



TECHNICAL DATA PACKAGE

NIACINAMIDE

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<u>IDENTIFICATION</u>	
NAME	NIACINAMIDE
SYNONYMS	Nicotinamide; Nicotinic Acid Amide
FORMULA	C ₆ H ₆ N ₂ O
BATCH NUMBER	NIMA
SHELF LIFE	60 Months
MOLECULAR WEIGHT	122.12
CAS NUMBER	98-92-0
COUNTRY OF ORIGIN	INDIA

<u>PHYSICAL & CHEMICAL ANALYSIS</u>		
<u>PARAMETER</u>	<u>SPECIFICATION</u>	<u>METHODS</u>
1. APPEARANCE	Crystalline powder	Organoleptic
ODOR	Odorless	Organoleptic
COLOR	White	Organoleptic
FLAVOR	Bitter	Organoleptic
2. IDENTIFICATION		
IR TEST	Positive to IR reference standard	USP 42
UV TEST A ₂₄₅ to A ₂₆₂	0.63 -0.67	USP 42
3. PARTICLE SIZE (ASTM)	NLT 85% through 100 mesh sieve	USP 42
4. MELTING POINT	128° to 131°C	USP 42
5. LOSS ON DRYING	NMT 0.5%	USP 42
6. RESIDUE ON IGNITION	NMT 0.1%	USP 42
7. READILY CARBONIZABLE SUB.	No more color than matching Fluid A	USP 42
8. HEAVY METALS		
LEAD	NMT 2.0 ppm	USP 42
ARSENIC	NMT 2.0 ppm	USP 42
CADMIUM	NMT 0.5 ppm	USP 42
MERCURY	NMT 0.1 ppm	USP 42
9. ASSAY	98.5% to 101.5%	USP 42 (HPLC)

<u>MICROBIOLOGY CONTROL</u>		
TOTAL PLATE COUNT	NMT 1,000 cfu/g	USP 42
YEAST & MOLD	NMT 100 cfu/g	USP 42
E. COLI	Absent	USP 42
SALMONELLA	Absent	USP 42
ENTEROBACTERIA	Absent	USP 42
STAPHYLOCOCCUS AUREUS	Absent	USP 42

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 F-271 (A), MEWAR INDUSTRIAL AREA, MADRI, UDAIPUR- 313 001 (RAJASTHAN), INDIA TO MEET SUAN FARMA, INC. SPECIFICATIONS.

Juliana Chedid

 Julianna Chedid, QA/QC Assistant
 DATE PRINTED: December 5, 2019

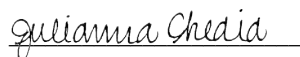


ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **Niacinamide** (product code: **NIMA**) does not contain the following allergens, nor are they present in the manufacturing facility:

- Egg or egg derivatives (e.g. from chicken, turkey, egg yolks, egg whites, etc.)
- Milk or Dairy Products
- Fish (e.g., bass, flounder, or cod)
- Peanuts
- Shellfish, including crustaceans, mollusks and their derivatives (specify type, e.g., crab, lobster, shrimp, scallops)
- Soybean or soybean derivatives
- Tree nuts (e.g., almonds, pecans, or walnuts)
- Wheat or wheat derivatives
- Animal products
- Gelatin
- Artificial color
- Artificial flavor
- Artificial preservative
- Artificial sweeteners (e.g. aspartame, saccharin, sucralose)
- Barley or barley derivatives
- Benzoates
- BHA / BHT or related compounds
- Celery
- Coal tar dyes
- Corn or corn derivatives (e.g. maltodextrin, corn starch, corn syrup)
- Fruit or fruit derivatives
- Gluten (e.g. from wheat, oats, barley, spelt, millet, amaranth, or rye grain)
- Lactose
- Lupins
- MSG
- Mustard
- Natural latex
- Oat or oat derivatives
- Rice or rice derivatives
- Sesame seeds and derivatives
- Sugar (specify source, e.g. fructose, sucrose, dextrose)
- Sugar alcohols (specify source e.g. sorbitol, mannitol)
- Sulphites, metaspulphites or sulfur dioxide
- Vegetables or vegetable derivatives
- Yeast or yeast derivatives
- Yellow5

Regards,



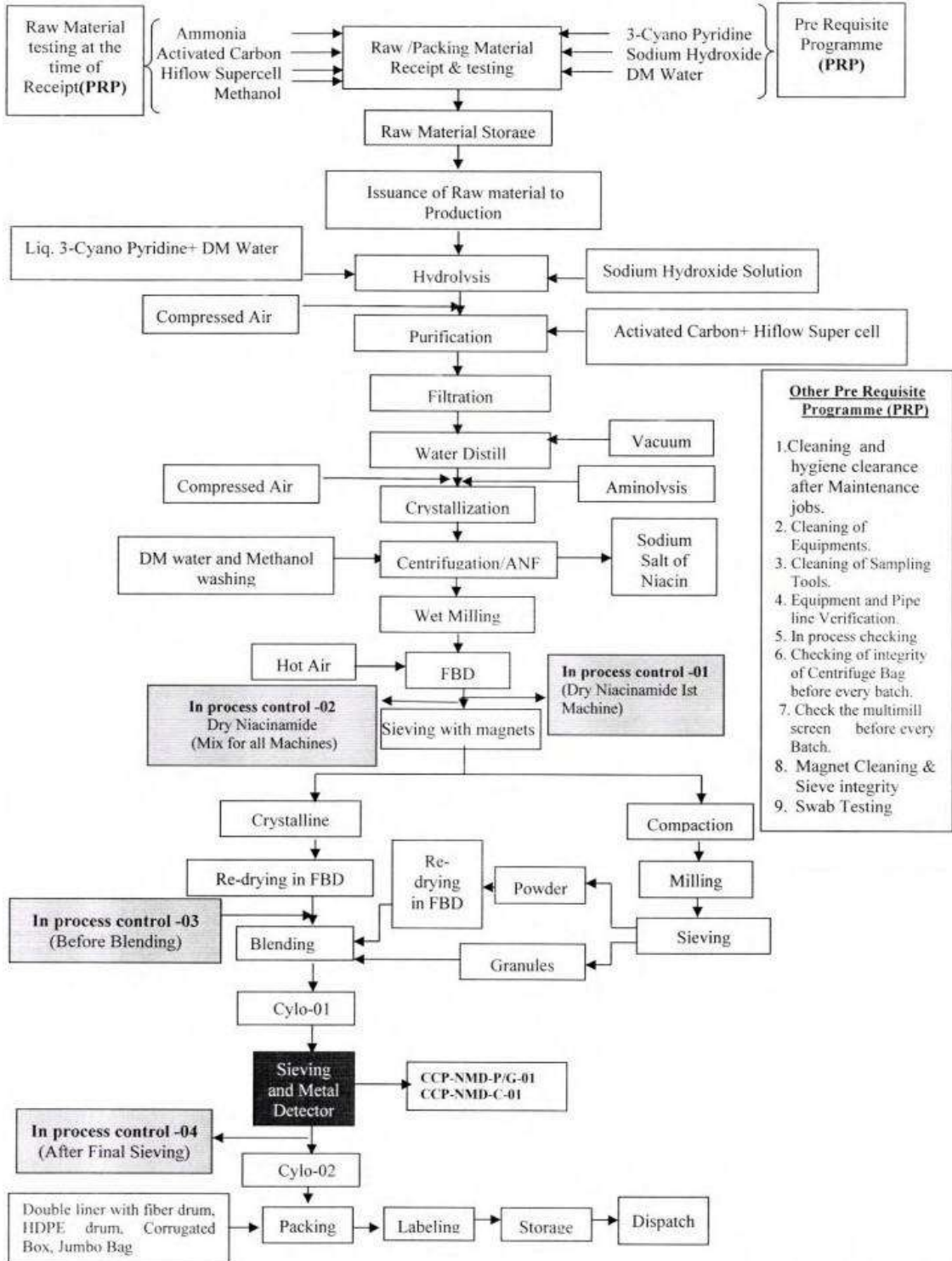
Julianna Chedid
QA/QC Assistant
December 2019

SUANFARMA

MANUFACTURING PROCESS FLOW CHART

Product Name: Niacinamide

Product Code: NIMA



CCP: Critical Control Point

SAFETY DATA SHEET

REVISION 01.2019

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

Product name:	NIACINAMIDE
CAS Number:	98-92-0
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

2.1 Classification of the substance or mixture

(Classification according to regulation (EC) No 1272/2008)

Hazard pictograms



GHS07

Signal word: Warning

Hazard-determining components of labelling: Void

Hazard statements

H319: Causes serious eye irritation.

Precautionary Statements:

P264: Wash hands, eyes and face thoroughly after handling

P280: Wear protective gloves/clothing and eye/face protection

First Aid Precautionary Statements (Response):

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing

P337+P313: If eye irritation persists: Get medical advice/attention

Information concerning particular hazards for human and environment: void

Physical hazards

Explosives conclusive but not sufficient for classification

Flammable gases conclusive but not sufficient for classification

Flammable aerosols conclusive but not sufficient for classification

Oxidizing gases conclusive but not sufficient for classification

Gases under pressure conclusive but not sufficient for classification

Flammable liquids conclusive but not sufficient for classification

Flammable solids conclusive but not sufficient for classification

Self-reactive substances and mixtures conclusive but not sufficient for classification

Pyrophoric liquids conclusive but not sufficient for classification

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Pyrophoric solids conclusive but not sufficient for classification
Self-heating substances and mixtures conclusive but not sufficient for classification
Substances and mixtures which in contact with water emits flammable gases conclusive but not sufficient for classification

Oxidizing liquids conclusive but not sufficient for classification
Oxidizing solids conclusive but not sufficient for classification
Organic peroxides conclusive but not sufficient for classification
Corrosive to metals conclusive but not sufficient for classification

Health hazards

Acute toxicity — oral conclusive but not sufficient for classification
Acute toxicity — dermal conclusive but not sufficient for classification
Acute toxicity — inhalation conclusive but not sufficient for classification
Skin corrosion / irritation conclusive but not sufficient for classification
Serious eye damage / eye irritation Eye Irrit. 2 H319: Causes serious eye irritation.
Respiratory sensitization conclusive but not sufficient for classification
Skin sensitization conclusive but not sufficient for classification
Aspiration hazard conclusive but not sufficient for classification
Reproductive toxicity conclusive but not sufficient for classification
Effects via lactation conclusive but not sufficient for classification
Germ cell mutagenicity conclusive but not sufficient for classification
Carcinogenicity conclusive but not sufficient for classification
Specific target organ toxicity — single conclusive but not sufficient for classification.
Specific target organ toxicity — repeated conclusive but not sufficient for classification

Environmental hazards:

Hazardous to the aquatic environment (acute/short-term) conclusive but not sufficient for classification
Hazardous to the aquatic environment (long-term) conclusive but not sufficient for classification
Hazardous to the ozone layer data lacking

2.2 Label elements:

Labeling according to Regulation (EC) No 1272/2008 : The substance is classified and labeled according to the CLP regulation.

Hazard pictograms



GHS07

Signal word Warning

Hazard-determining components of labeling: Void

Hazard statements

H319: Causes serious eye irritation.

Precautionary Statements:

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First Aid Precautionary Statements (Response):

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing

P337+P313: If eye irritation persists: Get medical advice/attention

2.3 Other Hazards:

Signs and Symptoms of Potential Overexposure:

Niacinamide is an eye irritant, but does not irritate the skin. May cause respiratory irritation upon exposure to dusty

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conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent.

Primary Route(s) of Exposure:

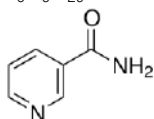
Skin contact and absorption, eye contact, and inhalation. Ingestion is not likely to be a primary route of exposure. Medical Conditions Aggravated by Exposure: Persons with pre-existing skin, liver, or kidney disorders may be at increased risk from overexposure to this material. This is not likely to be a problem when appropriate procedures are used to minimize exposure.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Nicotinamide / 3 Pyridine Carboxamide

Synonyms: Vitamin B3, Vitamin PP

Empirical formula: $C_6H_6N_2O$



Structural Formula:

Molar mass: 122.1 g/mol.

C.A.S no: 98-92-0

EINECS no: 202-713-4

Purity: Minimum 98.5%

Uses:

Nicotinamide is freely soluble in water, in alcohol and soluble in Glycerin, soluble Vitamin and finds its application as a nutrient supplement in Pharmaceutical products. It has been used in the enrichment of bread, flour and other grain derived products. Animal feed is routinely supplemented with Nicotinamide. It is also used in multi-vitamin preparations, dietary supplement and cosmetics. It is used in the treatment of pellagra.

SECTION 4: FIRST AID MEASURES

4. First-aid measures:

Key Symptoms

Acute effects: It causes serious eye irritation.

Chronic effects: Affects the kidneys, eyes & liver.

General Information:

Remove contaminated or saturated clothing at once.

Upon inhalation:

Remove the fresh air and keep at rest in a position comfortable for breathing. Call a physician if you feel unwell. Monitor the respiratory distress. Apply artificial respiration if not breathing. Do not use mouth-to-mouth method. If victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Toxic vapors may be released on thermal decomposition including nitrogen oxides, carbon monoxide and cyanide.

Following skin contact:

Wash well with water and soap. In case of remaining complaints seek medical advice.

Following eye contact:

Flush with plenty of water for at least 15 minutes. In case of remaining complaints seek medical advice.

Upon Ingestion (swallowing):

Do not induce vomiting. Rinse mouth and throat thoroughly with water. In case of persistent seek medical advice.

Most important symptoms and effects, both acute and delayed:

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



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Acute: Niacinamide is an eye irritant but does not irritate the skin. May cause respiratory irritation upon exposure to dusty conditions. In humans, nausea with or without vomiting was the main effect after acute exposure and was generally seen after doses in excess of 5 grams/day; no effects were persistent.

Delayed Effects: None known

Indication of any immediate medical attention and special treatment needed:

Thermal Exposure: Not applicable.

Note to Physician: No specific indications. Treatment should be based on the judgment of the physician in response to the reactions of the patient. One case of long-term niacinamide mega-dosing as a therapeutic agent led to nausea, vomiting, fever, rash, joint pains and increased levels of SGOT, SGPT and bilirubin. These symptoms abated six months after discontinuation of mega-dosing.

SECTION 5: FIRE FIGHTING MEASURES

Flash point: 182°C

Flammability: Non flammable Solid

Extinguishing Media:

Suitable extinguishing agents: Carbon dioxide (CO₂) extinguisher, Water Spray/fog, Alcohol-resistant foam.

Special hazards arising from the substance or mixture:

Hazardous Products of Combustion:

Cyanide and nitrogen oxides may be released during thermal decomposition.

High Vapor concentration may result in an explosion hazard.

Advice for Firefighters:

Protective equipment : Wear self-contained breathing apparatus (SCBA)

Additional information : Cool endangered containers with water spray jet

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Individual precautions, protective equipment and emergency procedures:

Ensure adequate ventilation

Wear protective equipment and keep away unprotected persons.

Avoid contact with skin and eyes.

Avoid breathing dust.

Remove all ignition sources.

6.2 Environmental precautions:

Prevent releases to soils, drains, sewers, and waterways.

6.3 Methods and material for containment and cleaning up:

Containment Techniques and Clean-up Procedures:

Remove all ignition sources. Ventilate the area of spill or leak. Wear protective equipment during clean-up. Material can then be collected for later disposal. After collection of material, flush area with water. Dispose of the material in accordance with standard practice for disposal of potentially hazardous materials as required by applicable federal, state or local laws. Dust deposits should not be allowed to accumulate on surfaces. as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Non sparking tools should be used.

Special Reporting Requirements: Not applicable.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.



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SECTION 7: HANDLING AND STORAGE

7.1 Handling

Advice on safe handling: Provide sufficient air exchange and/or exhaust in work rooms. Avoid formation of respirable particles.

Avoid contact with skin and eyes.

Advice on protection against fire and explosion: Avoid dust formation. Take precautionary measures against static discharges.

7.2 Storage

Do not Store in heat or direct sunlight. Keep Container tightly closed. Keep in dry and well ventilated place.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure controls:

Provide exhaust ventilation or other engineering controls to keep the relevant airborne concentrations below their respective occupational exposure limits. Local ventilation is usually preferred. Ensure that eyewash stations and safety showers are close to the work station location.

8.2 Personal protection:

General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Instantly remove any contaminated garments.

Wash hands during breaks and at the end of the work.

Use skin protection cream for preventive skin protection.

Do not eat, drink or smoke while working.

Breathing equipment:

Use breathing protection in case of dust formation.

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

Protection of hands:

The protective gloves to be used.

Eye protection:

Use safety glasses

Body protection:

Protective work clothing.

Protective clothing should be selected specifically for the working place.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical form (20° C) :	Powder/Granules/Crystalline
Color :	White
Odor :	Nearly odorless
Odor Threshold :	Not available
Melting Point/Melting Range :	128 — 131° C
Boiling Point/Boiling Range :	157 deg Cat -0.0005mm Hg
Flash Point :	182° C
Decomposition temperature :	> 140° C
Bulk density :	App. 600 Kg/m ³
Solubility in water (25°) :	Freely soluble in water in Alcohol and soluble in glycerin

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pH Value (50 g/l,20° C) :	6.0 — 7.5
Danger of Explosion :	Not explosive
Inflammability (solid, gaseous) :	Not inflammable
Self inflammability :	Not determined
Vapor pressure :	0.00045 Pa at 25 deg C
Vapor Density (air=1) :	Not applicable
Specific gravity (water=1) :	1.400 at 25 deg C
Critical values for explosion:	
Lower :	Not determined
Upper :	Not determined
Log Kow (octanol/water Coefficient) :	-0.37 (estimated)
Auto-ignition temperature :	No data available
Relative Density :	Not determined
Evaporation rate :	Not applicable
Viscosity :	Not applicable
Molecular Weight :	122.13
pKa (@20°C) :	3.35
Oxidizer :	No
Pvrophoric material :	No

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal temperature and conditions.

Thermal decomposition: No decomposition if used according to specifications. Avoid impact, friction, heat, sparks, and electrostatic charges.

Conditions to avoid: Avoid Static Discharge and dust generation.

Materials to avoid: Strong Acids, Strong Bases (hydrolysis), Strong Oxidizing agents

Hazardous decomposition products: Cyanide and Nitrogen oxides (NOx) may be released during thermal decomposition.

Hazardous Polymerization: Not expected.

Note: Drying operations at the lowest temperatures possible.

SECTION 11: TOXICOLOGY INFORMATION

a) Acute toxicity:

Acute toxicity: it causes irritation to the mucous membranes and upper respiratory tract.

It causes eye irritation.

b) Chronic effects:

Affects the Kidneys, eyes and liver.

RTECS#: QS3675000

LD50/LC50:

Acute Oral LD50 (Rat) 3530-3540 mg/kg

Acute Oral LD50 (Mouse) =2500 mg/kg

Acute Dermal LD50 (Rabbit) No data available

Acute Inhalation LC50 > 2000mg/kg

Sensitization Not sensitizing

Skin corrosion/irritation No information is available.

Serious eye damage/irritation Causes serious eye irritation.

Respiratory or skin sensitization No information is available.

Germ cell Mutagenicity No data is available.



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Carcinogenicity	No data is available.
Reproductive toxicity	No data is available.
STOT-single exposure	No data is available.
STOT-repeated exposure	No data is available.
Aspiration Hazards	No data is available.

SECTION 12: ECOLOGICAL INFORMATION

Fish Toxicity (Ecotoxicity):

Aquatic EC50 (24h) Daphnia magna > 1000 mg/L
Aquatic LC50 (96h) Poecilia reticulata (guppy) > 1000 mg/L
Aquatic EC50 (72h) Scenedesmus subspicatus > 1000 mg/L
Algeal toxicity: Desmodesmus subspicatus NOEC: 560 mg/1/72h.

Persistence and Degradability:

AEROBIC: Nicotinamide was determined to be readily biodegradable in an aerobic screening test recommended by the Department of Environment, Standing Committee of Analysis, UK (1).

ANAEROBIC: Nicotinamide was not degraded using a spore-forming rod (Clostridia sp.) bacteria isolated from Potomac River mud (1)

Bio accumulative potential (Predicted):

Not expected to bioconcentrate in aquatic species.

Mobility in soil:

This material is soluble in water. Its adsorption to soil and sediment should not be significant.

Other adverse effects:

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 Land transport (ADR/R1D)

UN number	Not dangerous goods
Class	Not dangerous goods
Classification code	Not dangerous goods
Packaging group	Not dangerous goods
Labels	Not dangerous goods

14.2 In land waterway transport (ADN(R))

UN number	Not dangerous goods
Class	Not dangerous goods
Classification code	Not dangerous goods
Packaging group	Not dangerous goods
Labels	Not dangerous goods

14.3 Marine transport (IMDG)

UN number	Not dangerous goods
Proper shipping name and description	
Chemical Name	Not dangerous goods
Class	Not dangerous goods
EmS number	Not dangerous goods



SAFETY DATA SHEET

Packaging group Not dangerous goods

Labels Not dangerous goods

14.4 Air transport ICAO/IATA

UN number Not dangerous goods

Proper shipping name and description Not dangerous goods

Chemical name Not dangerous goods

Class Not dangerous goods

Packaging group Not dangerous goods

Labels Not dangerous goods

It is considered to be Non-hazardous for transport by Road/Rail/Sea/Air and not regulated by ADR/RID/IMDG/IATA/ICAO/IMO.

Environmental hazards:

It is expected that this chemical is not a marine pollutant and is not Harmful to the Aquatic environment.

SECTION 15: REGULATORY INFORMATION

European Union information

Safety Phrases:

S336/37/39: Wear suitable protective clothing, glove and eye/face protection.

Classification as per CLP Regulation 1272/2008:

Eye Irrit Cat.2

Hazard Statements: H319

US information

TSCA

CAS#98-92-0 is listed on the TSCA inventory.

WGK (Water Danger/Protection)

CAS#98-92-0: 0

Canada

CAS#98-92-0 is listed on Canada's DSL List.

CAS #98-92-0 is not listed on Canada's Ingredient Disclosure list.

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 **Niacinamide** (product code: **NIMA**) is manufactured in accordance with the following guidelines:

- 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).
The above material has not been genetically modified or exposed to genetically modified organisms during the production process and is therefore GMO free.
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. Niacinamide is chemically synthesized and is therefore aflatoxin free.
The above material is composed of 100% Niacinamide. No carriers or excipients are used in the manufacturing process.
Niacinamide has not been tested on animals at any point in the production process.
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.
The above material has not been treated with ETO (ethylene oxide) or any other chemical sterilizing agent.
Niacinamide is suitable for vegetarian and vegan consumption.

Typical nutritional data for the above material is as follows:

Table with 4 columns: Parameter, Result, Unit, Test Method. Rows include Energy, Total Sugars, Starch, Dietary Fiber, Crude Fiber, Protein, Carbohydrates, Salt content, Total Saturated Fatty Acid, Total Monounsaturated Fatty Acid, Total Polyunsaturated Fatty Acid, Vitamin B3, Vitamin K, Sodium as Na, Calcium as Ca, Iron as Fe.

Remark: As Niacinamide is 99.0%, protein, carbohydrates, and energy are taken as absent.

Regards,

Julianna Chedid

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