

# TECHNICAL DATA PACKAGE

### ALPHA-GLYCERYLPHOSPHORYLCHOLINE 98%

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



#### PRODUCT SPECIFICATION SHEET

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**REVISION 1.2019** 

NAME SYNONYMS FORMULA PRODUCT CODE SHELF LIFE MOLECULAR WEIGHT CAS NUMBER SOLVENT(S) USED COUNTRY OF ORIGIN		ALPHA-GLYCERYLPHOSPHORYLCHOLINE 98% <i>L-Alpha glycerylphosphorylcholine; alpha-GPC</i> C <sub>8</sub> H <sub>20</sub> NO <sub>6</sub> P AGP98 24 Months 257.221 28319-77-9 Ethanol China			
PHYSICAL & CHEMICAL	ANALYSIS				
PAF	AMETER		SPECIFICATION	METHODS	
1.	APPEARANCE COLOR ODOR		Hygroscopic Powder White Neutral	Organoleptic Organoleptic Organoleptic	
2.	IDENTIFICATION		Positive to reference standard	TLC	
3.	COLOR OF SOLUTION		NMT Y7	USP	
4.	SPECIFIC ROTATION		-2.4° ~ -2.8°	USP	
5.	pH		4.5 ~ 6.5	USP	
6.	PARTICLE SIZE		80% through 20 mesh	USP	
7.	WATER CONTENT		NMT 2.0%	USP	
8.	IMPURITIES RELATED SUBSTANCES		NMT a single spot	TLC	
9.	RESIDUAL SOLVENTS		NMT 1.0% Ethanol	GC	
10.	HEAVY METALS		NMT 20 ppm	USP	
11.	ASSAY [ON DRIED BASIS]		98.5 ~ 101.5%	Titration	
MICROBIOLOGICAL CON	ITROL				
	TOTAL PLATE COUNT YEAST & MOLD E. COLI		NMT 1,000 cfu/g NMT 100 cfu/g Absent	USP USP USP	

MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT NO.16, HAIWANG RD., CHANGSHU ADVANCED MATERIAL INDUSTRIAL PARK, JIANGSU, CHINA TO MEET SUAN FARMA, INC. SPECIFICATIONS.

Julianna Chedia Julianna Chedid, QA/QC Assistant

DATE PRINTED: July 31, 2019



### ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **Alpha**-Glycerylphosphorylcholine 98% (product code **A**GP98) does not contain allergens listed in the Annex II of the Regulation (EU) No. 1169/2011 and in the US Food Allergen Labeling and Customer Protection Act (FALCPA):

- o Cereals containing gluten and products thereof
- Crustaceans and products thereof
- o Eggs and products thereof
- o Peanuts and products thereof
- o Soybeans and products thereof
- Milk and products thereof (including lactose)
- o Nuts and products thereof
- Celery and products thereof
- Mustard and products thereof
- o Sesame seeds and products thereof
- $\circ$  Sulphur dioxide and sulfites (> 10 mg/kg or 10 mg/L as SO<sub>2</sub>)
- o Lupin and products thereof
- o Mollusks and products thereof
- o Flax, common flax linseed and products thereof
- o Buckwheat and products thereof
- o Royal jelly and products thereof

We also confirm that the allergen free status of said product is guaranteed by our allergen control measures, including the nature of manufacturing method, raw materials used, cleaning procedure, separation storage of materials, labeling of materials, process and equipment, and so on.

Regards,

Julianna Chedia

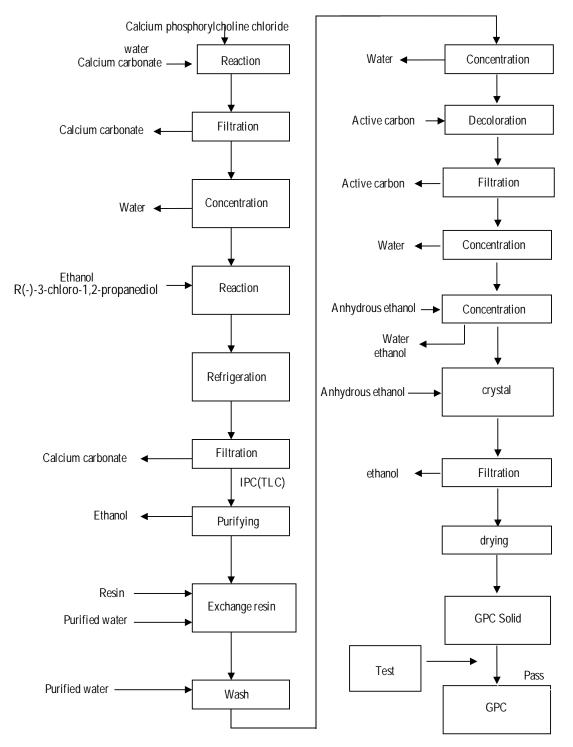
Julianna Chedid QA/QC Department Suan Farma, Inc. October 2019



### MANUFACTURING PROCESS FLOW CHART

Product Name: Alpha-Glycerylphosphorylcholine 98%

### Product Code: AGP98



SUAN FARMA, INC. 17-09 ZINK PLACE UNIT 7, FAIR LAWN, NJ 07410 <u>www.suanfarmausa.com</u> Tel: (201) 343-1188 Fax: (201) 343-1102



REVISION 01.2019

### SECTION 1: PRODUCT & COMPANY IDENTIFICATION

Product name: CAS number: Chemical family:	ALPHA-GLYCERYLPHOSPHORYLCHOLINE 98% 29319-77-9 Phospholipid synthetic		
Chemical formula:	$C_8H_{20}NO_6P$		
Recommended use:	Dietary supplements		
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: <u>adminus@suanfarma.com</u>		
Emergency telephone num	Der: CHEMTREC (24-hr Access) 800-424-9300; International CHEMTREC, call: 703-527-3887		

SECTION 2: HAZARD(S) IDENTIFICATION

#### **Emergency Overview:**

OSHA Hazards: No known OSHA hazards Not a dangerous substance according to GHS. HMIS Classification Health hazard: 0 Flammability: 0 Physical hazards: 0 NFPA Rating Health hazard: 0 Fire: 0 Reactivity Hazard: 0

#### Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation. Skin: May be harmful if absorbed through skin. May cause skin irritation. Eyes: May cause eye irritation. Ingestion: May be harmful if swallowed.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Formula: Molecular Weight: C<sub>8</sub>H<sub>20</sub>NO<sub>6</sub>P 257.22 g/mol

No ingredients are hazardous according to HCS criteria.



## SECTION 4: FIRST AID MEASURES

#### If inhaled:

If breathed in, move person into fresh air. If not breathing, give artificial respiration. In case of skin contact: Wash off with soap and plenty of water. In case of eye contact: Flush eyes with water as a precaution. If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water.

## SECTION 5: FIRE FIGHTING MEASURES

#### Conditions of flammability:

Not flammable or combustible. Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Special protective equipment for firefighters: Wear self contained breathing apparatus for firefighting if necessary. Hazardous combustion products: Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Oxides of phosphorus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Avoid breathing vapors, mist or gas. Environmental precautions: Do not let product enter drains. Methods and materials for containment and cleaning up: Keep in suitable, closed containers for disposal.

## SECTION 7: HANDLING AND STORAGE

#### Conditions for safe storage:

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

#### Recommended storage temperature:

2-8 °C Hygroscopic. Keep in a dry place.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values. Personal protective equipment: Respiratory protection: SUAN FARMA, INC. 17-09 ZINK PLACE, UNIT 7, FAIR LAWN, NJ 07410, USA www.suanfarmausa.com



**Respiratory protection:** not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

#### Hand protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

#### Eye protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

#### Skin and body protection:

Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

#### Hygiene measures:

General industrial hygiene practice

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### Appearance

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Melting point/freezing point
Boiling point
Flash point
Ignition temperature
Autoignition temperature
Lower explosion limit
Upper explosion limit
Vapor pressure
Density
Water solubility
Partition coefficient (n-octanol/water)
Relative vapor density
Odor
Odor Threshold
Evaporation rate

Form: powder no data available soluble no data available no data available no data available no data available no data available

## SECTION 10: STABILITY AND REACTIVITY

#### Chemical stability:

Stable under recommended storage conditions. Possibility of hazardous reactions: No data available. Conditions to avoid: Hygroscopic Materials to avoid: Strong oxidizing agents Hazardous decomposition products: Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), Oxides of phosphorus Other decomposition products - no data available SUAN FARMA, INC. 17-09 ZINK PLACE, UNIT 7, FAIR LAWN, NJ 07410, USA www.suanfarmausa.com



### SECTION 11: TOXICOLOGY INFORMATION

Acute toxicity: Oral LD50: LD50 Oral - mouse - > 13,000 mg/kg Inhalation: LC50 no data available Dermal LD50: no data available Other information on acute toxicity: no data available Skin corrosion/irritation: no data available Serious eye damage/eye irritation: no data available Respiratory or skin sensitization: no data available Germ cell mutagenicity: no data available Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA. Reproductive toxicity: no data available Teratogenicity: no data available Specific target organ toxicity - single exposure (Globally Harmonized System): No data available Specific target organ toxicity - repeated exposure (Globally Harmonized System): No data available Aspiration hazard: No data available Potential health effects: Inhalation: May be harmful if inhaled. May cause respiratory tract irritation. Ingestion: May be harmful if swallowed. Skin: May be harmful if absorbed through skin. May cause skin irritation. Eyes: May cause eye irritation. Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Synergistic effects: No data available Additional Information: RTECS: KH2775000



## SECTION 12: ECOLOGICAL INFORMATION

Toxicity:

No data available Persistence and degradability: No data available Bioaccumulative potential: No data available Mobility in soil: No data available PBT and vPvB assessment: No data available Other adverse effects: No data available

### SECTION 13: DISPOSAL CONSIDERATIONS

#### Product:

Offer surplus and non-recyclable solutions to a licensed disposal company. **Contaminated packaging:** Dispose of as unused product.

## SECTION 14: TRANSPORT INFORMATION

DOT (US): Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

### SECTION 15: REGULATORY INFORMATION

#### OSHA Hazards:

No known OSHA hazards SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. SARA 311/312 Hazards: No SARA Hazards Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act. Pennsylvania Right To Know Components: L-α-Glycerophosphorylcholine CAS-Number: 28319-77-9

#### New Jersey Right To Know Components:

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L-a-Glycerophosphorylcholine CAS-Number: 28319-77-9 California Bron 65 Component

#### California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

### SECTION 16: OTHER INFORMATION

#### Further information

This information is based upon the present state of our knowledge. This SDS had been complied 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 **Alpha-Glycerylphosphorylcholine 98%** (product code: **AGP98**) is manufactured in accordance with the following guidelines:

- o Neither Alpha-Glycerylphosphorylcholine 98% nor its components have been tested on animals.
- No animal derived products have been used in the manufacture of the above, making this material free from components which can cause Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE).
- The above material is composed of 100% Alpha-Glycerylphosphorylcholine. No carriers or excipients are used in the manufacturing process.
- The above extract has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
- At no point in the process is the above material derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g).
- 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 ETO (ethylene oxide) or any other chemical sterilizing agent.
- o Alpha-Glycerylphosphorylcholine 98% is suitable for vegetarian and vegan consumption.

Typical nutritional information for the above material is as follows:

Per 100 grams				
Protein	0			
Fat (of which)	0			
- Saturated fatty acids	0			
- Mono unsaturated fatty acids	0			
- Polyunsaturated fatty acids	0			
Cholesterol	0			
Carbohydrates (of which)	0			
- Sugars	0			
- Starch	0			
- Polyols	0			
Dietary fiber	0			
Ethyl Alcohol	0			
Organic Acids	0			
Calorific Value (kCal)	0			
Energetic value (kJ)	0			
Sodium	0			

Regards,

Julianna Chedia

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