

# Scientific Documentation

## Amitriptyline Hydrochloride, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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# Specification for Amitriptyline Hydrochloride, USP (A1322)

Item Number	A1322
Item	Amitriptyline Hydrochloride, USP
CAS Number	549-18-8
Molecular Formula	C <sub>20</sub> H <sub>23</sub> N•HCl
Molecular Weight	313.86
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
pH OF A 1 IN 100 SOLUTION	5.0	6.0
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES		AS REPORTED
ORGANIC IMPURITIES:		
AMITRIPTYLINE RELATED COMPOUND A		0.05 %
AMITRIPTYLINE RELATED COMPOUND B		0.15 %
NORTRIPTYLINE		0.15 %
CYCLOBENZAPRINE		0.15 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE	
EXPIRATION DATE		
DATE OF MANUFACTURE		

Test	Specification	
	Min	Max
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

***Spectrum Chemical Mfg Corp***

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<i><b>Corporate Headquarters:</b></i>	<i><b>West Coast Facility:</b></i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	A1322	Lot Number	4MI0092
Item	Amitriptyline Hydrochloride, USP	Manufacturer Lot	CAMPT/2111093
CAS Number	549-18-8	Manufacturer Code	12458
Molecular Formula	C <sub>20</sub> H <sub>23</sub> N•HCl	Molecular Weight	313.86

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	100.3 %
pH OF A 1 IN 100 SOLUTION	5.0	6.0	5.2
LOSS ON DRYING		0.5 %	0.3 %
RESIDUE ON IGNITION		0.1 %	0.003 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
ORGANIC IMPURITIES:			.
AMITRIPTYLINE RELATED COMPOUND A		0.05 %	0.0 %
AMITRIPTYLINE RELATED COMPOUND B		0.15 %	0.0 %
NORTRIPTYLINE		0.15 %	0.0 %
CYCLOBENZAPRINE		0.15 %	0.0 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.10 %	0.0 %
TOTAL IMPURITIES		1.0 %	0.0 %
IDENTIFICATION A ( FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCES
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
IDENTIFICATION (C)	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
EXPIRATION DATE			31-OCT-2026
DATE OF MANUFACTURE			01-NOV-2021

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE TO CREAM COLOR CRYSTALLINE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / TETRAHYDROFURAN			<720 ppm
CLASS 2 (solvent) / TOLUENE			<890 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
06-OCT-23 09:22:44

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

MCAMACHO  
Matheu Camacho  
06-OCT-23 09:24:03

**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Vasudha Pharma Chem Limited at Unit III, Plot No. 23, 24 Jawaharlal Nehru Pharma City, Visakhapatnam, Andhra Pradesh (AP) 531019, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

## SAFETY DATA SHEET

Preparation Date: 10/3/2017

Revision date 2/20/2019

Revision Number: G2

### 1. IDENTIFICATION

#### Product identifier

**Product code:** A1322  
**Product Name:** AMITRIPTYLINE HYDROCHLORIDE, USP

#### Other means of identification

**Synonyms:** Amitriptyline chloride  
 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  
 Rantorin  
 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  
**CAS #:** 549-18-8  
**RTECS #** HO9450000  
**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

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Tom Tyner (USA - West Coast)  
**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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Store locked up

#### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

### 4. FIRST AID MEASURES

#### First aid measures

<b>General Advice:</b>	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.
<b>Skin Contact:</b>	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops.
<b>Eye Contact:</b>	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
<b>Inhalation:</b>	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.
<b>Ingestion:</b>	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

<b>Symptoms</b>	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
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#### Indication of any immediate medical attention and special treatment needed

<b>Notes to Physician:</b>	Treat symptomatically.
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#### 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 (CO<sub>2</sub>). 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 (NO<sub>x</sub>). 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.

**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**

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Practically white.
<b>Odor:</b> None.	<b>Taste</b> No information available.	<b>Formula</b> C20-H23-N.HCl
<b>Molecular/Formula weight (g/mole):</b> 313.86	<b>Flammability (solid, gas)</b> no data available	<b>Flashpoint (°C/°F):</b> No information available
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 196-197 °C/384.8-386.6 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b> No information available	<b>Partition coefficient (n-octanol/water):</b> No information available	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Freely soluble in Chloroform Freely soluble in alcohol Solubility in Water: 50% @ 20°C/68°F 1g 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

**Conditions to avoid:**

Heat. Ignition sources. Avoid dust formation. Incompatible materials.

**Incompatible Materials:**

Oxidizing agents

**Hazardous decomposition products:**

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

**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 LC50 information** = 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.

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<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Ingestion</b>	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 protrusion of the tongue. May cause Parkinson's-like symptoms (Pseudo-parkinsonism). 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.
<b>Aspiration hazard</b>	No information available.

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

<b>Chronic Toxicity</b>	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 enlargement in men, ejaculatory 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.
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**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**

No information available.

#### **STOT - repeated exposure**

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 soil**

No information available

#### **Other adverse effects**

No 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**

**Product code:** A1322

**Product name:** AMITRIPTYLINE  
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**DOT**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solids, organic, n.o.s. (amitriptyline hydrochloride)  
**Hazard Class** 6.1  
**Subsidiary Class** No information available  
**Packing group:** III  
**Emergency Response Guide Number** 154  
**Marine Pollutant** Severe Marine Pollutant  
**DOT RQ (lbs):** No information available  
**Special Provisions** IB8, 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:** III  
**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** III  
**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:** III  
**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



**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**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 - Response** 6L  
**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 Hydrochloride	549-18-8	Present	Present KE-10614	Present	Not present	Not listed	Present	Present 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 Reproductive Toxicity	Female Reproductive 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	CAS No	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

### WHMIS 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-phrases(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-phrases(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  
HYDROCHLORIDE, USP

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 Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
A1322	Amitriptyline Hydrochloride, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

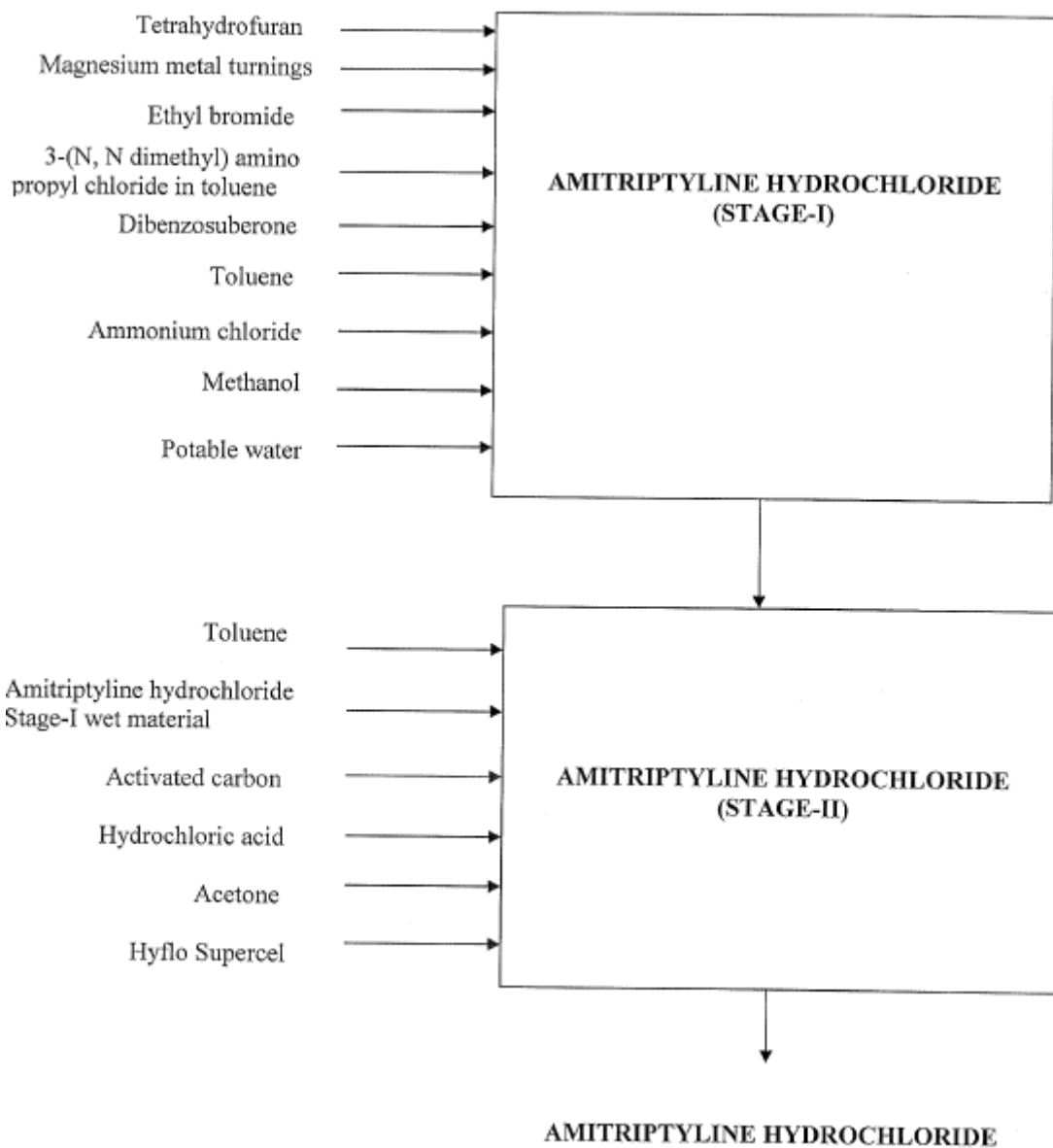
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Amitriptyline Hydrochloride, USP (Cat# A1322)



### CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

### WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## A1322, Amitriptyline Hydrochloride, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |              |
|---------------------|--------------|
| • Aflatoxins        | • Parabens   |
| • Antibiotics       | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • Preservatives     |              |



**RE: Elemental Impurities - Amitriptyline Hydrochloride, USP (Cat# A1322)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843





**RE: Residual Solvents - Amitriptyline Hydrochloride, USP (Cat# A1322)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Tetrahydrofuran	2	< 720 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



Exp. Date: 00-00-0000



**DANGER**

• Toxic if swallowed • Causes serious eye irritation • Causes skin irritation • Suspected of damaging fertility or the unborn child.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** 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 attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF SWALLOWED: Immediately call a POISON CENTER or physician. Rinse mouth.

**KEEP FROM CHILDREN**

**A1322**

**SIZ SY**

**Amitriptyline Hydrochloride**

**USP**

CAS 549-18-8

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.

**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

DOT: UN2811, Toxic solid, organic, n.o.s. (amitriptyline hydrochloride), 6.1, PG III

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{20}H_{23}N \cdot HCl$  F.W. 313.86

Manufacturer/Supplier Code ..... ?

Manufacturer Lot Number ..... ?

Assay (Dried Basis) ..... 98.0-102.0%

pH of a 1 in 100 Solution ..... 5.0-6.0

MAXIMUM LIMITS

Loss on Drying ..... 0.5%

Residue on Ignition ..... 0.1%

Elemental Impurities ..... As reported

Organic Impurities:

Amitriptyline Related Compound A ..... 0.05%

Amitriptyline Related Compound B ..... 0.15%

Nortriptyline ..... 0.15%

Cyclobenzaprine ..... 0.15%

Any Individual Unspecified Impurity ..... 0.10%

Total Impurities ..... 1.0%

Residual Solvents ..... To pass test

**WARNING:** Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

Repackaged by Spectrum as:

Lot No. XQ####

B 13/16GHS-A ?

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000