

GRN 706

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

Prepared for Hunan Nutramax Inc.

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PART 1. SIGNED STATEMENTS AND A CERTIFICATION

Pursuant to 21 CFR Part 170, subpart E, Hunan Nutramax Inc. (hereinafter referred to as 'Nutramax') submits a Generally Recognized as Safe (GRAS) notice and claims that the use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract in foods, 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

Contact person: Zhang BaoTang

Company name: Hunan Nutramax Inc.

Address: Baiyashi Industrial District, Dong'an, Yongzhou City, Hunan Province 425900
China

Telephone number: +86 731 82939656

E-mail address: sales@nutra-max.com

1.B. Common or Trade Name

Luo Han Guo fruit extracts, Monk fruit extract, or *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts

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

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

Siraitia grosvenorii Swingle (Luo Han Guo) fruit extracts are intended for use as a sugar substitute in various foods.

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

The substance will be used as a sugar substitute in the same foods at levels proportional to those specified in GRNs 301, 359, 522, and 556. The quantity of consumption of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract is self-limiting due to the off taste that occurs with increasing quantity, similar to other natural high intensity sweeteners (such as stevia products) and would be limited in the consumer acceptance of products when added as a sugar substitute.

1.C.3. Purpose for Which the Substance will be Used

The substance will be used as a sugar substitute (a table-top sweetener and a general purpose non-nutritive sweetener).

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

The population expected to consume the substance consists of members of 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 that are the basis for this GRAS conclusion will be made available to FDA upon request by contacting Susan Cho at NutraSource, Inc. at the address above. The data and information will be made available to the 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

Privileged or confidential information such as trade secrets and/or commercial or financial information has been redacted from this document and the information contained in this dossier can be made publicly available if warranted. A separate dossier containing the redacted information can be made available to the FDA on request if warranted. 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

Nutramax certifies that, to the best of its knowledge, that this GRAS conclusion is based on a complete, representative, and balanced dossier that includes all relevant information, available and obtainable by Nutramax, including any favorable or unfavorable information and any data pertinent to the evaluation of the safety and GRAS status of the use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract. Nutramax accepts responsibility for the GRAS determination that has been made for *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts, as described in this dossier.

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

(b) (6)

Name:

Date: May 8, 2017

Title: C

Address correspondence to
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Agent for Nutramax, Ltd.
Susanscho1@yahoo.com

1.I. FSIS/USDA Statement

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

PART 2. IDENTITY, MANUFACTURING, SPECIFICATION, TECHNICAL EFFECTS

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

2.A.1. Identity Related Information of *S. grosvenorii* Swingle (Luo Han Guo) Extracts

Luo Han Guo fruit extracts or *S. grosvenorii* Swingle fruit extracts are mixtures of compounds naturally occurring in the Luo Han Guo fruit. The primary components are cucurbitane glycosides known as mogrosides (II-VI) that are responsible for imparting the characteristic sweet taste. In particular, mogroside V, the major sweetness component of the fruit. Mogroside V, has been found in whole fruits at concentrations of 0.8-1.3 % w/w (Lee, 1975; Makapugay et al., 1985; Pawar et al., 2013). 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.

This GRAS document discusses extract products containing 25 - 95% mogroside V.

2.A.1.1. Chemical Names of Main component

Mogroside V, mogro-3-O-[beta-D-glucopyranosyl(1-6)-beta-D-glucopyranoside]-24-O-[[beta-D-glucopyranosyl(1-2)]-[beta-D-glucopyranosyl (1-6)]-beta-D-glucopyranoside

2.A.1.2. Chemical Abstract Service (CAS) Registry Number

Since Luo Han Guo fruit extracts are mixtures of various components, no CAS Registry Number has been assigned to this substance. However, a main component responsible for sweetness Mogroside V has a CAS Registry Number of 88901-36-4.

Other mogrosides also have CAS numbers as follows:

Mogroside IV: CAS #89590-95-4 and

Mogroside VI: CAS #89590-98-7.

2.A.1.3. Molecular Formula

Mogroside V - C₆₀H₁₀₂O₂₉

2.A.1.4. Structural Formula

Figure 1 presents the chemical structure of mogroside V.

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

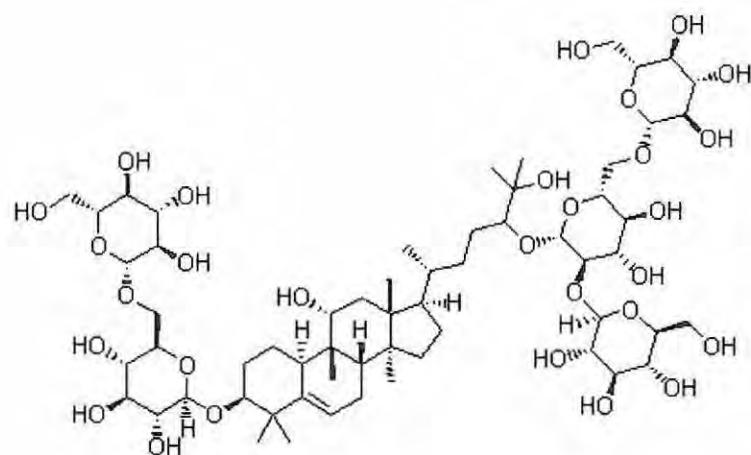


Figure 1. Chemical Structure of Mogroside V

2.A.1.5. Molecular Weight

Mogroside V has a molecular weight of 1287.43

2.A.1.6. Sweetness Intensity of Nutramax's Luo Han Guo Fruit Extract

This GRAS document discusses extract products containing 25 - 95% mogroside V. Table 1 shows the sweetness intensity of Luo Han Guo fruit extract products when tested against a water solution of 10% sucrose. It is commonly accepted that the sweetness intensity of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract is proportional to the concentration of mogrosides present in it. However, it also depends on the concentration of mogroside V in a particular concentrate. At high concentrations of mogrosides, there might be slight leveling off of sweetness.

Table 1. Sweetness Intensity of Nutramax's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract Relative to Sucrose

Product	Sweetness intensity
Luo Han Guo Fruit Extract MV 25	160
Luo Han Guo Fruit Extract MV 30	180
Luo Han Guo Fruit Extract MV 50	280
Luo Han Guo Fruit Extract MV 55	300
Luo Han Guo Fruit Extract MV 60	330
Luo Han Guo Fruit Extract MV 65	350
Luo Han Guo Fruit Extract MV 95	420

2.A.1.7. Typical composition of Nutramax's Luo Han Guo fruit extract

Table 2 presents typical compositional analysis of Nutramax's Luo Han Guo fruit extract

Table 2. Typical Compositional Analysis of Nutramax's Luo Han Guo Fruit Extract

Component, %	MV 25	MV 30	MV 50	MV 55	MV 60	MV 65	MV 95	FCC specifications
Mogroside V	≥25.0	≥30.0	≥40.0	≥50.0	≥55.0	≥60.0	≥95.0	≥30.0
Protein	42.2	35.8	11.3	6.9	5.5	5.4	0.28	NA
Ash	0.83	0.8	0.7	0.7	0.43	0.33	0.12	<5.0
Moisture	3.35	3.6	3.55	3.74	3.35	3.09	0.77	<6.0
Dietary Fiber	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	NA
Mono- and disaccharides	0.17	0.14	<0.1	<0.1	<0.1	<0.1	<0.1	NA
Total fat	0.22	0.25	0.25	0.34	0.37	0.39	0.13	NA
Maximum total carbohydrates	27.8	28.9	43.6	38.7	34.6	30.3	3.1	

MV=mogroside V; NA=not applicable; CHO=carbohydrates; Total carbohydrate content was calculated by the difference method and may include other mogrosides (Reference, GRN 301-page; GRN 556-page 7).

The literature indicates that the hydrolysis products of Luo Han Guo fruit contain 18 amino acids, including eight of the essential amino acids (Li et al., 2014). Among the 18 amino acids, the content of aspartic acid was the highest (900-1,125 mg/100 g in dried fruits), with that of *gamma*-aminobutyric acid the lowest (16-36 mg/100 g in dried fruits) (Li et al., 2014).

GRN 301 included data on the presence of ribosome inactivating proteins (RIP) in the seeds of *Momordica charantia* at an average concentration of 0.192%. They were not observed in *S. grosvenorii*. Tsang and Ng (2001) reported a homology of only 39% between momorcharins from *M. charantia* and momorgrosvin from *S. grosvenorii*. They concluded that these cucurbitanes are distinctly different, and also identified the RIP in *M. charantia* seeds as alpha- and beta-momorcharins (Tsang and Ng, 2001). In an analysis of acetone extracts of *S. grosvenorii* seeds, they identified a different RIP in powdered decoated seeds, which they termed momorgrosvin (0.00024%). This single-chained glycoprotein had a molecular weight of 27.7 kDa (type 1 RIP). Tsang and Ng (2001) noted that the seeds of *S. grosvenorii* are not normally included in the manufacture of Luo Han Guo fruit extract, and that acetone is not used in the extraction process.

Type 1 RIPs are widely distributed in the plant kingdom, occurring in the seeds of such important food crops as wheat, rye, and barley (GRN 301). Concentrations of RIP range from less than 1 to over 100 mg/100 g. GRN 301 noted that type 1 RIPs occur at relatively high concentrations in a large variety of widely consumed foods with no indication of adverse effects.

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They are present in the seeds of *S. grosvenorii* at small concentrations, and their activity would almost certainly be completely destroyed by the extraction process. Thus, it was concluded that the intended use of Luo Han Guo fruit extracts relative to these proteins raised no safety concerns.

It is noteworthy that none of the Luo Han Guo fruit extract components are known to be of health concern. A 90-day oral toxicity study in rats by Qin et al. (2006) assessed a 30% mogroside V product containing 7.8-14.1% of unidentified components. It found no toxicity at daily doses of up to 3% of the diet, the highest dose tested. A 28-day oral toxicity study by Marone et al. (2008) also evaluated a mogroside V product containing 35% of unidentified components. They reported that Luo Han Guo fruit extract was safe at daily doses of up to 10% of total daily dietary intake.

Luo Han Guo fruit juice concentrate without removal of impurities has received a “no questions” letter from the FDA (GRN 627, FDA, 2016).

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

Potential toxicants have not been identified. No pesticide residues (organochlorine and organophosphorus) have been detected in Nutramax’s Luo Han Guo fruit extracts. Details are presented in Appendix B.

2.A.3. Particle Size

NLT 95% pass 80 mesh.

2.B. Method of Manufacture

Figure 2 shows a picture of a Luo Han Guo plant with mature fruit. Nutramax’s Luo Han Guo fruit extract powders are manufactured in a process similar to those described in previous GRNs. However, the Nutramax’s manufacturing process adds more purification steps to produce highly purified products (Nutramax vs. Food Chemical Codex [FCC]: up to 95% mogroside V vs. 30% mogroside V) under current Good Manufacturing Practices (cGMP).

Figure 2. Luo Han Guo Plant with Fresh Fruits (left) and Mature Fruits (right)



Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

The following outlines the procedures by which Nutramax processes its *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract powders:

- 1) Select and weigh fresh fruit with the peel intact. Inspect mature fruits from the Luo Han Guo plant (Figure 3) upon arrival at the processing plant. Use distilled water to wash the fruit and remove any impurities.
- 2) Leave fruit seeds intact; crush the rest of the fruit.
- 3) Add hot purified water into an extractor, then perform interlayer-heating. Boil at 100 °C for one hour, with three extractions. Use the third extraction as the solvent for the first extract solution of the next batch.
- 4) Cool the extraction to 45-50 °C (Subject it to horizontal) to precipitate suspended substances, e.g., broken cell tissues.
- 5) Filtrate the centrifugate by ceramic membrane to remove partial macromolecular compounds, such as pectin, polysaccharide, and protein.
- 6) Pass and absorb the clear filtrate from step 5 through a D101 macroporous adsorptive resin (copolymer of divinylbenzene; complies with 21CFR 173.25) column. Successively wash the column with purified water and 20% ethanol to remove impurities.
- 7) Use 50% ethanol for MV desorption. Concentrate the desorption and spray it dry to get product No.1, 18-32% MV. For higher MV content, concentrate the desorption into 28-32% solid content, cool it to 25-30 °C, then centrifuge the concentrate to remove insoluble substances.
- 8) Use purified water to dilute the centrifugate to a suitable concentration (about 4% solid content), then pass it through a regenerated sulfonated copolymer of styrene D900 resin (which complies with 21CFR 173.25). This will adsorb colored compounds, such as melanoidin and flavonoids. Once segmented, collect the decolored liquid outflow from the 5BV resin column (BV: bed volume). (To regenerate the D900 resin column: flush with a food grade 1% solution of hydrochloric acid, followed by purified water until the pH of the effluent liquid is neutral. Next, flush it with a food grade 0.5% solution of sodium hydroxide. Finally, flush the column with purified water until the pH of the effluent liquid is neutral.)

Eluates from D900 resin are divided into 3 parts; Foremost eluate-BV1-BV3; Intermediate column outflows as BV4; Last outflow as BV5.

- 9) Collect the foremost liquid outflow from BV1-BV3 (BV: bed volume of resin column). Use the nanofiltration membrane for further purification, then concentrate and spray dry the interceptions to get product No. 2, 58-65% MV.

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

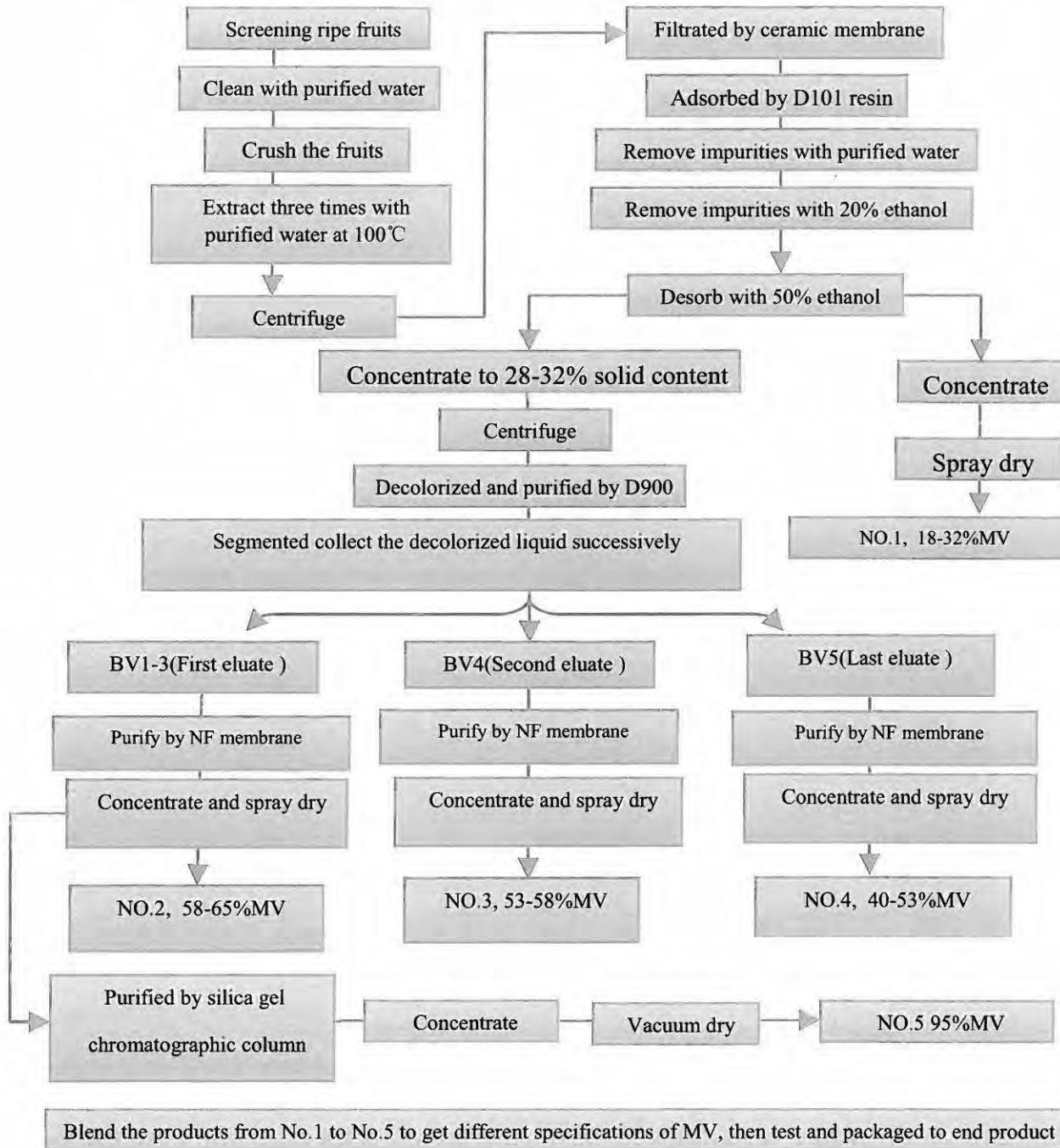
- 10) Collect the intermediate column outflow liquid from BV4. Use the nanofiltration membrane for further purification, then concentrate and spray dry the interceptions to get product No. 3, 53-58% MV.
- 11) Collect the last outflow from BV5. It has the lowest MV purity. Use the nanofiltration membrane for further purification, then concentrate and spray dry the interceptions to get product No. 4, 40-53% MV.
- 12) Further purify the concentrate from step 9 with a silica gel chromatographic column, then concentrate and vacuum dry it to get product No. 5, 95% MV.
- 13) Blend products No. 1 to No. 5 for different specifications of MV, then test and package these for use in the end product.

Siraitia grosvenorii Swingle (Luo Han Guo) fruit extract are manufactured under cGMP using common food industry materials and processes in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations. Nutramax uses a Hazard Analysis and Critical Control Points (HACCP)-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications.

The food grade ethanol used in the purification process complies with the FCC's 10th Edition specifications. The ion exchange resins (sulfonated copolymer of styrene and divinylbenzene) and adsorption resins used in the manufacturing process are food grade and comply with 21 CFR 173.25. Food-grade sodium hydroxide and hydrochloric acid are used to regenerate the resin. Both are both GRAS substances (21 CFR §184.1763 and 8182.1057, respectively) with use limited only by current Good Manufacturing Practices (cGMP).

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

Figure 3. Manufacturing Process of Nutramax's Luo Han Guo Fruit Extracts



Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

2.C. Specifications of Nutramax's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts

As shown in Tables 3-1 to 3-8, Nutramax 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 extracts. The specifications for mercury, arsenic, cadmium, and lead meet FCC specifications and do not exceed 0.1, 0.5, 0.05 and 0.5 ppm, respectively. The subjects of this GRAS notice are Luo Han Guo (*Siraitia grosvenorii*, Swingle) fruit extracts (containing mogroside V at concentrations of $\geq 25.0\%$, $\geq 30.0\%$, $\geq 50.0\%$, $\geq 55.0\%$, $\geq 60.0\%$, $\geq 65.0\%$, and $\geq 95.0\%$).

Table 3-1. Specifications for Luo Han Guo Fruit Extract with 25% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	$\geq 25\%$	CP2010
Color	Brown yellow	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	$\leq 5.0\%$	USP31-921
Ash	$\leq 5.0\%$	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	$\leq 1,000$ cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopoeia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

Table 3-2. Specifications for Luo Han Guo Fruit Extract with 30% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 30%	CP2010
Color	Brown yellow	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopoeia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

Table 3-3. Specifications for Luo Han Guo Fruit Extract with 50% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 50%	CP2010
Color	White	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopedia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

Table 3-4. Specifications for Luo Han Guo Fruit Extract with 55% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 55%	CP2010
Color	White	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopedia; AOAC=Association of Official Analytical Chemists; USP= United States Pharmacopeia.

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Table 3-5. Specifications for Luo Han Guo Fruit Extract with 60% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 60%	CP2010
Color	White	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopoeia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

Table 3-6. Specifications for Luo Han Guo Fruit Extract with 65% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 65%	CP2010
Color	White	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

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GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopoeia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

Table 3-7. Specifications for Luo Han Guo Fruit Extract with 95% Mogroside V

Parameter	Specification	Test Method
Assay: Mogroside V	≥ 95%	CP2010
Color	White	GB/T 5492-2008
Odor	Mild fruity characteristic	GB/T 5492-2008
Taste	Sweet	GB/T 5492-2008
Sieve Analysis	NLT 95% pass 80 mesh	CP2010
Method of Extraction	Water	\
Moisture Content	≤ 5.0%	USP31-921
Ash	≤ 5.0%	USP31-281
Mercury (Hg)	≤ 0.1 ppm	USP39<2232>
Arsenic (As)	≤ 0.5 ppm	USP39<2232>
Cadmium (Cd)	≤ 0.05 ppm	USP39<2232>
Lead (Pb)	≤ 0.5 ppm	USP39<2232>
Residual Ethanol	≤ 500 ppm	USP 37
Total Plate Count	≤ 1,000 cfu/g	AOAC 990.12
Salmonella	Negative	AOAC 2004.03
Yeast & Mold	≤ 100 cfu/g	ISO21527-1:2008
<i>E. coli</i>	Negative	AOAC 991.14

GB/T=Recommended Chinese National Standard; cfu=Colony Forming Units; CP=Chinese Pharmacopoeia; AOAC= Association of Official Analytical Chemists; USP= United States Pharmacopeia.

2.D. Intended Technical Effects

Siraitia grosvenorii Swingle (Luo Han Guo) fruit extracts can be used as a sugar substitute.

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PART 3. DIETARY EXPOSURE

3.A. Intended Use

The subjects of the present GRAS assessment contain 25, 30, 50, 55, 60, 65, or 95% mogroside V. Luo Han Guo fruit extracts, that contain mogroside V as the principal sweetening component, are intended to be used as a sugar substitute (a table-top sweetener and a general purpose non-nutritive sweetener) in various foods. The standards of identity exist for these foods, and are located in Title 21 of the Code of Federal Regulations. The intended use will be as a non-nutritive 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. The amounts of purified *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract to be added to foods will not exceed the amounts reasonably required to accomplish its intended technical effect as required by FDA regulation (21 CFR 182.1(b)(1)). Nutramax does not intend to use *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract as a component of infant formula or in foods under the USDA's jurisdiction such as meat, poultry, and egg products.

Siraitia grosvenorii Swingle (Luo Han Guo) fruit extract are intended for use in the same foods and at levels proportional to those specified in GRNs 301, 359, 522, and 556.

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

The EDIs of Nutramax's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract have been calculated using the methodology presented in GRN 301 (Tables 4-1 to 4-7). Renwick (2008) reported that the amount of sucrose replaced by an intense sweetener equals the dietary exposure for that sweetener multiplied by its relative sweetness intensity compared with sucrose. The EDIs of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract were then calculated by dividing the estimated sucrose equivalent intakes by the relative sweetness of a Luo Han Guo fruit extract at specific concentrations of mogroside V. The EDIs of mogroside V were calculated by multiplying the EDI values of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract by the concentration of mogroside V. The EDIs were reported for average and high consumers of intense sweeteners. The high consumers were considered those at 90th to 97th percentile consumption levels.

EDIs of mogroside V for high consumers ($\geq 90^{\text{th}}$ percentile) ranged from 1.05 mg/kg body weight (BW)/day (product containing 25% mogroside V) to 2.24 mg/kg BW/day (product containing 95% mogroside V). When MV95 (Luo Han Guo fruit extract containing 95% mogroside V) is consumed, the EDIs for high consumers in the general population, diabetic adults, healthy children, and diabetic children are up to 1.53, 2.03, 2.23, and 2.05 mg mogroside V/kg BW/day, respectively. When MV25 (Luo Han Guo fruit extract containing 25% mogroside V) is consumed, the corresponding EDIs for high consumers are 1.05, 1.40, 1.55, and 1.42 mg mogroside V/kg BW/day. All predicted EDIs for mogroside V are less than 2.3 mg/kg BW/day, which is equivalent to less than 161 mg per 70 kg adult. Each concentration will be used independently of the others for each application; thus, cumulative exposure is not expected. Based on the totality of scientific evidence and as discussed below, these intake levels are considered safe.

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EDIs of mogroside V for average consumers ranged from 0.4-1.05 mg/kg BW/day (MV25: product containing 25% mogroside V) to 0.58-1.52 mg/kg BW/day (MV95: product containing 95% mogroside V).

In this GRAS assessment, *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract are intended to be used as alternatives for the currently marketed Luo Han Guo fruit extract products. Thus, the overall exposure to *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract is not expected to increase as a result of the introduction of Nutramax's Luo Han Guo fruit extract products into the market. As described in Renwick (2008), as well as in GRNs 301 and 359, calculations made in this GRAS assessment likely overestimate the potential intake of Luo Han Guo fruit extracts.

Table 4-1. EDIs of Luo Han Guo Fruit Extract with 25% Mogroside V (Luo Han Guo Fruit Extract MV25- -sweetness intensity 160)

Subpopulation Group	Intakes of sweetener (mg sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 25 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg BW/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	1.6	4.2	0.40	1.05
Diabetic Adults	280	897	1.8	5.6	0.44	1.40
Healthy Children	425	990	2.7	6.2	0.66	1.55
Diabetic Children	672	908	4.2	5.7	1.05	1.42

^a See Renwick, 2008. ^bCalculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 20% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

Table 4-2. EDIs of Luo Han Guo Fruit Extract with 30% Mogroside V (Luo Han Guo Fruit Extract MV30 - sweetness intensity 180)

Subpopulation Group	Intakes of sweetener (mg sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 30 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg BW/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	1.4	3.8	0.43	1.13
Diabetic Adults	280	897	1.6	5.0	0.47	1.50
Healthy Children	425	990	2.4	5.5	0.71	1.65
Diabetic Children	672	908	3.7	5.0	1.12	1.51

^a See Renwick, 2008. ^bCalculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 20% mogroside V in Luo Han Guo fruit extract. BW=body weight; MV=mogroside V.

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Table 4-3. EDIs of Luo Han Guo Fruit Extract with 50% Mogroside V (Luo Han Guo Fruit Extract MV 50 - sweetness intensity 280)

Subpopulation Group	Intakes of sweetener (mg sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 50 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg BW/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	0.91	2.4	0.46	1.21
Diabetic Adults	280	897	1.0	3.2	0.50	1.60
Healthy Children	425	990	1.5	3.5	0.76	1.77
Diabetic Children	672	908	2.4	3.2	1.20	1.62

^a See Renwick, 2008.

^b Calculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 50% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-4. EDIs of Luo Han Guo Fruit Extract with 55% Mogroside V (Luo Han Guo Fruit Extract MV 55 - sweetness intensity 300)

Subpopulation Group	Intakes of sweetener (mg sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 55 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg BW/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	0.85	2.3	0.47	1.24
Diabetic Adults	280	897	0.93	3.0	0.51	1.64
Healthy Children	425	990	1.4	3.3	0.78	1.82
Diabetic Children	672	908	2.2	3.0	1.23	1.66

^a See Renwick, 2008. ^b Calculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 55% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

Table 4-5. EDIs of Luo Han Guo fruit extract with 60% Mogroside V (Luo Han Guo Fruit Extract MV 60 - sweetness intensity 330)

Subpopulation Group	Intakes of sweetener (mg sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 60 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg BW/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	0.77	2.0	0.46	1.23
Diabetic Adults	280	897	0.85	2.7	0.51	1.63
Healthy Children	425	990	1.3	3.0	0.77	1.80
Diabetic Children	672	908	2.0	2.8	1.22	1.65

^a See Renwick, 2008. ^b Calculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 60% mogroside V in Luo Han Guo fruit extract.
BW=body weight; MV=mogroside V.

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Table 4-6. EDIs of Luo Han Guo fruit extract with 65% Mogroside V
(Luo Han Guo Fruit Extract MV 65 - sweetness intensity 350)

Subpopulation Group	Intakes of sweetener (g sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 95 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg bw/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	0.73	1.9	0.47	1.25
Diabetic Adults	280	897	0.80	2.6	0.52	1.67
Healthy Children	425	990	1.21	2.8	0.79	1.84
Diabetic Children	672	908	1.9	2.6	1.25	1.69

^a See Renwick, 2008. ^b Calculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 95% mogroside V in Luo Han Guo fruit extract.

BW=body weight; MV=mogroside V.

Table 4-7. EDIs of Luo Han Guo Fruit Extract with 95% Mogroside V
(Luo Han Guo Fruit Extract MV 95 - sweetness intensity 420)

Subpopulation Group	Intakes of sweetener (g sucrose/kg BW/day) ^a		EDI of Luo Han Guo Fruit Extract MV 95 (mg/kg BW/day) ^b		EDI of mogroside V (mg/kg bw/day) ^c	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	255	675	0.61	1.6	0.58	1.53
Diabetic Adults	280	897	0.67	2.1	0.63	2.03
Healthy Children	425	990	1.0	2.4	0.96	2.24
Diabetic Children	672	908	1.6	2.2	1.52	2.05

^a See Renwick, 2008. ^b Calculation method was adopted from GRNs 301 and 556.

^c Calculated based on the minimum of 95% mogroside V in Luo Han Guo fruit extract.

BW=body weight; MV=mogroside V.

3.C. EDIs of Mogroside V from the Diet

It is not expected that people would consume mogroside V in a typical American diet.

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

The EDIs of other nutrients in *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract were calculated based on the EDIs of Luo Han Guo fruit extract (Tables 4-1 to 4-7) and the protein and carbohydrate content of each preparation (Table 2). For example, in healthy individuals the 90th percentile EDI of Luo Han Guo fruit extract MV30 is 3.8 mg/kg BW/day. Given that the concentration of protein in Luo Han Guo fruit extract MV30 is 35.8%, the EDI can then be calculated by multiplying 3.8 by 0.358. The resulting EDI value for protein is 1.36 mg/kg BW/day. Nutrients present in negligible amounts (such as dietary fiber and total fat) were not included in the calculations of EDIs from the diet.

The highest protein and carbohydrate intakes would be observed when MV25 is used: the 90th percentile protein and carbohydrates intakes would be 2.62 and 1.72 mg/kg BW/day in healthy children, respectively. The estimated protein and carbohydrate intakes under the intended use (Tables 5-1 to 5-8) are negligible compared to usual intakes of these nutrients (Table 6) from

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the diet. For example, the 90th percentile usual intakes of protein in children aged 4-13 years are estimated to be 1,700-5,100 mg/kg BW/day. Intended use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract would result in 2.6 mg/kg BW/day, which is 650 -1,960 times lower than usual protein intakes from the diet. In other words, intended use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract would have no significant impact on other nutrient intakes in Americans regardless of mogroside V concentrations.

Table 5-1. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 25% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 25 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 42.2% protein		EDI of carbohydrates (mg/kg BW/day) ^a <27.8% total carbohydrates	
	Average	≥90 th Pctl	Average	≥90 th Pctl	Average	≥90 th Pctl
Healthy Population	1.6	4.2	0.68	1.77	0.44	1.17
Diabetic Adults	1.8	5.6	0.76	2.36	0.50	1.56
Healthy Children	2.7	6.2	1.14	2.62	0.75	1.72
Diabetic Children	4.2	5.7	1.77	2.41	1.17	1.58

^a Calculated based on protein content of 42.2% and total carbohydrate content of 27.8% in the MV 25 preparation. MV=mogroside V.

Table 5-2. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 30% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 30 (mg/kg BW/day) ^b		EDI of protein (mg/kg BW/day) ^a 35.8% protein		EDI of carbohydrates (mg/kg BW/day) ^a <28.9% total carbohydrates	
	Average	≥90 th Pctl	Average	≥90 th Pctl	Average	≥90 th Pctl
Healthy Population	1.4	3.8	0.50	1.36	0.40	1.10
Diabetic Adults	1.6	5.0	0.57	1.79	0.46	1.45
Healthy Children	2.4	5.5	0.86	1.97	0.69	1.59
Diabetic Children	3.7	5.0	1.32	1.79	1.07	1.45

^a Calculated based on protein content of 35.8% and total carbohydrate content of 28.9% in the MV 30 preparation.

Table 5-3. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 50% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 50 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 11.3% protein		EDI of carbohydrates (mg/kg BW/day) ^a <43.6% total carbohydrates	
	Average	≥90 th Pctl	Average	≥90 th Pctl	Average	≥90 th Pctl
Healthy Population	0.91	2.4	0.10	0.27	0.40	1.05
Diabetic Adults	1.0	3.2	0.11	0.36	0.44	1.40
Healthy Children	1.5	3.5	0.17	0.40	0.65	1.53
Diabetic Children	2.4	3.2	0.27	0.36	1.05	1.40

^a Calculated based on protein content of 11.3% and total carbohydrate content of 43.6% in the MV 50 preparation.

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Table 5-4. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 55% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 55 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 6.87% protein		EDI of carbohydrates (mg/kg BW/day) ^a <38.7% total carbohydrates	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	0.85	2.2	0.058	0.15	0.33	0.85
Diabetic Adults	0.93	3.0	0.064	0.21	0.36	1.16
Healthy Children	1.4	3.3	0.096	0.23	0.54	1.28
Diabetic Children	2.2	3.0	0.15	0.21	0.85	1.16

^a Calculated based on protein content of 6.87% and total carbohydrate content of 38.7% in the MV 55 preparation.

Table 5-5. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 60% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 60 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 5.53% protein		EDI of carbohydrates (mg/kg BW/day) ^a <34.6% total carbohydrates	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	0.77	2.0	0.043	0.11	0.27	0.69
Diabetic Adults	0.85	2.7	0.047	0.15	0.29	0.93
Healthy Children	1.3	3.0	0.072	0.17	0.45	1.04
Diabetic Children	2.0	2.8	0.11	0.15	0.69	0.97

^a Calculated based on protein content of 5.6% and total carbohydrate content of 34.6% in the MV 60 preparation.

Table 5-6. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 65% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 60 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 5.39% protein		EDI of carbohydrates (mg/kg BW/day) ^a <30.3% total carbohydrates	
	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl	Average	$\geq 90^{\text{th}}$ Pctl
Healthy Population	0.73	1.9	0.039	0.10	0.22	0.58
Diabetic Adults	0.80	2.6	0.043	0.14	0.24	0.79
Healthy Children	1.3	2.8	0.070	0.15	0.39	0.85
Diabetic Children	1.9	2.6	0.10	0.14	0.58	0.79

^a Calculated based on protein content of 5.33% and total carbohydrate content of 30.3% in the MV 60 preparation.

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Table 5-7. EDIs of Other Nutrients from Luo Han Guo Fruit Extract with 95% Mogroside V under the Intended Use

Subpopulation Group	EDI of Luo Han Guo Fruit Extract MV 95 (mg/kg BW/day)		EDI of protein (mg/kg BW/day) ^a 0.28% protein		EDI of carbohydrates (mg/kg BW/day) ^a <3.1% total carbohydrates	
	Average	≥90 th Pctl	Average	≥90 th Pctl	Average	≥90 th Pctl
Healthy Population	0.61	1.6	0.002	0.004	0.02	0.05
Diabetic Adults	0.67	2.1	0.002	0.006	0.02	0.07
Healthy Children	1.0	2.4	0.003	0.007	0.03	0.07
Diabetic Children	1.6	2.2	0.004	0.006	0.05	0.07

^a Calculated based on protein content of 0.28% and total carbohydrate content of 3.1% in the MV 95 preparation.

3.E. EDIs of Other Nutrients from the Diet

The EDIs or usual intake values of other nutrients from the diet were adopted from What We Eat in America. These were based on the NHANES 2007-2010 dataset (Table 6). What We Eat in America is conducted as a partnership between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS).

Adult males, aged 19 years and older, had the highest protein intake with the 90th percentile EDI of 132.9 g/day (or 1.5 g/kg BW/day). Male teenagers (14-18 years) consumed the highest amount of carbohydrates with the 90th percentile EDI of 434 g/day or 5.9 g/kg BW/day. The estimated intakes of protein and carbohydrates under the intended use (Tables 5-1 to 5-7) are negligible compared to usual intakes of these nutrients from the diet (Table 6). For example, the 90th percentile usual intakes of protein and carbohydrates from the diet in all populations are estimated at 1,200 and 4,200 mg/kg BW/day, respectively. Intended use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract would result in the maximum protein and carbohydrate intakes of up to 2.6 and 1.7 mg/kg BW/day, which are 460-2,470 times lower than usual intake values from the diet. The intended use of Luo Han Guo fruit extract has no significant impact on other nutrients intakes in Americans, regardless of their Mogroside V concentrations.

Table 6. Usual Intakes of Protein and Carbohydrates in the United States

Age, years	Protein, g/day		Carbohydrates, g/day		EDI, g/kg BW/d	
	Mean	90 th Pctl	Mean	90 th Pctl	Protein, 90 th Pctl	Carbohydrates, 90 th Pctl
Males 1-3	51.5	70.8	191	258	5.0	18.3
Males 4-8	59.3	77.6	239	306	5.1	12.5
Males 9-13	76.8	91.4	281	368	1.9	7.8
Males 14-18	93.3	126.0	323	434	1.7	5.9
Males 19+	96.8	132.9	290	420	1.5	4.7
Females 1-3	49.6	68.3	177	244	5.1	18.2
Females 4-8	57.5	77.4	228	298	3.1	12.1

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Females 9-13	63.8	79.9	249	329	1.7	7.0
Females 14-18	63.0	83.0	240	314	1.3	5.0
Females 19+	62.8	85.5	200	280	1.1	3.7
All individuals 1 and over:	66.0	89.0	216	305	1.2	4.2

Data Source: What We Eat in America, NHANES 2007-2010, dietary intake data of individuals of one year or older (excluding breast-fed children and pregnant or lactating females). Prepared by the Food Surveys Research Group, Beltsville Human Nutrition Research Center, and the Agricultural Research Service, U.S. Department of Agriculture. The EDIs, in mg/kg BW/day, were calculated using body weight values estimated from the 2007-2010 NHANES dataset.

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PART 4. SELF LIMITING LEVELS OF USE

The quantity of consumption of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract is self-limiting due to a lack of palatability (off taste) that occurs with increasing quantity. This occurs with any of the natural high intensity sweeteners (e.g., stevia products) and limits consumer acceptance of these products when added as a sugar substitute.

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PART 5. HISTORY OF CONSUMPTION

Not applicable.

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PART 6. BASIS FOR GRAS DETERMINATION

6.A. Current Regulatory Status

USA

The FDA has issued 'no question' letters on four GRAS notifications related to food uses of Luo Han Guo fruit extract concentrates (GRN 301, FDA, 2010; GRN 359, FDA, 2011; GRN 522, FDA 2014; GRN 556, FDA 2015a). The GRAS notices are summarized in Table 7.

Table 7. Summary of GRAS Notices That Passed FDA Review

GRN (year of closure)	Mogroside V content, %	The maximum 90 th Percentile EDI of mogroside V	Intended use	Company
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 and as a sweetener in foods, excluding infant formula, meat, and poultry product	GLG Life Tech Corp., Canada
556 (2015a)	12.5, 20, 25, 30, 40, 50, 55, or 90	2.17	As a table-top and general purpose non-nutritive sweetener, and as a flavor modifier for use in foods other than infant formula, meat, and poultry products	Hunan Huacheng Biotech, Inc., China
Present notice	25, 30, 50, 55, 60, 65, or 95	2.23	As a sugar substitute (a table-top and general purpose non-nutritive sweetener) in foods, excluding infant formula, meat, and poultry products	Nutramax Inc., China

EDI=Estimated Dietary Intake.

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The extracts in this GRAS notice are similar to those described in GRN 359 (up to 55% mogroside V), GRN 301 (up to 30% mogroside V), GRN 522 (up to 60% mogroside V), and GRN 556 (up to 90% mogroside V). But they are of higher purity, up to 95% mogroside V. In this GRAS notice, the EDIs of mogroside V for high consumers are estimated to be up to 2.23 mg/kg BW/day.

The FDA did not question the summary of safety concluding that *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract intake up to 2.5 mg mogroside V/kg BW/day is safe. The FDA did not question the acceptability and suitability of these studies to establish the safety of Luo Han Guo fruit extract concentrates for the proposed food uses. The safety and related information in the above mentioned GRAS notices is hereby incorporated by reference to this independent GRAS determination.

The pertinent information is available as indicated below:
GRN 301 (stamped pages 52-72 or submitter's pages 22-42): http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=301&sort=GRN_Noℴ=DESC&startrow=1&type=classic&search=luo%20han%20guo.

GRN 359 (stamped pages 32-38 or submitter's pages 24-30):
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=359&sort=GRN_Noℴ=DESC&startrow=1&type=classic&search=luo%20han%20guo

GRN 522 (pages 19-28):
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=522&sort=GRN_Noℴ=DESC&startrow=1&type=classic&search=luo%20han%20guo.

GRN 556 (stamped pages 36-42; submitter's pages 21-27):
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=556&sort=GRN_Noℴ=DESC&startrow=1&type=classic&search=luo%20han%20guo.

In addition, two New Dietary Ingredient (NDI) notifications were accepted by the FDA with no objection to the use of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract as a dietary supplement (FDA, 1996, 1999). It is noteworthy that Luo Han Guo fruit juice concentrate, with no impurities removed, has received a 'no question' letter from FDA (GRN 627, FDA, 2016).

In 2015, the FDA issued 'Additional Information about High-Intensity Sweeteners Permitted for Use in Food in the United States' (FDA, 2015b). The agency included *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts (SGFE) in the high-intensity sweetener category and stated that, 'High-intensity sweeteners are commonly used as sugar substitutes or sugar alternatives because they are many times sweeter than sugar but contribute only a few to no calories when added to foods. High-intensity sweeteners, like all other ingredients added to food in the United States, must be safe for consumption.' (FDA, 2015b).

Joint FAO/WHO Food Standards Programme

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In March 2012, monk fruit extract/Luo Han Guo/*Siraitia grosvenorii* fruit extract was included on the priority list for the 44th session of the Codex Committee on Food Additives, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Standards Programme held in Hangzhou, China. The questions before the committee included those of safety assessment and the establishment of specifications (FAO/WHO, 2012). In March 2014, the 46th session of the JECFA Standards Program/Codex Committee on Food Additives maintained *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract on the priority list of substances proposed for evaluation, as proposed by the U.S. (FAO/WHO, 2014).

Health Canada

On March 14, 2013, Health Canada proposed adding monk fruit extracts to the *List of Permitted Sweeteners*. Monk fruit was added to Health Canada's List of Permitted Sweeteners on December 2, 2013 as Item M.4. Monk fruit extracts or *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract was authorized for use in Canada as a table-top sweetener at a maximum use level of 0.8% calculated as mogroside V (Health Canada, 2013).

6.B. Review of Safety Data

As noted above, the FDA has issued 'no question' letters on four GRAS notices related to food uses of Luo Han Guo fruit extracts. As the *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract in this GRAS determination are similar in specifications to the other *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract 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 extract in this GRAS determination. Therefore, this notice incorporates by reference the safety and metabolism studies discussed in previous GRNs (GRN 301- pages 22-42; GRN 359-pages 24-30; GRN 522-pages 19-28; GRN 556-stamped pages 21-42) and will not discuss previously reviewed references in detail. Additionally, this notice discusses an additional animal study that has been published since the FDA's last review in 2015 (Xu et al., 2015). The subject of the present GRAS assessment is *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract (powder form).

6.B.1. Metabolism of Luo Han Guo Fruit Extracts

Since the FDA's last completed review in 2015 (GRN 556 -stamped page 36), one animal metabolism study of mogroside V has been published (Xu et al., 2015). Thus, this GRAS notice includes this additional metabolism study in animals.

Murata et al. (2010) examined the metabolism of mogroside V in 10 week old Wistar rats (4-6 rats per group). The rats were given free access to a standard pellet diet and water. After 16 hours of fasting, they were orally administered 1 ml of *Siraitia grosvenorii* (Swingle) glycoside (containing 72% mogroside V, 117 mg/ml) powder in solution. After 2 hours, the contents of the small intestine and portal blood were collected. After 24 hours, feces were collected. The distributions of mogroside V and its metabolites were analyzed in the small intestine, portal blood, and whole blood after a single ingestion of SG-gly. When administered to rats, mogroside V was mostly degraded by digestive enzymes and intestinal microflora, and was excreted in the feces as mogrol (aglycone) and its mono- and diglucosides. The amount of mogrosides found in

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the feces was equivalent to 61% of the administered mogroside V, and no SG triterpenoids were found excreted in the urine. Most of the orally ingested mogroside V is excreted without absorption. As no SG triterpenoids were detected in whole blood, the absorbed amount of SG-gly and its metabolites was very low. Trace amounts of mogrol and its monoglucoside were found in the portal blood as sulfates and/or glucuronide conjugates.

A study by Xu et al. (2015) confirmed a previous finding (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.

In this study, 8 rats were equally divided into 2 groups: a test group (mogroside V, 50 mg/kg BW in water, by oral gavage) and a control group. The duration of this animal experiment was 10 days. Days 1–3 were used as an adaptation period, and control urine and feces samples were collected on days 4–5. All 48-h urine and fecal samples from the test group rats were collected and merged as control urine and fecal samples. Mogroside V-containing urine and fecal samples were collected on days 6–9. On day 10, blood and organs (heart, liver, spleen, lungs, kidneys, stomach, and small intestine of the rats) were separately collected from each rat. Many metabolites of mogroside V that were not detected in plasma were identified in the organs. Mogroside V was detected in different organ samples and was ranked as follows: stomach \geq intestine \geq spleen \geq lung \geq heart \geq kidney \geq liver. Because the peak area of mogroside V was significantly larger than that of any detected metabolites in rat urine, plasma, and stomach samples, and the mass response of mogroside V (1.000) was smaller than most reference compounds (except 0.804 of isomogroside V and 0.999 of 11-oxomogroside V), mogroside V could be regarded as the most abundant compound in rat urine, plasma, and stomach samples.

To clarify its biotransformation process and identify its effective forms *in vivo*, the study also evaluated metabolism of mogroside V in a human intestinal bacteria incubation system (*in vitro*), a rat hepatic 9000 g supernatant (S9) incubation system (*in vitro*), and rats (*in vivo*). The distribution of mogroside V and its metabolites was also reported. Xu et al. (2015) identified 77 new metabolites, including 52 oxidation products formed by mono- to tetra-hydroxylation/dehydrogenation. Specifically, 14 metabolites were identified in the *in vitro* human intestinal bacteria incubation system, 4 in the *in vitro* hepatic S9 incubation system, 58 in feces, 29 in urine, 14 in plasma, 34 in heart, 33 in liver, 39 in spleen, 39 in lungs, 42 in kidneys, 45 in stomach, and 51 in small intestine. Of the 77 metabolites, 65 metabolites were found from organs. Mogroside V and its metabolites were distributed unevenly in the organs of treated rats. Seven bioactive metabolites of mogroside V were identified, among which mogroside IIE was abundant in the heart, liver, spleen, and lung, suggesting that it may contribute to the bioactivities of mogroside V. Based on metabolite profiles, the authors proposed metabolic pathways of mogroside V as deglycosylation, hydroxylation, dehydrogenation, isomerization, glucosylation, and methylation. Quantitative values for metabolites were reported in peak areas or relative values, not in absolute values, indicating the need for further evaluation.

6.B.2. Mutagenicity and Genotoxicity Studies

Since the FDA's last review in 2015 (GRN 556-stamped pages 36-37), no new mutagenicity studies have been published. Thus, this GRAS notice summarizes the studies

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already reviewed in previous GRAS notices. In the previous GRAS notices to the FDA, the safety of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract has been established in mutagenicity and genotoxicity studies.

As described in GRN 359, an Ames test (Ames et al., 1975) was conducted at Huntingdon Life Sciences (2009a; HLS Study No. HUD0D72) to assess Luo Han Guo fruit extract for its ability to cause point mutation in *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA100 as well as in *Escherichia coli* strain WP2uvrA. Five concentrations separated by approximately half-log₁₀ intervals were tested, with a maximum of 5,000 µg of mogroside V per plate with and without S9 activation. In addition to the test article, strains were assayed with an aqueous negative control and with positive controls. No cytotoxic activity was observed at the concentrations tested. There were no substantial increases in revertant colony numbers over aqueous control counts at any concentration tested, with or without S9 mix. Under those test conditions, Luo Han Guo fruit extract did not exhibit any cytotoxic or mutagenic potential.

6.B.3. Animal Toxicity Studies

Since the FDA's last completed review of 2015 (GRN 556-stamped pages 37-39), no new animal toxicity studies have been published. Thus, this GRAS notice summarizes the studies already reviewed in previous GRAS notices. The notified substances in this notice are *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract at varying concentrations of mogroside V; thus, it also includes safety studies of mogroside V as the basis for discussing the safety of Luo Han Guo fruit extract. Results of animal toxicity studies are summarized in Table 8 (Hirose, 1999; Huntingdon Life Science, 2009b; Hussain et al., 1990; Jin et al., 2007; Lee, 1975; Makapugay et al., 1985; Marone et al., 2008; Qin et al., 2006).

Overall, studies found that the LD₅₀ for an aqueous extract of *S. grosvenori* fruit and mogrosides is over 10 g/kg BW in mice (Lee, 1975). A compound that has a LD₅₀ value over 5 g/kg BW in rodents is classified as 'practically nontoxic', and a compound with a LD₅₀ value over 15 g/kg BW as 'relatively harmless' (Altug, 2003). According to these findings, Luo Han Guo fruit extract and mogrosides belong to the group with the lowest toxicity rating.

As shown in Table 8, subchronic studies reported that NOAELs for Luo Han Guo fruit extract were over 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively, and those of mogroside V were over 1,717 and 2,062 mg/kg BW/day in male and female rats, respectively (Huntingdon Life Science, 2009b).

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Table 8. Summary of Animal Toxicity Studies of Luo Han Guo Fruit Extracts
(adopted from GRN 556-stamped page 40)

Species	Dose	Duration	NOAEL	Reference
Mice	Up to 2 g/kg BW Luo Han Guo fruit extract	Single dose	LD ₅₀ ≥ 2 g/kg BW Luo Han Guo fruit extract	Hussain et al., 1990
Mice	Up to 2 g/kg BW mogroside V	Single dose	LD ₅₀ ≥ 2 g/kg BW mogroside V	Makapuya et al., 1985
Mice	Up to 10 g/kg BW Luo Han Guo fruit extract	Single dose	LD ₅₀ ≥ 10 g/kg BW Luo Han Guo fruit extract	Lee, 1975
Subacute toxicity				
6 Dogs; 3M+3F	Luo Han Guo fruit extract (30% mogroside V) at 0 or 3,000 mg/kg/day	28 days	3,000 mg/kg/day of Luo Han Guo fruit extract powder; or 900 mg/kg BW/day of mogroside V, the highest level tested	Qin et al., 2006
104 Sprague -Dawley rats	Luo Han Guo fruit extract at 0, 1, 3, or 10% of diet (containing 30% mogroside V)	4 weeks	M: 7,070 mg/kg/day F: 7,480 mg/kg/day for Luo Han Guo fruit extract powder; M: 2,310 mg/kg BW/day and F: 2,244 mg/kg BW/day for mogroside V, the highest level tested	Marone et al., 2008
Subchronic toxicity				
80 young adult Wistar Hannover rats	Luo Han Guo fruit extract 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	Luo Han Guo fruit extract powder (30% mogroside V) at 0 or 3,000 mg/kg/day	28 or 90 days	3,000 mg/kg BW/day of Luo Han Guo fruit extract powder; or 900 mg/kg BW/day of mogroside V	Qin et al. 2006
100 rats	Luo Han Guo fruit extract powder (30% mogroside V) at conc. of 0, 0.25, 0.5, 1.0, or 2.0% in water	90 days	2.0% Luo Han Guo fruit extract in water	Hirose, 1999
160 rats	0, 1.25, 2.5, or 5% Luo Han Guo fruit extract containing 55% mogroside V	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	Huntingdon Life Science, 2009b

Adopted from GRN 556; M=male; F=female. BW=body weight.

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6.B.4. Animal Efficacy Studies

Since the FDA's last completed review in 2015 (GRN 556-stamped page 41), no new animal efficacy studies have been published. Thus, this GRAS notice briefly summarizes the studies already reviewed in previous GRAS notices.

Di et al. (2011) assessed the anti-inflammatory properties of mogrosides in a murine ear edema model. Results showed that mogrosides inhibited 12-O-tetradecanoylphorbol-13-acetate-induced inflammation by down-regulating COX-2 and IL-6 and up-regulating PARP1, BCL2L1, TRP53, MAPK9, and PPAR δ gene expression.

Shi et al. (2014) reported protective effects and mechanisms of mogroside V on lipopolysaccharide-induced acute lung injury in female BALB/c mice.

Wang et al. (2014) reported that cucurbitane glycosides derived from mogroside IIE, a bitter triterpenoid saponin that is the main component of unripe Luo Han Guo fruit and a precursor of mogroside V, have antioxidant activity.

6.B.5. Human Clinical Studies

Since the FDA's last completed review in 2015, one human clinical study has been published (Tey et al., 2016). This GRAS notice also briefly summarizes the studies already reviewed in previous GRAS notices (Table 7-modified from GRN 556-stamped pages 41-42). Two unpublished clinical studies (Xu et al., 2005a and 2005b) on *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract were reported in GRN 301.

Tey et al. (2016) compared the effects of consuming non-nutritive sweeteners and sucrose (65 g) on energy intake and blood glucose and insulin response. Thirty healthy males received one of four treatments: aspartame-, monk fruit (Luo Han Guo fruit extract)-, Stevia-, and sucrose-sweetened beverages. On each test day, participants were asked to consume a standardized breakfast in the morning and were provided with the test beverage (beverage type-not specified) as a preload in the mid-morning. An ad libitum lunch was provided an hour after the test beverage was consumed. Blood glucose and insulin concentrations were measured every 15 min within the first hour of preload consumption and every 30 min for the subsequent 2 hours. Participants left the study site three hours after preload consumption and completed a food diary for the rest of the day. Results showed that there were no differences in total daily energy intakes among the treatments. Whereas, the sucrose-sweetened beverage led to large spikes in blood glucose and insulin responses within the first hour, these responses were higher for all three non-nutritive sweetener beverages following the test lunch. Thus, there were no differences between the four test beverages in total area under the curve (AUC) for glucose and insulin over three hours. The authors concluded that the consumption of non-nutritive sweeteners had minimal influences on total daily energy intake and postprandial glucose and insulin concentrations compared to a sucrose-sweetened beverage. No adverse effects of Luo Han Guo fruit extract were reported.

Xu et al. (2005a) used a crossover design to assess the comparative effect of consuming Luo Han fruit concentrate containing 30% mogroside V on blood glucose concentration in a

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crossover design. After fasting overnight, 5 healthy men and 5 healthy women aged 19-25 years consumed 200 mg/kg BW of the Luo Han Guo fruit extract concentrate (30% mogroside V) dissolved in water. Their blood glucose levels were tested at 0, 15, 30, 60, 120, and 180 minutes after dosing. Ingestion of Luo Han Guo fruit extract concentrate had no effect on blood glucose. No adverse effects of Luo Han Guo fruit extract were reported.

Xu et al. (2005b) used a similar crossover design to assess the effect of Luo Han Guo fruit extract concentrate containing 30% mogroside V and that of water on blood levels of liver enzymes. Six healthy males aged 19-25 years fasted overnight and then consumed 200 mg/kg BW of Luo Han Guo fruit extract concentrate dissolved in water. Three days later they consumed only water. On both days, blood samples were taken at 0, 1, 2, 3, and 6 hours after administration. No significant changes were observed in 5 liver enzymes; alkaline phosphatase, gamma-glutamyl transpeptidase, alanine aminotransferase, aspartate aminotransferase, and lactate dehydrogenase. No adverse effects of Luo Han Guo fruit extract were reported.

Table 9. Summary of Human Studies of Luo Han Guo Fruit Extracts

Subjects	Daily dose	Duration	Measurement	Reference
A study published since the FDA's last review in 2015				
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., 2016
Studies included in previous GRAS notices				
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	Xu et al., 2005b

Adopted from GRNs 556 and 301. BW=body weight.

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6.C. Safety Determination

Numerous human and animal studies have reported benefits of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract with varying concentrations of mogroside V with no major adverse effects. Nutramax uses a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. There is broad-based and widely disseminated knowledge concerning the chemistry of mogroside V, a major active component of Luo Han Guo fruit extract. This GRAS determination is based on the data and information generally available for the safety of Luo Han Guo fruit extract. The literature indicates that *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract offers consumers benefits without adverse effects.

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

1. Nutramax's Luo Han Guo fruit extracts (powder form) are manufactured under cGMP using common food industry materials and processes.
2. Analytical data from multiple lots indicate that the Luo Han Guo fruit extract powders comply reliably with established food-grade product specifications and meet all applicable purity standards.
3. Nutramax's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract will be used as a sugar substitute (a table-top and general purpose non-nutritive sweetener) in various foods other than infant formulas and meat and poultry products. Intended use is the same as that described in GRNs 301, 359, 522, and 556. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting.
4. The EDIs under the intended use, are estimated to be up to 2.2 mg mogroside V/kg BW/day for high consumers. The 90th percentile EDIs for *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract ranged from 1.6 to 6.2 mg/kg BW/day, depending on the concentration of mogroside V in each Luo Han Guo fruit extract product. These levels are far below the reference dose safe for human exposure. In addition, subchronic studies reported that NOAELs for Luo Han Guo fruit extract were over 3,120 mg/kg BW/day and 3,750 mg/kg BW/day in male and female rats, respectively; those of mogroside V were over 1,717 and 2,062 mg/kg BW/day, respectively.
5. The EDI values are based on the assumption that Nutramax's *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract will replace currently marketed Luo Han Guo fruit extract. Thus, cumulative exposures are not expected. In addition, the EDIs presented in this notice are highly amplified estimates.
6. In previous GRAS notices (GRNs 301, 359, 522, and 556) to the FDA, the safety of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract was established in

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toxicological studies in animals and mutagenicity/genotoxicity studies, and is further supported by clinical studies in humans. The FDA responses to GRAS notifications on *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract indicate that the FDA is satisfied with the safety-in-use of the Luo Han Guo fruit extract, as long as consumption is 2.5 mg mogroside V/kg BW/day. Furthermore, historical consumption of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract support the safety of Luo Han Guo fruit extract.

7. Additional animal studies published subsequent to the FDA GRAS notices continue to support the safety of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract as a food ingredient.
8. All of the ingredients used in the production of the Luo Han Guo extracts are GRAS for the intended uses.

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

Several sources of *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract have been evaluated by the FDA and other global regulatory agencies over the past 10 years for proposed incorporation of Luo Han Guo fruit extracts as a sugar substitute in foods for human consumption. Relevant US GRAS notifications include GRN 301 (FDA, 2010), GRN 359 (FDA, 2011), GRN 522 (FDA, 2014) and GRN 556 (FDA 2015a). All of the GRAS notices provided information/clinical study data that supported the safety of the proposed Luo Han Guo fruit extract ingredients for use in human foods. In all of the studies summarized in these notifications, there were no significant adverse effects/events or tolerance issues attributable to Luo Han Guo fruit extract. Because this safety evaluation was based on generally available and widely accepted data and information, it also satisfies the so-called “common knowledge” element of a GRAS determination.

In addition, the intended uses of Luo Han Guo fruit extracts have been determined to be safe though scientific procedures as set forth in 21 CFR 170.3(b), thus satisfying the so-called “technical” element of the GRAS determination. The specifications of the proposed GRAS substance, Nutramax’s Luo Han Guo fruit extract, is comparable to those that have received FDA no question letters.

The Luo Han Guo fruit extracts 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.

Literature searches did not identify safety/toxicity concerns related to Luo Han Guo fruit extracts. Toxicity studies of Luo Han Guo fruit extracts include acute, subacute, and subchronic toxicity and a battery of genotoxicity studies. In all of these reports, no evidence of toxicity was

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noted at up to 3,120-3,750 mg/kg bw/day of Luo Han Guo fruit extracts, the highest dose levels tested. The publicly available scientific literature on the consumption and safety of Luo Han Guo fruit extracts in human clinical studies is extensive and sufficient to support the safety and GRAS status of the proposed Luo Han Guo fruit extracts.

The Nutramax concluded that these uses of Luo Han Guo fruit extract 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.

Nutramax is not aware of any information that would be inconsistent with a finding that the proposed use of PQQ disodium salt meets appropriate specifications, and its use according to cGMP, is GRAS. Recent reviews of the scientific literature revealed no potential adverse health concern.

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PART 7. REFERENCES

7.A. A list of the Data and Information That Are Generally Available

All the references cited in this GRAS determination, except the reports from Huntington Life Sciences, are generally available as the data/information are either published or can be found from various websites as indicated below.

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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.

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7.B. A List of the Data and Information Are Not Generally Available

Details of the following reports are not generally available. However, the summaries of these reports have been generally available since they were presented in GRN 301.

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Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

APPENDIX A. CERTIFICATES OF ANALYSIS

1 Sample 01: MV25% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	January 10, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	500 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 25.00%	25.37%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.20%	USP31-921
Ash	NMT 5.0%	0.83%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	200	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	January 9, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

2 Sample 02: MV25% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	September 21, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	500 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 25.00%	25.21%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.36%	USP31-921
Ash	NMT 5.0%	0.88%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.15	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	September 20, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

3 Sample 03: MV25% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	November 28,2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	500 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 25.00%	25.32%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.50%	USP31-921
Ash	NMT 5.0%	0.77%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.15	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000CFU/g Max	300	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	November 27, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

4 Sample 04: MV30% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	January 20, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	400 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 30.00%	30.42%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.96%	USP31-921
Ash	NMT 5.0%	0.67%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	200	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	January 19, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

5 Sample 05: MV30% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	September30, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	500 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 30.00%	30.14%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.56%	USP31-921
Ash	NMT 5.0%	0.78%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	September 29, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

6 Sample 06: MV30% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	December 9, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	400 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 30.00%	30.23%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	Brown yellow powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.28%	USP31-921
Ash	NMT 5.0%	0.94%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	December 8, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

7 Sample 07: MV50% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	March 5, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	300 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 50.00%	50.21%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.63%	USP31-921
Ash	NMT 5.0%	0.62%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.12	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	March 4, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

8 Sample 08: MV50% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	October 10, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	400 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 50.00%	50.40%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.26%	USP31-921
Ash	NMT 5.0%	0.74%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	300	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	October 9, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

9 Sample 09: MV50% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	December 18, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	400 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 50.00%	50.38%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.76%	USP31-921
Ash	NMT 5.0%	0.75%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.11	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	December 17, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

10 Sample 10: MV55% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	March 16, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	300 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 55.00%	55.25%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.89%	USP31-921
Ash	NMT 5.0%	0.59%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1 ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5 ppm	0.4	USP39<2232>
Cadmium(Cd)	NMT 0.05 ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	March 15, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

11 Sample 11: MV55% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	October 20, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	400 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 55.00%	55.35%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.78%	USP31-921
Ash	NMT 5.0%	0.87%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.38	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	October 19, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

12 Sample 12: MV55% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	December28, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	300 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 55.00%	55.30%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.56%	USP31-921
Ash	NMT 5.0%	0.65%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.38	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	December27, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

13 Sample 13: MV60% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	March 30, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	200 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 60.00%	60.47%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.84%	USP31-921
Ash	NMT 5.0%	0.36%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.41	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5 ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	300	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	March 29, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

14 Sample 14: MV60% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	October29, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	200 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 60.00%	60.37%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.25%	USP31-921
Ash	NMT 5.0%	0.44%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.21	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000CFU/g Max	200	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	October28, 2017		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

15 Sample 15: MV60% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	January 10, 2017
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	300 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 60.00%	60.29%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	2.95%	USP31-921
Ash	NMT 5.0%	0.49%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.10	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	January 9, 2019		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

16 Sample 16: MV65% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	April 10, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	100 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 65.00%	65.26%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.24%	USP31-921
Ash	NMT 5.0%	0.36%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.36	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	400	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	20	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	April 9, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

17 Sample 17: MV65% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	November 8, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	100 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 65.00%	65.43%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	2.86%	USP31-921
Ash	NMT 5.0%	0.34%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.36	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	300	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	November 7, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

18 Sample 18: MV65% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	January 22, 2017
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February 25, 2017
Ananlysis:	100 Kg	Report Date	March 4, 2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 65.00%	65.36%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	3.18%	USP31-921
Ash	NMT 5.0%	0.29%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.35	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	20kg/drum. Packing in paper drum and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	January 21, 2019		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

19 Sample 19: MV95% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	April 20, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	20 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 95.00%	95.13%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	0.79%	USP31-921
Ash	NMT 5.0%	0.10%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.12	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	1kg/bag. Packing in aluminum foil bag and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	April 19, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

20 Sample 20: MV95% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	November 18, 2016
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	20 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 95.00%	95.11%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	0.87%	USP31-921
Ash	NMT 5.0%	0.12%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.14	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	1kg/bag. Packing in aluminum foil bag and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	November 17, 2018		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

21 Sample 21: MV95% (b) (6)

CERTIFICATE OF ANALYSIS

Product and Batch Information			
Product Name:	Luo Han Guo Extract	Country of Origin:	P. R. China
Latin Name:	Momordica Grosvenori Swingle	Type of extraction:	Water
Batch No:	(b) (6)	Manufacture Date	February13, 2017
Plant Part:	Fruit (Fresh, 100% Natural)	Analysis Date	February25,2017
Ananlysis:	30 Kg	Report Date	March4,2017
Item	Requirement	Result	Test Method
Active Ingredients			
Mogroside V	NLT 95.00%	95.55%	CP2010
Physical Control			
Identification	Positive	Conforms	CP2010
Appearance	White powder	Conforms	GB/T 5492-2008
Odor	Mild fruity characteristic	Conforms	GB/T 5492-2008
Taste	Sweet	Conforms	GB/T 5492-2008
Sieve Analysis	100% pass 80 mesh	Conforms	CP2010
Moisture Content	NMT 5.0%	0.65%	USP31-921
Ash	NMT 5.0%	0.14%	USP31-281
Chemical Control			
Mercury(Hg)	NMT 0.1ppm	ND (0.01)	USP39<2232>
Arsenic (As)	NMT 0.5ppm	0.13	USP39<2232>
Cadmium(Cd)	NMT 0.05ppm	ND (0.01)	USP39<2232>
Lead (Pb)	NMT 0.5ppm	ND (0.10)	USP39<2232>
Residual Ethanol	NMT 500 ppm	ND (50)	USP 37
Microbiological Control			
Total Plate Count	1000 CFU/g Max	100	AOAC 990.12
Salmonella	Negative	Not detected	AOAC 2004.03
Yeast & Mold	100 CFU/g Max	10	ISO21527-1:2008
<i>E. Coli</i>	Negative	Not detected	AOAC 991.14
Packing and Storage			
Packing	1kg/bag. Packing in aluminum foil bag and two plastic-bags inside.		
Storage	Store in a well-closed place with constant low temperature and no direct sun light		
Shelf Life	2 years.		
Expiration Date	February 12, 2019		

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

APPENDIX B. PESTICIDE RESIDUE ANALYSIS

The analysis of the pesticides listed below shows that no pesticides are present in Nutramax's Luo Han Guo fruit extracts. A composite of three non-consecutive batches of MV25, least purified products among Natramax's Luo Han Guo fruit extract ingredients, was analyzed. A composite analysis of MV 20 (which is not the subject of this GRAS notice) also presents that that no pesticides are present in Nutramax's Luo Han Guo fruit extracts.

Organochlorine pesticides

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- (0.4)	Dichlorobenzophenone, p,p- (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)	Octachlorostyrene (0.01)
Oxyfluorfen (0.01)	Pendimethalin (0.01)	Pentachloranisole (0.0)

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

Pentachloroaniline (0.005)	Pentachlorothioanisole (0.005)	Permethrin (0.02)
Plifenate (0.005)	Polychloroterpenes (Camphechlor) (0.2)	Profluralin (0.005)
Propanil (0.02)	Quintozen (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)

Organophosphorus pesticides

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 (0.05)	Dialifos (0.05)
Diazinon (0.02)	Dicaphthon (0.01)	Dichlofenthion (0.02)
Dichlorvos (0.01)	Dicrotophos (0.02)	Dimefox (0.02)
Dimethoate (0.02)	Dimethoate/Omethoate (sum) ()	Dimethylvinphos (0.02)
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)	Etrimsfos (0.02)	Famophos (0.05)
Fenamiphos (0.02)	Fenamiphos (sum) ()	Fenamiphos-sulfone (0.02)
Fenamiphos-sulfoxide (0.02)	Fenchlorphos (0.02)	Fenchlorphos oxon (0.
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)

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

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)
Phentoate (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)
Prothifofos (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)

Organonitrogen pesticide

Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)	Pesticide (detection limit, ppm)
2-Phenylphenol (0.02)	Acetochlor (0.02)	Alachlor (0.02)
Ametryn (0.02)	Atrazine (0.02)	Azaconazole (0.02)
Azoxystrobin (0.02)	Biphenyl (0.02)	Bitertanol (0.02)
Bromacil (0.02)	Bromopropylate (0.02)	Buprofezin (0.02)
Chlorobenzilate (0.02)	Chloropropylate (0.02)	Chlorpropham (0.02)
Clodinafop-propargyl (0.02)	Cyanazine (0.02)	Cycloate (0.02)
DCIP (0.4)	Dichlofluanid (0.04)	Diphenylamine (0.02)
Etoxazole (0.02)	Fenazaquin (0.02)	Fluazifop-P-butyl (0.02)
Fluminoxazin (0.02)	Fluquinconazole (0.02)	Hexazinone (0.02)
Iprodione (0.02)	Lenacil (0.02)	Mepronil (0.02)
Metazachlor (0.02)	Metconazole, cis- (0.02)	Metconazole, trans- (0.02)
Methoprotryne (0.02)	Metolachlor (0.02)	Myclobutanil (0.02)
Napropamide (0.02)	Paclobutrazol (0.02)	Piperonyl butoxide (0.02)
Procymidone (0.02)	Prometryn (0.02)	Propachlor (0.02)
Propargite (0.02)	Propazine (0.02)	Propham (0.02)

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

Propiconazole (0.02)	Pyraclofos (0.02)	Pyridaben (0.02)
Pyrifenoxy (0.02)	Pyrimethanil (0.02)	Sebuthylazine (0.02)
Silafluofen (0.02)	Simazine (0.02)	Tebufenpyrad (0.02)
Terbutylazine (0.02)	Terbutryn (0.02)	Tetradifon (0.02)
Tolylfluanid (0.02)	Triticonazole (0.02)	Vinclozolin (0.02)



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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV25% (Luo Han Guo Extract) (Lot No.: (b) (6))	
Test Type	Test Only	
Job Number	(b) (6)	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

Ava Ren- Group Leader of Analytical Testing Service
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227032249

J-00252381

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227032249

J-00252381

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227032249

J-00252381

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www.nsfcinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV25% (Luo Han Guo Extract) (Lot No.: (b) (6))	
Test Type	Test Only	
Job Number	(b) (6)	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227032249

J-00252382

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.15
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227032249

J-00252382

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Picture of sample



Sample in Bag

End of Report

FI20170227032249

J-00252382

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www.nsfchina.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV25% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

(b) (6)

Report Authorization

Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227032812

J-00252383

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.15
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227032812

J-00252383

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Picture of sample



Sample in Bag

End of Report

FI20170227032812

J-00252383

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www.nsfcinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV30% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227032904

J-00252385

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227032904

J-00252385

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.



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检测技术有限公司
Shanghai Testing Technology Co., Ltd.

Picture of sample



Sample in Bag

End of Report

FI20170227032904

J-00252385

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.





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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV30% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227032958

J-00252386

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227032958

J-00252386

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.



Picture of sample



Sample in Bag

End of Report

FI20170227032958

J-00252386

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Minhang District, Shanghai, China
Tel: +86.21.2428.6300 | Fax: +21.2428.6299
www.nsfcinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV30% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227033049

J-00252387

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033049

J-00252387

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Picture of sample



Sample in Bag

End of Report

FI20170227033049

J-00252387

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV50% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

(b) (6)

Report Authorization

Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033203

J-00252388

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.12
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033203

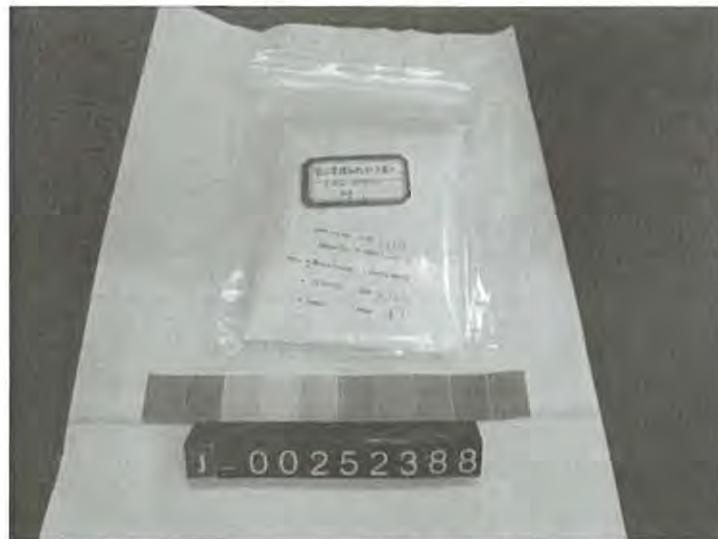
J-00252388

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227033203

J-00252388

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV50% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033252

J-00252389

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033252

J-00252389

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227033252

J-00252389

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV50% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033344

J-00252390

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.11
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033344

J-00252390

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Picture of sample



Sample in Bag

End of Report

FI20170227033344

J-00252390

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www.nsfcinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV55% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227033432

J-00252391

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.40
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033432

J-00252391

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227033432

J-00252391

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.





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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result Complete

Report Date 27-Feb-2017

Customer Name Hunan Nutramax Inc.
Description MV55% (Luo Han Guo Extract) (Lot No.: [REDACTED])
Test Type Test Only
Job Number [REDACTED]
Sample Reception Date 20-Feb-2017
Testing Date 20-Feb-2017~27-Feb-2017

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033546

J-00252392

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.38
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033546

J-00252392

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Picture of sample



Sample in Bag

End of Report

FI20170227033546

J-00252392

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV55% (Luo Han Guo Extract) (Lot No. (b) (6))	
Test Type	Test Only	
Job Number	(b) (6)	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227033642

J-00252393

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.38
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033642

J-00252393

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Picture of sample



Sample in Bag

End of Report

FI20170227033642

J-00252393

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Minhang District, Shanghai, China
Tel: +86.21.2428.6300 | Fax: +21.2428.6299
www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV60% (Luo Han Guo Extract) (Lot No.: (b) (6))	
Test Type	Test Only	
Job Number	(b) (6)	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033734

J-00252394

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.41
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

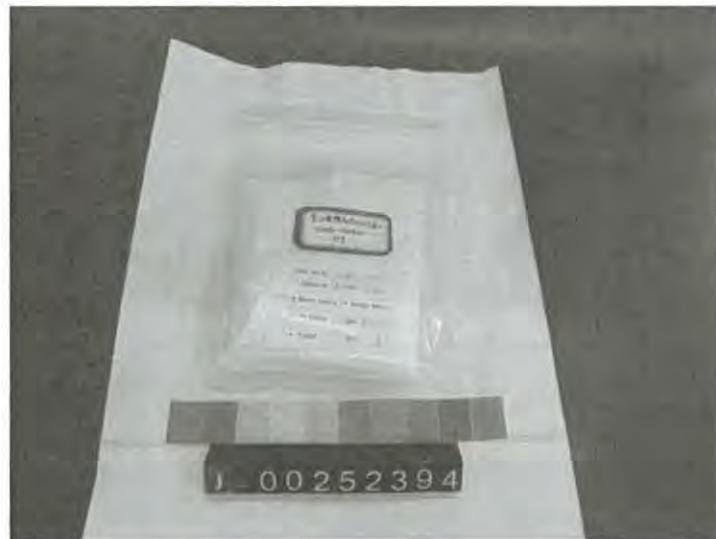
FI20170227033734

J-00252394

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Picture of sample



Sample in Bag

End of Report

FI20170227033734

J-00252394

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Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV60% (Luo Han Guo Extract) (Lot No.:)	
Test Type	Test Only	
Job Number	 	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

(b) (6)

Report Authorization

Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033823

J-00252395

Page 1 / 3

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1. Determination of Heavy Metals in the Sample.

1.1 Testing Procedure:

With Reference to USP 39<2232>

1.2 Testing Result:

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.21
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033823

J-00252395

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227033823

J-00252395

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Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV60% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227033911

J-00252396

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.10
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227033911

J-00252396

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Cerification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.



Page 2 / 3
EXAMINING & TESTING SERVICE
SHANGHAI (上海) 檢測技術有限公司

Picture of sample



Sample in Bag

End of Report

FI20170227033911

J-00252396

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Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV65% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227034008

J-00252397

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.36
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034008

J-00252397

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227034008

J-00252397

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV65% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analyse
NSF (Shanghai) Testing Technology



Date 27-Feb-2017

FI20170227034103

J-00252398

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 **Testing Procedure:**

With Reference to USP 39<2232>

1.2 **Testing Result:**

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.36
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034103

J-00252398

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result (s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.



Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227034103

J-00252398

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www.nsfchinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F, Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Result Complete

Report Date 27-Feb-2017

Customer Name Hunan Nutramax Inc.
Description MV65% (Luo Han Guo Extract) (Lot No.:)
Test Type Test Only
Job Number
Sample Reception Date 20-Feb-2017
Testing Date 20-Feb-2017~27-Feb-2017

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

(b) (6)

Report Authorization

Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227034151

J-00252399

Page 1 / 3

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1. Determination of Heavy Metals in the Sample.

1.1 Testing Procedure:

With Reference to USP 39<2232>

1.2 Testing Result:

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.35
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034151

J-00252399

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Page 2 / 3

Picture of sample



Sample in Bag

End of Report

FI20170227034151

J-00252399

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www.nsfcnlab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha, 410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha, 1001 , China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV95% (Luo Han Guo Extract) (Lot No. (b) (6))	
Test Type	Test Only	
Job Number	(b) (6)	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

Ava Ren- Group Leader of Analyse
NSF (Shanghai) Testing Technology

(b) (6)



Date 27-Feb-2017

FI20170227034205

J-00252400

Page 1 / 3

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1. **Determination of Heavy Metals in the Sample.**

1.1 Testing Procedure:

With Reference to USP 39<2232>

1.2 Testing Result:

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.12
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034205

J-00252400

The reports will set forth in writing the findings of NSF solely with respect to the products identified therein and, unless specifically indicated in the reports, the results set forth in such reports will not be indicative or representative of the characteristics of the product may be taken. Improper use for publicity purposes using the test result(s) is prohibited except with the specific written authorization of NSF. This report shall not be reproduced, except in its entirety, without the written approval of NSF. This report does not represent NSF Certification or authorization to use the NSF Mark. Authorization to use the NSF Mark is limited to products appearing in the Company's Official NSF Listing (www.nsf.org). The results relate only to those items tested, in the condition received at the laboratory.



Picture of sample



Sample in Bag

End of Report

FI20170227034205

J-00252400

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NSF International

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Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha, 1001 , China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV95% (Luo Han Guo Extract) (Lot No.: [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-2017	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

Report Authorization

(b) (6)
Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



1. Determination of Heavy Metals in the Sample.

1.1 Testing Procedure:

With Reference to USP 39<2232>

1.2 Testing Result:

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.14
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034248

J-00252401

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Picture of sample



Sample in Bag

End of Report

FI20170227034248

J-00252401

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NSF International

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Minhang District, Shanghai, China
Tel: +86.21.2428.6300 | Fax: +21.2428.6299
www.nsfcinalab.org

Result Summary

Send To: C0164123

Facility: C0164124

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha,410016, China

Hunan nutramax Inc.
25/F,Jiahege Building, No.217 Wanjiali Road,
Changsha, 1001 , China

Result	Complete	Report Date
Customer Name	Hunan Nutramax Inc.	27-Feb-2017
Description	MV95% (Luo Han Guo Extract) (Lot No. [REDACTED])	
Test Type	Test Only	
Job Number	[REDACTED]	
Sample Reception Date	20-Feb-201	
Testing Date	20-Feb-2017~27-Feb-2017	

Summary of Results

Testing Parameters and Standards	Result
Determination of Heavy Metals in the Sample with Reference to USP 39<2232>	See Page 2

(b) (6)

Report Authorization

Ava Ren- Group Leader of Analysis
NSF (Shanghai) Testing Technology

Date 27-Feb-2017



FI20170227034303

J-00252402

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1. Determination of Heavy Metals in the Sample.

1.1 Testing Procedure:

With Reference to USP 39<2232>

1.2 Testing Result:

Testing Parameter	Unit	Result
Lead(Pb)	mg/kg	ND(0.10)
Arsenic(As)	mg/kg	0.13
Mercury(Hg)	mg/kg	ND(0.01)
Cadmium(Cd)	mg/kg	ND(0.01)

Remark: ND = Not Detected, less than reporting limit.

FI20170227034303

J-00252402

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Picture of sample



Sample in Bag

End of Report

FI20170227034303

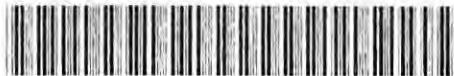
J-00252402

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Analytical Report

Sample Code (b) (6) Report date 02-Mar-2017
Certificate No. AR-17-SU-008681-01



HUNAN NUTRAMAX INC.

Huanhuan Zhang

F25, Jiahege BLDG, #217 Wanjiali Road,
Changsha, China

Our reference:	502-2017-00007266/ AR-17-SU-008681-01		
Client Sample Code:	(b) (6) [REDACTED]		
Sample described as:	Luo Han Guo Extract MV 25%		
Sample Packaging:	Sealed plastic bag		
Sample reception date:	18-Feb-2017		
Analysis starting date:	18-Feb-2017		
Analysis ending date:	02-Mar-2017		
Arrival Temperature (°C)	17.4	Sample Weight	250g
Sample Type	Powder		

		Results	Unit	LOQ	LOD
★ SP201	Organochlorine Pesticides, Pyrethroides Screened pesticides	Method: ASU L00.00-34 Not Detected			
★ SP203	Organophosphorus Pesticides Screened pesticides	Method: ASU L00.00-34 Not Detected			

List of screened and not detected molecules (* = limit of quantification)

Organochlorine Pesticides, Pyrethroids (LOQ* mg/kg)					
Acilonen (0.01)	Aznnathrin (0.02)	Aldrin (0.005)	Benfluralin (0.005)	Bifenox (0.02)	Binapacryl (0.02)
Bifenithrin (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)	Chlorhepten-prop-methyl (0.01)	Chlorsulfenol (0.01)	Chlorothalonil (0.01)	Chlorothalonil (0.01)
Chlorbutol-d-methyl (0.005)	Cyfluthrin (0.02)	Cyhalothrin, lambda (0.02)	Cypermethrin (0.02)	Cyphosol (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)	DDT, p,p- (0.005)
Diallate (0.05)	Dichlobenil (0.01)	Dichlorane (0.02)	Dicloran (0.005)	Dichlorobenzophenone, o,p- (0.04)	Dichlorobenzophenone, p,p- (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)	Efenvalerate (0.02)
Ethaflurin (0.01)	Etridiazole (0.01)	Fenfluthrin (0.02)	Fenpropathrin (0.02)	Fenxon (0.01)	Fenvalerate (RR-1SS-isomers) (0.01)
Fenvalerate (RS-/SR-Isomers) (0.01)	Fluhenzimine (0.01)	Fluochloralin (0.01)	Flucythrinate (0.02)	Flumetralin (0.01)	Fluorodifen (0.02)
Fluoromide (0.02)	Genetol (0.01)	Halifenprox (0.02)	HCH, alpha- (0.005)	HCH, beta- (0.01)	HCH, delta- (0.005)
HCH, epsilon- (0.005)	Lindane (gemme-HCH) (0.005)	Heptachlor (0.005)	Heptachlor epoxide, cis- (0.005)	Heptachlor epoxide, trans- (0.005)	Hexachlorobenzene (HCB) (0.005)
Isoxynil-octanoate (0.005)	Isobenzan (0.005)	Isodrin (0.005)	Isopropalin (0.01)	Methoxychlor (0.01)	Minex (0.005)
Nitrapyrin (0.01)	Nitrofen (0.01)	Ocidschlorostyrene (0.01)	Oxyfluorfen (0.01)	Pendimethalin (0.01)	Pentachloranisole (0.005)
Pentachloroanisole (0.005)	Pentachlorothioanisole (0.005)	Permethrin (0.02)	Piperfan (0.005)	Polychloroepoxide (Camphechlor) (0.2)	Proprulalin (0.005)
Propenol (0.02)	Quintozen (0.005)	S 421 (0.005)	tau-Fluvalinate (0.02)	Tacnonene (0.005)	Tefluthrin (0.02)
Tetraditon (0.01)	Tetrasul (0.01)	Traioneithrin (0.02)	Triallate (0.02)	Trichloronat (0.01)	Trifluralin (0.005)
Organophosphorus Pesticides (LOQ* mg/kg)					
Acephate (0.02)	Amidithion (0.02)	Azamethiphos (0.04)	Azinphos-ethyl (0.05)	Azinphos-methyl (0.05)	Bomyl (0.02)
Bromfenovinfos (0.02)	Bromphos-methyl (0.02)	Bromphos-ethyl (0.02)	Butanatos (0.02)	Cadusaphos (0.02)	Carbofenthion (0.02)
Carbofenthion-methyl (0.02)	Chlorfenvynphos (0.02)	Chloromephos (0.02)	Chlorpyrifos (-ethyl) (0.02)	Chlorpyrifos-methyl (0.02)	Chlorthon (0.02)
Chlorthiophos (0.02)	Coumaphos (0.05)	Crotoloxphos (0.02)	Crofomate (0.02)	Cyanoferphos (0.05)	Cyanophos (0.02)
Demeton-S-methyl (0.05)	Demeton-5-methyl-sulfone (0.05)	Dialisofos (0.05)	Diazinon (0.02)	Dicaphos (0.01)	Dichlofenthion (0.02)
Dichlorvos (0.01)	Dicrotothios (0.02)	Dimefox (0.02)	Dimethoate (0.02)	Dimethoate/Omethoate (sum) (0)	Dimethylvinphos (0.02)
Dioxabenzoates (0.02)	Dioxathion (0.02)	Disulfoton (0.02)	Disulfoton-sulfon (0.02)	Disulfoton-sulfoxide (0.04)	Dimilinos (0.02)
Edifenphos (0.05)	EPN (0.05)	Ethion (0.01)	Ethiphenphos (0.02)	Ethrinlos (0.02)	Famphos (0.05)
Fenamphos (0.02)	Fenamphos (sum) (0)	Fenamphos-sulfone (0.02)	Fenamphos-sulfoxide (0.02)	Fenchlorphos (0.02)	Fenchlorphos oxon (0.02)
Fenitrothion (0.01)	Fensulfolin (0.02)	Fensulfolin-oxon-sulfone (0.05)	Fensulfolin-oxon-sulfoxide (0.02)	Fensulfolion-sulfone (0.02)	Fenthion (0.01)
Fenthion-oxon (0.02)	Fenthion-oxon-sulfone (0.05)	Fenthion-sulfone (0.05)	Fenthion-sulfoxide (0.02)	Fenofos (0.02)	
Formothion (0.02)	Fosthiazate (0.02)	Fosthiazate (0.02)	Heptanophos (0.02)	Iodoferphos (0.02)	Iprabenitos (0.02)
Isazophos (0.02)	Isocarbilos (0.02)	Isophenphos (0.02)	Isophenphos-methyl (0.02)	Ioxathion (0.05)	Leptophos (0.05)
Malaoxon (0.02)	Malathion (0.02)	Mecarban (0.02)	Mephosfan (0.02)	Morphos (0.02)	Methacphos (0.02)
Methamphidios (0.02)	Methidathion (0.02)	Mevinphos (0.02)	Monocrotophos (0.01)	Morphothion (0.05)	Naled (0.02)

SP203 Organophosphorus Pesticides (LOQ* mg/kg)					
N-Desethyl-priniphos-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)	Phenoate (0.02)	Phorate (0.02)	Phorate (sum) ()
Phorate-sulfone (0.02)	Phorate-sulfoxide (0.02)	Phosaline (0.04)	Phosfolan (0.02)	Phosmet (0.05)	Phosphamidon (0.02)
Piperophos (0.02)	Priniphos-ethyl (0.02)	Priniphos-methyl (0.02)	Profenotol (0.02)	Propophos (0.02)	Propalamphos (0.02)
Prothiophos (0.02)	Prothoate (0.02)	Pyraclofos (0.05)	Pyrazophos (0.05)	Pyridaphenthion (0.02)	Pyrimitate (0.02)
Quinalphos (0.02)	Quintofos (0.02)	Sulfotep (0.02)	Suproto (0.05)	Tebupirimfos (0.02)	TEPP (0.02)
Terbufos (0.02)	Terbufos (sum) ()	Terbufos-sulfone (0.01)	Tetrachlorvinphos (0.02)	Thiomelon (0.02)	Thionazin (0.02)
Tetclofos-methyl (0.02)	Triemphos (0.05)	Thiazophos (0.01)	Tribufos (0.04)	Trichlorfon (0.05)	Vamidothion (0.04)

SIGNATURE (b) (6)

Lily Liu
Residues Manager

EXPLANATORY NOTE

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

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END OF REPORT



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Analytical Report
Sample Code
(b) (6)
Report date 02-Mar-2017

Certificate No.
AR-17-SU-008682-01

HUNAN NUTRAMAX INC.
Huanhuan Zhang
**F25, Jiahege BLDG, #217 Wanjiali Road,
Changsha, China**

Our reference:	502-2017-00007271/ AR-17-SU-008682-01
Client Sample Code:	(b) (6)
Sample described as:	Luo Han Guo Extract MV 25%
Sample Packaging:	Sealed plastic bag
Sample reception date:	18-Feb-2017
Analysis starting date:	18-Feb-2017
Analysis ending date:	02-Mar-2017
Arrival Temperature (°C)	17.4
Sample Type	Powder
Sample Weight	250g

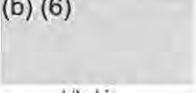
			Results	Unit	LOQ	LOD
★ SP201	Organochlorine Pesticides, Pyrethroids	Method: ASU L00.00-34	Not Detected			
	Screened pesticides					
★ SP203	Organophosphorus Pesticides	Method: ASU L00.00-34	Not Detected			
	Screened pesticides					

List of screened and not detected molecules (* = limit of quantification)

SP201 Organochlorine Pesticides, Pyrethroids (LOQ* mg/kg)					
Acetonfon (0.01)	Acinathrin (0.02)	Aldrin (0.005)	Benfluralin (0.005)	Bifenox (0.02)	Binapacryl (0.02)
Bifenthrin (0.02)	Bromocyclon (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)	Chlortenfon (0.01)	Chlorophenol (0.05)	Chlorophenol (0.01)
Chlorthal-dimethyl (0.005)	Cyfluthrin, lambda- (0.02)	Cyhalothrin, lambda- (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)	Dichlorone (0.02)	Disloran (0.005)	Dichlorobenzophenone, o,p- (0.04)	Dichlorobenzophenone, p,p- (0.04)
Dicofol, o,p- (0.04)	Dicofol, o,p- (0.04)	Dieldrin (0.005)	Dicrotochlor (0.02)	Dimethrinate (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)
Ethofluralin (0.01)	Etdiazole (0.01)	Endfenuthrin (0.02)	Enproprafen (0.02)	Fenson (0.01)	Fenvalerate (RR-/S5-Isomers) (0.01)
Fenvalerate (RS-/SR-Isomers) (0.01)	Flubenzimine (0.01)	Fluchlorazin (0.01)	Flueyfenthane (0.02)	Flumetralin (0.01)	Fluoridifen (0.02)
Fluorimide (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)
Isopropyl- <i>o</i> -octenolide (0.005)	Isobenzan (0.005)	Isodrin (0.005)	Isopropalin (0.01)	Methoxychlor (0.01)	Mirex (0.005)
Nitrapyn (0.01)	Nitrofen (0.01)	Octa-chlorostyrene (0.01)	Oxyfluorfen (0.01)	Pendimethalin (0.01)	Pentachloroanisole (0.005)
Pentachloroanisole (0.005)	Pentachloroanisole (0.005)	Permethrin (0.02)	Pifenox (0.005)	Poly(chloroterpene) (Camphachlor) (0.2)	Profumalin (0.005)
Propanil (0.02)	Quintozene (0.005)	S 421 (0.005)	tau-Fluvalinate (0.02)	Tecnazine (0.005)	Tefluthrin (0.02)
Tetradifon (0.01)	Tetrasul (0.01)	Tetralin (0.02)	Triaflate (0.02)	Trichloronat (0.01)	Trifluralin (0.005)
SP203 Organophosphorus Pesticides (LOQ* mg/kg)					
Acephate (0.02)	Amidithion (0.02)	Azamiphos (0.04)	Azinphos-ethyl (0.05)	Azinphos- methyl (0.05)	Bomyl (0.02)
Bromfenvinphos (0.02)	Bromophos-methyl (0.02)	Bromophos-ethyl (0.02)	Butamfos (0.02)	Cedaspaphos (0.02)	Carbofenthion (0.02)
Carbofenthion-methyl (0.02)	Chlorfenvinphos (0.02)	Chloromephos (0.02)	Chlorpyrifos (-ethyl) (0.02)	Chlorpyrifos-methyl (0.02)	Chlorthion (0.02)
Chlorthiophos (0.02)	Coumaphos (0.05)	Crotophos (0.02)	Crifomate (0.02)	Cyanoferphos (0.05)	Cyanophos (0.02)
Demeton-S-methyl (0.05)	Demeton-S-methyl-sulfone (0.05)	Dialifos (0.05)	Diazinon (0.02)	Dicapthion (0.01)	Dichlorfenthion (0.02)
Dichlorvos (0.01)	Diclorophos (0.02)	Dimefox (0.02)	Dimethoate (0.02)	Dimethoate/Ometoate (sum)	Dimethylvinphos (0.02)
Dioxabenzofos (0.02)	Dioxathion (0.02)	Disulfoton (0.02)	Disulfoton-sulfur (0.02)	Disulfoton-sulfoxide (0.04)	Ditaimfos (0.02)
Edifenphos (0.05)	EPN (0.05)	Etrion (0.01)	Ethoprophos (0.02)	Etrimos (0.02)	Famophos (0.05)
Fenamiphos (0.02)	Fenamiphos (sum) (0.02)	Fenamiphos-sulfone (0.02)	Fenamiphos-sulfoxide (0.02)	Fenchlorphos (0.02)	Fenchlorphos oxon (0.02)
Fenitrothion (0.01)	Fensulfolation (0.02)	Fensulfolation-oxon-sulfone (0.05)	Fensulfolation-oxon-sulfoxide (0.02)	Fensulfolation-sulfone (0.02)	Fenthion (0.01)
Fenthion-oxon (0.02)	Fenthion-oxon-sulfone (0.05)	Fenthion-oxon-sulfoxide (0.02)	Fenthion-sulfone (0.05)	Fenthion-sulfoxide (0.02)	Fonofos (0.02)
Formothion (0.02)	Fosfihetan (0.02)	Fosfihetan (0.02)	Heptenophos (0.02)	Iodofenphos (0.02)	Iprobenitos (0.02)
Iazophos (0.02)	Isocarbophos (0.02)	Isophenphos (0.02)	Isophenphos-methyl (0.02)	Isoxathion (0.05)	Leptophos (0.05)
Malexon (0.02)	Malathion (0.02)	Mecarbam (0.02)	Mephosfolan (0.02)	Mephos (0.02)	Methacryphos (0.02)
Methamidophos (0.02)	Methidathion (0.02)	Mevinphos (0.02)	Monoctophos (0.01)	Morphothion (0.05)	Naled (0.02)



SP203 Organophosphorus Pesticides (LOQ* mg/kg)					
N-Diethyl-p-nitrophos-methyl (0.02)	Omeothate (0.02)	Oxydemeton-methyl (0.05)	Paraoxon-ethyl (0.02)	Paraoxon-methyl (0.02)	Parathion (0.02)
Parathion-methyl (0.02)	Parathion-methyl/Paroxon-methyl (sum) (1)	Phenkapton (0.02)	Phenthroate (0.02)	Phorate (0.02)	Phorate (sum) (1)
Phorate-sulfone (0.02)	Phorate-sulfoxide (0.02)	Phosalone (0.04)	Phosfolan (0.02)	Phoermet (0.05)	Phosphamidon (0.02)
Piperophos (0.02)	Primiphos-ethyl (0.02)	Primiphos-methyl (0.02)	Profenofos (0.02)	Propaphos (0.02)	Propetamphos (0.02)
Prothiophos (0.02)	Prothioate (0.02)	Pyridofos (0.05)	Pyridophos (0.05)	Pyridophenthion (0.02)	Pymitrate (0.02)
Quinalphos (0.02)	Quinolfole (0.02)	Sulfotep (0.02)	Sulprofos (0.03)	Tebupirimfos (0.02)	TEPP (0.02)
Terbufos (0.02)	Terbufos (sum) (1)	Terbufos-sulfone (0.01)	Tetrachlorvinphos (0.02)	Thiometon (0.02)	Thionazin (0.02)
Tolclofos-methyl (0.02)	Triamphos (0.05)	Triazophos (0.01)	Tribufos (0.04)	Trichlorfon (0.05)	Vamsudithion (0.04)

SIGNATURE	(b) (6)
 Lily Liu Residues Manager	

EXPLANATORY NOTE	
≥ Greater than or equal to	★ means the test is subcontracted within Eurofins group
< Less than	● means the test is subcontracted outside Eurofins group
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N/A means Not applicable	
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END OF REPORT

Analytical Report

Sample Code

(b) (6)

Report date 02-Mar-2017

Certificate No.

AR-17-SU-008683-01



HUNAN NUTRAMAX INC.

Huanhuan Zhang

 F25, Jiahege BLDG, #217 Wanjiali Road,
 Changsha, China

Our reference:	502-2017-00007276/ AR-17-SU-008683-01			
Client Sample Code:	(b) (6)			
Sample described as:	Luo Han Guo Extract MV 25%			
Sample Packaging:	Sealed plastic bag			
Sample reception date:	18-Feb-2017			
Analysis starting date:	18-Feb-2017			
Analysis ending date:	02-Mar-2017			
Arrival Temperature (°C)	17.4	Sample Weight	250g	
Sample Type	Powder			
		Results	Unit	LOQ
★ SP201	Organochlorine Pesticides, Pyrethroids	Method: ASU L00.00-34		
	Screened pesticides	Not Detected		
★ SP203	Organophosphorus Pesticides	Method: ASU L00.00-34		
	Screened pesticides	Not Detected		

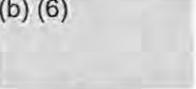
List of screened and not detected molecules (* = limit of quantification)

SP201 Organochlorine Pesticides, Pyrethroids (LOQ* mg/kg)				
Acetonfen (0.01)	Acinathrin (0.02)	Aldrin (0.005)	Benfurain (0.005)	Bifenox (0.02)
Bifenthrin (0.02)	Bromocyclen (0.02)	Bromoxynil-ocianate (0.01)	Butrafin (0.02)	Binapacryl (0.02)
Chlordane, trans- (0.005)	Chlordanepyr (0.005)	Chlordanprop-methyl (0.01)	Chlordan, cis- (0.005)	Chlordan, oxy- (0.005)
Chlorheptan-dimethyl (0.005)	Cyfluthrin (0.02)	Cyhalothrin, lambda- (0.02)	Chloroneb (0.06)	Chlorothalonil (0.01)
DDO, o,p- (0.005)	DDE, o,p- (0.005)	Cypermethrin (0.02)	Cyphenothrin (0.02)	DDO, o,p- (0.005)
Deltate (0.05)	Dichlobenil (0.01)	DDE, p,p- (0.005)	DDT, o,p- (0.005)	Deltamethrin (0.02)
Dicofol, o,p- (0.04)	Dicofol, o,p- (0.04)	Dichlor (0.02)	DDT, p,p- (0.005)	Dichlorobenzophenone, o,p- (0.04)
Endosulfan, alpha- (0.005)	Endosulfan sulphate (0.01)	Dieldrin (0.005)	Dicloran (0.005)	Dichlorobenzophenone, p,p- (0.04)
Ethflurazin (0.01)	Etdiazole (0.01)	Endosulfan, beta- (0.005)	Dieldrin (0.01)	Dinobutin (0.02)
Fenvalerate (RS-/SR-isomers) (0.01)	Flobenzimine (0.01)	Fenfluthrin (0.02)	Endrin (0.01)	Efenvanerate (0.02)
Fluorolide (0.02)	Genite (0.01)	Fenpropidin (0.02)	Fenson (0.01)	Fenvanlate (RR-/SS-isomers) (0.01)
HCH, epsilon- (0.005)	Lindane (gamma-HCH) (0.005)	Halphenox (0.02)	Fluendriatrin (0.01)	Fluorodifen (0.02)
Isoxynil-octanoate (0.005)	Isobenzan (0.005)	Heptachlor (0.005)	HCH, alpha- (0.005)	HCH, delta- (0.005)
Nitrapyrin (0.01)	Nitrofen (0.01)	Isopropalin (0.01)	Heptachlor epoxide, trans- (0.005)	Hexachlorobenzene (HCB) (0.005)
Penachloroaniline (0.005)	Penachlorothiophanisole (0.005)	Oclachlorstyrene (0.01)	Methoxychlor (0.01)	Mirex (0.005)
Propanil (0.02)	Quintozene (0.005)	Permethrin (0.02)	Penimethalin (0.01)	Pentachloranisole (0.005)
Tetradifon (0.01)	Quintozene (0.005)	S 421 (0.005)	Polychlorotarpenes (Camphochlor) (0.2)	Profurain (0.005)
	Tetrasul (0.01)	Tralomethrin (0.02)	tau-Fluvalinate (0.02)	Tetluthrin (0.02)
			Trisilate (0.02)	Trichloran (0.01)
				Trifluralin (0.005)
SP203 Organophosphorus Pesticides (LOQ* mg/kg)				
Acaphate (0.02)	Amidithion (0.02)	Azamethiphos (0.04)	Azinphos-ethyl (0.05)	Bomyl (0.02)
Bromfenimprinos (0.02)	Bromophos-methyl (0.02)	Bromophos-ethyl (0.02)	Cadusaphos (0.02)	Carbofenthion (0.02)
Carbofenthion-methyl (0.02)	Chlorfenvinphos (0.02)	Chlorfenvinphos (0.02)	Chlorpyrifos-methyl (0.02)	Chlorthion (0.02)
Chlothiophos (0.02)	Coumaphos (0.05)	Clotophos (0.02)	Cyanocephos (0.05)	Cyanocephos (0.02)
Demeton-S-methyl (0.05)	Demeton-S-methyl-sulfone (0.05)	Diafenthro (0.05)	Dicaphthon (0.01)	Dichlorfenthion (0.02)
Dichlorvos (0.01)	Dicrotophos (0.02)	Dimefox (0.02)	Dimethoate (0.02)	Dimethylvinphos (0.02)
Dioxabenzofos (0.02)	Dioxathion (0.02)	Disulfoton (0.02)	Disulfoton-sulfate (0.02)	Ditalimfos (0.02)
Edifenphos (0.05)	EPN (0.05)	Ethion (0.01)	Ethoprophos (0.02)	Famphos (0.05)
Fenamiphos (0.02)	Fenamiphos (sum) (i)	Fenamiphos-sulfone (0.02)	Fenamiphos-sulfoxide (0.02)	Fenchlorphos oxon (0.02)
Fenitrothion (0.01)	Fenulifothion (0.02)	Fenulifothion-oxon-sulfone (0.05)	Fensulifothion-sulfone (0.02)	Fenthion (0.01)
Fenthion-oxon (0.02)	Fenthion-oxon-sulfone (0.05)	Fenthion-oxon-sulfone (0.02)	Fenthion-sulfone (0.05)	Fenthion-sulfoxide (0.02)
Formothion (0.02)	Fosfthiazate (0.02)	Fosfihexan (0.02)	Heptenophos (0.02)	Iprobenic (0.02)
Isophosphos (0.02)	Isocarbofos (0.02)	Isofenthphos-methyl (0.02)	Isoxathion (0.05)	Leptophos (0.05)
Melaoxon (0.02)	Melation (0.02)	Mecarbam (0.02)	Mephosfolan (0.02)	Melaphosphos (0.02)
Methamidophos (0.02)	Methidathion (0.02)	Mevinphos (0.02)	Monocrotophos (0.01)	Morphothion (0.05)
				Naled (0.02)

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SP203	Organophosphorus Pesticides (LOQ* mg/kg)				
N-Decethyl-pramiphos-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)	Phenoate (0.02)	Phorate (0.02)	Phorate (sum) ()
Phorate-sulfone (0.02)	Phorate-sulfoxide (0.02)	Phosalone (0.04)	Phosfolen (0.02)	Phoamet (0.05)	Phosphamidon (0.02)
Piperophos (0.02)	Pirimiphos-ethyl (0.02)	Pirimiphos-methyl (0.02)	Profenofos (0.02)	Propiphos (0.02)	Propetamphos (0.02)
Prothiophos (0.02)	Prothiophos (0.02)	Pyrazofos (0.05)	Pyrazophos (0.05)	Pyridaphenthion (0.02)	Pyrimitu (0.02)
Quinalphos (0.02)	Quinalfos (0.02)	Sulfotep (0.02)	Suprofos (0.05)	Tebupirimfos (0.02)	TEPP (0.02)
Terbufos (0.02)	Terbufos (sum) ()	Terbufos-sulfone (0.01)	Tetachlorvinphos (0.02)	Thiomelon (0.02)	Thionazin (0.02)
Toxiclos-methyl (0.02)	Triamiphos (0.05)	Triazophos (0.01)	Tribufos (0.04)	Trichlorfon (0.05)	Vamidothion (0.04)

SIGNATURE	(b) (6)
 Lily Liu Residues Manager	

EXPLANATORY NOTE	
≥ Greater than or equal to	
< Less than	* means the test is subcontracted within Eurofins group
≤ Less than or equal to	⊕ means the test is subcontracted outside Eurofins group
N/A means Not applicable	
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Analytical Report

Sample Code

(b) (6)

Report date 19-Dec-2016

Certificate No.

AR-16-SU-066359-01



HUNAN NUTRAMAX INC.

Huanhuan Zhang

 F25, Jiahege BLDG, #217 Wanjiali Road,
 Changsha, China

Our reference:	502-2016-00068265/ AR-16-SU-066359-01			
Sample described as:	Luo Han Guo Extract MV 20%			
Sample Packaging:	Sealed plastic bag			
Sample reception date:	01-Dec-2016			
Analysis starting date:	01-Dec-2016			
Analysis ending date:	13-Dec-2016			
Arrival Temperature (°C)	17.8	Sample Weight	60g	
Sample Type	Powder			
		Results	Unit	LOQ
★ SP201	Organochlorine Pesticides, Pyrethroids	Method: ASU L00.00-34		LOD
	Screened pesticides	Not Detected		
★ SP203	Organophosphorus Pesticides	Method: ASU L00.00-34		
	Screened pesticides	Not Detected		
★ SP205	Organonitrogen Pesticides	Method: ASU L00.00-34		
	Screened pesticides	Not Detected		

List of screened molecules (* = limit of quantification)

SP201 Organochlorine Pesticides, Pyrethroids (LOQ* mg/kg)				
Acitonfen (0.01)	Acitonfen (0.02)	Aldrin (0.005)	Bifenthrin (0.02)	Binapacryl (0.02)
Bilfenthrin (0.02)	Bromopcyden (0.02)	Bromoxylin-octanoate (0.01)	Chlordane, cis- (0.005)	Chlordane, oxy- (0.005)
Chlordane, trans- (0.005)	Chlordanepyr (0.005)	Chlorfenprop-methyl (0.01)	Chlorfenson (0.05)	Chlorothalonil (0.01)
Chloorthol-dimethyl (0.005)	Cyluthrin (0.02)	Chloathrin, lamellar (0.02)	Cyphenothrin (0.02)	DDO, o,p- (0.005)
DDO, o,p- (0.005)	DDE, o,p- (0.005)	Cypermethrin (0.02)	DDT, p,p- (0.005)	Delamethrin (0.02)
Diolote (0.05)	Dichoben (0.01)	DDE, p,p- (0.005)	Dichlorobenzophenone, o,p- (0.04)	Dichlorobenzophenone, p,p- (0.04)
Dicofol, o,p- (0.04)	Dicofol, o,p- (0.04)	Dieldrin (0.005)	Dimethrinate (0.01)	Dimobulon (0.02)
Endosulfan, alpha- (0.005)	Endosulfan sulfate (0.01)	Endosulfan, beta- (0.005)	Endrin (0.01)	Esfenvalerate (0.02)
Eththaluralin (0.01)	Etridiazole (0.01)	Fentufluhrin (0.02)	Fenpropidin (0.02)	Fenvalerate (RR-SS-Isomers) (0.01)
Fenvalerate (RS-/SR-Isomers) (0.01)	Flubenzamine (0.01)	Fluclorinalin (0.01)	Fluometralin (0.01)	Fluorodifen (0.02)
Fluoromide (0.02)	Geotrope (0.01)	Fluoropropox (0.02)	HCH, alpha- (0.005)	HCH, delta- (0.005)
HCH, epsilon- (0.005)	Lindane (gamma-HCH) (0.005)	Heptachlor (0.005)	Hep'tachlor epoxide, cis- (0.005)	Hexachlorobenzene (HCB) (0.005)
Ioxynil-octanate (0.005)	Isobenzan (0.005)	Isopropalin (0.01)	Isopropalin (0.01)	Mirex (0.005)
Nitropirin (0.01)	Nitrofen (0.01)	Decachlorostyrene (0.01)	Pendimethalin (0.01)	Penitochloranisole (0.0)
Penitochloraniline (0.005)	Pentachlorothiophenol (0.005)	Permethrin (0.02)	Piperate (0.005)	Pirofuran (0.005)
Propanil (0.02)	Quinolozene (0.005)	S 421 (0.005)	Iau-Fluvalinate (0.02)	Tecnazeze (0.005)
Tetradon (0.01)	Tetralug (0.01)	Tralomethrin (0.02)	Triallate (0.02)	Teuluhrin (0.02)
SP203 Organophosphorus Pesticides (LOQ* mg/kg)				
Acephate (0.02)	Amidithion (0.02)	Azamiphos (0.04)	Azinphos-methyl (0.05)	Bornyl (0.02)
Bromfenveprinolos (0.02)	Bromophos-methyl (0.02)	Bromophos-ethyl (0.02)	Cadusaphos (0.02)	Carbofenthion (0.02)
Carbofenthion-methyl (0.02)	Chlorfenveprinolos (0.02)	Chlorophos (0.02)	Chlorpyrifos-methyl (0.02)	Chlorothion (0.02)
Chlortholos (0.02)	Coumaphos (0.05)	Crotolophos (0.02)	Cyanoophos (0.05)	Cyanophos (0.02)
Demeton-S-methyl (0.05)	Demeton-S-methyl-sulfone (0.05)	Diafolos (0.05)	Dicaphion (0.01)	Dichlofenthion (0.02)
Dichlorvos (0.01)	Diclorophos (0.02)	Dimefox (0.02)	Dimethoate (0.02)	Dimethylvinphos (0.02)
Dioxabenzolos (0.02)	Dioxathion (0.02)	Disulfoton (0.02)	Disulfoton-sulfone (0.02)	Dikalimtos (0.02)
Edifenphos (0.05)	EPN (0.05)	Ethion (0.01)	Ethiphophos (0.02)	Famphos (0.05)
Fenamiphos (0.02)	Fenamiphos (sum) ()	Fenamiphos-sulfone (0.02)	Fenamiphos-sulfonate (0.02)	Fenchlorphos oxon (0.01)
Fentrolithon (0.01)	Fensulfothion (0.02)	Fensulfothion-oxon-sulfone (0.05)	Fensulfothion-oxon-sulfoxide (0.02)	Fensulfothion-sulfone (0.02)
Fenthion-oxon (0.02)	Fenthion-oxon-sulfone (0.05)	Fenthion-oxon-sulfoxide (0.02)	Fenthion-sulfaxide (0.02)	Fondos (0.02)
Fomethox (0.02)	Fosthiazate (0.02)	Fosthietan (0.02)	Iodofenphos (0.02)	Iprobenitos (0.02)
Iazophos (0.02)	Ioscarbfos (0.02)	Iacfenphos (0.02)	Iosathion (0.05)	Leptophos (0.05)
Malaoxon (0.02)	Malathion (0.02)	Mecabam (0.02)	Mephosfolan (0.02)	Methacriphos (0.02)

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SP203 Organophosphorus Pesticides (LOQ* mg/kg)					
Methomilophos (0.02)	Methidathion (0.02)	Mevinphos (0.02)	Monocrotophos (0.01)	Morphthion (0.05)	Naled (0.02)
- N-Desethyl-primpnos-methyl (0.02)	Dimethoate (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) ()	Phenaketon (0.02)	Phenate	Phorate (0.02)	Phorate (sum) ()
Phorate-sulfone (0.02)	Phorate-sulfone (0.02)	Phosalone (0.04)	Phosolan (0.02)	Phosmet (0.05)	Phosphamidon (0.02)
Piperophos (0.02)	Primiphos-ethyl (0.02)	Primiphos-methyl (0.02)	Profenitos (0.02)	Propaphos (0.02)	Propanaphos (0.02)
Prothiophos (0.02)	Prothoate (0.02)	Pyraclofos (0.05)	Pyrazophos (0.05)	Pyridaphenthion (0.02)	Pyrimidale (0.02)
Quinalphos (0.02)	Quintofos (0.02)	Sulfotep (0.02)	Suprofos (0.05)	Tebupirimfos (0.02)	TEPP (0.02)
Terbufos (0.02)	Terbufos (sum) ()	Terbufos-sulfone (0.01)	Tetrachlorvinphos (0.02)	Thiomecton (0.02)	Thiouazin (0.02)
Tetlocllos-methyl (0.02)	Triemiphos (0.05)	Triazaphos (0.01)	Tribufos (0.04)	Trichlorfon (0.05)	Vamidothion (0.04)

SP205 Organonitrogen Pesticides (LOQ* mg/kg)					
2-Phenylphenol (0.02)	Acetochlor (0.02)	Alethochlor (0.02)	Ametryn (0.02)	Atrazine (0.02)	Azacorazole (0.02)
Azoxystrobin (0.02)	Biphenyl (0.02)	Bifenthrin (0.02)	Bromacil (0.02)	Bromopropylate (0.02)	Buprofezin (0.02)
Chlorbenzilate (0.02)	Chlorpropylate (0.02)	Chlorpropham (0.02)	Clodinafop-propargyl (0.02)	Cyanazine (0.02)	Cycloate (0.02)
DCIP (0.4)	Dichlofuanid (0.04)	Diphenylamine (0.02)	Etoxazole (0.02)	Fenazaquin (0.02)	Fluazifop-P-butyl (0.02)
Fumoxuzin (0.02)	Fluquinconazole (0.02)	Hexazinone (0.02)	Iprodione (0.02)	Isopacil (0.02)	Meproni (0.02)
Melazachlor (0.02)	Melconazole, cis- (0.02)	Melconazole, trans- (0.02)	Methoprotione (0.02)	Metolachlor (0.02)	Myclobutanil (0.02)
Napropamide (0.02)	Packbutrazol (0.02)	Piperonyl butoxide (0.02)	Procymidone (0.02)	Prometryn (0.02)	Propachlor (0.02)
Propargite (0.02)	Propazine (0.02)	Propham (0.02)	Propiconazole (0.02)	Pyraclofos (0.02)	Pyradaben (0.02)
Pyrifenoxy (0.02)	Pyrimethanil (0.02)	Sebutylazine (0.02)	Sisfipronil (0.02)	Simazine (0.02)	Tabufenpyrad (0.02)
Terbutylazine (0.02)	Terbutryn (0.02)	Tetradifon (0.02)	Tolyfluanid (0.02)	Triticonazole (0.02)	Vinclozolin (0.02)

SIGNATURE

(b) (6)

 Lily Liu
 Residues Manager

EXPLANATORY NOTE

≥ Greater than or equal to

< Less than

≤ Less than or equal to

N/A means Not applicable

The result(s) relate(s) only to the item (s) tested.

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For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

GRAS Notice (GRN) 706 amendment

From: [Susan S Cho](#)
To: [Morissette, Rachel](#)
Subject: Amendment to GRN 706 S. grosvenorii (Luo Han Guo) fruit extract
Date: Monday, July 03, 2017 12:19:38 PM
Attachments: [Amendment to GRN 706 S. grosvenorii Swingle \(Luo Han Guo\) fruit extract.pdf](#)

Dear Dr. Morissette,

Please find an amendment to GRN 706, *S. grosvenorii* (Luo Han Guo) fruit extract. We would appreciate your kind attention to this matter. Have a nice July 4th holiday! Thanks

Sincerely,
Susan
Susan Cho, Ph.D.
NutraSource, Inc.
6309 Morning Dew Ct Clarksville, MD 21029 +1-410-531-3336 (O) +1-301-875-6454 (C)

NutraSource, Inc.
6309 Morning Dew Ct.
Clarksville, MD 21029, USA

July 3, 2017

Rachel Morissette, Ph.D.
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
U.S. Food and Drug Administration

Subject: Amendment to GRN 706, *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extracts

Dear Dr. Morissette,

Please find an amendment to page 39, the 3rd row from the bottom: PQQ disodium salt has been replaced with *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract. We would appreciate your kind attention to this matter.

Respectfully Submitted by



Susan Cho, Ph.D.
Chief Science officer

Siraitia grosvenorii Swingle (Luo Han Guo) Fruit Extracts

noted at up to 3,120-3,750 mg/kg bw/day of Luo Han Guo fruit extracts, the highest dose levels tested. The publicly available scientific literature on the consumption and safety of Luo Han Guo fruit extracts in human clinical studies is extensive and sufficient to support the safety and GRAS status of the proposed Luo Han Guo fruit extracts.

The Nutramax concluded that these uses of Luo Han Guo fruit extract 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.

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