



SAFETY DATA SHEET

Preparation Date: 10/3/2017 Revision date 2/20/2019 Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: A1322

AMITRIPTYLINE HYDROCHLORIDE, USP **Product Name:**

Other means of identification

Amitriptyline chloride Synonyms:

Damilen hydrochloride

Deprex Laroxyl Lentizol Limbitrol DS Miketorin

Proheptadien monohydrochloride

1-Propanamine,

3-(10,11-dihydro-5H-dibenzo(a,d)cyclohepten-5-ylidene)-N,N-dimethyl-, hcl

Rantoron Saroten Triavil

10,11-Dihydro-N,N-dimethyl-5H-dibenzo(a,d)cycloheptene-delta(sup

5,gamma)-propylamine HCl

5-(3-Dimethylaminopropylidene)dibenzo(a,d)(1,4)cycloheptadiene hydrochloride

Domical

Elavil hydrochloride Endep

Etrafon **Tryptizol** 549-18-8

CAS #: HO9450000 RTECS# CI#: Not available

Recommended use of the chemical and restrictions on use Recommended use: Medication. Antidepressant.

Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp

14422 South San Pedro St. Gardena, CA 90248

(310) 516-8000

https://www.spectrumchemical.com Order Online At:

Chemtrec 1-800-424-9300 Emergency telephone number

Tom Tyner (USA - West Coast) Contact Person: **Contact Person:** Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 2

Label elements

Danger

Hazard statements

Toxic if swallowed
Causes skin irritation
Causes serious eye irritation

Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water

If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

Precautionary Statements - Storage

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Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

	Component	CAS No	Weight-%
Г	Amitriptyline Hydrochloride	549-18-8	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect

himself.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention if irritation develops.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms

persist, call a physician.

Inhalation: Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial

respiration. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is

required.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an

unconscious person. Toxic if swallowed. Immediate medical attention is required. Call a

physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms Causes serious eye irritation

Moderately irritating to the eyes

Causes skin irritation

Moderately irritating to the skin

Ingestion may cause nausea, vomiting, and diarrhea

May cause stomach cramping
Central nervous system effects
May affect the cardiovascular system

May affect respiration

May affect the urinary system

May affect the liver It may affect the blood May cause hyperglycemia It may affect the thyroid

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of

contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray mist or

foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx).

hydrogen chloride gas.

Specific hazards May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus

pressure-demand, MSHA/NIOSH (approved or equivalent)

and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Do not touch

damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust

formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent

spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated

surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Amitriptyline Hydrochloride	549-18-8	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Amitriptyline Hydrochloride	549-18-8	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Amitriptyline Hydrochloride	549-18-8	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Safety glasses with side-shields. or Goggles

Skin and body protection: Long sleeved clothing

Chemical resistant apron

Gloves

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to

the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified

respirator or equivalent.

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Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and

immediately after handling the product When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color:

Solid Crystalline powder. White. Practically white.

Odor: Taste Formula

None. No information available. C20-H23-N.HCl

Molecular/Formula weight (g/mole): Flammability (solid, gas) Flashpoint (°C/°F):

313.86 no data available No information available

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%): Not available

No information available

No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available 196-197 °C/384.8-386.6 °F No information available

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

No information available
No information available
No information available

Specific gravity: pH Vapor pressure @ 20°C (kPa):

Evaporation rate: Vapor density: VOC content (g/L):
No information available
No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

No information available

Miscibility: Solubility:

No information available Freely soluble in Chloroform

Freely soluble in alcohol Solubility in Water: 50% @

20°C/68°F1g dissolves in about 1ml water and in about 60ml alcohol

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

<u>Conditions to avoid:</u> Heat. Ignition sources. Avoid dust formation. Incompatible materials.

<u>Incompatible Materials:</u> Oxidizing agents

Hazardous decomposition Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Hydrogen chloride gas.

products:

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Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Amitriptyline Hydrochloride

CAS No 549-18-8

LD50/oral/rat = 240 mg/kg Oral LD50 Rat

LD50/oral/mouse = 140 mg/kg

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = 240 mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 140 mg/kg

LD50/dermal/rabbit

Value - Acute Tox = No information available

LD50/dermal/rat

VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation. Moderately irritating to the skin.

Eye Contact: Causes serious eye irritation. Moderately irritating to the eyes.

Inhalation

May cause irritation of respiratory tract.

Ingestion

Toxic if swallowed. May cause dry mouth, thirst. Ingestion may cause nausea, vomiting, diarrhea. May cause constipation. May cause loss of appetite. May affect the cardiovascular system (vasodilation, hypotension, tachycardia, chest pain). May affect the cardiovascular system (cardiac arrhythmias). May affect respiration (difficult or labored breathing resulting in shortness of breath). May affect respiration (dyspnea, respiratory depression). May cause mydriasis (dilated pupils). May cause urinary retention. May cause headache. May cause blurred or foggy vision. May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (somnolence, convulsions, tremor, ataxia). May affect behavior/central nervous system (fatigue, weakness). May affect behavior/central nervous system (agitation, disorientation, hallucinations, delusion, anxiety, insomnia, trouble concentrating, nightmares, confusion, irritability, restlessness, tremor, problems with speech, impaired consciousness, fainting, coma. May cause dystonia, which is defined as prolonged or abnormal contractions of muscle groups. Symptoms may include: spasm of the neck muscles, sometimes progressing tightness of the throat, difficulty swallowing, difficulty breathing, and/or protusion of the tongue. May cause Parkinson's-like symptoms (Pseudo-parkinonism). They may include: mask-like facies, shuffling gait, cogwheel rigidity, pillrolling motion, drooling, tremors). May affect the peripheral nervous system (peripheral neuropathy with paresthesia - a tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities)),. May cause hyperglycemia. May cause hypoglycemia (low blood sugar). May cause tinnitus.

Aspiration hazard

No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity

May cause Tardive Dyskinesia. It most commonly occurs in patients with psychiatric conditions who are treated with antipsychotic drugs for many months or years. This is a disorder that involves involuntary movements, especially of the lower face. Symptoms include facial grimacing, finger movement, jaw swinging, repetitive chewing and tongue thrusting. There may also be myoclonic jerks (rapid jerking movements). Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired). Prolonged or repeated ingestion may cause menstrual irregularities or loss of menstrual periods women, abnormal production of breast milk in non-breast feeding women, breast enlargment in men, eiaculatory disorders/impotence in men. Prolonged or repeated ingestion may cause spontaneous flow of milk from the breast, breast enlargement, absence of menstrual period. Prolonged or repeated ingestion may affect the blood (leukopenia, agranulocytosis, eosinophilia, pancytopenia, thrombocytopenic purpura, bone marrow depression). Prolonged or repeated ingestion may affect the thyroid. Prolonged or repeated ingestion may affect the urinary system. Prolonged or repeated skin contact may cause allergic reaction. Prolonged or repeated inhalation may cause allergic reaction.

Sensitization:

No information available.

Mutagenic Effects:

May affect genetic material

Animal experiments showed mutagenic effects

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH -	NTP	OSHA HCS -	Australia -	Australia -
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			Carcinogens		Carcinogens	Notifiable Carcinogenic Substances	Prohibited Carcinogenic Substances
Amitriptyline Hydrochloride	549-18-8	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: May cause adverse reproductive effects

Experiments have shown reproductive toxicity effects on laboratory animals There are no adequate and well-controlled studies in humans. Data in humans

were insufficient to evaluate the effects on reproduction

Developmental Effects: No information available

Teratogenic Effects: May cause birth defects (teratogenic effects)

Possible risk of harm to the unborn child

Specific Target Organ Toxicity

STOT - single exposure
STOT - repeated exposure
No information available.
No information available.

Target Organs: Central nervous system. Cardiovascular system.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: Potential for bioconcentration in aquatic organisms is very high.

Mobility in soilNo information availableOther adverse effectsNo information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Amitriptyline Hydrochloride	549-18-8	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811

Proper Shipping Name: Toxic solids, organic, n.o.s. (amitriptyline hydrochloride)

Hazard Class 6.7

Subsidiary Class No information available

Packing group: III Emergency Response Guide 154

Number

Marine PollutantSevere Marine PollutantDOT RQ (lbs):No information availableSpecial ProvisionsIB8, IP3, T1, TP33

Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical

names of the hazardous material must be entered in parentheses, in association

with the basic description.

Description: UN2811, Toxic solids, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

TDG (Canada)

UN-No: UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.

Hazard Class 6.1

Subsidiary Risk: No information available

Packing Group:

Marine Pollutant No Information available

Description: UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

ADR

UN Number UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.

Transport hazard class(es) 6.1
Packing group

Subsidiary Risk: No information available

Special Provisions 274, 614

Description: UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

IMDG

UN-No: UN2811

Proper Shipping Name: Toxic solids, organic, n.o.s. (amitriptyline hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group:

Marine Pollutant No information available

EMS: F-A Special Provisions 223, 274

Description UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

RID

UN Number UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.

Transport hazard class(es) 6.1

Subsidiary Risk: 6.1

Packing group III

Special Provisions 274, 614

Description: UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

ICAO (air)

UN-No: UN2811

Product code: A1322 Product name: AMITRIPTYLINE Page

Proper Shipping Name: Toxic solid, organic, n.o.s.

Hazard Class 6.1

Subsidiary Risk: No information available

Packing Group:

Description: UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

Special Provisions A3, A5

IATA

UN Number UN2811

Proper Shipping Name: Toxic solid, organic, n.o.s.

Transport hazard class(es) 6.1

Subsidiary Risk: No information available

Packing group III
Precautionary Statements - 6L

Response

Special Provisions No information available

Description: UN2811, Toxic solid, organic, n.o.s. (Amitriptyline Hydrochloride), 6.1, III

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
Amitriptyline	549-18-8	Present	Present	Present	Not present	Not listed	Present	Present
Hydrochloride			KE-10614					208-964-6

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male	Female
				Reproductive	Reproductive
				Toxicity	Toxicity:
Amitriptyline Hydrochloride	549-18-8	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Amitriptyline Hydrochloride	549-18-8	None	None	None	None	None

U.S. TSCA

Component		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Amitriptyline Hydrochloride	549-18-8	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous

Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Amitriptyline Hydrochloride	549-18-8	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Amitriptyline Hydrochloride	549-18-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject
		to Mandatory Reporting
Amitriptyline Hydrochloride	549-18-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)	
Amitriptyline Hydrochloride	549-18-8	No information	

EU - CLP (1272/2008)

R-phrase(s)

R22 - Harmful if swallowed

R63 - Possible risk of harm to the unborn child

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Amitriptyline Hydrochloride	549-18-8		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful

Xn



16. OTHER INFORMATION

Product code: A1322 **Product name: AMITRIPTYLINE** Page

Preparation Date: 10/3/2017
Revision date 2/20/2019
Prepared by: Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This

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End of Safety Data Sheet