



TECHNICAL DATA PACKAGE

N-ACETYL-L-CYSTEINE

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SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2020

IDENTIFICATION

NAME	N-ACETYL-L-CYSTEINE
SYNONYMS	(2R)-2-acetamido-3-sulfanylpropanoic acid
CAS NUMBER	616-91-1
MOLECULAR FORMULA	C ₅ H ₉ NO ₃ S
BATCH NUMBER	CYSNA-200213
SHELF LIFE	36 Months
ORIGIN	Acetylation, using fermentation Cys
COUNTRY OF ORIGIN	China

PHYSICAL & CHEMICAL ANALYSIS

PARAMETER	SPECIFICATION	METHODS
1. APPEARANCE	Crystalline powder or colorless crystals	Visual
COLOR	White or almost white	Visual
2. SOLUBILITY	Freely soluble in water, very soluble in alcohol	Visual
3. PARTICLE SIZE	100% through 20 mesh	USP 41
4. IDENTIFICATION	Positive to IR reference standard	USP 41
5. SPECIFIC ROTATION	+21.3° ~ +27.0° (t = 25°C)	USP 41
6. pH	2.0 ~ 2.8	USP 41
7. LOSS ON DRYING	NMT 1.0%	USP 41
8. RESIDUE ON IGNITION	NMT 0.2%	USP 41
9. CHLORIDE	NMT 0.04%	In-house
10. SULFATE	NMT 0.03%	In-house
11. AMMONIUM	NMT 0.02%	In-house
12. IRON	NMT 20 ppm	In-house
13. HEAVY METALS	NMT 10 ppm	USP 41
LEAD	NMT 0.2 ppm	USP 41
ARSENIC	NMT 0.5 ppm	USP 41
CADMIUM	NMT 0.5 ppm	USP 41
MERCURY	NMT 0.1 ppm	USP 41
14. ZINK	NMT 10 ppm	USP 41
15. RELATED SUBSTANCES		
L-CYSTINE (IMPURITY)	NMT 0.5%	EP 8
L-CYSTEINE (IMPURITY)	NMT 0.5%	EP 8
N,N'-DIACETYL-L-CYSTINE (IMPURITY)	NMT 0.5%	EP 8
N,S'-DIACETYL-L-CYSTEINE (IMPURITY)	NMT 0.5%	EP 8
ANY OTHER IMPURITY	NMT 0.5%	EP 8
TOTAL IMPURITIES	NMT 0.5%	EP 8
16. ASSAY	98.5% ~ 101.0%	USP 41

MICROBIOLOGY CONTROL

TOTAL PLATE COUNT	NMT 1,000 cfu/g	USP 41
YEAST & MOLD	NMT 100 cfu/g	USP 41
ENTEROBACTERIACEAE	Absent/10g	ISO
SALMONELLA	Absent/25g	USP 41
COLIFORMS	Absent/g	USP 41
E. COLI	Absent/g	USP 41
STAPHYLOCOCCUS AUREUS	Absent/g	USP 41
BACILLUS SP.	Absent/g	GB
COLISTRIDIUM SP.	Absent/g	USP 41

STORAGE CONDITIONS: PRESERVE IN TIGHTLY-SEALED CONTAINERS UNDER COOL, DRY CONDITIONS. AVOID EXCESSIVE EXPOSURE TO SUNLIGHT.

MANUFACTURING SITE: THIS MATERIAL HAS BEEN CUSTOM MADE AND PROCESSED AT NO. 799 FENG XIANG RD., XIEPU, ZHENHAI, NINGBO 315204 CHINA TO MEET SUAN FARMA, INC. SPECIFICATIONS.

Juliana Chedid
 Juliana Chedid, QA/QC Assistant
 DATE PRINTED: April 29, 2020

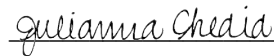


ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **N-Acetyl-L-Cysteine** (product code: **CYSNA**) does not contain allergens listed in the EU allergen labeling regulation, EU No 1169/2011 or US Food Allergen Consumer Protection Act (FALCPA) as follows:

- Milk and products thereof
- Eggs and products thereof
- Cereals containing gluten (wheat, rye, barley, oat, spelt, kamut)
- Shellfish/Crustaceans and products thereof
- Mollusks and mollusk products
- Fish and products thereof
- Peanuts and products thereof
- Tree Nuts and products thereof
- Soy and products thereof
- Celery and products thereof
- Lupin and products thereof
- Sesame and products thereof
- Mustard and products thereof
- Sulphur dioxide and sulphites

Regards,

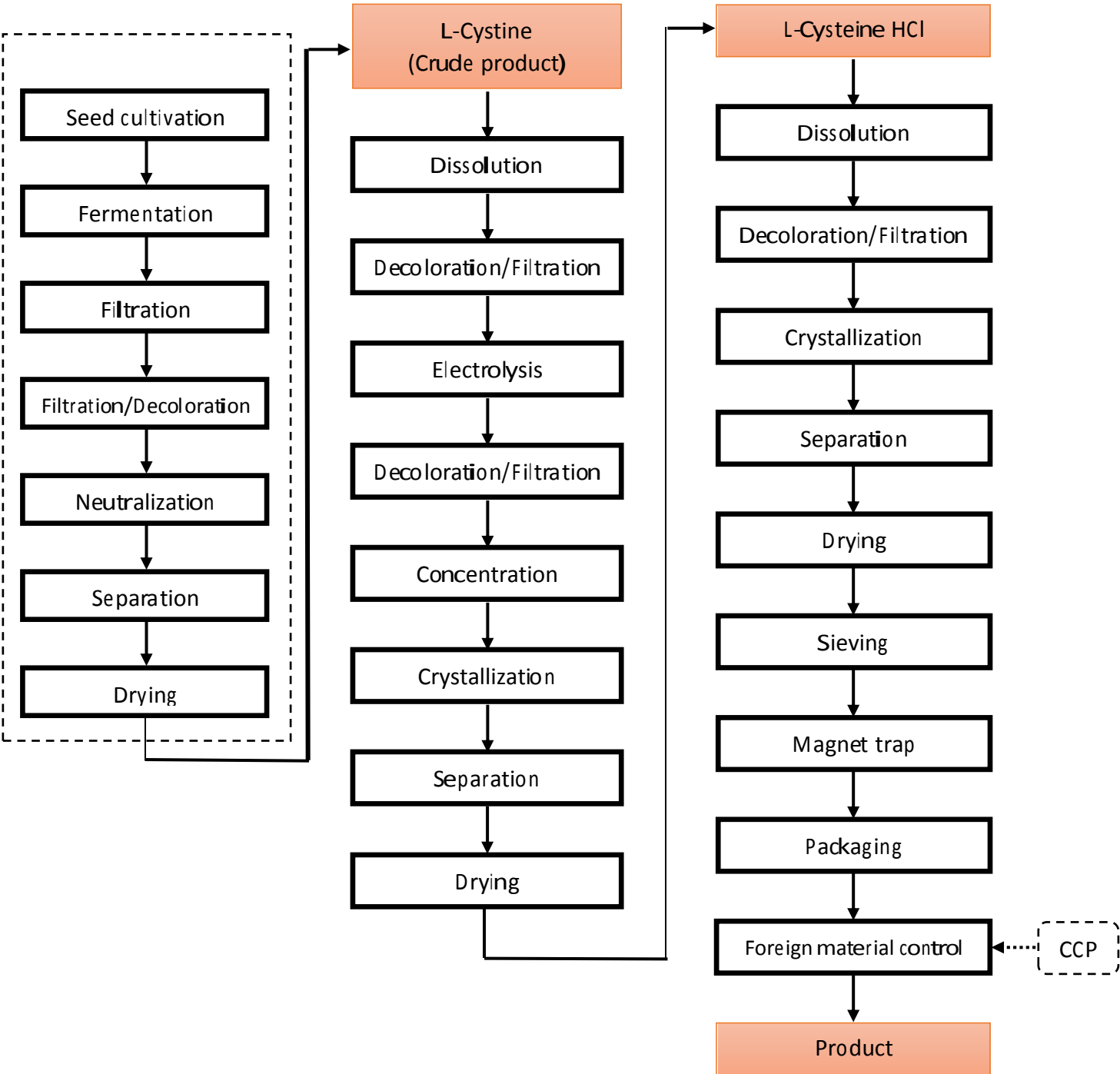


Julianna Chedid
QA/QC Assistant
December 2019

MANUFACTURING PROCESS FLOW CHART

Product Name: N-Acetyl-L-Cysteine

Product Code: CYSNA





SAFETY DATA SHEET

REVISION 01.2018

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

Product Name: N-ACETYL-L-CYSTEINE
CAS# 616-91-1

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 Phone Number: CHEMTREC (24-hr Access) 800-424-9300;
International CHEMTREC, call: 703-527-3887

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008 This substance is not classified as dangerous according to Directive 67/548/EEC.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards – none

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms: NAC, LNAC
Formula: C₅H₉NO₃S
Molecular Weight: 163.19 g/mol
CAS Number: 616-91-1
EC Number: 210-498-3

SECTION 4: FIRST AID MEASURES

4.1 Description of 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.



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If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NOx), Sulphur oxides

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

No data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapours, mist or gas.

For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters.



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8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection

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

Skin 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.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Breakthrough time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374 If used in solution, or mixed with other substances, and under conditions which differ from EN 374 contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance	Form: crystalline Color: white
b) Odor	No data available
c) Odor Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	Melting point/range: 106 - 108 °C - lit.
f) Initial boiling point and boiling range	No data available

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



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g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	No data available
k) Vapor pressure	No data available
l) Vapor density	No data available
m) Relative density	No data available
n) Water solubility	No data available
o) Partition coefficient: n-octanol/water	No data available
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

9.2 Other safety information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.6 Incompatible materials

Heavy metals, Heavy metal salts, Rubber, Oxygen, Oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - no data available

In the event of fire: see section 5

SECTION 11: TOXICOLOGY INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - rat – 5,050.0 mg/kg

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



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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.

Reproductive toxicity

No data available

Specific no data available target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: HA1660000

bronchospasm, Nausea, Vomiting, stomatitis, nasal discharge

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

SUANFARMA

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14.5 Environmental Hazards

ADR/RID: no

IMDQ Marine pollutant: no

IATA: no

14.6 Special precautions for user

No data available

SECTION 15: REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

no data available

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

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 **N-Acetyl-L-Cysteine** (product code: **CYSNA**) 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 N-Acetyl-L-Cysteine derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g)
- o Aflatoxins are a family of toxins produced by certain fungi that are found on agricultural crops such as maize (corn), peanuts, cottonseed, and tree nuts. N-Acetyl-L-Cysteine complies with USP limits for Aflatoxins.
- o The above material is free of any binders, carriers, or excipients (composed of NLT 99% N-Acetyl-L-Cysteine)
- o N-Acetyl-L-Cysteine has not been tested on animals at any stage of the production process.
- 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 N-Acetyl-L-Cysteine is sourced from fermented corn. It is suitable for both vegetarian and vegan consumption.
- o N-Acetyl-L-Cysteine complies with a particle size specification of NLT 100% through 20 mesh.

Typical nutritional data for the above material is as follows:

Per 100 grams:

Nutrient	Amount	Nutrient	Amount
Calories	451 kCal	Vitamin D (IU)	0
Energetic Value	1887 kJ	Vitamin E (IU)	0
Total Fat (g)	0	Vitamin K (mcg)	0
Saturated fat (g)	0	Thiamin (mg)	0
Polyunsaturated fat (g)	0	Riboflavin (mg)	0
Monounsaturated fat (g)	0	Niacin (mg)	0
Trans-fatty acids (g)	0	Vitamin B6 (mg)	0
Cholesterol (mg)	0	Folic acid (mcg)	0
Sodium (mg)	0	Vitamin B12 (mcg)	0
Potassium (mg)	0	Biotin (mcg)	0
Total carbohydrate (g)	0	Pantothenic acid (mcg)	0
Dietary fiber (g)	0	Phosphorus (mg)	0
Soluble fiber (g)	0	Iodine (mcg)	0
Insoluble fiber (g)	0	Magnesium (mg)	0
Sugars (g)	0	Zinc (mg)	0
Protein (g)	74 g	Selenium (mcg)	0
Vitamin A (IU)	0	Copper (mg)	0
Vitamin C (mg)	0	Manganese (mg)	0
Calcium (mg)	0	Chromium (mcg)	0
Iron (mg)	0	Molybdenum (mcg)	0

Regards,

Julianna Chedid

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