



# TECHNICAL DATA PACKAGE

## NIACIN

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IDENTIFICATION

NAME	NIACIN
SYNONYMS	Vitamin B3, nicotinic acid 3-Carboxypyridine; 3-Pyridinecarboxylic acid; Pyridine-3-carboxylic acid; 3-Picolinic acid
FORMULA	C <sub>6</sub> H <sub>5</sub> NO <sub>2</sub>
PRODUCT CODE	NIAC
SHELF LIFE	60 Months
MOLECULAR WEIGHT	123.11
CAS NUMBER	59-67-6
COUNTRY OF ORIGIN	INDIA

PHYSICAL & CHEMICAL ANALYSIS

<u>PARAMETER</u>	<u>SPECIFICATION</u>	<u>METHODS</u>
1. APPEARANCE COLOR	Crystals or crystalline powder White	Organoleptic Organoleptic
2. IDENTIFICATION IR TEST UV TEST A <sub>239</sub> to A <sub>263</sub> HPLC – RT of major peaks	Positive to IR reference standard No. 2 0.46 ~ 0.52 RT of sample & standard solution correspond in major peaks	USP 42 USP 42 USP 42
3. PARTICLE SIZE (ASTM)	NLT 99.5% through 100 mesh	Manufacturing Specifications
4. LOSS ON DRYING	NMT 1.0%	USP 42
5. RESIDUE ON IGNITION	NMT 0.1%	USP 42
6. RELATED COMPOUNDS (by HPLC)	Disregard any impurity peak less than 0.03% (See Table 2)	USP 42
7. CHLORIDE	NMT 0.02%	USP 42
8. SULPHATE	NMT 0.02%	USP 42
9. HEAVY METALS LEAD ARSENIC CADMIUM MERCURY	NMT 2.0 ppm NMT 2.0 ppm NMT 0.5 ppm NMT 0.1 ppm	USP 42 USP 42 USP 42 USP 42
10. ASSAY (on dried basis)	98.0% to 102.0%	USP 42 (HPLC)

MICROBIOLOGY CONTROL

TOTAL PLATE COUNT	NMT 1,000 cfu/g	USP 42
YEAST & MOLD	NMT 100 cfu/g	USP 42
E. COLI	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

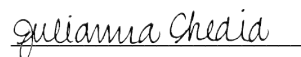
*Juliana Chedia*  
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 Julianna Chedia, QA/QC Assistant  
 DATE PRINTED: November 1, 2019

## ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **Niacin** (product code: **NIAC**) 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



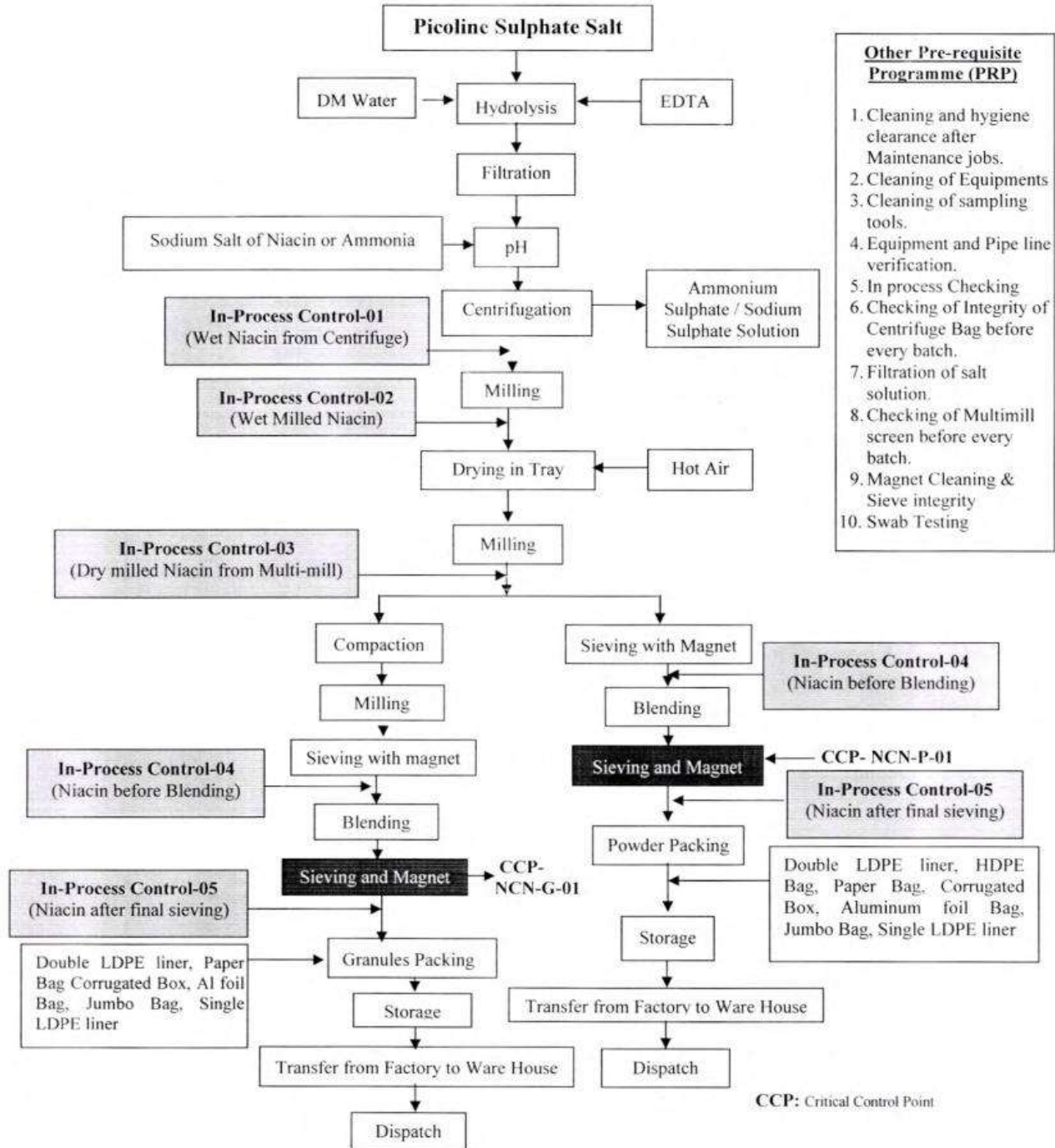
# SUANFARMA

## MANUFACTURING PROCESS FLOW CHART

**Product Name:** Niacin

**Product Code:** NIAC

Manufacturing process of Niacin (via Centrifuge Route)



## SAFETY DATA SHEET

REVISION 01.2019

### SECTION 1: PRODUCT & COMPANY IDENTIFICATION

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Product name: NIACIN  
CAS Number: 59-67-6

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](mailto:adminus@suanfarma.com)

Emergency telephone number: CHEMTREC (24-hr Access) 800-424-9300;  
International CHEMTREC, call: 703-527-3887

### SECTION 2: HAZARD(S) IDENTIFICATION

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2.1 Classification of the substance or mixture  
(Classification according to regulation (EC) No 1272/2008)

Classification under CLP: Eye irrit. 2: H319  
Most important adverse effects: Causes serious eye irritation

2.2 Label elements:

Labeling according to Regulation (EC) No 1272/2008

Label elements under CLP:

Hazard statement: H319: Causes serious eye irritation

Signal words: Warning

Hazard pictograms



GHS07: Exclamation mark

2.3 Other Hazards

PBT: This product is not identified as PBT/vPvB substance.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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Chemical characterization: Nicotinic Acid / 3-Pyridine-carboxylic Acid  
Labelling according to EU statutory order on dangerous substances: Xi: Irritating



## SAFETY DATA SHEET

Synonyms: Vitamin B3, Vitamin PP  
Empirical formula:  $C_6H_5NO_2$

Molar mass: 123.1 g/mol.  
C.A.S no: 59-67-6  
EINECS no: 200-441-0  
Purity: Minimum 98.5%  
Safetyphrases: S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

### SECTION 4: FIRST AID MEASURES

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**General Information** : Remove contaminated or saturated clothing at once.  
**Upon inhalation** : Breathe fresh air. In case of remaining complaints seek medical advice.  
**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 swallowing** : Do not induce vomiting. Rinse mouth and throat thoroughly with water. In case of persistent seek medical advice.  
Information for doctor:  
Most important symptoms and effects, both acute and delayed No further relevant information available.  
Indication of any immediate medical attention and special treatment needed  
No further relevant information available.

### SECTION 5: FIRE FIGHTING MEASURES

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Extinguishing media:  
Suitable extinguishing agents: Carbon dioxide (CO) extinguishing powder or water spray/fog. Fight larger fires with water spray/fog or alcohol-resistant foam.  
Unsuitable extinguishing agents: Water with a full water jet.  
Special hazards arising from the substance or mixture  
Can be released in case of fire:  
Nitrogen oxides (NOx) Carbon monoxide (CO) and Carbon dioxide (CO')  
Under certain fire conditions, traces of other toxic gases cannot be excluded  
Advice for firefighters:  
**Protective equipment** : Wear self-contained breathing apparatus.  
**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

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Individual precautions, protective equipment and emergency procedures:



## SAFETY DATA SHEET

Ensure adequate ventilation

Wear protective equipment and keep away unprotected persons.

Avoid contact with skin and eyes.

Avoid breathing dust.

Remove all ignition sources.

**Environmental precautions:** Hand over spilled material to recycling or to waste disposal.

**Procedure of cleaning/ take up:** Take up by mechanical means, avoid dust formation.

### 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.

## SECTION 7: HANDLING AND STORAGE

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### Storage

Store in dry place

Store in a well closed container

Store locked up

Protect from light.

Protect from Moisture

Keep away from heat/spark/open flames/hot surfaces. No Smoking.

Information about protection against explosions and fires:

Take precautionary measures against static discharge

Do not spray on an open flame or other ignition source

Handling Precautions for Safe handling

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with skin and eyes.

Avoid breathe dust.

Prevent formation of dust.

Any deposit of dust which cannot be avoided must be removed regularly.

Make sure that all applicable workplace limits are observed.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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**Further information :** Apply local exhaust ventilation

construction of plants This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build up of static electricity.

Exposure controls

Personal protective equipment

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.





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### 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:

#### Protective gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Check the permeability prior to each renewed use of the glove.

To avoid skin problems reduce the wearing of gloves to the required minimum.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/the chemical mixture.

#### Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

#### Penetration time of glove material

Protective gloves should be replaced at first signs of wear.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

### Eye protection:

Tightly sealed safety glasses

### Body protection:

Protective work clothing.

Protective clothing should be selected specifically for the working place.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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Physical form :	Powder/Granules
Color :	White to off-white
Odor :	Not available
Odor Threshold :	Not available
Melting Point/Melting Range :	234 – 238° C
Boiling Point/Boiling Range :	Not determined
Flash Point :	Not available
Thermal decomposition :	Not available
Bulk density :	App. 550 Kg/m <sup>3</sup>
Solubility in water (20°) :	13-15 g/l
pH Value (50 g/l,20° C) :	3.2 – 3.3

## SECTION 10: STABILITY AND REACTIVITY

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**Chemical Stability:** Stable under normal temperature and conditions.



## SAFETY DATA SHEET

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

Conditions to avoid: Light/humidity

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

Hazardous decomposition products: Nitrogen oxides (NO<sub>x</sub>) Carbon monoxide (CO) and Carbon dioxide (CO)

**Hazardous Polymerization:** Not expected.

**Note:** Drying operations at the lowest temperatures possible.

## SECTION 11: TOXICOLOGY INFORMATION

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Acute toxicity:

Acute Oral LD50 (Rat)	3530 mg/kg (OECD 401)
Acute Dermal LD50 (Rabbit)	>2000 mg/kg (Limit-Test, OECD 402) Prim. Irritation
Skin, rabbit	Not irritating (OECD 404)
Eye, rabbit	Irritating (OECD 405) Gen toxicity
Ames test	Positive and negative (Salmonella typhimurium)
Gen toxicity in vitro	Positive and negative (mutagen test with various end points)
Gen toxicity in vivo	Negative (Mouse, OECD 474) Substance or chronic toxicity
Rat, oral, 28 day test, subacute	NOEL: 215 mg/kg (OECD 407)
Carcinogenicity	No tumors (mouse, 110 weeks)
Teratogenity/embryo toxicity	Not known until yet

## SECTION 12: ECOLOGICAL INFORMATION

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Ready biodegradability	: Readily biodegradable. 96 %, 28 days (Modified OECD Screening Test. OECD No.301 E)
Ecotoxicity	: Barely toxic for fish (guppy) LC50 (96 h) > 1000mg/l : Barely toxic for planktonic crustaceans (Daphnia magna) EC50 (48 h):>1000mg/l : Barely toxic for micro organisms (Vorticella campanula) NOEC 3500 mg/l : Barely toxic for algae (green algae) EbC50(72 h) > 1000mg/l
Air pollution	: Observe local /national regulations

## SECTION 13: DISPOSAL CONSIDERATIONS

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

## SECTION 14: TRANSPORT INFORMATION

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14.1 Land transport (ADR/R1D)

UN number Not dangerous goods

## SAFETY DATA SHEET

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
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

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Safety, health and environmental regulations/legislation specific for the substance or mixture.  
 Reach Pre-Registration No.:- 17-2119943215-42-0000

## SECTION 16: OTHER INFORMATION

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### 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



## SAFETY DATA SHEET

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 **Niacin** (product code: **NIAC**) 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% Niacin. No carriers or excipients are used in the manufacturing process.
- Niacin 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.
- Niacin is suitable for vegetarian and vegan consumption.

Typical nutritional data for the above material is as follows:

<b>Nutrient</b>	<b>Value</b>	<b>Test Method</b>
Crude Fiber	< 0.1 g/100g	TUV/02/SOP/026
Dietary Fiber	< 0.1 g/100g	TUV/02/SOP/027
Energy	< 0.1 kCal/100g	IS:9487:1980 (RA: 2005)
Protein	< 0.1 g/100g	TUV/02/SOP/002
Salt	< 0.1 g/100g	TUV/02/SOP/030
Starch Content	< 0.1 g/100g	IS:4706(P-I):1978 RA 2010
Sugar	< 0.4 g/100g	TUV/02/SOP/013
Carbohydrate	< 0.1 g/100g	IS:1656-2007 (RA: 2009)
Calcium	0.028 g/100g	Based on AOAC 984.27 & 999.10 20th Edition By ICP-OES
Iron	0.0046 g/100g	Based on AOAC 984.27 & 999.10 20th Edition By ICP-OES
Potassium	0.00043 g/100g	Based on AOAC 984.27 & 999.10 20th Edition By ICP-OES
Sodium	0.0415 g/100g	Based on AOAC 984.27 & 999.10 20th Edition By ICP-OES
Total Fat	< 0.1 g/100g	TUV/02/SOP/005
Monounsaturated Fatty Acid	< 0.1 g/100g	TUV/03/SOP/023 Based on AOAC 996.06
Polyunsaturated Fatty Acid	< 0.1 g/100g	TUV/03/SOP/023 Based on AOAC 996.06
Saturated Fat	< 0.1 g/100g	TUV/03/SOP/023 Based on AOAC 996.06
Trans Fat	< 0.1 g/100g	TUV/03/SOP/023 Based on AOAC 996.06
Vitamin B3	98.2%	Based on UMA-6032

Regards,

*Julianna Chedid*

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