



# TECHNICAL DATA PACKAGE

## MILK THISTLE EXTRACT 80%

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# SUANFARMA

PRODUCT SPECIFICATION SHEET

REVISION 1.2019

IDENTIFICATION

NAME	MILK THISTLE EXTRACT 80%
BOTANICAL NAME	<i>Silybum marianum (L.) Gaertn</i>
PLANT PART USED	Seeds
PRODUCT CODE	MTE80
SHELF LIFE	36 Months
SOLVENTS USED	Acetone & Water
COUNTRY OF ORIGIN	China

PHYSICAL & CHEMICAL ANALYSIS

<u>PARAMETER</u>	<u>SPECIFICATION</u>	<u>METHODS</u>
1. APPEARANCE	Fine Powder	Visual
COLOR	Yellow to brown	Visual
ODOR	Characteristic	Organoleptic
TASTE	Characteristic	Organoleptic
2. PARTICLE SIZE	NLT 90% through 80 mesh	USP40<786>
3. ASSAY		
Silymarin	NLT 80.0%	UV
	NLT 45.0%	HPLC
Silybin + Isosilybin	NLT 30.0%	HPLC
Labeled amount of Silymarin calculated as dry Silybin	90.0 ~ 110.0%	USP40<565>
Sum Silydianin and Silychristin, of total content of Silymarin	20.0 ~ 45.0%	USP40<565>
Sum Silybin of total content of Silymarin	40.0 ~ 65.0%	USP40<565>
Sum Isosilybin of total content of Silymarin	10.0 ~ 20.0%	USP40<565>
4. IDENTIFICATION	Positive by TLC	TLC
5. LOSS ON DRYING	NMT 5.0%	USP40<731>
6. SULPHATED ASH	NMT 0.6%	USP40<281>
7. BULK DENSITY	0.35 ~ 0.55 g/ml	USP40<616>
8. HEAVY METALS	NMT 10 ppm	USP40<232>
LEAD	NMT 5 ppm	ICP-MS
ARSENIC	NMT 2 ppm	ICP-MS
CADMIUM	NMT 0.5 ppm	ICP-MS
MERCURY (Total)	NMT 1 ppm	ICP-MS
METHYLMERCURY (as Hg)	NMT 0.2 ppm	ICP-MS
9. RESIDUAL SOLVENTS		
ETHANOL	NMT 3000 ppm	USP40<467>
ACETONE	NMT 3000 ppm	USP40<467>
N-HEXANE	NMT 290 ppm	USP40<467>
BENZENE	NMT 2 ppm	USP40<467>
10. PESTICIDE RESIDUES	Comply with USP requirements	USP40<561>
11. AFLATOXINS	Absent	USP40<561>

MICROBIOLOGY CONTROL

TOTAL PLATE COUNT	NMT 1,000 cfu/g	USP40<61>
YEAST & MOLD	NMT 100 cfu/g	USP40<61>
E. COLI	Absent/g	USP40<62>
SALMONELLA	Absent/10 g	USP40<62>
STAPHYLOCOCCUS AUREUS	Absent/g	USP40<62>

**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 LIANGZHONG TOWN, PANSHAN COUNTY, PANJIN CITY, LIAONING PROVINCE, CHINA 124123 TO MEET SUAN FARMA, INC. SPECIFICATIONS.

*Julianna Chedid*

Julianna Chedid, QA/QC Assistant

DATE PRINTED: December 9, 2019



## ALLERGEN STATEMENT

We, Suan Farma, Inc., hereby declare that **Milk Thistle Extract 80%** (product code: **MTE80**) does not contain the following allergens and sensitivities:

- Milk and products thereof (including lactose)
- Egg and products thereof
- Fish and products thereof
- Crustaceans/Mollusks/Shellfish and products thereof
- Peanuts and products thereof
- Tree nuts and products thereof (almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut, Queensland nut)
- Soybean and products thereof (including lecithin)
- Cereals containing gluten and products thereof (wheat, German wheat, rye, barley, oats, spelt, kamut, hybridized strains, gluten)
- Lupin and products thereof
- Sesame seeds and products thereof (including oil)
- Mustard and products thereof
- Sulfur dioxide and sulphites (Report quantity as SO<sub>2</sub> if > 10 ppm)
- Added salt or salt substitutes
- Added sugars
- Artificial color
- 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
- Level of chloropropanols if present
- Maize or maize derivatives
- Nandrolone
- Nature identical color

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- Nut cross contamination
- Nuts or products thereof
- Oats
- Oils of Crustaceans/shellfish
- Oils of nuts (state type)
- Oils of seeds
- Other animal products or by-products
- Other antioxidants
- Other preservatives
- Phenylalanine
- Polyols
- Porcine products or by-products
- Potato and derivatives thereof
- Product banned by the International Olympic committee
- Rice and rice derivatives thereof
- Seeds
- Starch or dextrans
- Vanillin
- Vegetables and vegetable derivatives
- Wheat or wheat derivatives
- Yeast or yeast extract or yeast derivatives

Regards,

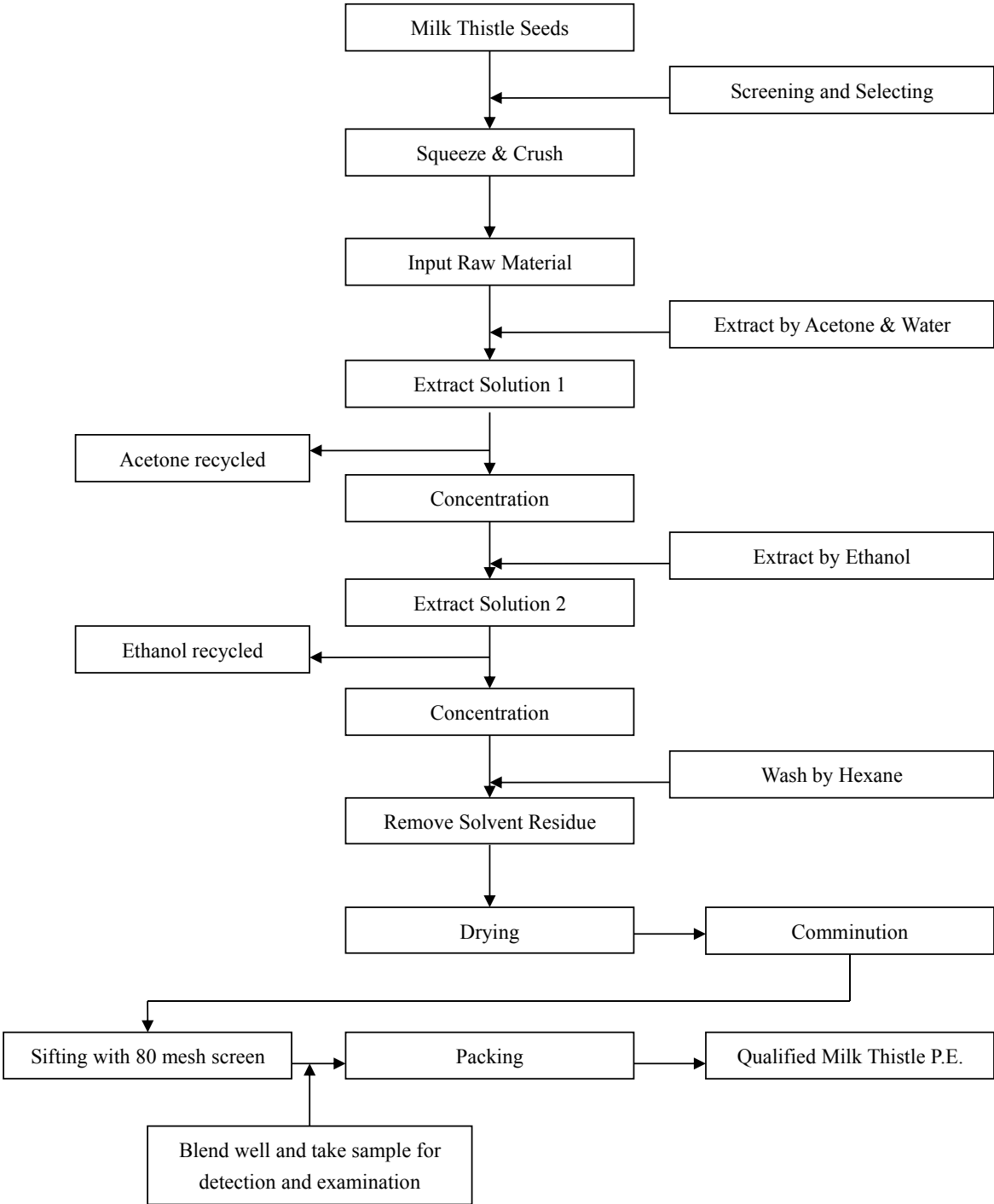
*Julianna Chedid*

Julianna Chedid  
QA/QC Assistant  
December 2019

## MANUFACTURING PROCESS FLOW CHART

**Product Name:** Milk Thistle Extract 80%

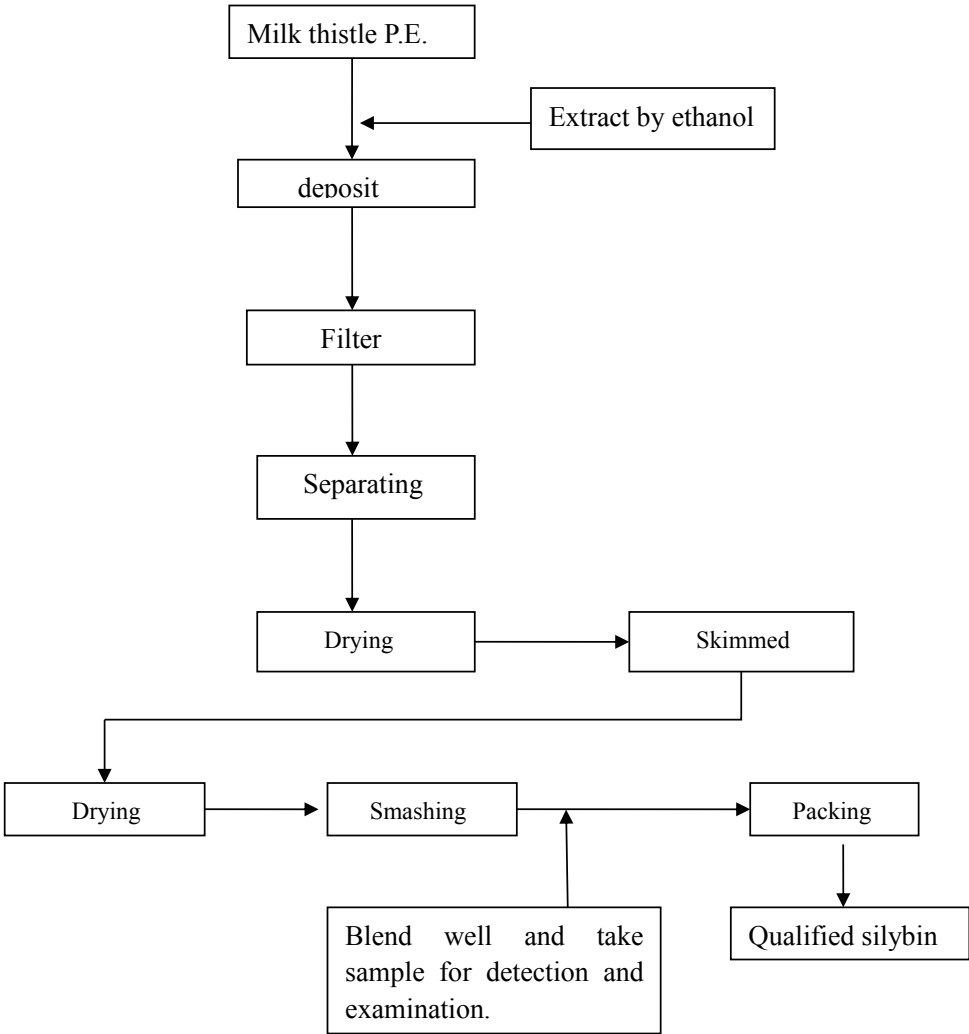
**Product Code:** MTE80



## MANUFACTURING PROCESS FLOW CHART

**Product Name:** Milk Thistle Extract 80%

**Product Code:** MTE80





## SAFETY DATA SHEET

REVISION 01.2019

### SECTION 1: PRODUCT & COMPANY IDENTIFICATION

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<b>Product name:</b>	MILK THISTLE EXTRACT 80%
<b>Synonyms:</b>	<i>Silybum marianum</i>
<b>Recommended use:</b>	Further manufacturing or processing as a dietary ingredient, laboratory chemical, or other substance.
<b>Restrictions of use:</b>	No known restrictions
<b>Supplier name:</b>	Suan Farma, Inc. 17-09 Zink Place, Unit 7 Fair Lawn, NJ 07410 Phone: 201-343-1188 FAX: 201-343-1102 E-mail: <a href="mailto:adminus@suanfarma.com">adminus@suanfarma.com</a>
<b>Emergency telephone number:</b>	CHEMTREC (24-hr Access) 800-424-9300; International CHEMTREC, call: 703-527-3887

### SECTION 2: HAZARD(S) IDENTIFICATION

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GHS CLASSIFICATION (29 CFR 1910/OSHA HCS): Acute toxicity, oral (category 4), H302 (see Section 16 for full H-Statements).



<b>PICTOGRAM:</b>	
<b>SIGNAL WORD:</b>	Warning
<b>HAZARD STATEMENT:</b>	Harmful if swallowed.
<b>PRECAUTIONARY STATEMENT:</b>	Wash skin thoroughly after handling; do not eat, drink, or smoke when using this product.
<b>IF SWALLOWED:</b>	Call a POISON CENTER or doctor/physician if negative symptoms outcome occurs. Dispose of contents/container according to appropriate local, state, and federal regulations.
<b>OTHER HAZARDS (HNOC) OR THOSE NOT COVERED BY GHS:</b>	May cause irritation

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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<b>CHEMICAL FORMULA:</b>	C <sub>25</sub> H <sub>22</sub> O <sub>10</sub>
<b>CAS NUMBER:</b>	84606-20-6
<b>EC NUMBER:</b>	N/A
<b>MOLECULAR WEIGHT:</b>	482.44
<b>COMPOSITION:</b>	100% (w/w) Silymarin

### SECTION 4: FIRST AID MEASURES

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## SAFETY DATA SHEET

<b>GENERAL INFORMATION:</b>	Consult a physician; provide this SDS to the doctor in attendance; move out of dangerous area.
<b>INHALATION:</b>	Move person to fresh air; provide artificial respiration if not breathing; consult a physician.
<b>SKIN CONTACT:</b>	Wash off with soap and plenty of water; consult a physician.
<b>EYE CONTACT:</b>	Flush eyes with plenty of water as a precaution; consult a physician.
<b>INGESTION:</b>	Rinse mouth out with plenty of water; don't provide anything orally if person is unconscious; consult a physician.
<b>MOST IMPORTANT SYMPTOMS &amp; EFFECTS (ACUTE &amp; DELAYED):</b>	See section 2 and/or 11.
<b>SPECIAL IMMEDIATE MEDICAL ATTENTION OR TREATMENT NEEDED:</b>	No information available.

## SECTION 5: FIRE FIGHTING MEASURES

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<b>SUITABLE EXTINGUISHING MEDIA:</b>	Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.
<b>SPECIAL HAZARDS FROM PRODUCTS OF COMBUSTION:</b>	These products include carbon oxides (CO, CO <sub>2</sub> ) & sulfur oxides (SO <sub>2</sub> , SO <sub>3</sub> ...).
<b>RECOMMENDATION TO FIRST RESPONDERS:</b>	Wear self-contained breathing apparatus or firefighting if necessary.
<b>FURTHER INFORMATION:</b>	None available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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<b>PERSONAL PRECAUTIONS, PERSONAL PROTECTIVE EQUIPMENT (PPE), &amp; EMERGENCY PROCEDURES:</b>	Use PPEs; avoid dust formation; avoid breathing vapors, mist, or gas; ensure adequate ventilation; avoid breathing dust. For PPEs, see section 8.
<b>ENVIRONMENTAL PRECAUTIONS:</b>	Avoid material entering water drainage systems.
<b>METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:</b>	Pickup waste debris and arrange for disposal without creating dust. Sweep up and/or shovel; keep in suitable & appropriate closed containers for disposal.
<b>REFERENCE TO OTHER SECTIONS:</b>	For proper disposal, see Section 13.

## SECTION 7: HANDLING AND STORAGE

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<b>PRECAUTIONS FOR SAFE HANDLING:</b>	Avoid contact with skin and eyes; avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Provide appropriate exhaust ventilation at places where dust is formed. Refer to Section 2 for further precautions.
<b>STORAGE:</b>	Store in a tightly-closed container. Store in a cool, dry, well-ventilated area. Avoid excessive exposure to sunlight, heat, humidity, and any other contaminants.
<b>SPECIFIC END USE(S):</b>	Other than those mentioned in Section 1, no other specific uses are stipulated.





## SAFETY DATA SHEET

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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**WORKPLACE CONTROL PARAMETERS:**

No substances with occupational exposure limit values.

**APPROPRIATE ENGINEERING CONTROLS:**

Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of each workday when handling this or similar materials.

**EYE PROTECTION:**

Safety glasses with side-shields conforming to EN 166; 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 that are inspected before use. Use proper glove removal techniques (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.

**BODY PROTECTION:**

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**RESPIRATORY PROTECTION:**

For nuisance exposures, use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection, use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**ENVIRONMENT EXPOSURE CONTROL:**

Do not allow product to enter water drainage systems.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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<b>APPEARANCE:</b>	Amorphous Powder
<b>COLOR:</b>	Yellow to yellowish-brown
<b>ODOR:</b>	Characteristic
<b>pH:</b>	Not Available.
<b>BOILING POINT:</b>	Not Available.
<b>MELTING POINT:</b>	Not Available.
<b>VAPOR PRESSURE:</b>	Not Available.
<b>SOLUBILITY IN WATER:</b>	Hardly soluble
<b>SOLUBILITY IN OTHER SOLVENTS:</b>	Not Available.
<b>FLASH POINT:</b>	Not Available.
<b>EVAPORATION RATE:</b>	Not Available.
<b>FLAMMABILITY (SOLID, GAS):</b>	Not Available.
<b>UPPER/LOWER FLAMMABILITY OR EXPLOSIVE LIMITS:</b>	Not Available.
<b>VAPOR PRESSURE:</b>	Not Available.
<b>VAPOR DENSITY:</b>	Not Available.
<b>RELATIVE DENSITY:</b>	Not Available.
<b>PARTITION COEFFICIENT: n-OCTANOL/WATER:</b>	Not Available.
<b>AUTO-IGNITION TEMPERATURE:</b>	Not Available.
<b>DECOMPOSITION TEMPERATURE:</b>	Not Available.
<b>VISCOSITY:</b>	Not Available.
<b>EXPLOSIVE PROPERTIES:</b>	Not Available.
<b>OXIDIZING PROPERTIES:</b>	Not Available.



## SAFETY DATA SHEET

### SECTION 10: STABILITY AND REACTIVITY

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<b>REACTIVITY:</b>	Not Available.
<b>CHEMICAL STABILITY:</b>	Stable under recommended storage conditions.
<b>POSSIBLE HAZARDOUS REACTIONS:</b>	Not Available.
<b>CONDITIONS TO AVOID:</b>	Not Available.
<b>INCOMPATIBLE MATERIAL(S):</b>	Strong oxidizing agents.
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	Not Available; in the event of a fire, refer to Section 5.

### SECTION 11: TOXICOLOGY INFORMATION

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<b>ACUTE TOXICITY:</b>	Not Available.
<b>INHALATION:</b>	Not Available.
<b>DERMAL:</b>	Not Available.
<b>LD50:</b>	Not Available.
<b>SKIN CORROSION/IRRITATION:</b>	Not Available.
<b>EYE DAMAGE/EYE IRRITATION:</b>	Not Available.
<b>RESPIRATORY OR SKIN SENSITIZATION:</b>	Not Available.
<b>GERM CELL MUTAGENICITY:</b>	Not Available.
<b>CARCINOGENICITY:</b>	IARC – no component $\geq 0.1\%$ as identified as a probable, possible, or confirmed human carcinogen by IARC; ACGIH – no component $\geq 0.1\%$ as identified as a carcinogen or potential carcinogen by ACGIH; NTP – no component $\geq 0.1\%$ as identified as a known or anticipated carcinogen by NTP; OSHA – no component $\geq 0.1\%$ as identified as a carcinogen or potential carcinogen by OSHA.
<b>REPRODUCTIVE TOXICITY:</b>	Not Available.
<b>SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:</b>	Not Available.
<b>SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:</b>	Not Available.
<b>ASPIRATION HAZARD:</b>	Not Available.
<b>ADDITIONAL INFORMATION:</b>	RTECS: JP1192000

### SECTION 12: ECOLOGICAL INFORMATION

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<b>TOXICITY:</b>	Not available.
<b>PERSISTENCE &amp; DEGRADABILITY:</b>	Not available.
<b>BIOACCUMULATIVE POTENTIAL:</b>	Not available.
<b>MOBILITY IN SOIL:</b>	Not available.



## SAFETY DATA SHEET

RESULTS OF PBT & vPvB ASSESSMENT: Not available.  
OTHER ADVERSE EFFECTS: Not available.

### SECTION 13: DISPOSAL CONSIDERATIONS

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**PRODUCT:** Surplus, rejected, or wasted material should be disposed of by a licensed disposal company.  
**CONTAMINATED PACKAGING:** Dispose of as unused product.

### SECTION 14: TRANSPORT INFORMATION

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**DOT (US):** Not considered dangerous goods.  
**IMDG:** Not considered dangerous goods.  
**IATA:** Not considered dangerous goods.

### SECTION 15: REGULATORY INFORMATION

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**SARA 302 COMPONENTS:**

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313 COMPONENTS:**

This material does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels established by SARA Title III, 313.

**MASSACHUSETTS RIGHT TO KNOW COMPONENTS:**

No components are subject to this act.

**PENNSYLVANIA RIGHT TO KNOW COMPONENTS:**

5-(Dithiolan-3-yl)valeric acid, CAS number 84606-20-6

**NEW JERSEY RIGHT TO KNOW COMPONENTS:**

5-(Dithiolan-3-yl)valeric acid, CAS number 84606-20-6

**CALIFORNIA PROP. 65 COMPONENTS:**

No-known components known to the State of California to cause cancer, birth defects, or any other reproductive harm.

### SECTION 16: OTHER INFORMATION

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**ACUTE TOXICITY:**

Harmful if swallowed.

**HMIS RATING:**

Health Hazard-1; Chronic Health Hazard-N/A; Flammability-0; Physical Hazard-0

**NFPA RATING:**

Health Hazard-1; Fire Hazard-0; Reactivity Hazard-0

**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.



## SAFETY DATA SHEET

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 **Milk Thistle Extract 80%** (product code: **MTE80**) is manufactured in accordance with the following guidelines:

- No animal derived products have been used in the manufacture of the above extract, 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.
At no point in the process is Milk Thistle Extract 80% derived from, produced using, or handled with sewage sludge, as defined in 7 CFR 205.105(g).
The above extract is free of any carriers, excipients, binders, or preservatives. It is composed of 100% milk thistle seeds.
Milk Thistle Extract 80% has not been tested on animals at any stage of the manufacturing process.
The above extract 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 Ethylene Oxide (ETO) or any other form of chemical sterilization.
Milk Thistle Extract 80% is suitable for vegetarian and vegan consumption.

Typical nutritional data for the above material is as follows:

Per 100 grams:

Table with 2 columns: Nutrient, Amount. Rows include: Calories (0.00 g), Ash (0.57 g), Moisture (3.40 g), Total fat (1.20 g), Cholesterol (0.00 g), Total Carbohydrate (93.10 g), Dietary fiber (0.68 g), Sugars (0.45 g), Starch (0.00 g), Protein (1.70 g), Vitamin A (0.00 mg), Vitamin B1 (0.13 mg), Vitamin B2 (0.05 mg), Vitamin B6 (0.01 mg), Vitamin B12 (0.00 mg), Vitamin C (0.00 mg), Vitamin E (0.66 mg), Calcium (36.00 mg), Iron (1.74 mg), Sodium (1.38 mg), Phosphate (67.10 mg).

Regards,

Julianna Chedid

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