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GRAS Notice (GRN) No. 359

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ORIGINAL SUBMISSION

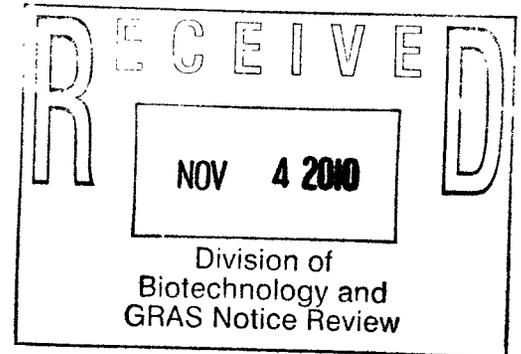
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CANTOX
HEALTH SCIENCES INTERNATIONAL

1011 US Highway 22, Ste 200
Bridgewater, NJ 08807-2950
Phone: (908) 429-9202
Fax: (908) 429-9260

November 3, 2010

Robert L. Martin, Ph.D.
Deputy Director
Division of Biotechnology and GRAS Notice Review (HFS-255)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740



Dear Dr. Martin:

Pursuant to proposed 21 CFR 170.36 (62 FR 18960; April 17, 1997), Guilin Layn Natural Ingredients Corp. (Layn) of Guangxi, China, through myself as agent, hereby provides notice of a claim that powder extracts from the Luo Han fruit (*Siraitia grosvenori*) containing up to 55% mogroside V (*i.e.*, Go-Luo™ powder extracts) are exempt from the premarket approval requirement of the Federal Food, Drug, and Cosmetic Act because Layn has determined that their use as general purpose sweeteners and flavor modifiers in conventional foods, as described in the enclosed notification document, is generally recognized as safe (GRAS) based on scientific procedures.

Enclosed please find three copies of the notification. All data and information that are the basis for this GRAS determination are available for FDA's review and copying at reasonable times at Cantox U.S. Inc., 1011 US Highway 22, Suite 200, Bridgewater, NJ 08807, and will be sent to FDA upon request.

If you have any questions regarding this notification, please feel free to contact me at 908-429-9202 or dbechtel@cantox.com.

Sincerely,

(b) (6)

David H. Bechtel, Ph.D., DABT
Vice President & Senior Scientific Consultant

Encl.

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GRAS Exemption Claim for the use of Go-Luo™ Powder Extracts from Luo Han Fruit (*Siraitia grosvenori*) as General Purpose Sweeteners and Flavor Modifiers in Foods

1. Name and Address of Notifier

Guilin Layn Natural Ingredients Corp.
3/F, Block A, No. 22
Lijiang Road
Guilin 541004
Guangxi, China

Contact: David H. Bechtel, Ph.D., DABT
Telephone: (909) 429-9202
Fax: (908) 429-9260
E-mail: dbechtel@cantox.com

2. Name of GRAS Substance

The subject of this GRAS Notice is powder extracts from the Luo Han fruit (*Siraitia grosvenori*) containing up to 55% mogroside V, to be marketed under the trade name Go-Luo™. Layn intends to market three Go-Luo™ powder extracts with a mogroside V content of 25%, 45%, and 55%. Mogroside V is one of the cucurbitane glycosides responsible for the sweetness of the fruit.

3. Intended Use and Consumer Exposure

Go-Luo™ powder extracts are intended to be added to conventional foods as a general purpose sweetener and flavor modifier at the concentrations needed, consistent with GMP. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting. Projected exposures to mogroside V among adults and children from consumption of foods containing Go-Luo™ powder extracts are approximately 10 times lower than what might be considered the reference dose safe for human exposure (18.92 mg/kg bw/day).

4. Basis for GRAS Determination

Go-Luo™ powder extracts are similar in composition to BioVittoria's PureLo® Luo Han Fruit concentrate, a material previously affirmed GRAS (GRN 000301) with no questions from the US FDA CFSAN/Office of Food Additive Safety. However, Go-Luo™ powder extracts are more purified and contain up to 55% mogroside V, compared to the ≥ 30% mogroside V in PureLo®.

To make a determination that the use of Go-Luo™ powder extracts in foods as general purpose sweeteners and flavor modifiers is generally recognized as safe (GRAS) through scientific procedures, Layn has relied on the primary evidence of safety described in GRN 000301, supported by additional studies of Go-Luo™ 55% (mogroside V) powder extract. This information was compiled into a dossier provided to an Expert Panel that deliberated on the qualifications of three Go-Luo™ powder extracts (25, 45, and 55% mogroside V) as GRAS food ingredients.

After a critical independent evaluation of the available safety and other information, the Expert Panel conferred and unanimously determined that the use of Go-Luo™ powder extracts containing 25, 45, and 55% mogroside V as general purpose sweeteners and flavor modifiers in foods would entail a reasonable certainty of no harm and qualify as GRAS food ingredients.

5. Availability of Information

All data and information that are the basis for this GRAS determination are available for FDA's review and copying at reasonable times at Cantox U.S. Inc., 1011 US Highway 22, Suite 200, Bridgewater, NJ 08807, and will be sent to FDA upon request.

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HEALTH SCIENCES INTERNATIONAL

Notice to U.S. FDA CFSAN / Office of Food Additive Safety:

The use of Go-Luo™ Powder Extracts from Luo Han Fruit (*Siraitia grosvenori*) in Foods as a General Purpose Sweetener and Flavor Modifier is Generally Recognized as Safe (GRAS)

Prepared for: Guilin Layn Natural Ingredients Corp.
3/F, Block A, No. 22
Lijiang Road
Guilin 541004
Guangxi, China

Prepared by: Cantox Health Sciences International
1011 U.S. Highway 22, Suite 200
Bridgewater, New Jersey
08807-2950

November 3, 2010

Cantox Offices:

**Mississauga, ON
CANADA
905-542-2900**

**Bridgewater, NJ
USA
908-429-9202**

**Fleet, Hampshire
UK
+44 (0) 870 351 3780**

**Shinjuku, Tokyo
JAPAN
81-3-5287-3522**

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Notice to U.S. FDA CFSAN/Office of Food Additive Safety: The use of Go-Luo™ Powder Extracts from Luo Han Fruit (*Siraitia grosvenori*) in Foods as a General Purpose Sweetener is Generally Recognized as Safe (GRAS)

Table of Contents

1.0	INTRODUCTION	1
1.1	Background	1
1.2	Summary of Information Supporting GRAS Determination	1
2.0	MANUFACTURING PROCESS	3
3.0	PRODUCT SPECIFICATIONS AND ANALYSES	7
4.0	INTENDED FOOD USE APPLICATIONS	13
4.1	Intended Uses	13
4.2	Sweetness Intensity	13
4.3	Exposure Estimates	13
4.4	Assessments of Risk	17
4.4.1	Assessments of Go-Luo™ Powder Extract Risk Based Upon Primary Evidence of Safety	17
4.4.2	Comparative Assessments of PureLo® Based Upon Primary Evidence of Safety	19
4.4.3	Assessments of Go-Luo™ Powder Extract Risk Based Upon Supporting Evidence of Safety	20
4.4.4	Comparative Assessments of PureLo® Based Upon Supporting Evidence of Safety	22
5.0	SAFETY DATA	24
5.1	Primary Evidence of Safety	24
5.2	Supporting Evidence of Safety	25
5.2.1	Mutagenicity Assay	25
5.2.2	90-Day Oral (Dietary) Toxicity Study in Rats	26
5.3	Additional Safety Data	28
5.4	Ribosome-Inactivating Proteins (RIP)	29
5.5	Other Supportive Non-Safety Studies	30
6.0	SUMMARY AND CONCLUSION	31
7.0	REFERENCES	32

APPENDIX 1: EXPERT PANEL OPINION REGARDING THE GRAS USE OF GUILIN LAYN GO-LUO™ POWDER EXTRACTS IN FOODS	1
APPENDIX 2: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 25% POWDER EXTRACT	2
APPENDIX 3: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 45% POWDER EXTRACT	3
APPENDIX 4: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 55% POWDER EXTRACT	4
APPENDIX 5: ASSAY FOR ANALYSIS OF MOGROSIDE V CONTENT IN GO-LUO™ POWDER EXTRACTS	5
APPENDIX 6: QUALITY ASSURANCE ANALYSES FOR MULTIPLE BATCHES OF GO-LUO™ 55% POWDER EXTRACT	6
APPENDIX 7: ASSAY OF SWEETNESS INTENSITY FOR GO-LUO™ POWDER EXTRACTS	7

Tables and Figures

Figure 2-1	Overview of the production process for Go-Luo™ 25% Powder Extract (25% mogroside V)	4
Figure 2-2	Overview of the production process for Go-Luo™ 45% Powder Extract (45% mogroside V)	5
Figure 2-3	Overview of the production process for Go-Luo™ 55% Powder Extract (55% mogroside V)	6
Table 3-1	Summary of Go-Luo™ 25% Powder Extract analyses	8
Table 3-2	Summary of Go-Luo™ 45% Powder Extract analyses	9
Table 3-3	Summary of Go-Luo™ 55% Powder Extract analyses	10
Table 3-4	Summary of quality assurance analyses for multiple batches of Go-Luo™ 55% Powder Extract	11
Table 4-1	Sweetness Potency of Different Specifications of Go-Luo™ Powder Extracts	13
Table 4-2	Estimated Intake of Go-Luo™ 25% Powder Extract and Mogroside V by Population Group	15
Table 4-3	Estimated Intake of Go-Luo™ 45% Powder Extract and Mogroside V by Population Group	15
Table 4-4	Estimated Intake of Go-Luo™ 55% Powder Extract and Mogroside V by Population Group	15
Table 4-5	Estimated Intake of PureLo® Fruit Concentrate Powder Extract and 30% Mogroside V by Population Group	16
Table 4-6	Estimated Intake of PureLo® Fruit Concentrate Powder Extract and 39% Mogroside V by Population Group	16
Table 4-7	Tabular Summary Assessment of Safety Factors Based Upon Primary Evidence of Safety Specific to the Maximum Intakes of Go-Luo™ and Go-Luo™-Derived Mogroside V	19
Table 4-8	Comparative Tabular Summary Assessment of Safety Factors Based Upon Primary Evidence of Safety Specific to the Maximum Intakes of PureLo® and PureLo®-Derived Mogroside V	20
Table 4-9	Tabular Summary Assessment of Safety Factors Based Upon Supporting Safety Data Specific to the Maximum Intakes of Go-Luo™ and Go-Luo™-Derived Mogroside V	22
Table 4-10	Comparative Tabular Summary Assessment of Safety Factors Based Upon Supporting Safety Data Specific to the Maximum Intakes of PureLo® and PureLo®-Derived Mogroside V	23

1.0 INTRODUCTION

1.1 Background

Guilin Layn Natural Ingredients Corp. (Layn) has made a determination that the use of powdered fruit extracts (Go-Luo™) derived from the luo han fruit, also known as luo han guo (LHG) and lo han kuo (LHK), in foods as general purpose sweeteners and flavor modifiers is generally recognized as safe (GRAS) through scientific procedures. Use in meat and other products regulated by USDA is not intended.

LHG has been previously reviewed by the US Food and Drug Administration (FDA). In response to a New Dietary Ingredient premarket notification for Lo Han Kuo Fruit Extract (*Siraitia grosvenorii* (swingle) C. Jeffrey) submitted by Nature's Marvel International, CFSAN/Office of Food Additive Safety indicated that Lo Han Kuo is a conventional food ingredient (Agency Response Letter, Oct. 8, 1999, docket number 95S-03 16). The Agency also had no questions regarding BioVittoria's notification that the use of a *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract (SGFE) (PureLo® brand) as a flavor modifier and sweetener is GRAS through scientific procedures (Agency Response Letter to GRAS Notice No. GRN 000301, January 15, 2010). BioVittoria's product is a liquid or powder product composed of a mixture of mogrosides (II, III, IV, V, and VI), flavonoids and melanoidins. Mogroside V (CAS Reg. No. 88901-36-4) is identified as the major component, constituting over 30% of the product, and is primarily responsible for the sweetness of the product.

The present document notifies CFSAN/Office of Food Additive Safety that Layn considers Go-Luo™ powder extracts containing up to 55% mogroside V exempt from the definition of "food additive" and thus from the premarket approval requirements outlined in section 201(s) of the Federal Food, Drug, and Cosmetic Act based on (1) the available technical evidence of safety and (2) the opinion of an independent Expert Panel regarding the value of this information in supporting consensus of GRAS among their peers.

1.2 Summary of Information Supporting GRAS Determination

A comprehensive report (GRAS dossier) that included information on the nature of the substance(s), specifications, manufacturing, proposed uses, and technical evidence of safety was provided to an Expert Panel that deliberated on the qualifications of three Go-Luo™ powder extracts (25, 45, and 55% mogroside V) as GRAS food ingredients. Go-Luo™ powder extracts are intended for use in foods as general purpose sweeteners and flavor modifiers.

In its deliberation, the Expert Panel considered the following elements. A full Expert Panel opinion statement is attached as Appendix 1.

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- The source material of the Go-Luo™ powder extracts, the *Siraitia grosvenorii* Swingle fruit, has a long-time safe presence as a conventional food in the human diet;
- Go-Luo™ powder extracts are manufactured under Good Manufacturing Practices (GMP) using common food industry materials and processes;
- Analytical data from multiple lots indicate that Go-Luo™ powder extracts comply reliably with the established food-grade product specifications and meet all applicable purity standards;
- While similar in composition to BioVittoria's PureLo® Luo Han Fruit concentrate (with ≥ 30% mogroside V), a material previously affirmed GRAS (GRN 000301) with no questions from the Agency, Go-Luo™ powder extracts are purer and contain up to 55% mogroside V;
- Layn is relying on the primary evidence of safety described in GRN 000301, a no-observable-adverse-effect level (NOAEL) from a 28-day study in rats (Marone *et al.*, 2008). Data from additional studies showing (1) no cytotoxic or mutagenic potential, and (2) no adverse effects in rats receiving up to 50,000 ppm of Go-Luo™ 55% (mogroside V) powder extract in the diet for 90 days (HLS Study No. 08-2085) further support safety;
- The possible presence of low levels of ribosome-inactivating proteins (RIP) in *Momordica* species was addressed in GRN 000301 and not considered a safety concern. The same applies to Go-Luo™ powder extracts, since RIP occur at relatively high concentrations in a large variety of widely-consumed foods with no indication of adverse effects. Also, their activity is likely to be completely destroyed by the extraction process; and
- Go-Luo™ powder extracts are intended for use as general purpose sweeteners and flavor modifiers in a variety of food products. Due to the characteristic intense sweet flavor of the fruit and its derivatives, use is expected to be self-limiting and therefore subject only to current Good Manufacturing Practices (GMP).
- Projected exposures to mogroside V among adults and children from consumption of foods containing Go-Luo™ powder extracts are approximately 10 times lower than what might be considered the reference dose safe for human exposure (18.92 mg/kg bw/day), obtained by applying a 100-fold safety factor the apparent no-observable-adverse-effect level (NOAEL) from the subchronic rat toxicity study of Guo-Lo™ 55% powder extract (HLS Study No. 08-2085).

After a critical independent evaluation of the available safety and other information, the Expert Panel conferred and unanimously determined that the use of Go-Luo™ powder extracts

containing 25, 45, and 55% mogroside V as general purpose sweeteners and flavor modifiers in foods would entail a reasonable certainty of no harm and qualify as GRAS food ingredients.

2.0 MANUFACTURING PROCESS

Go-Luo™ powder extracts are manufactured under Good Manufacturing Practices (GMP) using common food industry materials and processes in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations.

The three Go-Luo™ powder extracts presently under consideration appear as white, water-soluble powders. Go-Luo™ 45% and 55% powder extracts contain approximately 45% and 55% mogroside V, respectively; both are derived through further processing of Go-Luo™ 25% powder extract, the least refined form, which contains approximately 25% mogroside V. The processes for each of the Go-Luo™ powder extracts are shown schematically in Figures 2-1, 2-2, and 2-3, respectively. The process involves crushing, heating, aqueous extraction, filtering, centrifugation, and various other procedures commonly employed in food production. Activated carbon (*i.e.*, activated charcoal) and adsorption/separation polymer resins (*e.g.*, divinyl polymer) meeting US FDA standards are used during production to extract the glycosides (*i.e.*, mogroside V), and to remove unwanted 'licorice' flavor undertones (*i.e.*, herbal notes) and pigments before spray drying and packaging.¹

¹ Xi'an SunResin Technology Ltd. resins meet US FDA standards for resins used in food and pharmaceutical processing.

Figure 2-1 Overview of the production process for Go-Luo™ 25% Powder Extract (25% mogroside V)

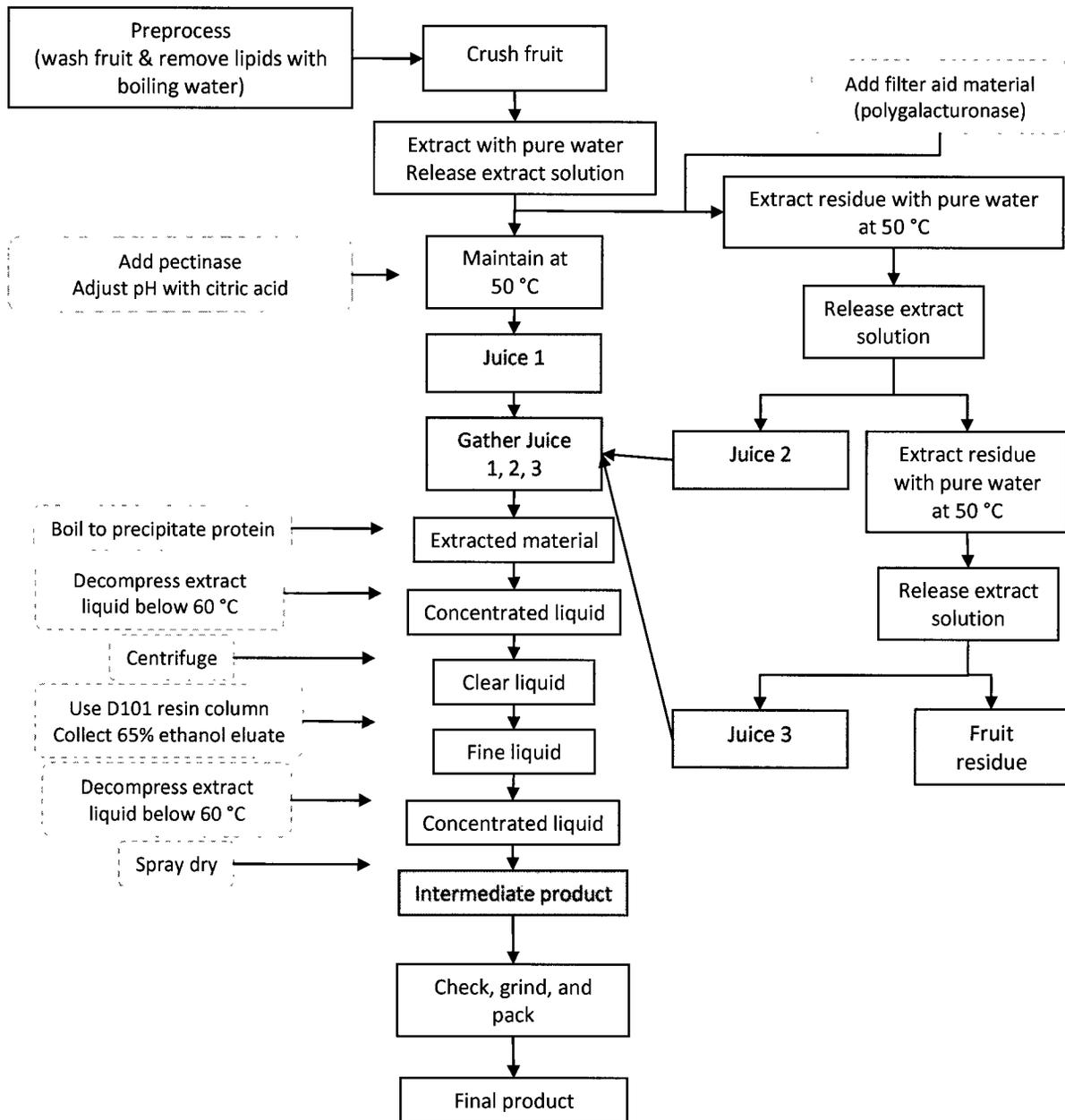


Figure 2-2 Overview of the production process for Go-Luo™ 45% Powder Extract (45% mogroside V)

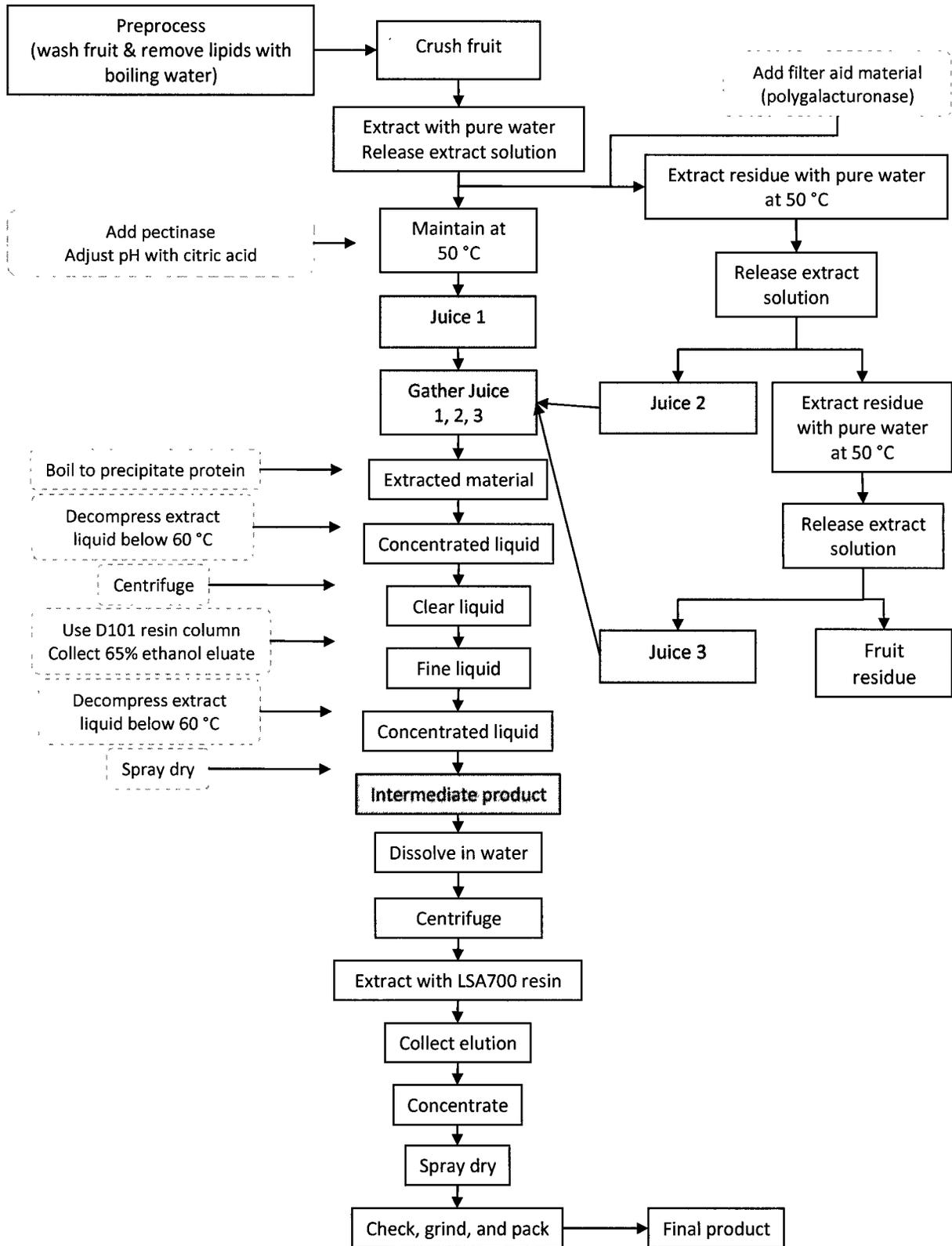
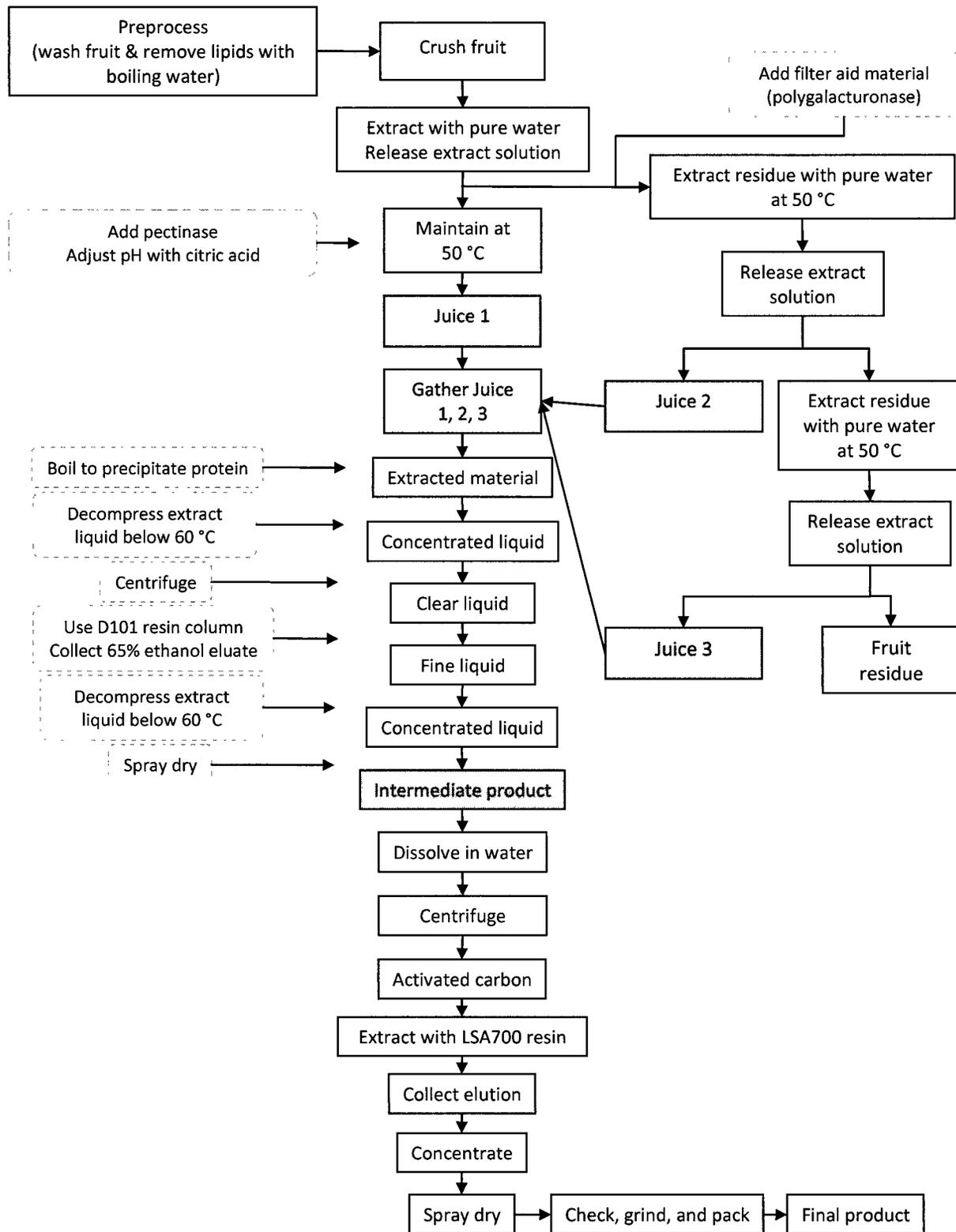


Figure 2-3 Overview of the production process for Go-Luo™ 55% Powder Extract (55% mogroside V)



3.0 PRODUCT SPECIFICATIONS AND ANALYSES

Go-Luo™ powder extracts are derived from the luohanshan fruit (*Siraitia grosvenori*). The Go-Luo™ products are manufactured by Guilin Layn Natural Ingredients Corp., and intended for use as general purpose sweeteners and flavor modifiers in a variety of food products. Manufacture is conducted employing a proprietary variation of procedures widely used in the food industry. Quality control and quality assurance standards have been implemented to ensure product quality and consistency. In addition, every lot of the respective Go-Luo™ powder extracts is tested to ensure compliance with the established standards. Tables 3-1, 3-2, and 3-3 provide specifications and confirmatory analytical results for Go-Luo™ 25% powder extract, Go-Luo™ 45% powder extract, and Go-Luo™ 55% powder extract, respectively. Actual certificates of analysis are provided in Appendices 2, 3, and 4, respectively.

The primary component imparting the characteristic sweet taste to the various Go-Luo™ powder extract products is mogroside V. Copies of the assay methods by which total mogroside V content is determined are provided in Appendix 5. Cucurbitacins, a group of bitter, highly-oxygenated and toxic plant secondary metabolites based on the same cucurbitane skeleton mogrosides, are not found in luohanshan fruit.

Table 3-4 provides a more comprehensive list of tests performed on 3 batches of Go-Luo™ 55% powder extract for pesticide residues, heavy metals, and microbiological content. Original analytical results are provided in Appendix 6.

Table 3-1 Summary of Go-Luo™ 25% Powder Extract analyses

Product Name:	Luo Han Guo P.E.				
Latin Name:	<i>Momordica grosvenori</i> Swingle				
Manufacture Date:	-----	12/20/09	12/01/09	11/05/09	
Testing Date:	-----	12/21/09	12/02/09	11/06/09	
Expire Date:	-----	12/20/11	11/30/11	11/04/11	
Shelf Life:	-----	2 years	2 years	2 years	
ATTRIBUTES	SPECIFICATION	METHODS	LOT # 091101	LOT # 091201	LOT # 091211
Description					
Appearance	White Powder	Visual	Complies	Complies	Complies
Taste	Sweet (Odor Reduced)	Gustatory	Complies	Complies	Complies
Country Of Origin	China	/	Complies	Complies	Complies
Particle Size	Through 80 Mesh	USP32<786>	Complies	Complies	Complies
Plant Part Used	Fruit	/	Complies	Complies	Complies
Chemical Tests					
mogroside V	≥ 25%	HPLC	25.12%	25.36%	25.19%
Loss On Drying	< 5%	USP32 <731>	2.98%	2.98%	2.98%
Ash	< 5%	USP32 <561>	1.21%	1.21%	1.21%
Heavy Metals					
Heavy Metals	< 10 mg/kg	USP32<231>	Complies	Complies	Complies
Arsenic (As)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Lead (Pb)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Cadmium (Cd)	< 0.05 mg/kg	AOAC 993.14	Complies	Complies	Complies
Mercury (Hg)	< 0.1 mg/kg	AOAC 993.14	Complies	Complies	Complies
Microbiological Tests					
Total Plate Count	< 1000 cfu/g	USP32 <61>	Complies	Complies	Complies
Yeast And Mold	< 100 cfu/g	USP32 <61>	Complies	Complies	Complies
Salmonella	Negative	USP32 <61>	Complies	Complies	Complies
<i>E. coli</i>	Negative	USP32 <61>	Complies	Complies	Complies
<i>Staphylococcus aureus</i>	Negative	USP32 <61>	Complies	Complies	Complies
Aflatoxins	< 0.2 ppb	USP32 <61>	Complies	Complies	Complies
Storage	Store In Cool And Dry Place. Keep Away From Strong Light And Heat.				

NOTE: Representative analytical data demonstrating the low occurrence or absence of heavy metals and pesticide residues in 3 lots of Go-Luo™ 55% Powder Extract are provided in Table 3-4. Quantitative analytical data demonstrating the low occurrence of pesticide residues in Go-Luo 25% Powder Extract are provided as part of the original Certificates of Analysis provided in Appendix 2.

Table 3-2 Summary of Go-Luo™ 45% Powder Extract analyses

Product Name:	Luo Han Guo P.E.				
Latin Name:	<i>Momordica grosvenori</i> Swingle				
Manufacture Date:	-----	11/03/09	11/06/09	11/08/09	
Testing Date:	-----	11/04/09	11/07/09	11/09/09	
Expire Date:	-----	11/03/11	11/05/11	11/07/11	
Shelf Life:	-----	2 years	2 years	2 years	
ATTRIBUTES	SPECIFICATION	METHODS	LOT # 091101	LOT # 091102	LOT # 091103
Description					
Appearance	White Powder	Visual	Complies	Complies	Complies
Taste	Sweet (Odor Reduced)	Gustatory	Complies	Complies	Complies
Country Of Origin	China	/	Complies	Complies	Complies
Particle Size	Through 80 Mesh	USP32<786>	Complies	Complies	Complies
Plant Part Used	Fruit	/	Complies	Complies	Complies
Chemical Tests					
mogroside V	≥ 45%	HPLC	45.21%	45.46%	45.29%
Loss On Drying	< 5%	USP32 <731>	3.01%	3.01%	3.01%
Ash	< 5%	USP32 <561>	1.32%	1.32%	1.32%
Heavy Metals					
Heavy Metals	< 10 mg/kg	USP32<231>	Complies	Complies	Complies
Arsenic (As)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Lead (Pb)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Cadmium (Cd)	< 0.05 mg/kg	AOAC 993.14	Complies	Complies	Complies
Mercury (Hg)	< 0.1 mg/kg	AOAC 993.14	Complies	Complies	Complies
Microbiological Tests					
Total Plate Count	< 1000 cfu/g	USP32 <61>	Complies	Complies	Complies
Yeast And Mold	< 100 cfu/g	USP32 <61>	Complies	Complies	Complies
Salmonella	Negative	USP32 <61>	Complies	Complies	Complies
<i>E. coli</i>	Negative	USP32 <61>	Complies	Complies	Complies
<i>Staphylococcus aureus</i>	Negative	USP32 <61>	Complies	Complies	Complies
Aflatoxins	< 0.2 ppb	USP32 <61>	Complies	Complies	Complies
Storage	Store In Cool And Dry Place. Keep Away From Strong Light And Heat.				

NOTE: Representative analytical data demonstrating the low occurrence or absence of heavy metals and pesticide residues in 3 lots of Go-Luo™ 55% Powder Extract are provided in Table 3-4. Quantitative analytical data demonstrating the low occurrence of pesticide residues in Go-Luo 45% Powder Extract are provided as part of the original Certificates of Analysis provided in Appendix 3.

Table 3-3 Summary of Go-Luo™ 55% Powder Extract analyses

Product Name:	Luo Han Guo P.E.				
Latin Name:	<i>Momordica grosvenori</i> Swingle				
Manufacture Date:	-----	01/04/10	01/06/10	01/08/10	
Testing Date:	-----	01/05/10	01/07/10	01/09/10	
Expire Date:	-----	01/03/12	01/05/12	01/07/12	
Shelf Life:	-----	2 years	2 years	2 years	
ATTRIBUTES	SPECIFICATION	METHODS	LOT # 100101	LOT # 100102	LOT # 100103
Description					
Appearance	White Powder	Visual	Complies	Complies	Complies
Taste	Sweet (Odor Reduced)	Gustatory	Complies	Complies	Complies
Country Of Origin	China	/	Complies	Complies	Complies
Particle Size	Through 80 Mesh	USP32<786>	Complies	Complies	Complies
Plant Part Used	Fruit	/	Complies	Complies	Complies
Chemical Test					
mogroside V	≥ 55%	HPLC	55.26%	55.35%	55.21%
Loss On Drying	< 5%	USP32 <731>	2.97%	2.97%	2.97%
Ash	< 5%	USP32 <561>	1.22%	1.22%	1.22%
Heavy Metals					
Heavy Metals	< 10 mg/kg	USP32<231>	Complies	Complies	Complies
Arsenic (As)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Lead (Pb)	< 0.5 mg/kg	AOAC 993.14	Complies	Complies	Complies
Cadmium (Cd)	< 0.05 mg/kg	AOAC 993.14	Complies	Complies	Complies
Mercury (Hg)	< 0.1 mg/kg	AOAC 993.14	Complies	Complies	Complies
Microbiological Tests					
Total Plate Count	< 1000 cfu/g	USP32 <61>	Complies	Complies	Complies
Yeast And Mold	< 100 cfu/g	USP32 <61>	Complies	Complies	Complies
Salmonella	Negative	USP32 <61>	Complies	Complies	Complies
<i>E. coli</i>	Negative	USP32 <61>	Complies	Complies	Complies
<i>Staphylococcus aureus</i>	Negative	USP32 <61>	Complies	Complies	Complies
Aflatoxins	< 0.2 ppb	USP32 <61>	Complies	Complies	Complies
Storage	Store In Cool And Dry Place. Keep Away From Strong Light And Heat.				

NOTE: Representative analytical data demonstrating the low occurrence or absence of heavy metals and pesticide residues in 3 lots of Go-Luo™ 55% Powder Extract are provided in Table 3-4. Quantitative analytical data demonstrating the low occurrence of pesticide residues in Go-Luo 55% Powder Extract are provided as part of the original Certificates of Analysis provided in Appendix 4.

**Table 3-4 Summary of quality assurance analyses for multiple batches of Go-Luo™
55% Powder Extract**

Luo Han Guo Extract - 55% mogroside V	Batch # L WV50-100401		Batch # L WV50-100402		Batch # L WV50-100403	
	Result	Units	Result	Units	Result	Units
ICP MS Heavy Metals						
Arsenic	<0.01	ppm	0.012	ppm	0.015	ppm
Cadmium	<0.001	ppm	<0.001	ppm	<0.001	ppm
Lead	0.015	ppm	0.036	ppm	0.037	ppm
Mercury	0.0410	ppm	0.0508	ppm	0.0352	ppm
Multi Residue Pesticide Screen						
Alachlor	<0.02	ppm	<0.02	ppm	<0.02	ppm
Aldrin and Dieldrin (sum of)	<0.02	ppm	<0.02	ppm	<0.02	ppm
Azinphos-methyl	<0.02	ppm	<0.02	ppm	<0.02	ppm
Bromopropylate	<0.02	ppm	<0.02	ppm	<0.02	ppm
Chlordane (sum of cis-, trans- & oxy-)	<0.02	ppm	<0.02	ppm	<0.02	ppm
Chlorfenvinphos	<0.02	ppm	<0.02	ppm	<0.02	ppm
Chlorpyrifos	<0.02	ppm	<0.02	ppm	<0.02	ppm
Chlorfenvinphos-methyl	<0.02	ppm	<0.02	ppm	<0.02	ppm
Cypermethrin (and isomers)	<0.02	ppm	<0.02	ppm	<0.02	ppm
DDT (sum of DDTpp, DDTop, DDEpp)	<0.02	ppm	<0.02	ppm	<0.02	ppm
Deltamethrin	<0.02	ppm	<0.02	ppm	<0.02	ppm
Diazinon	<0.02	ppm	<0.02	ppm	<0.02	ppm
Dichlorvos	<0.02	ppm	<0.02	ppm	<0.02	ppm
Endosulfan (sum of isomers and sulfa)	<0.02	ppm	<0.02	ppm	<0.02	ppm
Endrin	<0.02	ppm	<0.02	ppm	<0.02	ppm
Ethion	<0.02	ppm	<0.02	ppm	<0.02	ppm
Fenitrothion	<0.02	ppm	<0.02	ppm	<0.02	ppm
Fenvalerate	<0.02	ppm	<0.02	ppm	<0.02	ppm
Fonofos	<0.02	ppm	<0.02	ppm	<0.02	ppm
Heptachlor & Heptachlor epoxide	<0.02	ppm	<0.02	ppm	<0.02	ppm
Hexachlorobenzene	<0.02	ppm	<0.02	ppm	<0.02	ppm
Hexachlorocyclohexane isomers-no g	<0.02	ppm	<0.02	ppm	<0.02	ppm
Lindane (gamma-hesachlorocyclo	<0.02	ppm	<0.02	ppm	<0.02	ppm
Malathion	<0.02	ppm	<0.02	ppm	<0.02	ppm
Methidathion	<0.02	ppm	<0.02	ppm	<0.02	ppm
Parathion-ethyl	<0.02	ppm	<0.02	ppm	<0.02	ppm
Parathion-methyl	<0.02	ppm	<0.02	ppm	<0.02	ppm
Permethrin	<0.02	ppm	<0.02	ppm	<0.02	ppm
Phosalone	<0.02	ppm	<0.02	ppm	<0.02	ppm
Piperonyl butoxide	<0.02	ppm	<0.02	ppm	<0.02	ppm
Pirimiphos-methyl	<0.02	ppm	<0.02	ppm	<0.02	ppm
Pyrethrins (sum of)	<0.02	ppm	<0.02	ppm	<0.02	ppm
Quintozene, PCA, m-ppc sulfide	<0.02	ppm	<0.02	ppm	<0.02	ppm

Luo Han Guo Extract - 55% mogroside V	Batch # L WV50-100401		Batch # L WV50-100402		Batch # L WV50-100403	
	Result	Units	Result	Units	Result	Units
Dithiocarbamates (as CS ₂)	0.10	ppm	<0.10	ppm	<0.10	ppm
Aerobic Colony Count USP	350	CFU/g	25 est.	CFU/g	<10	CFU/g
<i>E. coli</i> USP	Negative	/10g	Negative	/10g	Negative	/10g
Salmonella USP	Negative	/10g	Negative	/10g	Negative	/10g
<i>Staphylococcus aureus</i> USP	Negative	/10g	Negative	/10g	Negative	/10g
Yeasts and Molds USP						
Yeast	<10	CFU/g	50	CFU/g	<10	CFU/g
Mold	<10	CFU/g	<10	CFU/g	<10	CFU/g

4.0 INTENDED FOOD USES

4.1 Intended Uses

Guilin Layn Natural Ingredients Corp. (Layn) intends to produce powdered fruit extracts (Go-Luo™) derived from the loo han fruit (*Siraitia grosvenori*), also known as loo han guo (LHG) and lo han kuo (LHK), for use as general purpose sweeteners and flavor modifiers in a variety of food products in the United States. Use in meat and other products regulated by USDA is not intended.

Three Go-Luo™ powder extracts with a mogroside V content of 25%, 45%, and 55% are presently under consideration. Mogroside V imparts the loo han fruit and fruit extracts with their characteristic sweet taste. Go-Luo™ 45% and 55% powder extracts are derived through further processing of Go-Luo™ 25% powder extract, the least refined form.

4.2 Sweetness Intensity

All three Go-Luo™ powder extracts appear as a white, water-soluble powder. Samples were taken from a single batch of Go-Luo™ 25% powder extract, Go-Luo™ 45% powder extract, and Go-Luo™ 55% powder extract specification (*i.e.*, each product containing mogroside V 25%, mogroside V 45%, and mogroside V 55%, respectively). Their sweetness intensity were tested by the method of "ISO 8587:2006 Sensory analysis -- Methodology --Ranking". An original copy of the sweetness intensity results is provided in Appendix 7. The results are reproduced in Table 4-1.

Table 4-1 Sweetness Potency of Different Specifications of Go-Luo™ Powder Extracts

Sample	Go-Luo™ Concentration (Sweetness equivalent to 5.0% sucrose solution (20 °C))	Sweetness Intensity
mogroside V 25%	0.032%	160 fold sweeter than sucrose
mogroside V 45%	0.024%	210 fold sweeter than sucrose
mogroside V 55%	0.02%	250 fold sweeter than sucrose

4.3 Exposure Estimates

Using published dietary exposure data for other high intensity sweeteners (*i.e.*, acesulfame, alitame, aspartame, cyclamate, saccharine, and sucralose) in several western populations, with adjustment for their relative sweetness intensities, Renwick (2008) estimated rebaudioside A exposure in various population subgroups. The intakes of a variety of different intense sweeteners were converted to sucrose equivalents by multiplying daily intakes, expressed in mg specific sweetener per kg body weight, into mg sucrose per kg body weight. The sweetness

potencies relative to sucrose were utilized to therefore predict the intake of a novel intense sweetener that may be calculated by dividing the estimated sucrose equivalent intakes by the relative sweetness for that intense sweetener. The Renwick methodology has recently been applied in the GRAS Notification process of numerous general purpose sweeteners, including that for rebaudioside A purified from *Stevia rebaudiana* (GRN 000253), as well as that for the compositionally equivalent product PureLo® (GRN 000301). In both cases, the FDA was not in disagreement that the products were GRAS. Moreover, as described in Renwick 2008, the FDA has also employed a similar method to predict the intakes of acesulfame-K and sucralose.

Using the estimated sucrose intake data specified by Renwick (2008), Table 6-2 shows the projected intakes of Go-Luo™ 25% powder extract and mogroside V by average and high consumers in different population groups. Table 4-3 shows the projected intakes of Go-Luo™ 45% powder extract and mogroside V by average and high consumers in different population groups. Table 4-4 shows the projected intakes of Go-Luo™ 55% powder extract and mogroside V by average and high consumers in different population groups.

In order to properly compare the estimated intake of Go-Luo™ powder extracts and that of the compositionally equivalent PureLo® product, Tables 4-5 and 4-6 cite the current daily intake of PureLo®, as described in GRN 000301. The calculation of PureLo® intake, employing the Methodology by Renwick (2008) assume a relative sweetness of 100 for the PureLo® product to replace the other intense sweeteners to which it was compared. However, in order to better compare the relative consumption of mogroside V between these respective products, the mogroside V intake from PureLo® is also estimated. The minimum specification for mogroside V in PureLo® is greater than or equal to 30%. However, the proximate composition of PureLo® cited within the GRAS Notification cited a mogroside V content of 35%, with an additional 8% 11-oxo-mogroside V present in the finished product. This oxidized form of mogroside V also impart the characteristic sweet taste to products derived from the luohanshan fruit, including PureLo® and the respective Go-Luo™ Powder concentrates. Mogroside V intake assuming a minimum concentration of 30% mogroside V is described in Table 4-5. In the safety study undertaken by Marone *et al.* (2008), the mogroside V content of PureLo® is described as approximately 39% mogroside V. Mogroside V intake assuming a concentration of 39% mogroside V is described in Table 4-6. Therefore, the estimated range of mogroside V intake may be conservatively estimated to range between 30% and 39% in finished batches of PureLo® (excluding 11-oxo-mogroside V content), as described in Tables 4-5 and 4-6.

Table 4-2 Estimated Intake of Go-Luo™ 25% Powder Extract and Mogroside V by Population Group

Population Group	Intake of intense sweeteners ¹ (mg/kg)		Projected intakes of Go-Luo™ Powder Extract (mg/kg)		Equivalent intake of Mogroside V ² (mg/kg)	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	1.59	4.22	0.40	1.06
Diabetic adults	280	897	1.75	5.61	0.44	1.40
Non-diabetic children	425	990	2.66	6.19	0.67	1.55
Diabetic children	672	908	4.20	5.68	1.05	1.42

¹ Expressed as sucrose equivalents (Renwick, 2008).

² Values are estimated as 25% of Go-Luo™ 25% Powder Extract since this product contains 25% mogroside V.

Table 4-3 Estimated Intake of Go-Luo™ 45% Powder Extract and Mogroside V by Population Group

Population Group	Intake of intense sweeteners ¹ (mg/kg)		Projected intakes of Go-Luo™ Powder Extract (mg/kg)		Equivalent intake of Mogroside V ² (mg/kg)	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	1.21	3.21	0.55	1.45
Diabetic adults	280	897	1.33	4.27	0.60	1.92
Non-diabetic children	425	990	2.02	4.71	0.91	2.12
Diabetic children	672	908	3.20	4.32	1.44	1.95

¹ Expressed as sucrose equivalents (Renwick, 2008).

² Values are estimated as 45% of Go-Luo™ 45% Powder Extract since this product contains 45% mogroside V.

Table 4-4 Estimated Intake of Go-Luo™ 55% Powder Extract and Mogroside V by Population Group

Population Group	Intake of intense sweeteners ¹ (mg/kg)		Projected intakes of Go-Luo™ Powder Extract (mg/kg)		Equivalent intake of Mogroside V ² (mg/kg)	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	1.02	2.70	0.56	1.49
Diabetic adults	280	897	1.12	3.59	0.62	1.97
Non-diabetic children	425	990	1.70	3.96	0.94	2.18
Diabetic children	672	908	2.69	3.63	1.49	1.99

¹ Expressed as sucrose equivalents (Renwick, 2008).

² Values are estimated as 55% of Go-Luo™ 55% Powder Extract since this product contains 55% mogroside V.

Table 4-5 Estimated Intake of PureLo® Fruit Concentrate Powder Extract and 30% Mogroside V by Population Group

Population Group	Intake of intense sweeteners ¹ (mg/kg)		Projected intakes of PureLo® (mg/kg) ²		Equivalent intake of Mogroside V ³ (mg/kg)	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	2.6	6.8	0.78	2.04
Diabetic adults	280	897	2.8	9.0	0.84	2.7
Non-diabetic children	425	990	4.2	9.9	1.26	2.97
Diabetic children	672	908	6.7	9.1	2.01	2.73

¹ Expressed as sucrose equivalents (Renwick, 2008).

² Calculated by BioVittoria and provided to FDA in GRN 000301.

³ Values are estimated as 30% of PureLo® since this product contains a minimum of 30% mogroside V.

Table 4-6 Estimated Intake of PureLo® Fruit Concentrate Powder Extract and 39% Mogroside V by Population Group

Population Group	Intake of intense sweeteners ¹ (mg/kg)		Projected intakes of PureLo® (mg/kg) ²		Equivalent intake of Mogroside V ³ (mg/kg)	
	Average Consumer	High Consumer	Average Consumer	High Consumer	Average Consumer	High Consumer
Non-diabetic adults	255	675	2.6	6.8	1.01	2.65
Diabetic adults	280	897	2.8	9.0	1.09	3.51
Non-diabetic children	425	990	4.2	9.9	1.64	3.86
Diabetic children	672	908	6.7	9.1	2.61	3.55

¹ Expressed as sucrose equivalents (Renwick, 2008).

² Calculated by BioVittoria and provided to FDA in GRN 000301.

³ Values are estimated as 39% of PureLo® since this was the estimated mogroside V content in the safety study undertaken by Marone *et al.*, 2008.

As shown in the tables above, the predicted ranges of Go-Luo™ exposure among non-diabetic high consumers is between 2.7 mg/kg body weight for 55% powder extract and 4.22 mg/kg body weight for the 25% powder extract. This correlates to a mogroside V intake among non-diabetic high consumers between 1.06 mg/kg body weight for 25% powder extract and 1.49 mg/kg body weight for the 55% powder extract. These estimates of intake for the respective low and high mogroside V concentrations of finished Go-Luo™ compare favorably with the estimated of intake of PureLo® among non-diabetic high consuming adults both for the finished product (6.8 mg/kg body weight) and the approximated lower and upper range of mogroside V content in that product 2.04 to 2.65 mg/kg body weight).

Due to differences in the relative sweetness of the products, which results from the refinement of the manufacturing process of Go-Luo™ relative to that employed by the manufacturers of

PureLo[®], consumers of both the low and high mogroside V Go-Luo[™] fruit extract products are expected to consume less finished product on a mg/kg/body weight basis. Similarly, non-diabetic high consumers are also expected to consume less mogroside V from any of the Go-Luo[™] powder extract product lines relative to the expected mogroside V consumption from PureLo[®] at even the lowest specified content of 30% mogroside V. This pattern of intake is repeated across other population groups (*i.e.*, diabetic adults, normal children, and diabetic children) for all three Go-Luo[™] powder extract product lines, regardless of whether finished product or mogroside V intake is considered. Due to the more refined nature of the respective Go-Luo[™] product line and their greater sweetness intensity relative to PureLo[®], it is anticipated that high consumers will simply consume less of any of the Go-Luo[™] powder extract products compared to the high consumer of products containing PureLo[®].

4.4 Assessments of Risk

4.4.1 Assessments of Go-Luo[™] Powder Extract Risk Based Upon Primary Evidence of Safety

Based on the 28-day rodent toxicity study conducted by Marone *et al.* (2008) the no-observed-adverse-effect level (NOAEL) for PureLo[®] was determined to be 100,000 ppm in the diet, equivalent to 7.07 and 7.48 g/kg bw/day for male and female rats, respectively. This corresponds to a mean NOAEL dose for both male and female rats of 7.28 g/kg bw/day. Through the application of a 10-fold safety factor for intraspecies differences and a 10-fold safety factor for interspecies differences, a reference dose of 72.8 mg/kg bw/day may be calculated as being safe for human exposure (EPA, 1993). Specific to the safe intake of mogroside V, assuming the minimum specification of 30% mogroside V in PureLo[®], a reference dose of 21.84 mg of mogroside V per kg of body weight per day may be calculated as being safe for human exposure. A tabular summary assessment of safety factors based upon primary evidence of safety and specific to the maximum intakes of Go-Luo[™] and Go-Luo[™]-derived mogroside V among sub-populations identified by Renwick, is discussed below and summarized in Table 4-7. A comparative tabular summary assessment of safety factors based upon primary evidence of safety and specific to the maximum intakes of PureLo[®] and PureLo[®]-derived mogroside V among sub-populations identified by Renwick, is also discussed below and summarized in Table 4-8.

Among normal adults, the highest consumer intake of any Guo-Lo[™] powder extract was calculated to be 4.22 mg/kg among high consumers of Guo-Lo[™] 25% powder extract, which is 17.25-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo[™] 55% powder extract (1.49 mg/kg/day), among normal adults their consumption is 14.7-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Among diabetic adults, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 5.61 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 12.98-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (1.97 mg/kg/day), among diabetic adults their consumption is 11.09-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Among normal children, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 6.19 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 11.76-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (2.18 mg/kg/day), among normal children their consumption is 10.02-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Among diabetic children, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 5.68 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 12.82-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (1.99 mg/kg/day), among diabetic children their consumption is 10.97-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Table 4-7 Tabular Summary Assessment of Safety Factors Based Upon Primary Evidence of Safety Specific to the Maximum Intakes of Go-Luo™ and Go-Luo™-Derived Mogroside V

Population Group	Primary Basis for Establishing Safety			Maximum Projected Intakes of Go-Luo™ Powder Extract (mg/kg) ⁴	Additional Safety Factor ⁵	Maximum Projected Intakes of Mogroside V (mg/kg) ⁶	Additional Safety Factor ⁷
	Mean NOAEL Dose (mg/kg/day) ¹	Reference Dose of PureLo® Safe for Human Exposure ²	Reference Dose of mogroside V Safe for Human Exposure ³				
Non-diabetic adults	7,280	72.8	21.84	4.22	17.25	1.49	14.7
Diabetic adults				5.61	12.98	1.97	11.09
Non-diabetic children				6.19	11.76	2.18	10.02
Diabetic children				5.68	12.82	1.99	10.97

1 As determined by Marone *et al.*, 2008

2 Derived through the application of a 100-fold safety factor to the NOAEL dose

3 Derived by assuming a minimum concentration of 30% mogroside V content in the PureLo® reference dose

4 Maximum projected intake of any finished Go-Luo™ product is expected to occur among high consumers of Go-Luo™ 25% Powder Extract (See Table 4-2)

5 Additional safety factors are calculated by dividing the PureLo®-derived reference dose safe for human exposure by the maximum projected intake of Go-Luo™ 25% Powder Extract

6 Maximum projected intake of mogroside V alone is expected to occur among high consumers of Go-Luo™ 55% Powder Extract (See Table 4-4)

7 Additional safety factors are calculated by dividing the PureLo®-derived mogroside V reference dose safe for human exposure by the maximum projected intake of mogroside V from Go-Luo™ 55% Powder Extract

4.4.2 Comparative Assessments of PureLo® Based Upon Primary Evidence of Safety

For comparison, among normal adults, the highest consumer intake of PureLo® was calculated to be 6.8 mg/kg, which is 10.71-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo® containing an estimated 39% mogroside V (2.65 mg/kg/day), among normal adults their consumption is 8.24-fold less than the reference dose of 21.84 mg of mogroside V per kg of body weight per day may be calculated as being safe for human exposure.

Among diabetic adults, the highest consumer intake of PureLo® was calculated to be 9.0 mg/kg, which is 8.09-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo® containing an estimated 39% mogroside V (3.51 mg/kg/day), among diabetic adults their consumption is 6.22-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Among normal children, the highest consumer intake of a PureLo® was calculated to be 9.9 mg/kg, which is 7.35-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo® containing

an estimated 39% mogroside V (3.86 mg/kg/day), among normal children their consumption is 5.65-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Among diabetic children, the highest consumer intake of PureLo[®] was calculated to be 9.1 mg/kg, which is 8.00-fold less than the safe reference dose of 72.8 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo[®] containing an estimated 39% mogroside V (3.55 mg/kg/day), among diabetic children their consumption is 6.15-fold less than the safe reference dose of 21.84 mg/kg/day in humans.

Table 4-8 Comparative Tabular Summary Assessment of Safety Factors Based Upon Primary Evidence of Safety Specific to the Maximum Intakes of PureLo[®] and PureLo[®]-Derived Mogroside V

Population Group	Primary Basis for Establishing Safety			Maximum Projected Intakes of PureLo [®] (mg/kg) ⁴	Additional Safety Factor ⁵	Maximum Projected Intakes of Mogroside V (mg/kg) ⁶	Additional Safety Factor ⁷
	Mean NOAEL Dose (mg/kg/day) ¹	Reference Dose of PureLo [®] Safe for Human Exposure ²	Reference Dose of mogroside V Safe for Human Exposure ³				
Non-diabetic adults	7,280	72.8	21.84	6.8	10.71	2.65	8.24
Diabetic adults				9.0	8.09	3.51	6.22
Non-diabetic children				9.9	7.35	3.86	5.65
Diabetic children				9.1	8.00	3.55	6.15

1 As determined by Marone *et al.*, 2008

2 Derived through the application of a 100-fold safety factor to the NOAEL dose

3 Derived by assuming a minimum concentration of 30% mogroside V content in the PureLo[®] reference dose

4 Maximum projected intake of PureLo[®] as determined by BioVittoria in GRN 000301 (See Table 4-5)

5 Additional safety factors are calculated by dividing the PureLo[®]-derived reference dose safe for human exposure by the maximum projected intake of PureLo[®] (GRN 000301).

6 Maximum projected intake of mogroside V alone is expected to occur among high consumers of PureLo[®] containing approximately 39% mogroside V, as cited by Marone *et al.*, 2008 (See table 4-6).

7 Additional safety factors are calculated by dividing the PureLo[®]-derived mogroside V reference dose safe for human exposure by the maximum projected intake of 39% mogroside V from PureLo[®] identified by Marone *et al.*, 2008.

4.4.3 Assessments of Go-Luo[™] Powder Extract Risk Based Upon Supporting Evidence of Safety

The proposed no-observeable-adverse-effect level (NOAEL) from the subchronic rat toxicity study of Guo-Lo[™] 55% powder extract (HLS Study No. 08-2085) was 50,000 ppm. This corresponds to a mean NOAEL dosage of 3.44 g/kg bw/day for both male and female rats. Through the application of a 10-fold safety factor for intraspecies differences and a 10-fold safety factor for interspecies differences, a reference dose of 34.4 mg/kg bw/day may be calculated as being safe for human exposure (EPA, 1993). Specific to the safe intake of mogroside V, a reference dose of 18.92 mg of mogroside V per kg of body weight per day may

be calculated as being safe for human exposure. A tabular summary assessment of safety factors based upon supporting safety data and specific to the maximum intakes of Go-Luo™ and Go-Luo™-derived mogroside V among sub-populations identified by Renwick, is discussed below and summarized in Table 4-9. A comparative tabular summary assessment of safety factors based upon supporting safety data and specific to the maximum intakes of PureLo® and PureLo®-derived mogroside V among sub-populations identified by Renwick, is also discussed below and summarized in Table 4-10.

Among normal adults, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 4.22 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 8.15-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (1.49 mg/kg/day), among normal adults their consumption is 12.70-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Among diabetic adults, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 5.61 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 6.13-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (1.97 mg/kg/day), among diabetic adults their consumption is 9.60-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Among normal children, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 6.19 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 5.56-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (2.18 mg/kg/day), among normal children their consumption is 8.68-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Among diabetic children, the highest consumer intake of any Guo-Lo™ powder extract was calculated to be 5.68 mg/kg among high consumers of Guo-Lo™ 25% powder extract, which is 6.06-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of Guo-Lo™ 55% powder extract (1.99 mg/kg/day), among diabetic children their consumption is 9.51-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Table 4-9 Tabular Summary Assessment of Safety Factors Based Upon Supporting Safety Data Specific to the Maximum Intakes of Go-Luo™ and Go-Luo™-Derived Mogroside V

Population Group	Primary Basis for Establishing Safety			Maximum Projected Intakes of Go-Luo™ Powder Extract (mg/kg) ⁴	Additional Safety Factor ⁵	Maximum Projected Intakes of Mogroside V (mg/kg) ⁶	Additional Safety Factor ⁷
	Mean NOAEL Dose (mg/kg/day) ¹	Reference Dose of Go-Luo™ Powder Extract Safe for Human Exposure ²	Reference Dose of mogroside V Safe for Human Exposure ³				
Non-diabetic adults	3,440	34.4	18.92	4.22	8.15	1.49	12.70
Diabetic adults				5.61	6.13	1.97	9.60
Non-diabetic children				6.19	5.56	2.18	8.68
Diabetic children				5.68	6.06	1.99	9.51

1 Based on HLS Study No. 08-2085

2 Derived through the application of a 100-fold safety factor to the NOAEL dose

3 Derived by assuming a minimum concentration of 55% mogroside V content in the Go-Luo™ 55% Powder Extract reference dose

4 Maximum projected intake of any finished Go-Luo™ product is expected to occur among high consumers of Go-Luo™ 25% Powder Extract (See Table 4-2)

5 Additional safety factors are calculated by dividing the Go-Luo™-derived reference dose safe for human exposure by the maximum projected intake of Go-Luo™ 25% Powder Extract

6 Maximum projected intake of mogroside V alone is expected to occur among high consumers of Go-Luo™ 55% Powder Extract (See Table 4-4)

7 Additional safety factors are calculated by dividing the Go-Luo™-derived mogroside V reference dose safe for human exposure by the maximum projected intake of mogroside V from Go-Luo™ 55% Powder Extract

4.4.4 Comparative Assessments of PureLo® Based Upon Supporting Evidence of Safety

For comparison, among normal adults, the highest consumer intake of PureLo® was calculated to be 6.8 mg/kg, which is 5.06-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo® containing an estimated 39% mogroside V (2.65 mg/kg/day), among normal adults their consumption is 2.30-fold less than the reference dose of 18.92 mg of mogroside V per kg of body weight per day may be calculated as being safe for human exposure.

Among diabetic adults, the highest consumer intake of PureLo® was calculated to be 9.0 mg/kg, which is 3.82-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo® containing an estimated 39% mogroside V (3.51 mg/kg/day), among diabetic adults their consumption is 5.39-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Among normal children, the highest consumer intake of a PureLo® was calculated to be 9.9 mg/kg, which is 3.47-fold less than the safe reference dose of 34.4 mg/kg/day in humans.

Considering the highest intake of only mogroside V, from high consumers of PureLo[®] containing an estimated 39% mogroside V (3.86 mg/kg/day), among normal children their consumption is 4.90-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Among diabetic children, the highest consumer intake of PureLo[®] was calculated to be 9.1 mg/kg, which is 3.78-fold less than the safe reference dose of 34.4 mg/kg/day in humans. Considering the highest intake of only mogroside V, from high consumers of PureLo[®] containing an estimated 39% mogroside V (3.55 mg/kg/day), among diabetic children their consumption is 5.33-fold less than the safe reference dose of 18.92 mg/kg/day in humans.

Table 4-10 Comparative Tabular Summary Assessment of Safety Factors Based Upon Supporting Safety Data Specific to the Maximum Intakes of PureLo[®] and PureLo[®]-Derived Mogroside V

Population Group	Primary Basis for Establishing Safety			Maximum Projected Intakes of PureLo [®] (mg/kg) ⁴	Additional Safety Factor ⁵	Maximum Projected Intakes of Mogroside V (mg/kg) ⁶	Additional Safety Factor ⁷
	Mean NOAEL Dose (mg/kg/day) ¹	Reference Dose of Go-Luo [™] Powder Extract Safe for Human Exposure ²	Reference Dose of mogroside V Safe for Human Exposure ³				
Non-diabetic adults	3,440	34.4	18.92	6.8	5.06	2.65	2.30
Diabetic adults				9.0	3.82	3.51	5.39
Non-diabetic children				9.9	3.47	3.86	4.90
Diabetic children				9.1	3.78	3.55	5.33

1 Based on HLS Study No. 08-2085

2 Derived through the application of a 100-fold safety factor to the NOAEL dose

3 Derived by assuming a minimum concentration of 55% mogroside V content in the Go-Luo[™] 55% Powder Extract reference dose

4 Maximum projected intake of PureLo[®] as determined by BioVittoria in GRN 000301 (See Table 4-5)

5 Additional safety factors are calculated by dividing the Go-Luo[™]-derived reference dose safe for human exposure by the maximum projected intake of PureLo[®] as determined by BioVittoria in GRN 000301 (See Table 4-5)

6 Maximum projected intake of mogroside V alone is expected to occur among high consumers of PureLo[®] containing approximately 39% mogroside V, as cited by Marone *et al.*, 2008 (See table 4-6).

7 Additional safety factors are calculated by dividing the Go-Luo[™]-derived mogroside V reference dose safe for human exposure by the maximum projected intake of 39% mogroside V from PureLo[®] identified by Marone *et al.*, 2008.

5.0 SAFETY DATA

The primary safety data presented below served as the basis of safety for PureLo[®], a compositionally equivalent Luo Han fruit extract manufactured by BioVittoria Ltd. that contains \geq 30% mogroside V. The use of PureLo[®] as a flavor modifier and sweetener was the subject of Notice No. GRN 000301, which generated no questions from US FDA CFSAN/Office of Food Additive Safety (Agency Response Letter to GRAS Notice No. GRN 000301). Data from a mutagenicity assay and a 90-day dietary study in rats described herein further support the safety of Go-Luo[™] powder extracts.

5.1 Primary Evidence of Safety

Marone *et al.* (2008) undertook a 28-day toxicity study in Hsd:SD rats to evaluate the safety of PureLo[®], a powdered concentrate of the Luo Han fruit composed of approximately 39% mogroside V. Animals were randomly assigned to four groups of 10 per each sex and fed 0, 10,000, 30,000, or 100,000 ppm of PureLo[®] in their diet, available *ad libitum*. Animals were fasted for at least 15 hours prior to clinical pathology evaluation. Urine was collected and analyzed for quality, pH, ketone, color, glucose, bilirubin, clarity, specific gravity, blood, volume, protein, urobilinogen, and microscopic urine sediment. Blood samples were taken *via* orbital sinus bleeding on Day 27. Hematology parameters assessed included erythrocyte count, hemoglobin concentration, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, red cell distribution width, absolute reticulocyte count, platelet count, total white blood cell, and differential leukocyte count. Mean corpuscular hemoglobin concentration was also calculated. Clinical chemistry parameters evaluated included serum aspartate aminotransferase, serum alanine aminotransferase, sorbitol dehydrogenase, alkaline phosphate, total bilirubin, urea nitrogen, blood creatinine, total cholesterol, triglycerides, fasting glucose, total serum protein, albumin, globulin, calcium, inorganic phosphorus, sodium, potassium, and chloride.

All animals were weighed, euthanized by exsanguinations, and necropsied on Day 29 and Day 30 for males and females, respectively. Animals were examined grossly and wet weights were recorded for the liver, kidneys, adrenals, brain, heart, thymus, spleen, ovaries, testes, and epididymides, and uteri. Histological examinations were performed on the following organs and tissues from the control and high-dose groups: lungs, trachea, brain (sections of the medulla/pons, cerebellar cortex and cerebral cortex), spinal cord (cervical, mid-thoracic, and lumbar), salivary glands, thymus, heart, sternum with bone marrow, adrenals, liver, spleen, kidneys, thyroid/parathyroid, urinary bladder, ovaries, and fallopian tubes, uterus, vagina, esophagus, ileum, cecum, accessory genital organs (prostate and seminal vesicles), peripheral, stomach, duodenum, jejunum, colon, rectum, representative lymph node (mesenteric and mandibular), pancreas, pituitary gland, aorta, female mammary gland, Harderian gland, skin, nasal turbinate's, and skeletal muscle.

Statistical analyses included Bartlett's test, ANOVA, Dunnett's *t*-test, Kruskal-Wallis analysis of variance, Dunn's test, Levene's test, and Shapiro-Wilk test. Data indicated significantly reduced body weights and body weight gains in both sexes in the high dose group, which consequently paralleled the results for food consumption. There were no significant differences in feed efficiency among the groups. This was evidence that these changes were due to sporadic reduction in food consumption. Statistically significant ($p < 0.05$) hematological results included the following: increase in hemoglobin and hematocrit (high-dose males), decrease in white blood cells and lymphocyte (high-dose males), increase in mean red blood cell hemoglobin concentration (mid-dose females), and decreased prothrombin time (mid- and high-dose females). These changes were not considered adverse or dose-related. Urinalysis findings did not show any treatment-related adverse effects. There were also no abnormalities found in the gross necropsy attributable to PureLo[®] administration. All animals survived to scheduled termination with no clinical adverse findings. Based on the evaluated toxicological endpoints, the no-observed-adverse-effect level (NOAEL) for PureLo[®] was determined to be 100,000 ppm in the diet, equivalent to 7.07 and 7.48 g/kg bw/day for male and female rats, respectively (Marone *et al.*, 2008).

5.2 Supporting Evidence of Safety

5.2.1 Mutagenicity Assay

A bacterial reverse mutation test or Ames Test (Ames *et al.*, 1975) was conducted at Huntingdon Life Sciences to assess Go-Luo[™] 55% powder extract for its ability to cause point (gene) mutation in *Salmonella typhimurium* strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* strain WP2uvrA. This study was conducted in compliance with the OECD Guideline for the Testing of Chemicals, Number 471 (Genetic Toxicology: Bacterial Reverse Mutation Test); current Good Laboratory Practice (cGLP); EC Commission Directive 2000/32/EC Annex 4D-B.13/14 (Mutagenicity- Reverse mutation test in bacteria); EPA Health Effects Test Guidelines (OPPTS 870.5100 Bacterial reverse mutation test) and FDA Redbook 2000 (Bacterial-Reverse Mutation Test).

Five concentrations separated by approximately half-log₁₀ intervals were tested, with a maximum of 5000 µg (of mogroside V) per plate (*i.e.*, 9090 µg Go-Luo[™] 55% powder extract). No cytotoxic activity was observed at the concentrations assayed. In addition to test article, strains were assayed in the presence of an aqueous negative control and in the presence of sodium azide, 9-aminoacridine, 2-nitrofluorene, and 4-nitroquinoline-1-oxide positive controls. These tests were undertaken in the absence of S9 mix. Moreover, strains were assayed in the presence of S9 mix plus test article at the identical concentrations, plus aqueous negative control, and 2-aminoanthracene and benzo[a]pyrene positive controls. There were no substantial increases in revertant colony numbers over aqueous control counts at any concentration up to 5000 µg/plate in the tested bacterial strains, either in the presence or

absence of S9 mix. Under the test conditions employed, Go-Luo™ 55% powder extract did not exhibit any cytotoxic or mutagenic potential (HLS Study No. HUD0072).

5.2.2 90-Day Oral (Dietary) Toxicity Study in Rats

A 90-day oral toxicity study of Go-Luo™ 55% powder extract was conducted at Huntingdon Life Sciences in CrI:CD® (SD) IGS BR rats. The study was carried out in accordance with: Part 58 of 21 CFR (FDA Good Laboratory Practice Regulations) and current Good Laboratory Practice (GLP).

Five- to six-week-old rats (Charles River Laboratories, Raleigh, North Carolina) were acclimatized to housing facilities for approximately two weeks prior to being placed into treatment groups. Animal room controls were set to maintain room temperature at approximately 18 to 26° C, relative humidity of 30 to 70%, and a light-dark cycle of 12 hours each. Animals received a commercially available laboratory rodent diet (PMI Nutrition International, St. Louis, Missouri) and drinking water *ad libitum*. Animals were assigned to groups by a computerized stratified randomization program in order to have comparable body weight means for each group. CrI:CD® (SD) rats (20 animals/sex/group) for the main study groups, plus an additional 10 animals/sex/group for dietary control and high-dose recovery groups, were fed with 0 (control), 12,500, 25,000, or 50,000 ppm Go-Luo™ 55% powder extract in the diet for 90 days. Animals were housed individually for food consumption and body weight determination. Fresh diets were prepared and provided on a weekly basis. Animals were examined twice daily for mortality and morbidity. Food consumption and body weights were measured weekly throughout the study. Ophthalmological examinations were performed during Pre-test Week 2, Week 13, and Recovery Week 5.

At the end of the treatment period, animals from the main study (20 animals/sex group) were euthanized and necropsied. The remaining animals (10/sex/group) from the control and high-dose groups were held for a 28-day treatment-free recovery period before being euthanized and necropsied. Animals were fasted overnight prior to blood collection. Blood samples were analyzed for the following hematological parameters: hemoglobin concentration (HGB), hematocrit (HCT), red blood cell (RBC) count, platelet (PLT) count, mean platelet volume (MPV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red cell distribution width (RDW), white blood cell (WBC) count, absolute reticulocyte (RETIC) count. Prothrombin time (PT), activated partial thromboplastin time (APTT), and fibrinogen (FIB) were measured using a blood coagulation analysis apparatus.

Blood for biochemical examinations was collected into tubes with no anticoagulant, allowed to clot, and centrifuged to obtain serum. Serum samples were analyzed for the following: alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, urea nitrogen, creatinine, glucose, total cholesterol, triglycerides, total protein, albumin, globulin (calculated as total

protein - albumin = globulin), albumin/globulin ratio (calculated), bilirubin (total), sodium, potassium, chloride, calcium, and phosphorus.

Urine was collected (20/sex/group at week 13; 10/sex/group in groups 1 and 4 during week 18) and evaluated for volume (16-hour), specific gravity, appearance, pH, nitrites, protein, glucose, ketones, urobilinogen, bilirubin, and urine chemistry (creatinine, phosphorus, and calcium).

At the time of necropsy, the following organs were removed and weighed for all animals: adrenal glands, heart, brain (medulla, pons, cerebrum, and cerebellum), kidneys, liver, ovaries, spleen, testis, epididymides, pituitary, prostate/seminal vesicles, thyroid with parathyroid glands, uterus (with cervix) and thymus. Paired organs were weighed together.

The following organs/tissues were collected from all animals: heart, aorta, lung, airway, liver, pancreas, tongue, salivary gland (sublingual gland, submandibular gland), gastrointestinal tract (esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum), thymus, spleen, lymph node (mesenteric lymph node), kidney, bladder, male genital organs (testes, epididymis, seminal vesicle, prostate), female genital organs (ovarium, uterus, vagina), mammary gland, pituitary gland, adrenal gland, thyroid gland, parathyroid, brain (cerebrum, cerebellum, medulla, pons), skin, eyes, accessory gland (Harderian gland), bone and bone marrow (sternum, femur). All tissue samples were fixed in 10% neutral-buffered formalin. Eyes and testes were placed in Modified Davidson's solution and then retained in 10% formalin.

No treatment-related mortality was observed. Four male rats (one from each of the four dose groups) were humanely euthanized or found dead. Based on their sporadic nature and the absence of any similar pathology in the terminal animals, none of these deaths were considered to be related to Go-Luo™ 55% powder extract administration. Ophthalmological examination revealed no abnormalities at the end of the dosing and recovery periods. There were no statistically significant differences in body weight or food consumption during the dosing and recovery periods.

Hematological results showed no remarkable effects. There was a slight increase in MPV at $\geq 25,000$ ppm in animals of both sexes; slightly increased MCH and slightly decreased RDW in 50,000 ppm males; and slightly increased circulating lymphocyte counts in $\geq 25,000$ ppm females. However, all these parameters were within historical control variation. Serum chemistry results were also unremarkable. Both sexes at $\geq 12,500$ ppm had a slight decrease in triglyceride values and females in the same dose-group had a slight decrease of total bilirubin. These changes were also within historical control variation.

There were no histopathological observations in any tissue samples or organs. A slight increase in the absolute and relative liver weights was noted in $\geq 12,500$ ppm females which appeared to be an adaptive response and was non-adverse. The results of the oral toxicity study showed no adverse effects in rats receiving 12,500, 25,000, and 50,000 ppm of Go-Luo™ in the diet for 90-

days. Although some variations in hematology, clinical chemistry, and in female liver weights were observed, none of these findings were considered treatment-related. Therefore, the no-observed-adverse-effect level (NOAEL) for Go-Luo™ 55% powder extract was considered to be a dietary concentration of 50,000 ppm. This was equivalent to a time-weighted average dose over the course of the dosing period of approximately 3.12 g/kg bw/day and 3.75 g/kg bw/day in male and female rats, respectively (HLS Study No. 08-2085).

5.3 Additional Safety Data

Qin *et al.* (2006) conducted a subchronic oral gavage toxicity study of PureLo® in dogs. In this combined 28- and 90-day study, 24 male and female hybrid dogs (weights of 8 to 9 kg) 24 to 30 weeks old were randomly divided into 4 groups consisting of 6 animals each (3/sex/group). Two groups, LHG I and LHG II, were given a limit dose of 3000 mg/kg body weight in the form of a 10 mL/kg bodyweight aqueous solution containing 30% Luo Han fruit extract (PureLo®) by gavage once per day. The other two groups, Control I and Control II, were given 10 mL/kg body weight of distilled water by gavage once per day. LHG I and Control I were dosed for 28 days and LHG II and Control II were dosed for 90 days. Treated groups were compared to their respective controls and data was analyzed by ANOVA. During the study, there were no significant differences in food consumption, body weight, or clinical signs. There were no mortalities or clinically relevant changes in hematology (RBC and WBC), clinical biochemistry (albumin (Alb), globulin (Glob), alanine aminotransferase (ALT), aspartame aminotransferase (AST), fasting glucose (Glu), and total serum protein (TP) as well as K⁺, P⁺⁺⁺, Cl⁻, and Ca⁺⁺), or urinalysis parameters in either time points. The NOAEL for PureLo® was determined to be 3000 mg/kg bw/day (Qin *et al.*, 2006). Although this study was in compliance to the guidelines of the People's Republic of China, it did not meet the regulatory requirements set by the OECD² or the US Food and Drug Administration³ for the conduct of non-rodent toxicity studies. However, the results of this study provide additional data to support the overall safety the PureLo® product. The results of this study were made available to the FDA as part of the PureLo® GRAS Notification (GRN 000301).

A 13-week repeated dose toxicity study in Wistar Hannover (GALAS) rats was conducted by Jin *et al.* (2007) to assess the safety of *Siraitia grosvenori* extract, provided from SARAYA Co. Ltd. Mogroside V content of the extract was not specified. Animals were divided into 5 groups of 8 per each sex and administered a diet containing 0%, 0.04%, 0.2% 1%, or 5% of *S. grosvenori*

² OECD guideline 409: Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents (1998)

³ Redbook 2000: IV.C.3.b Short-term Toxicity Study with Non-Rodents (2003)

extract. The stability of the admixture was confirmed and the test diet was prepared weekly. The daily intakes of the test material for males and females were determined to be 20, 90, 530, and 2520 mg/kg/day and 30, 130, 650, 3200 mg/kg/day for 0.04%, 0.2% 1%, or 5%, respectively. At the end of the study, blood samples were collected after 16 hour fasting period under light ether anesthesia. Hematological parameters including white blood cell count (WBC), red blood cell count (RBC), hemoglobin concentration (Hb), hematocrit (Ht), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC) and platelet (Plt) count were assessed using an automatic multichannel blood cell counter (Sysmex SE-9000, Sysmex Co., Hyogo, Japan). Serum biochemical examinations were performed for the following parameters: total protein (TP), albumin (Alb), albumin/globulin ratio (A/G), total cholesterol (T-Chol), blood urea nitrogen (BUN), creatinine (CRN), calcium (Ca), inorganic phosphate (IP), sodium (Na), potassium (K), chloride (Cl), aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP). Animals were then sacrificed and autopsied. The weights of the brain, heart, lungs, liver, kidneys, spleen, thymus, adrenal glands, pituitary gland, thyroid glands, testes, uterus, and ovaries were measured. In addition to these organs, the artery, bone/ marrow, coagulation gland, esophagus, epididymides, large intestine, lymph node, mammary gland, pancreas, peripheral nerve, prostate gland, salivary gland, skeletal muscle, skin, small intestine, spinal cord, stomach, urinary bladder, tongue, trachea, vagina were fixed in 10% neutral buffered formalin. Eyeballs and Harderian glands were fixed with Davidson's solution for 12 h and then replaced into 95% ethanol. Testes were fixed with 4% acetic acid/12% formalin mixture for 24 h and then were removed into 10% neutral buffered formalin. Bone was decalcified in Plank Rychlo solution before embedding. These tissues were routinely embedded in paraffin, sectioned at 4 μ m thick for hematoxylin and eosin staining, and examined by light microscopy. Histopathological examinations were carried out only on the control and 5% groups for both sexes. Statistical analyses included Dunnett's test and ANOVA. There were no mortalities during the in-life phase of the study and results showed no significant changes in clinical signs, body weight, food and water consumption, hematological parameters, organ weight or histopathological findings between the control and treated groups that were attributable to test article administration. The NOAEL was determined to be 5%, equivalent to 2520 and 3200 mg/kg/day in males and females, respectively (Jin *et al.*, 2007).

5.4 Ribosome-Inactivating Proteins (RIP)

The possible presence of low levels of ribosome-inactivating proteins (RIP) in seeds of *Momordica* species was addressed in BioVittoria's GRAS Notice GRN 000301 in support of the safety of PureLo[®]. This was not considered a safety concern. The same applies to Go-Luo[™] powder extracts, since RIP occur at relatively high concentrations in a large variety of widely-consumed foods, such as barley, rye, and wheat, with no indication of adverse effects. Also, the seed of *S. grosvenori* is not the intended source of Go-Luo[™] powder extracts and, were any RIP to be extracted, their activity is likely to be completely destroyed by the extraction process.

5.5 Other Supportive Non-Safety Studies

A number of additional experimental animal studies of LHG described in BioVittoria's GRAS Notice GRN 000301 in support of the safety of PureLo® would also apply to Go-Luo™ powder extracts. While these studies examined primarily nutritional and other benefits of Luo Han extracts, the absence of reported adverse effects in these studies corroborates the safety of Luo Han products.

6.0 SUMMARY AND CONCLUSION

Guilin Layn Natural Ingredients Corp. (Layn) intends to produce powdered fruit extracts (Go-Luo™) derived from the lo han fruit (*Siraitia grosvenori*), also known as lo han guo (LHG) and lo han kuo (LHK), for use as general purpose sweeteners and flavor modifiers in a variety of food products in the United States. Use in meat and other products regulated by USDA is not intended.

Three Go-Luo™ powder extracts with a mogroside V content of 25%, 45%, and 55% are presently under consideration. The extracts are manufactured under Good Manufacturing Practices (GMP) using common food industry materials and processes, and have been shown to consistently comply with the established food-grade product specifications and all applicable purity standards.

Go-Luo™ powder extracts are similar in composition to BioVittoria's PureLo® Luo Han Fruit concentrate, a material previously affirmed GRAS (GRN 000301) with no questions from the US FDA CFSAN/Office of Food Additive Safety. However, Go-Luo™ powder extracts are more purified and contain up to 55% mogroside V, compared to the ≥ 30% mogroside V in PureLo®.

To make a determination that the use of Go-Luo™ powder extracts in foods as general purpose sweeteners and flavor modifiers is generally recognized as safe (GRAS) through scientific procedures, Layn is relying on the primary evidence of safety described in GRN 000301, supported by additional studies of Go-Luo™ 55% (mogroside V) powder extract. This information was compiled into a dossier provided to an Expert Panel that deliberated on the qualifications of three Go-Luo™ powder extracts (25, 45, and 55% mogroside V) as GRAS food ingredients.

Layn hereby notifies US FDA CFSAN/Office of Food Additive Safety that it considers Go-Luo™ powder extracts containing up to 55% mogroside V exempt from the definition of "food additive" and thus from the premarket approval requirements outlined in section 201(s) of the Federal Food, Drug, and Cosmetic Act based on (1) the available technical evidence of safety and (2) the opinion of an independent Expert Panel regarding the value of this information in supporting consensus of GRAS among their peers.

7.0 REFERENCES

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000040

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**APPENDIX 1: EXPERT PANEL OPINION REGARDING THE GRAS
USE OF GUILIN LAYN GO-LUO™ POWDER
EXTRACTS IN FOODS**

000042

Expert Panel Opinion Statement: Evaluation of the Generally Recognized As Safe (GRAS) Status of Go-Luo™ Powder Extracts as Derived from the Luo Han Fruit (*Siraitia grosvenori*) When Used as a General Purpose Sweetener in Food

The undersigned, an independent Panel of recognized Experts (hereinafter referred to as the Expert Panel), qualified by scientific training and relevant international experience to evaluate the safety of food and food ingredients, was commissioned by the Guilin Layn Natural Ingredients Corp. (hereafter referred to as Layn), to determine the Generally Recognized as Safe (GRAS) status of their line of three Go-Luo™ powder extracts when used as a general purpose sweetener in a variety of food products.

Three forms of the Go-Luo™ powder extracts were proposed for GRAS status, each with slightly different product manufacturing techniques. Final specifications for the respective Go-Luo™ powder extracts range between 25% to 55% Mogroside V content. It is Mogroside V that imparts the Luo Han fruit and fruit extracts with their characteristic sweet taste. Mogroside V content, and therefore product specifications, vary according to each manufacturing process. In the least refined form of Go-Luo™ powder extract now proposed for GRAS status, which employs the most basic manufacturing process, Go-Luo™ 25% powder extract contains approximately 25% Mogroside V. This finished product may then be further refined by an additional step wherein the content of Mogroside V is further concentrated, resulting in a finished product containing up to 45% Mogroside V. A slight variation in this refining process results in another form of finished product containing up to 55% Mogroside V content. These three concentrations of the finished Go-Luo™ product, Go-Luo™ 25% powder extract, Go-Luo™ 45% powder extract, and Go-Luo™ 55% powder extract, were each proposed for GRAS status. Moreover, the specific Mogroside V content of individual lots of finished Go-Luo™ 45% powder extract and Go-Luo™ 55% powder extract are intended to be set at the time of manufacture, thereby providing manufacturers wishing to use Go-Luo™ as a general purpose sweetener the option to vary the concentration of Mogroside V, and therefore the sweetness of the finished product, according to their individual requirements. Aside from slight differences in their respective manufacturing processes, the possible range of Mogroside V content in either of the more refined manufacturing processes may be set as low as 25% Mogroside V.

A comprehensive search of the scientific literature for safety and toxicity information on Luo Han fruit and Mogroside V, a triterpene glycosides, which imparts the Go-Luo™ powder extracts with their characteristic sweet taste, was conducted through the end of July 2010 and made available to the Expert Panel. A report based on this comprehensive literature review aided and facilitated the work of the Expert Panel. The

Expert Panel Opinion Statement: Evaluation of the Generally Recognized As Safe (GRAS) Status of Go-Luo™ Powder Extracts as Derived from the Luo Han Fruit (*Siraitia grosvenori*) When Used as a General Purpose Sweetener in Food

Expert Panel independently evaluated the materials submitted by Layn, and any other materials deemed appropriate. Following their independent, critical evaluation, the Expert Panel conferred by telephone and unanimously agreed to the decisions described herein. A summary basis for the discussion of GRAS status is provided below and was further elaborated upon in the Report to the Expert Panel:

- The source material of the Go-Luo™ powder extracts possesses a long history of safe use in the human diet when consumed as a conventional food. Go-Luo™ liquid and powder fruit juice concentrates have previously been self-affirmed as GRAS;
- The processing steps, the facility, and the controls used in the manufacture of Go-Luo™ powder extracts are widely used in the food industry and conform to current Good Manufacturing Practices (cGMP) for human food in accordance with the applicable parts of 21 CFR, part 110 of the Code of Federal Regulations;
- The Go-Luo™ powder extracts are compositionally equivalent to PureLo®, a luo han fruit extract containing ≥ 30% Mogroside V that is manufactured by BioVittoria Ltd. (BioVittoria). PureLo® was recently self-affirmed GRAS and submitted to FDA for their evaluation (GRN 000301). The FDA was not in disagreement with BioVittoria's opinion that the PureLo® product was GRAS;
- The respective chemical compositions of the Go-Luo™ powder extracts, plus the compositionally equivalent PureLo® product, are well characterized. Manufacturing specifications for Mogroside V content in the Go-Luo™ powder extracts range between 25% and 55%, depending upon the manufacturing processes. The minimum Mogroside V content in PureLo® is ≥ 30%. Evidence of consistently reproducible analyses of the finished products is available for Go-Luo™ 25% powder extract, Go-Luo™ 45% powder extract, and Go-Luo™ 55% powder extract;
- Primary evidence of safety is available in the form of a 28-day oral dietary toxicity study in rats (Marone *et al.*, 2008) that has served as the basis of safety for another compositionally equivalent luo han fruit extract, PureLo®;

000044

Guilin Layn Natural Ingredients Corp.
August 12, 2010

Expert Panel Opinion Statement: Evaluation of the Generally Recognized As Safe (GRAS) Status of Go-Luo™ Powder Extracts as Derived from the Luo Han Fruit (*Siraitia grosvenori*) When Used as a General Purpose Sweetener in Food

- Supporting evidence of safety is also available in the form of an unpublished 90-day oral dietary toxicity study in rats (with a 28-day recovery period) as well as a standard Ames assay, both undertaken with Go-Luo™ 55% powder extract (Liao and Wypyszyk, 2010);
- The presence of ribosome-inactivating proteins (RIP) in *Momordica* species are addressed, as the biological relevance to the oral route of exposure in animals is questionable, particularly when potentially digestible, denaturable, or non-absorbable protein is the subject of investigation;
- An estimate of Go-Luo™ powder extract intakes from the proposed uses is provided through the use of published dietary exposure data for other high intensity sweeteners with adjustment for their relative sweetness intensities (Renwick, 2008). The same methodology was used by BioVittoria to estimate the intake of the compositionally equivalent product PureLo®. Among the sub-populations described by Renwick, the estimated intakes of the respective Go-Luo™ powder extracts, and of Go-Luo™-derived Mogroside V alone, remain below the reference dose calculated through the standard application of a hundred-fold margin of safety (EPA, 1993), as derived from the mean no-observed-adverse-effect level (NOAEL) dose (7.28 g/kg bw/day) taken from a 28-day oral dietary toxicity study in rats (Marone, *et al.*, 2008). Similar results were obtained employing the NOAEL dose (3.44 g/kg bw/day) taken from a 90-day oral dietary toxicity study in rats (Liao and Wypyszyk, 2010). Projected intake of Go-Luo™ powder extracts and of Go-Luo™-derived Mogroside V are consistently below the reference dose calculated as being safe for human exposure; and
- Go-Luo™ powder extracts are proposed for use as a general purpose sweetener in a variety of food products. However, due to the characteristic intense sweet flavor of the Luo Han fruit and products derived from LHG, use is expected to be self-limiting and therefore subject only to current Good Manufacturing Practices (cGMP).

Expert Panel Opinion Statement: Evaluation of the Generally Recognized As Safe (GRAS) Status of Go-Luo™ Powder Extracts as Derived from the Luo Han Fruit (*Siraitia grosvenori*) When Used as a General Purpose Sweetener in Food

After a critical independent evaluation of the available safety, clinical, and manufacturing information, the undersigned members of the Expert Panel conferred and unanimously determined that the Go-Luo™ powder extract line of products, Go-Luo™ 25% powder extract, Go-Luo™ 45% powder extract, and Go-Luo™ 55% powder extract, meeting food-grade specifications, and manufactured according to current Good Manufacturing Practice (cGMP; 21 CFR 182.1) are Generally Recognized as Safe (GRAS) when used as a general purpose sweetener in food.

(b) (6)

John A. Thomas, Ph.D.
Adjunct Professor
Indiana University School of Medicine, Indianapolis, IN

8/13/10
Date

(b) (6)

Robert Nicolosi, Ph.D., C.N.S.
Director
Center for Health and Disease Research
University of Massachusetts Lowell, Lowell, MA

8/16/10
Date

(b) (6)

David Bechtel, Ph.D., DABT
Vice President & Senior Scientific Consultant
Cantox U.S. Inc., Bridgewater, NJ

August 12, 2010
Date

000046

**APPENDIX 2: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 25%
POWDER EXTRACT**

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	11/05/2009
Latin Name:	Momordica grosvenori Swingle	Testing Date:	11/06/2009
Batch Number:		Expire Date:	11/04/2011
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥25%	HPLC	25.19%
LOSS ON DRYING	< 5%	USP32 <731>	2.98%
ASH	< 5%	USP32 <561>	1.21%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000048

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phmethrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolylfluamid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	12/01/2009
Latin Name:	Momordica grosvenori Swingle	Testing Date:	12/02/2009
Batch Number:		Expire Date:	11/30/2011
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥25%	HPLC	25.36%
LOSS ON DRYING	< 5%	USP32 <731>	2.98%
ASH	< 5%	USP32 <561>	1.21%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000053

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolylfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	12/20/2009
Latin Name:	Momordica grosvenori Swingle	Testing Date:	12/21/2009
Batch Number:		Expire Date:	12/20/2011
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥25%	HPLC	25.12%
LOSS ON DRYING	< 5%	USP32 <731>	2.98%
ASH	< 5%	USP32 <561>	1.21%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000058

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phmethrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd. Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

**APPENDIX 3: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 45%
POWDER EXTRACT**

000063

Certificate of Analysis

Product Name: Luo han guo P.E.	Manufacture Date: 11/03/2009
Latin Name: Momordica grosvenori Swingle	Testing Date: 11/04/2009
Batch Number:	Expire Date: 11/03/2011
Quantity:	Shelf Life: 2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥45%	HPLC	45.21%
LOSS ON DRYING	< 5%	USP32 <731>	3.01%
Total ASH	< 5%	USP32 <561>	1.32%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000064

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'	0.02
Dicofol, p, p'	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd. Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
PyrifenoX	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	11/06/2009
Latin Name:	Momordica grosvenori Swingle	Testing Date:	11/07/2009
Batch Number:		Expire Date:	11/05/2011
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥45%	HPLC	45.46%
LOSS ON DRYING	< 5%	USP32 <731>	3.01%
Total ASH	< 5%	USP32 <561>	1.32%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Diieldrin	0.02
Diieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclbutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	11/08/2009
Latin Name:	Momordica grosvenori Swingle	Testing Date:	11/09/2009
Batch Number:		Expire Date:	11/07/2011
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥45%	HPLC	45.29%
LOSS ON DRYING	< 5%	USP32 <731>	3.01%
Total ASH	< 5%	USP32 <561>	1.32%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000074

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane, alpha	0.01
Chlordane, gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD, p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'	0.02
Dicofol, p, p'	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd. Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

**APPENDIX 4: CERTIFICATES OF ANALYSIS FOR GO-LUO™ 55%
POWDER EXTRACT**

000079

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	01/04/2010
Latin Name:	Momordica grosvenori Swingle	Testing Date:	01/05/2010
Batch Number:		Expire Date:	01/03/2012
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥55%	HPLC	55.26%
LOSS ON DRYING	< 5%	USP32 <731>	2.97%
Total ASH	< 5%	USP32 <561>	1.22%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E. COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

000080

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd. Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

000084

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	01/06/2010
Latin Name:	Momordica grosvenori Swingle	Testing Date:	01/07/2010
Batch Number:		Expire Date:	01/05/2012
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥55%	HPLC	55.35%
LOSS ON DRYING	< 5%	USP32 <731>	2.97%
Total ASH	< 5%	USP32 <561>	1.22%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolylfluand	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

Certificate of Analysis

Product Name:	Luo han guo P.E.	Manufacture Date:	01/08/2010
Latin Name:	Momordica grosvenori Swingle	Testing Date:	01/09/2010
Batch Number:		Expire Date:	01/07/2012
Quantity:		Shelf Life:	2 years

ATTRIBUTES	SPECIFICATION	METHODS	TEST RESULTS
DESCRIPTION			
APPEARANCE	WHITE POWDER	VISUAL	COMPLIES
TASTE	SWEET (ODOR REDUCED)	GUSTATORY	COMPLIES
COUNTRY OF ORIGIN	CHINA	/	COMPLIES
PARTICLE SIZE	THROUGH 80 MESH	USP32<786>	COMPLIES
PLANT PART USED	FRUIT	/	COMPLIES
CHEMICAL TEST			
MOGROSIDE V	≥55%	HPLC	55.21%
LOSS ON DRYING	< 5%	USP32 <731>	2.97%
Total ASH	< 5%	USP32 <561>	1.22%
HEAVY METAL			
HEAVY METALS	< 10mg/kg	USP32<231>	COMPLIES
ARSENIC (As)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
LEAD (Pb)	< 0.5 mg/kg	AOAC 993.14	COMPLIES
CADMIUM (Cd)	< 0.05 mg/kg	AOAC 993.14	COMPLIES
MERCURY (Hg)	< 0.01 mg/kg	AOAC 993.14	COMPLIES
MICRO-BIOLOGICAL TEST			
TOTAL PLATE COUNT	<1000 CFU/G	USP32 <61>	COMPLIES
YEAST AND MOLD	<100 CFU/G	USP32 <61>	COMPLIES
SALMONELLA	NEGATIVE	USP32 <61>	COMPLIES
E.COLI	NEGATIVE	USP32 <61>	COMPLIES
STAPHYLOCOCCUS AUREUS	NEGATIVE	USP32 <61>	COMPLIES
AFLATOXINS	< 0.2 PPB	USP32 <61>	COMPLIES
STORAGE	STORE IN COOL AND DRY PLACE. KEEP AWAY FROMS STRONG LIGHT AND HEAT.		
PESTICIDES RESIDUE ANALYSIS			
PESTICIDES	SEE TABLE 1	USP32<561>	COMPLIES

Table 1

Substance	LOQ(mg/kg)
2-Phenylphenol	0.01
Acetochlor	0.02
Aclonifen	0.05
Aldrin	0.02
Ametryne	0.02
Aramite	0.05
Atrazine	0.02
Benfluralin	0.02
Bifenthrin	0.01
Biphenyl	0.02
Bromopropylate	0.02
Butachlor	0.01
Cadusafos	0.04
Captan	0.05
Chlorbenside	0.04
Chlordane(Sum)	
Chlordane,alpha	0.01
Chlordane,gamma	0.01
Chlorfenapyr	0.05
Chlorfenvinphos	0.02
Chlorobenzilate	0.01
Chlorothalonil	0.01
Chlorpyrifos	0.02
Chlorpyrifos-methyl	0.01
Chlorthal-dimethyl	0.01
Cyanazine	0.04
Cyanophos	0.04
Cyfluthrin	0.05
Cyhalothrin lambda	0.02
Cypermethrin	0.05
DDD, o, p'-	0.01
DDD,p, p'-	0.01
DDE ,o, p'-	0.01
DDE ,p, p'-	0.01
DDT(Sum)	
DDT, o, p'-	0.01

DDT, p, p'-	0.01
Deltamethrin	0.06
Dichlofluanid	0.02
Dichlorobenzophenone o, p'	0.02
Dichlorobenzophenone p, p'	0.02
Dichlorvos	0.05
Dicloran	0.05
Dicofol(Sum)	
Dicofol, o, p'-	0.02
Dicofol, p, p'-	0.02
Dieldrin	0.02
Dieldrin(Sum)	
Diphenylamine	0.02
Edifenphos	0.02
Endosulfan(Sum)	
Endosulfan,alpha-	0.05
Endosulfan,beta-	0.05
Endosulfan,sulfat-	0.02
Endrin	0.04
Ethion	0.04
Etridiazole	0.04
Etrimfos	0.02
Famoxadone	0.04
Fenamiphos	0.05
Fenitrothion	0.04
Fenpropathrin	0.04
Fenthion	0.04
Fenvalerate(RR-/SS)	0.04
Fenvalerate(RS-/SR)	0.04
Flucythrinate	0.05
Flucmioxazin	0.05
Fluquinconazole	0.04
Fluvalinate-tau	0.02
Folpet	0.05
Fonofos	0.04
Formothion	0.06
HCB	0.01
HCH(Sum, without Lindan)	
HCH gamma(Lindan)	0.02
HCH,alpha-	0.02

HCH,beta-	0.02
HCH,delta-	0.02
HCH,epsilon-	0.02
Heptachlor	0.01
Heptachlor(Sum)	
Heptachlor epoxide cis	0.01
Heptachlor epoxide trans	0.02
Heptenophos	0.02
Isocarbophos	0.04
Isodrin	0.04
Isofenphos	0.04
Isofenphos-methyl	0.01
Isoprothiolane	0.02
Kresoxim-methyl	0.01
Malaoxon	0.05
Malathion(Sum)	
Mecarbam	0.04
Mepronil	0.04
Methidathion	0.04
Metribuzin	0.04
Mevinphos	0.02
Nitrofen	0.02
Nitrothal-isopropyl	0.02
Octachlorodipropyl ether(S-421)	0.05
Ofurace	0.04
Oxadiazon	0.02
Oxyfluorfen	0.02
Paclobutrazol	0.04
Parathion	0.06
Parathion-methyl	0.04
Permethrin	0.04
Phrnothrin	0.04
Phenthoate	0.04
Phorate	0.04
Phosphamidon	0.04
Picoxystrobin	0.04
Pirimphos-ethyl	0.01
Procymidone	0.01
Profenofos	0.02
Prometryn	0.02
Propanil	0.02
Propazine	0.02
Pyrazphos	0.02
Pyridalyl	0.04



Guilin Layn Natural Ingredients Corp.
#18 Xiangjiang Rd. Xing'an County, Guilin 541300, China
Xicheng Rd. Lingui County, Guilin 541100, China
Tel: +86-773-3568000 Fax: +86-773-3568847
E-mail: info@layn.com.cn Web site : www.layn.com.cn

Pyridaphenthion	0.02
Pyrifenox	0.04
Pyrimethanil	0.01
Quinalphos	0.02
Quintozene	0.02
Quizalofop-P-ethyl	0.04
Silafluofen	0.02
Silthiofam	0.02
Tebufenpyrad	0.02
Tecnazene	0.02
Tefluthrin	0.02
Terbufos	0.02
Tetrachlorvinphos	0.02
Tetradifon	0.02
Tolyfluanid	0.04
Triallate	0.04
Triazamate	0.04
Triazophos	0.04
Trifluralin	0.02
Triticonazole	0.04

**APPENDIX 5: ASSAYS FOR ANALYSIS OF MOGROSIDE V
CONTENT IN GO-LUO™ POWDER EXTRACTS**

Analysis Method of mogrosides In

Grosvenor Momordica Extract (UV-VIS)

1. Reagent

Methanol(AR)

Vanillin(AR)

Glacial acetic acid(AR)

Perchloric acid(AR)

2. Process

a) Preparation of Standard

Weight dried standard 15mg(W) accurately into 10ml dissolution flask, add 8ml of Methanol solution and ultrasonic bath until sample has dissolved, Cool to room temperature , then diluting to volume with Methanol solution to 10ml exactly.

b) Preparation of Sample

Weight dried extract 30mg(W) accurately into 10ml dissolution flask, add 8ml of Methanol solution and ultrasonic bath until sample has dissolved, Cool to room temperature , then diluting to volume with Methanol solution to 10ml exactly. Then Filter this solution with 0.45μm membrane .

c) Analysis

Pipette 0.1ml of sample solution and 0.1ml of standard solution into 10ml test tube respective, transpire solution, then add 0.2ml glacial acetic acid with 5% Vanillin(G/G), 0.8ml Perchloric acid. Put it into the water bath at 60°C for 15 min, then take it out and cool with ice water, add 5ml glacial acetic acid and mix Well.

Measure the extinction (A) of the solution at the maximum at 590nm in 1cm cell, using Methanol solution as the blank.

Calculate the mogrosides by the formulas:

$$\text{mogrosides (\%)} = \frac{A_1 \times M_2}{A_2 \times M_1} \times 100\%$$

A₁ : absorbance of sample

M₁ : weight of sample (mg)

A₂ : absorbance of standard

M₂ : weight of standard (mg)

000097

HPLC Method Testing Mogroside v in Momordica grosvenori P.E.

1. Instrument

HP—Series 1100 (LC)

2. HPLC mobile phase

A: Acetonitrile—HPLC grade (filtered by 0.5µm film)

B: Distilled water (filtered by 0.5µm film)

3. Standard

Mogroside v (98%, made by ourselves)

4. Preparation of sample solution

4.1 Weight 5 ~ 10mg extract exactly into 10ml dissolution flask.

4.2 Add 8ml HPLC grade methanol and ultrasonic bath until sample has dissolved, Cool to room temperature , then diluting to volume with HPLC grade methanol.

4.3 Filtering sample through a 0.45µm membrane filter .

5. Preparation of standard solution

Weight Mogroside v to make the standard solution with the concentration of 0.3mg/ml (C_s).

6. HPLC chromatogram condition

Column: Hypersil NH₂, 4.6mm×250mm, 5µm

Mobile phase : A/B=71/29(v/v)

Flow rate : 1.0ml/min

Column temperature: room temperature

Inject volume: 5µl

Detect Wavelength: UV 203nm

7. Calculation

$$\text{Mogroside v \%} = \frac{A_i \times C_s \times 10}{A_s \times M} \times 100\%$$

A_i: Peak area of extract sample

A_s: Peak area of Mogroside v standard

C_s: Concentration of Mogroside v standard (mg/ml)

M: Weight of extract sample (mg)

000098

**APPENDIX 6: QUALITY ASSURANCE ANALYSES FOR MULTIPLE
BATCHES OF GO-LUO™ 55% POWDER EXTRACT**

000099



CERTIFICATE OF ANALYSIS

Silliker JR Laboratories

12-3871 North Fraser Way, Burnaby, BC V5J 5G6
 Tel. 604/ 432 9311 Fax. 604/ 432 7768

COA No:	BRN-33690355-0
Supersedes:	BRN-33672167-0
COA Date	5/7/10
Page 2 of 2	

TO:

Mr. Frank Fang
 NHP Industries Inc.
 8055 North Fraser Way
 Burnaby, BC V5J 5M8

Received From:	Burnaby, BC
Received Date:	4/14/10
P.O.# / ID:	2010-04-1
Location of Test: (except where noted) Burnaby, BC	

Analytical Results

Desc. 1:	Luo Han Guo Extract White Powder	Laboratory ID:	321022981		
Desc. 2:	50% Mogroside V	Condition Rec'd:	NORMAL		
Desc. 3:	Batch L# LWW50-100401	Temp Rec'd (°C):	20		
Analyte	Result	Units	Method Reference	Test Date	Loc.
Parathion-methyl	<0.02	ppm			
Permethrin	<0.02	ppm			
Phosalone	<0.02	ppm			
Piperonyl butoxide	<0.02	ppm			
Pirimiphos-methyl	<0.02	ppm			
Pyrethrins (sum of)	<0.02	ppm			
Quintozene, PCA, m-pcp sulfide	<0.02	ppm			
Dithiocarbamates (as CS2)	0	10 ppm			
Aerobic Colony Count USP	350	CFU/g	USP32,NF27,2009,2021	4/19/10	
E. coli USP	Negative	/10g	USP32,NF27,2009,2022	4/20/10	
Salmonella USP	Negative	/10g	USP32,NF27,2009,2022	4/18/10	
Staphylococcus aureus USP	Negative	/10g	USP32,NF27,2009,2022	4/18/10	
Yeasts and Molds USP			USP32,NF27,2009,2021	4/20/10	
Yeast	<10	CFU/g			
Mold	<10	CFU/g			

(b) (6)

Cathy Shevchuk

Laboratory Director

000101

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Except as otherwise stated, Silliker, Inc. Terms and Conditions for Testing Services apply.



CERTIFICATE OF ANALYSIS

Silliker JR Laboratories
 12-3871 North Fraser Way, Burnaby, BC V5J 5G6
 Tel. 604/ 432 9311 Fax. 604/ 432 7768

COA No:	BRN-33690356-0
Supersedes:	BRN-33672168-0
COA Date	5/7/10
Page 1 of 2	

TO:
 Mr. Frank Fang
 NHP Industries Inc.
 8055 North Fraser Way
 Burnaby, BC V5J 5M8

Received From:	Burnaby, BC
Received Date:	4/14/10
P.O.# / ID:	2010-04-01
Location of Test: (except where noted) Burnaby, BC	

Analytical Results

Desc. 1:	Desc. 2:	Desc. 3:	Result	Units	Method Reference	Test Date	Loc.
Luo Han Guo Extract White Powder	50% Mogroside V	Batch #L WV50-100402					
					EPA 3050/6020 USP730	4/27/10	
ICP MS Heavy Metals							
Arsenic			0.012	ppm			
Cadmium			<0.001	ppm			
Lead			0.036	ppm			
Mercury			0.0508	ppm			
ICP-MS Sample Prep			Acid Digest	-		4/20/10	
Multi Residue Pesticide Screen					USP 32/NF 27	4/28/10	
Alachlor			<0.02	ppm			
Aldrin and Dieldrin (sum of)			<0.02	ppm			
Azinphos-methyl			<0.02	ppm			
Bromopropylate			<0.02	ppm			
Chlordane (sum of cis-, trans- & oxy-)			<0.02	ppm			
Chlorfenvinphos			<0.02	ppm			
Chlorpyrifos			<0.02	ppm			
Chlorpyrifos-methyl			<0.02	ppm			
Cypermethrin (and isomers)			<0.02	ppm			
DDT (sum of DDTpp, DDTop, DDEpp)			<0.02	ppm			
Deltamethrin			<0.02	ppm			
Diazinon			<0.02	ppm			
Dichlorvos			<0.02	ppm			
Endosulfan (sum of isomers and sulfa)			<0.02	ppm			
Endrin			<0.02	ppm			
Ethion			<0.02	ppm			
Fenitrothion			<0.02	ppm			
Fenvalerate			<0.02	ppm			
Fonofos			<0.02	ppm			
Heptachlor & Heptachlor epoxide			<0.02	ppm			
Hexachlorobenzene			<0.02	ppm			
Hexachlorocyclohexane isomers-no g			<0.02	ppm			
Lindane (gamma-hexachlorocyclohex)			<0.02	ppm			
Malathion			<0.02	ppm			
Methidathion			<0.02	ppm			
Parathion-ethyl			<0.02	ppm			

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000102

Silliker JR Laboratories

12-3871 North Fraser Way, Burnaby, BC V5J 5G6
Tel. 604/ 432 9311 Fax. 604/ 432 7768

COA No:	BRN-33690356-0
Supersedes:	BRN-33672168-0
COA Date	5/7/10
Page 2 of 2	

TO:

Mr. Frank Fang
NHP Industries Inc.
8055 North Fraser Way
Burnaby, BC V5J 5M8

Received From:	Burnaby, BC
Received Date:	4/14/10
P.O.# / ID:	2010-04-01
Location of Test: (except where noted) Burnaby, BC	

Analytical Results

Desc. 1:	Luo Han Guo Extract White Powder	Laboratory ID:	321024329
Desc. 2:	50% Mogroside V	Condition Rec'd:	NORMAL
Desc. 3:	Batch #L WV50-100402	Temp Rec'd (°C):	20
Analyte	Result Units	Method Reference	Test Date Loc.
Parathion-methyl	<0.02 ppm		
Permethrin	<0.02 ppm		
Phosalone	<0.02 ppm		
Piperonyl butoxide	<0.02 ppm		
Pirimiphos-methyl	<0.02 ppm		
Pyrethrins (sum of)	<0.02 ppm		
Quintozene, PCA, m-pcp sulfide	<0.02 ppm		
Dithiocarbamates (as CS ₂)	<0.10 ppm		
Aerobic Colony Count USP	25 est. CFU/g	USP32,NF27,2009,2021	4/19/10
E. coli USP	Negative /10g	USP32,NF27,2009,2022	4/20/10
Salmonella USP	Negative /10g	USP32,NF27,2009,2022	4/18/10
Staphylococcus aureus USP	Negative /10g	USP32,NF27,2009,2022	4/18/10
Yeasts and Molds USP		USP32,NF27,2009,2021	4/20/10
Yeast	50 CFU/g		
Mold	<10 CFU/g		

(b) (6)

Cathy Shevchuk

Laboratory Director

000103

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Except as otherwise stated, Silliker, Inc. Terms and Conditions for Testing Services apply.

Silliker JR Laboratories

12-3871 North Fraser Way, Burnaby, BC V5J 5G6
Tel. 604/ 432 9311 Fax. 604/ 432 7768

COA No:	BRN-33690357-0
Supersedes:	BRN-33672169-0
COA Date	5/7/10
Page 1 of 2	

TO:

Mr. Frank Fang
NHP Industries Inc
8055 North Fraser Way
Burnaby, BC V5J 5M8

Received From:	Burnaby, BC
Received Date:	4/15/10
P.O.# / ID:	2010-04-01
Location of Test: (except where noted) Burnaby, BC	

Analytical Results

Desc. 1:	Desc. 2:	Desc. 3:	Laboratory ID:		
			321024500		
			Condition Rec'd: NORMAL		
			Temp Rec'd (°C): 20		
Analyte	Result	Units	Method Reference	Test Date	Loc.
ICP MS Heavy Metals			EPA 3050/6020 USP730	4/27/10	
Arsenic	0.015	ppm			
Cadmium	<0.001	ppm			
Lead	0.037	ppm			
Mercury	0.0352	ppm			
ICP-MS Sample Prep	Acid Digest	-		4/20/10	
Multi Residue Pesticide Screen			USP 32/NF 27	4/28/10	
Alachlor	<0.02	ppm			
Aldrin and Dieldrin (sum of)	<0.02	ppm			
Azinphos-methyl	<0.02	ppm			
Bromopropylate	<0.02	ppm			
Chlordane (sum of cis-, trans- & oxy-)	<0.02	ppm			
Chlorfenvinphos	<0.02	ppm			
Chlorpyrifos	<0.02	ppm			
Chlorpyrifos-methyl	<0.02	ppm			
Cypermethrin (and isomers)	<0.02	ppm			
DDT (sum of DDTpp, DDTop, DDEpp)	<0.02	ppm			
Deltamethrin	<0.02	ppm			
Diazinon	<0.02	ppm			
Dichlorvos	<0.02	ppm			
Endosulfan (sum of isomers and sulfa)	<0.02	ppm			
Endrin	<0.02	ppm			
Ethion	<0.02	ppm			
Fenitrothion	<0.02	ppm			
Fenvalerate	<0.02	ppm			
Fonofos	<0.02	ppm			
Heptachlor & Heptachlor epoxide	<0.02	ppm			
Hexachlorobenzene	<0.02	ppm			
Hexachlorocyclohexane isomers-no g	<0.02	ppm			
Lindane (gamma-hexachlorocyclohex)	<0.02	ppm			
Malathion	<0.02	ppm			
Methidathion	<0.02	ppm			
Parathion-ethyl	<0.02	ppm			

Results reported herein are provided "as is" and are based solely upon samples as provided by client. This report may not be distributed or reproduced except in full. Client shall not at any time misrepresent the content of this report. Silliker assumes no responsibility, and client hereby waives all claims against Silliker, for interpretation of such results.

Except as otherwise stated, Silliker, Inc. Terms and Conditions for Testing Services apply.



CERTIFICATE OF ANALYSIS

Silliker JR Laboratories
 12-3871 North Fraser Way, Burnaby, BC V5J 5G6
 Tel. 604/ 432 9311 Fax. 604/ 432 7768

COA No:	BRN-33690357-0
Supersedes:	BRN-33672169-0
COA Date	5/7/10
Page 2 of 2	

TO:
 Mr. Frank Fang
 NHP Industries Inc.
 8055 North Fraser Way
 Burnaby, BC V5J 5M8

Received From:	Burnaby, BC
Received Date:	4/15/10
P.O.# / ID:	2010-04-01
Location of Test: (except where noted) Burnaby, BC	

Analytical Results

Desc. 1:	Luo Han Guo Extract White Powder	Laboratory ID:	321024500		
Desc. 2:	50% Mogroside V	Condition Rec'd:	NORMAL		
Desc. 3:	Batch #L WV50-100403	Temp Rec'd (°C):	20		
Analyte	Result	Units	Method Reference	Test Date	Loc.
Parathion-methyl	<0.02	ppm			
Permethrin	<0.02	ppm			
Phosalone	<0.02	ppm			
Piperonyl butoxide	<0.02	ppm			
Pirimiphos-methyl	<0.02	ppm			
Pyrethrins (sum of)	<0.02	ppm			
Quintozene, PCA, m-ppc sulfide	<0.02	ppm			
Dithiocarbamates (as CS2)	<0.10	ppm			
Aerobic Colony Count USP	<10	CFU/g	USP32,NF27,2009,2021	4/19/10	
E. coli USP	Negative	/10g	USP32,NF27,2009,2022	4/20/10	
Salmonella USP	Negative	/10g	USP32,NF27,2009,2022	4/18/10	
Staphylococcus aureus USP	Negative	/10g	USP32,NF27,2009,2022	4/18/10	
Yeasts and Molds USP			USP32,NF27,2009,2021	4/20/10	
Yeast	<10	CFU/g			
Mold	<10	CFU/g			

(b) (6)

Cathy Shevchuk

Laboratory Director

000105

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**APPENDIX 7: ASSAY OF SWEETNESS INTENSITY FOR GO-LUO™
POWDER EXTRACTS**

Sweetness intensity of Luo Han Guo P.E.

All the sweetness intensity tests above were followed by the method of “ISO 8587:2006 Sensory analysis -- Methodology –Ranking” and its procedure were described below:

- Randomized complete block design
- # of panelists: 36
- # of evaluations: 5
- Rinsing materials: Purified water and unsalted crackers.

Test Protocol

- Panelists, who have high sweetness acuity and who are trained in taste profiling techniques, were presented with four samples (one 5.0% sucrose solution and three different specification Luo Han Guo P.E. solution). The assessors evaluate the samples given in random order and place them in rank order by their sweetness. This process was then replicated. Replication allows us to show respondent repeatability to correctly select the two samples which had the similar sweetness taste by their rank sums.
- Criterion for all significant differences: $p \leq 0.05$

Sweetness intensity of Luo Han Guo P.E. in 3 different specification Luo Han Guo P.E.

Luo Han Guo P.E. is a white, water soluble powder. Samples were taken from 3 batch of different specification (Mogroside V 25%, Mogroside V 45%, Mogroside V 55%) powdered Luo Han Guo P.E. material. Their sweetness intensity were tested (see **Table I**).

Table I Sweetness potency of different specification Luo Han Guo P.E.

Sample	Luo Han Guo P.E. Concentration (Sweetness equivalent to 5.0% sucrose solution (20°C))	Sweetness Intensity
Mogroside V 25%	0.032%	160 fold sweeter than sucrose
Mogroside V 45%	0.024%	210 fold sweeter than sucrose
Mogroside V 55%	0.02%	250 fold sweeter than sucrose

SUBMISSION END

000108

Pages 000109-000952 removed under Freedom of Information exemption 4.

Intertek



Intertek Cantox
1011 US Highway 22, Suite 200,
Bridgewater, New Jersey
08807-2950, U.S.A.

Phone: 908-429-9202
Fax: 908-429-9260
www.intertek.com

February 27, 2013

Ms. Judy Dausch, Ph.D.
FDA/OFAS/DBGNR

Re: Additional Communication: GRN000359

Dear Dr. Dausch:

I wish to submit this communication for the purpose of clarifying the mogroside V content specification for the powder extracts of Luo Han fruit (*Siraitia grosvenori*) as presented in the GRAS Notification GRN000359, dated November 3, 2010 and submitted on behalf of Guilin Layn Natural Ingredient Corporation of Guangxi, China.

The subject of the notification was Luo Han fruit extracts containing minimums of 25, 45, or 55 % mogroside V. As indicated throughout the notification and specifically presented in the extract specifications (Tables 3.1, 3.2, and 3.3) and verified by batch analysis (Appendices 2, 3, and 4), these extracts contain $\geq 25\%$, $\geq 45\%$, and $\geq 55\%$ mogroside V but were generically referred to as 25%, 45%, and 55% extracts.

The language of the notification may have inadvertently referred to extracts as being "up to" 55% mogrosides. This language might be misunderstood to mean that 55% is the maximum content. I wish to clarify that in fact "55%" was intended to denote the highest-content extract product, generically identified as the "55%" extract. The specified content characterization of the three extracts, $\geq 25\%$, $\geq 45\%$, and $\geq 55\%$, should be understood to denote *minimum* mogroside V content and not upper limits.

Sincerely,

(b) (6)

David H. Bechtel, Ph.D., D.A.B.T.
Vice President, New Jersey Office
Intertek Cantox

cc: Mr. Christopher Tower
Mr. Volker Wypyszyk