



TECHNICAL DATA PACKAGE

L-TRYPTOPHAN

Product Specification Sheet.....	1
Allergen Statement.....	2
Manufacturing Process Flow Chart.....	3
Safety Data Sheet.....	4
Additional Information.....	10

SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2018

<u>IDENTIFICATION</u>		
NAME	L-TRYPTOPHAN	
SOURCE OF MATERIAL	<i>c. glutamicum</i>	
PRODUCT CODE	LTRP	
SHELF LIFE	24 Months	
COUNTRY OF ORIGIN	China	
<u>PHYSICAL & CHEMICAL ANALYSIS</u>		
<u>PARAMETER</u>	<u>SPECIFICATION</u>	<u>METHODS</u>
1. APPEARANCE	Crystals or crystalline powder	Ocular estimate
COLOR	Yellowish-white	Ocular estimate
2. IDENTIFICATION	IR absorption	USP<197K>
3. SPECIFIC ROTATION	-29.4° ~ -32.8°	USP<781S>
4. pH	5.5 ~ 7.0	USP<791>
5. CHLORIDE	NMT 0.05%	USP<221>
6. IRON	NMT 30 ppm	USP<241>
7. SULFATE	NMT 0.03%	USP<221>
8. HEAVY METALS	NMT 15 ppm	USP<231>
LEAD	NMT 3 ppm	GB 10765-2010
ARSENIC	NMT 2 ppm	GB 10765-2010
CADMIUM	NMT 1 ppm	GB 10765-2010
MERCURY	NMT 0.1 ppm	GB 10765-2010
9. DENSITY		
BULK	0.20 ~ 0.40 g/mL	USP<616>
TAPPED	0.30 ~ 0.50 g/mL	USP<616>
10. PARTICLE SIZE	100% through 60 mesh	R40/3
11. LOSS ON DRYING	NMT 0.30%	USP<731>
12. RESIDUE ON IGNITION	NMT 0.10%	USP<281>
13. IMPURITIES		
IMPURITY 1	NMT 100 ppm	USP<621>
IMPURITY 2	NMT 300 ppm	USP<621>
TRYPTOPHAN RELATED COMPOUND A	NMT 10 ppm	USP<621>
14. PEAKS E AND X	Absent	EP8 2.2.29
15. ASSAY	98.5% ~ 101.5%	USP<541>
<u>MICROBIOLOGY CONTROL</u>		
TOTAL PLATE COUNT	NMT 1,000 cfu/g	GB 4789.2-2010
YEAST & MOLD	NMT 100 cfu/g	GB 4789.15-2010
E.COLI	Absent	GB 4789.38-2008
SALMONELLA	Absent	GB 4789.4-2010
<p>STORAGE CONDITIONS: PRESERVE IN TIGHTLY-SEALED CONTAINERS UNDER COOL, DRY CONDITIONS. AVOID EXCESSIVE EXPOSURE TO SUNLIGHT. <u>MANUFACTURING SITE:</u> THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT NO. 889 DALIAN ROAD, HIGH-TECH DEVELOPMENT DISTRICT, ANTONG, JIANGSU, CHINA TO MEET SUAN FARMA, INC. SPECIFICATIONS.</p>		
		<p><i>Julianna Chedia</i> Julianna Chedia, QA/QC Assistant DATE PRINTED: April 17, 2019</p>

ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **L-Tryptophan** (product code: **LTRP**) does not contain or come in contact with the following allergens and sensitivities:

- Milk and products thereof (including lactose)
- Egg and egg products thereof
- Fish and fish products thereof
- Crustaceans/Mollusks/Shellfish and products thereof
- Peanuts and products thereof
- Tree nuts and products thereof (Almonds, Hazelnuts, Walnuts, Cashews, Pecans, Brazil nuts, Pistachio nuts, Macadamia nuts, Queensland nuts)
- Soybeans and products thereof
- Cereals containing gluten and products thereof (Wheat, German wheat, Rye, Barley, Oats, Spelt, Hybrid, Gluten)
- Lupin and products thereof
- Sesame seeds and products thereof (including oil)
- Mustard and products thereof
- Sulfur dioxide and sulphites (Report quantity as SO₂ if > 10 ppm)
- Added salt or salt substitutes
- Added sugars
- Artificial colors
- Artificial sweeteners
- Azo and coal tar dyes
- Benzoates
- Bovine products or by-products
- Caffeine
- Cinnamon
- Cocoa
- Coconut and derivatives thereof
- Coriander
- Flavorings (natural, artificial, smoke, etc.)
- Fruit and fruit derivatives
- Garlic
- Gelatin
- Glutamate including MSG
- Gluten
- Histamine
- Honey
- HVP/TVP
- Legumes and pulses
- Maize or maize derivatives
- Nandrolone
- Nature identical color
- Nut cross contamination
- Nuts or products thereof
- Oats
- Oils of crustaceans/shellfish
- Oils of nuts
- Oils of seeds
- Other animal products or by-products
- Other antioxidants
- Other preservatives
- Phenylalanine
- Polyols
- Porcine products or by-products
- Potato and derivatives thereof
- Products banned from the International Olympic Committee
- Rice and rice derivatives thereof
- Seeds

Regards,

Julianna Chedid

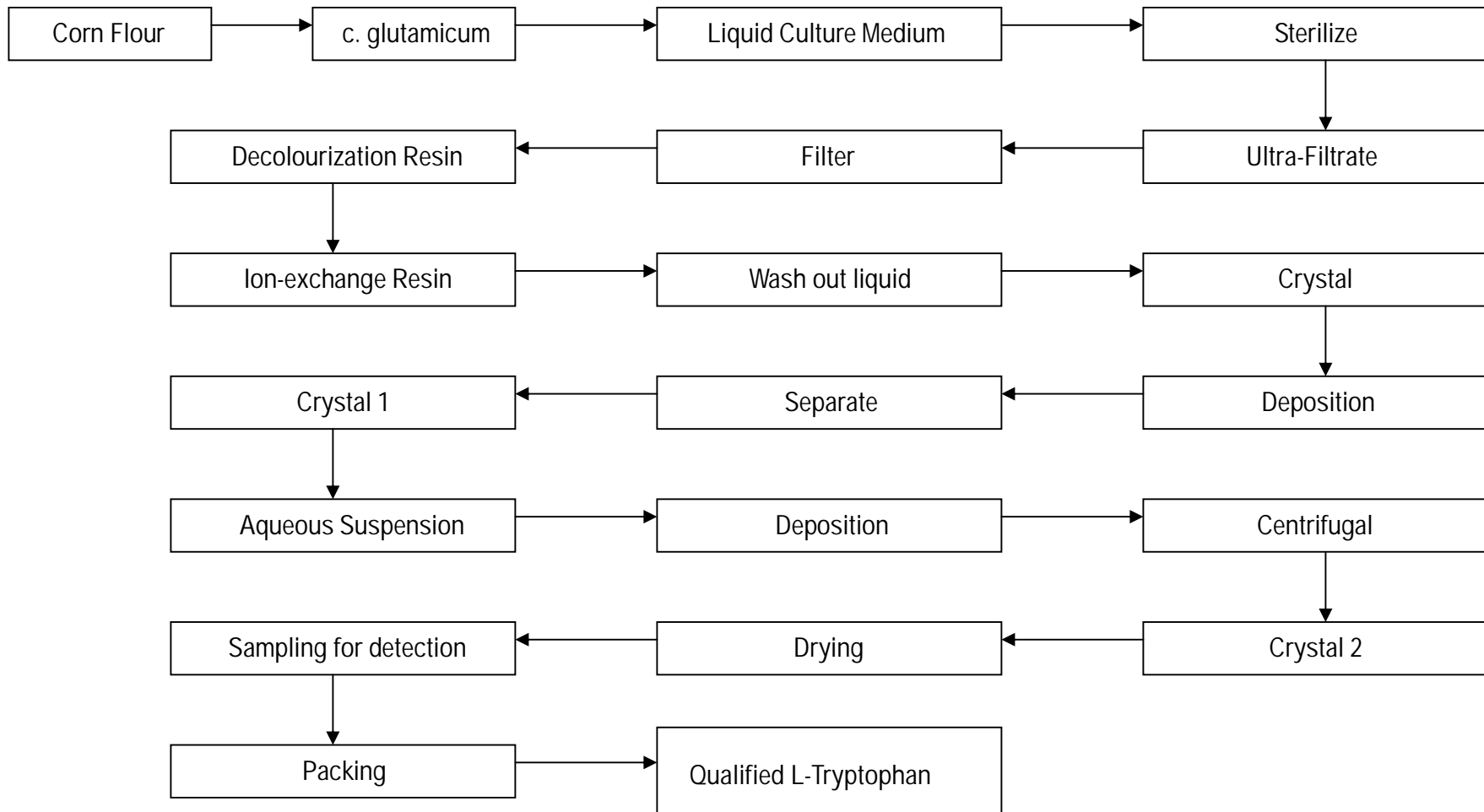
Julianna Chedid
QA/QC Assistant
December 2019



MANUFACTURING PROCESS FLOW CHART

Product Name: L-Tryptophan

Product Code: LTRP



SAFETY DATA SHEET

REVISION 01.2019

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

Product name:	L-TRYPTOPHAN
Synonyms:	L(-)-Tryptophan; (S)-2-Amino-3-(1H-indol-3-yl)propanoic acid; L-alpha-Amino-3-indolepropionic acid; Indole-3-alanine
CAS number:	73-22-3
Chemical formula:	C ₁₁ H ₁₂ N ₂ O ₂
Supplier name:	Suan Farma, Inc. 17-09 Zink Place, Unit 7 Fair Lawn, NJ 07410 Phone: 201-343-1188 FAX: 201-343-1102 E-mail: adminus@suanfarma.com
Emergency telephone number:	CHEMTREC (24-hr Access) 800-424-9300; International CHEMTREC, call: 703-527-3887

SECTION 2: HAZARD(S) IDENTIFICATION

Classification of the substance or mixture in according with 29 CFR 1910(OSHA HCS)

The substance is not classified as hazardous according to 29 CFR 1910(OSHA GHS).

Hazards not otherwise classified: No information known.

Label Elements

GHS label elements:	Not applicable.
Hazard pictograms:	Not applicable.
Signal word:	Not applicable.
Hazard statement:	Not applicable.
WHMIS classification:	Not controlled.

Classification system

HMIS ratings (scale 0~4)

Hazardous Materials Identification System

HEALTH	1
FIRE	1
REACTIVITY	1

Other hazards

Result of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

Potential Acute Health Effects:

Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Mutagenic for bacteria and/or yeast.

TERATOGENIC EFFECTS: Not available.



SAFETY DATA SHEET

DEVELOPMENTAL TOXICITY: Not available.
Repeated or prolonged exposure is not known to aggravate medical condition.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Name	CAS Number	% by Weight
L-Tryptophan	73-22-3	100

Toxicological data on ingredients: Not applicable.

SECTION 4: FIRST AID MEASURES

Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:

Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact:

Not available.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation:

Not available.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion:

Not available.

SECTION 5: FIRE FIGHTING MEASURES

Flammability of the Product:

May be combustible at high temperature.

Auto-Ignition Temperature:

Not available.

Flash Points:

Not available.

Flammable Limits:

Not available.

Products of Combustion:

These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat. Non-flammable in presence of oxidizing materials.

Explosion Hazards in Presence of Various Substances:

Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder.

SUAN FARMA, INC. 17-09 ZINK PLACE, UNIT 7, FAIR LAWN, NJ 07410, USA www.suanfarmausa.com



SAFETY DATA SHEET

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards:

As with most organic solids, fire is possible at elevated temperatures.

Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

SECTION 7: HANDLING AND STORAGE

Precautions:

Keep away from heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, acids.

Storage:

Store in a closed container with double PE layer PE bags inside, at 22°C ~25°C in a dry and cool place and relative humidity 55~65%.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance:	Solid. (Crystalline solid.)
Odor:	Odorless.
Taste:	Bitter. (Slight.)
Molecular Weight:	204.22 g/mole
Color:	White.

SAFETY DATA SHEET

pH (1% soln/water):	5.5 – 6.4
Boiling Point:	Not available.
Melting Point:	282 deg. C
Decomposition temperature:	289°C (552.2°F)
Critical Temperature:	Not available.
Specific Gravity:	Not available.
Vapor Pressure:	Not applicable.
Vapor Density:	Not available.
Volatility:	Not available.
Odor Threshold:	Not available.
Water/Oil Dist. Coeff.:	Not available.
Ionicity (in Water):	Not available.
Dispersion Properties:	See solubility in water.
Solubility:	Soluble in hot water. Partially soluble in cold water. Insoluble in diethyl ether. Slightly soluble in acetic acid. Solubility in water: 0.23 g/l @ 0 deg. C; 11.4 g/l @ 25 deg C; 17.1 g/l @ 50 deg. C; 27.95 g/l @ 75 deg. C; 49.9 g/l @ 100 deg. C Insoluble in chloroform. Soluble in hot alcohol and solutions of dilute acids, and alkali hydroxides.

SECTION 10: STABILITY AND REACTIVITY

Condition to be avoided:	Humidity, sunshine, high-temp.
Substances to be avoided:	Acidic, alkaline substance
Hazardous decomposition:	Acid, base

SECTION 11: TOXICOLOGY INFORMATION

Routes of Entry:	Inhalation. Ingestion.
Toxicity to Animals:	Acute oral toxicity (LD50): >16000 mg/kg [Rat].
Chronic Effects on Humans:	
MUTAGENIC EFFECTS:	Mutagenic for bacteria and/or yeast.
Other Toxic Effects on Humans:	
	Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.
Special Remarks on Toxicity to Animals:	Not available.
Special Remarks on Chronic Effects on Humans:	May cause adverse reproductive effects based on animal test data. May cause cancer based on animal test data. May affect genetic material (mutagenic)
Special Remarks on other Toxic Effects on Humans:	
Acute Potential Health Effects:	
Skin:	May cause skin irritation.
Eyes:	May cause eye irritation.
Inhalation:	May cause respiratory tract irritation.
Ingestion:	Causes severe initial nausea. May affect behavior/central nervous system (drowsiness, headache, excitement, somnolence, insomnia, muscle weakness, and anxiety), respiration (acute pulmonary edema), skin (dermatitis). May affect blood and cause L-Tryptophan induced eosinophilia myalgia syndrome. This illness is



SAFETY DATA SHEET

characterized by musculoskeletal symptoms including myalgias, arthralgias, and paresthesias. The physical findings consist of muscle tenderness, neuropathies, rash, peripheral and periorbital edema, eosinophilia.

Chronic Potential Health Effects:

Ingestion:

Prolonged or repeated ingestion may affect the liver, metabolism (weight loss), blood (changes in red blood cell count, eosinophilia), and respiration (dyspnea, chronic pulmonary edema), urinary system.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

Not available.

BOD5 and COD:

Not available.

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation:

The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation:

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

DOT Classification:

Not a DOT controlled material (United States).

Identification:

Not applicable.

Special Provisions for Transport:

Not applicable.

SECTION 15: REGULATORY INFORMATION

Federal and State Regulations:

TSCA 8(b) inventory: L-Tryptophan

Other Regulations:

EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): This product is not classified according to the EU regulations. S24/25- Avoid contact with skin and eyes.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):



SAFETY DATA SHEET

Health: 1
Flammability: 1
Reactivity: 0
Specific hazard:

Protective Equipment:

Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

SECTION 16: OTHER INFORMATION

Further information

This information is based upon the present state of our knowledge. This SDS had been compiled and is solely intended for this product.

Notice to reader

Employers should use this information only as a supplement to other information gathered by them and should make independent judgement of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty and any use of the product not in conformance with this Safety Data Sheet or in combination with any other product or process is the responsibility of the user.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use, users should make their own investigations to determine the suitability of the information for their purposes. In no way shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.



ADDITIONAL INFORMATION

We, Suan Farma, Inc., hereby declare that **L-Tryptophan** (product code: **LTRP**) is manufactured in accordance with the following guidelines:

- o No animal derived products have been used in the manufacture of the above material, making it free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).
- o The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
- o At no point in the process is L-Tryptophan derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g).
- o Melamine is wrongfully added to food to artificially elevate the protein content values of products. Melamine has not been used in L-Tryptophan at any stage of the manufacturing process.
- o The above material is free of any carriers, excipients, binders, preservatives, and artificial colors or flavors.
- o The above material has not been irradiated per 7 CFR 205.105(f) requirements with the understanding that "irradiation" shall be defined as outlined in 21 CFR 179.26.
- o The above material has not been treated with Ethylene Oxide (ETO) or any other form of chemical sterilization.
- o L-Tryptophan is suitable for vegetarian and vegan consumption.

Typical nutritional data for the above material is as follows:

Item	Data	Unit	Method
Energy	1694	kJ/100g	GB/T 24154-2009
Protein	81.3	g/100g	GB 5009.5-2010
Fat	Not detected	g/100g	GB/T 5009.6-2003
Carbohydrate	18.1	g/100g	GB/T 24154-2009
Sodium	1.94	mg/100g	GB/T 5009.91-2003

Regards,

Julianna Chedid

Julianna Chedid
QA/QC Assistant
Suan Farma, Inc.
May 2020