conditions used in this test.

Table 1 Bacterial mutation assay results (- S9) [a]

Group	Dose (μg/plate)	Mean revertant colony counts per plate				
		TA97	TA98	TA100	TA102	TA1535
Vehicle control	—	141.5±11.7	29.6±3.3	140.5±4.1	236.6±13.9	15.9±3.4
10 brix	5000	166.8±9.4	36.3±4.4	154.5±6.6	232.9±14.8	15.7±3.7
	2500	132.0±13.4	26.7±5.4	126.3±14.2	292.3±23.7	13.3±4.1
	1250	150.6±15.9	33.2±7.2	138.8±17.0	244.4±30.6	17.5±4.9
65 brix	5000	152.8±18.4	24.1±5.4	157.8±12.1	252.2±42.1	19.1±3.4
	2500	144.2±10.1	22.9±5.1	135.6±12.8	211.4±8.0	18.6±5.5
	1250	163.6±14.7	23.5±3.4	129.9±18.8	254.4±29.8	12.8±3.6
NPD	20	812.9±29.5**	—	—	—	—
DAM	10	—	278.7±41.1**	—	—	—
NaN_3	1.5	—	—	537.6±59.9**	—	198.8±41.8**
MMS	2	—	—	—	911.8±87.9**	—

Abbreviations: NPD =4-Nitro-o-phenylenediamine; DAM = daunomycin; NaN_3 = sodium azide; MMS = methyl methanesulfonate.

[a] Values are the mean of triplicate plates.

** $P<0.01$, compared with vehicle control.

Table 2 Bacterial mutation assay results (+ S9) [a]

Group	Dose (μg/plate)	Mean revertant colony counts per plate				
		TA97	TA98	TA100	TA102	TA1535
Vehicle control	—	144.8±15.3	34.1±1.3	169.1±9.2	314.5±16.9	16.2±4.1
10 brix	5000	110.5±6.81	41.6±18.5	177.7±18.3	374.0±24.4	17.4±3.4
	2500	121.0±32.5	34.2±8.2	169.5±11.5	348.4±55.5	13.5±4.3
	1250	133.6±21.8	40.8±6.6	182.3±17.6	322.4±43.9	16.9±5.7
65 brix	5000	156.8±7.1	45.3±8.8	168.5±23.3	289.7±27.6	20.2±5.6
	2500	166.3±7.8	33.5±1.9	180.1±9.2	308.1±12.5	19.5±6.7
	1250	154.4±8.3	39.8±4.7	160.8±15.4	288.3±14.8	17.3±2.5
2-AF	20	577.7±51.5**	389.6±23.8**	667.8±49.3**	—	—
1,8-DT	50	—	—	—	989.3±77.1**	—
2-AA	5	—	—	—	—	189.5±31.7**

Abbreviations: 2-AF = 2-aminofluorene; 1,8-DT = 1,8-Dihydroxyanthraquinone; 2-AA = 2-aminoanthracene.

[a] Values are the mean of triplicate plates.

** $P<0.01$, compared with vehicle control.

5. Conclusion

Under our test conditions, a reverse mutation assay using five strains of *Salmonella typhimurium* (TA97, TA98, TA100, TA102, and TA1535), 10 brix and 65 brix (5,000, 2,500, 1,250 μg/plate, respectively) did not increase the number of revertant colonies in any tester strains regardless of metabolic activation by S9 mix. The data indicated that 10 brix and 65 brix were non-mutagenic under the conditions used in this test.