

## SECTION 1: PRODUCT IDENTIFICATION

<b>PRODUCT NAME</b>	<b>STEARIC ACID 50, NF</b>
<b>PRODUCT CODE</b>	<b>1877</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

## SECTION 2: HAZARDS IDENTIFICATION

<b>GHS CLASSIFICATION</b>	Based on available data, the classification criteria are not met.			
<b>PICTOGRAM</b>	Not Applicable			
<b>SIGNAL WORD</b>	Not applicable			
<b>HAZARD STATEMENT(S)</b>	Not applicable			
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.			
<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Not applicable		
	<b>Response</b>	Not applicable		
	<b>Storage</b>	Not applicable		
	<b>Disposal</b>	Not applicable		
<b>HMS CLASSIFICATION</b>	<b>Health Hazard</b>	1	<b>Flammability</b>	1
	<b>Reactivity</b>	0	<b>Personal Protection</b>	E

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Not applicable
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	Mixture of Stearic Acid C <sub>18</sub> H <sub>36</sub> O <sub>2</sub> + Palmitic Acid C <sub>16</sub> H <sub>32</sub> O <sub>2</sub>
CHEMICAL FAMILY	Saturated long-chain fatty acid
CAS NUMBER	57-11-4
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	Not applicable
COMPOSITION	

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
PALMITIC ACID	57-10-3	200-312-9	~48
STEARIC ACID	57-11-4	200-313-4	~48

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**NOTES** Chemical family: Linear aliphatic derivative (glyceride); fatty acid.

## SECTION 4: FIRST-AID MEASURES

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
<b>MEDICAL ATTENTION AND SPECIAL TREATMENT</b>	Get emergency medical help.
<b>SYMPTOMS CAUSED BY EXPOSURE</b>	Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

<b>SPECIFIC HAZARDS ARISING FROM THE CHEMICAL</b>	Not applicable
<b>FLAMMABLE PROPERTIES</b>	May be combustible at high temperature
<b>HAZARDOUS COMBUSTION PRODUCTS</b>	Under fire conditions, hazardous fumes will be present.
<b>SUITABLE &amp; UNSUITABLE EXTINGUISHING MEDIA</b>	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.
<b>PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS</b>	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR  
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**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 disposal information.

## SECTION 7: HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE  
HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE  
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: PALMITIC ACID CAS #: 57-10-3

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

Chemical Name: STEARIC ACID CAS #: 57-11-4

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

#### EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

#### PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

#### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

#### BIOLOGICAL MONITORING

Not available

#### CONTROL BANDING

Not available

#### NOTES

STEARIC ACID: USP: ELV: TWA: 10 mg/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL STATE

Solid

#### DESCRIPTION

Hard, white or faintly yellowish, somewhat glossy and crystalline solid, or white or yellowish white powder. Its odor is slight, suggesting tallow.

#### SOLUBILITY

Practically insoluble in water; freely soluble in chloroform and in ether; soluble in alcohol.

#### ODOR

Slight odor suggesting tallow

#### FLAMMABILITY

May be combustible at high temperature

#### AUTO-IGNITION TEMPERATURE

395 °C, 743 °F

#### BOILING POINT

(232 - 385.8 )°C,  
(449.6-726.44)°F

#### DECOMPOSITION TEMPERATURE

Not available

#### EVAPORATION RATE

Not available

#### EXPLOSIVE LIMIT

Not available

#### FLASH POINT

196°C, 384.8°F  
(closed cup)

log P (OCTANOL-WATER)	8.23	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(69 - 72)°C, (156.2-161.6)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	0.98	SPECIFIC GRAVITY	0.839	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	9.8	VAPOR PRESSURE	Not available	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants, alkali, caustics
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	<p>STEARIC ACID:</p> <p>Oral: Rat: LD50: (mg/kg): 4600</p> <p>Dermal: Rabbit LD50: (mg/kg): &gt; 5000</p> <p>Inhalation: Rat: LC50: (mg/L/4hr): Not available</p> <p>PALMITIC ACID:</p> <p>Oral: Rat: LD50: (mg/kg): &gt;10 000</p> <p>Dermal: Rabbit LD50: (mg/kg): &gt; 2000</p> <p>Inhalation: Rat: LC50: (mg/L/4hr): Not available</p>
SKIN CORROSION/IRRITATION	<p>Based on available data, the classification criteria are not met.</p> <p>STEARIC ACID</p> <p>Skin irritation; Result: Mild; Species: Human; Test Duration: 3 day.</p> <p>Skin irritation; Result: Negative; Species: Rabbit; Test Duration: 24 hours; Observation Period: 72 hours.</p>
SERIOUS EYE DAMAGE/EYE IRRITATION	<p>Based on available data, the classification criteria are not met.</p> <p>Due to lack of data the classification is not possible.</p>
RESPIRATORY SENSITIZATION	<p>Due to lack of data the classification is not possible.</p>

<b>SKIN SENSITIZATION</b>	Based on available data, the classification criteria are not met. 7 % Skin sensitization; Result: Negative, Species: Human
<b>GERM CELL MUTAGENICITY</b>	Due to lack of data the classification is not possible.
<b>CARCINOGENICITY</b>	<p><b>OSHA</b> No component of this product, present at <math>\geq 0.1\%</math>, is listed.</p> <p><b>NTP</b> No component of this product, present at <math>\geq 0.1\%</math>, is listed.</p> <p><b>IARC</b> No component of this product, present at <math>\geq 0.1\%</math> has been evaluated.</p> <p><b>California Proposition</b> No component of this product, present at <math>\geq 0.1\%</math> is known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	Based on available data, the classification criteria are not met.
<b>REPRODUCTIVE TOXICITY</b>	Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<p><b>ROUTES OF EXPOSURE:</b> Oral</p> <p><b>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:</b> Not available</p> <p><b>DELAYED HEALTH EFFECT FROM EXPOSURE:</b> Not available</p> <p>Not expected to present a significant hazard under anticipated conditions of normal use.</p>
<b>POTENTIAL HEALTH EFFECTS</b>	<p><b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation. If inhaled, may cause sneezing, coughing, shortness of breath and possible chest discomfort; high dust concentrations may cause an impairment of lung function.</p> <p><b>Ingestion</b> May be harmful if swallowed. If swallowed, it may cause a slight to moderate irritation to the gastrointestinal tract and is characterized by nausea, vomiting, abdominal discomfort and/or diarrhea.</p> <p><b>Skin</b> May be harmful if absorbed through skin. May cause skin irritation. Exposure to the skin may cause redness and a possible itching sensation.</p> <p><b>Eyes</b> May cause eye irritation. Exposure to the eyes may cause tearing, redness, possible swelling and a stinging sensation.</p>

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available</p> <p>LC50: 96 Hr: Fish: (mg/L): Not available</p> <p>EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
<b>PERSISTENCE AND DEGRADABILITY</b>	Not available
<b>BIOACCUMULATIVE POTENTIAL</b>	<p>LogPow: 8.23 (Stearic Acid)</p> <p>LogPow: 7.17 (Palmitic Acid)</p>
<b>MOBILITY IN SOIL</b>	Practically insoluble in water
<b>OTHER ADVERSE EFFECTS</b>	Not available

This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

### DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

## SECTION 14: TRANSPORT INFORMATION

### UN PROPER SHIPPING NAME

Not dangerous good

### UN NUMBER

Not applicable

### CLASS

Not applicable

### PACKING GROUP

Not applicable

### AUSTRALIA

#### HAZCHEM

Not applicable

### EU

#### TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

### ENVIRONMENTAL HAZARDS

Not available

### SPECIAL SHIPPING INFORMATION

Not applicable

## SECTION 15: REGULATORY INFORMATION

### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
			Appendix A	Appendix B				
PALMITIC ACID, 57-10-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L
STEARIC ACID, 57-11-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
PALMITIC ACID, 57-10-3	N/L	N/L	N/L	Listed	N/L	N/L
STEARIC ACID, 57-11-4	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

### EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
PALMITIC ACID, 57-10-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L
STEARIC ACID, 57-11-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT                      Not applicable

## SECTION 16: OTHER INFORMATION

### REFERENCES

### ABBREVIATIONS AND ACRONYMS

Available upon request

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

### LAST REVISION

01/2023

### SUPERSEDES

09/2019

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

### DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

### SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.