


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	AMITRIPTYLINE HYDROCHLORIDE, USP
PRODUCT CODE	0189
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	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
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 3) Toxic to Reproduction (Category 1B) Chronic Aquatic Toxicity (Category 1) Eye Damage (Category 1) Specific Target Organ Toxicity - Single Exposure (Category 1) - (nervous system)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	Toxic if swallowed. Causes skin irritation. May damage fertility or the unborn child. Very toxic to aquatic life with long lasting effects. Causes serious eye damage. Causes damage to organs (nervous system). May cause allergic reaction
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S)	Prevention	Wash thoroughly after handling. Do not touch eyes. Do not eat, drink or smoke when using this product. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid release to the environment. Do not breathe dust/fume/gas/mist/ vapors/spray.	
	Response	IF SWALLOWED: Immediately call a poison center or medical professional. Get emergency medical help immediately. Rinse mouth. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor. COLLECT SPILLAGE IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help; Immediately call a poison center or medical professional.	
	Storage	Store locked up.	
	Disposal	Dispose of contents and/or container in accordance with local regulations.	
HMS CLASSIFICATION	Health Hazard	2	Flammability 0
	Reactivity	0	Personal Protection G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	1-Propanamine, 3-(10, 11-dihydro-5H-dibenzo [a, d] cyclohepten-5-ylidene)-N,N-dimethyl-, hydrochloride.								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	C ₂₀ H ₂₃ N·HCl								
CHEMICAL FAMILY	Dibenzocycloheptadiene derivative								
CAS NUMBER	549-18-8								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	313.9								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>AMITRIPTYLINE HCl</td> <td>549-18-8</td> <td>208-964-6</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	AMITRIPTYLINE HCl	549-18-8	208-964-6	100
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT						
AMITRIPTYLINE HCl	549-18-8	208-964-6	100						

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.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

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.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: AMITRIPTYLINE HCl CAS #: 549-18-8

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
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

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/m³

**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

TLV: TWA/8h: 0.1 mg/m³

USP: ELV: Industrial use: TWA: 0.1 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
**PHYSICAL
STATE**

Solid

DESCRIPTION

White or practically white, odorless or practically odorless, crystalline powder or small crystals.

SOLUBILITY

Freely soluble in water, in alcohol, in chloroform, and in methanol; insoluble in ether.

ODOR

Practically odorless or odorless

FLAMMABILITY	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	372 °C, 701.6 °F	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	4.9 (20°C)	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	85 mg/L	MELTING/FREEZING POINT	(196 - 197)°C, (384.8-386.6)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5 - 6 (1%)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.1 - 0.2	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 1 mm Hg (20°C)	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. Acids. Bases.
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	Oral: Rat: LD50: (mg/kg): 240 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Rabbit: 500 mg Skin irritation; Result: Non-irritant. Suspected skin irritant: The Danish QSAR database contains information indicating that the substance is predicted as skin irritant.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes serious eye damage. Rabbit: 0.1 ml Eye irritation; Result: Severe irritation; severe corneal capacity and ulceration observed.

RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA AMITRIPTYLINE HCl is not listed.</p> <p>NTP AMITRIPTYLINE HCl is not listed.</p> <p>IARC AMITRIPTYLINE HCl is not evaluated.</p> <p>California Proposition This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	<p>May damage fertility or the unborn child.</p> <p>The substance administered subcutaneously in female mice during pregnancy (9 days after conception) at a dose of 60 mg/kg/day, caused craniofacial abnormalities and central nervous system defects, fetal toxicity and death of the fetus; administered orally in male mice before mating, at a dose of 70 mg/kg/day, the substance caused adverse effects in spermatogenesis. Studies on rats administered the substance at a dose of 220 mg/kg/day have shown adverse effects on the fetuses.</p> <p>For tricyclic antidepressants: Withdrawal symptoms such as colic, cyanosis, rapid breathing, and irritability have been observed in infants whose mothers received tricyclic antidepressants prior to delivery.</p> <p>Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value).</p> <p>Causes damage to organs (nervous system).</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Due to lack of data the classification is not possible.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eyes</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Tricyclic antidepressants: Cardiac dysrhythmias. Severe hypotension. Serotonin syndrome. CNS depression. Coma. Death.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics Tricyclic antidepressants: Dizziness. Drowsiness. Stupor. Restlessness. Vomiting. Troubled breathing. Tiredness. Enlarged pupils. Fever. Headache. Dry mouth. Weakness. Increased appetite. Diarrhea. Excessive sweating. Heartburn. Blurred vision. Eye pain. Confusion. Hallucinations. Difficult urination. Difficulty speaking or swallowing. Nervousness. Loss of balance. Convulsions.</p> <p>Cross sensitivity Persons sensitive to one tricyclic antidepressant, carbamazepine, maprotiline, or trazodone may be sensitive to this material also.</p> <p>Medical conditions aggravated by exposure: Tricyclic antidepressants: Cardiovascular disorders. Narrow-angle glaucoma. Active alcoholism. Asthma. Bipolar disorder. Blood disorders. Gastrointestinal disorders. Hyperthyroidism. Enlarged prostate gland. Schizophrenia. Seizure disorder. Urinary retention. Impaired liver function. Impaired kidney function.</p>

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	Toxic if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	Causes serious eye damage.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: Daphnia: (mg/L): < 1*
 LC50: 96 Hr: Fish: (mg/L): < 1*
 EC50: 96 Hr: Algae: Green Algae: (mg/L): < 1*

**PERSISTENCE AND
DEGRADABILITY**

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

Expected to bioaccumulate: Log Pow: 4.9 (20°C)
 Half-Life Elimination in Human: 21 (range 13-36 h)
 BFC=1226, the potential for bioconcentration is very high.

MOBILITY IN SOIL

Freely soluble in water

OTHER ADVERSE EFFECTS

Not available

NOTES

This product is not intended to be released into the environment

*Danish QSAR database

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

TOXIC SOLID, ORGANIC, N.O.S.

UN NUMBER

2811

CLASS

6.1

PACKING GROUP

III

AUSTRALIA
HAZCHEM

2X

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 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
AMITRIPTYLINE HCl, 549-18-8	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
AMITRIPTYLINE HCl, 549-18-8	N/L	Listed as Schedule 4*	N/L	Listed*	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
AMITRIPTYLINE HCl, 549-18-8	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

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

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

02/2023

SUPERSEDES

04/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at 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.