1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product code: A1322
Product Name: AMITRIPTYLINE HYDROCHLORIDE, USP
Chemical Name: 5H-Dibenzo(a,d)cycloheptene-delta(sup 5),gamma-propylamine, 10,11-dihydro-N,N-dimethyl-,hydrochloride
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
- 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
- Elavit hydrochloride
- Endep
- Etrafon
- Tryptizol

Recommended use: Medication. Antidepressant.
CAS #: 549-18-8
Formula: C20-H23-N.HCl
RTECS #: HO9450000
C#: Not available
Supplier: Spectrum Chemicals and Laboratory Products, Inc.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000
Order Online At: https://www.spectrumchemical.com

See Section 8.
2. HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW**

**WARNING!**
Harmful if swallowed
May cause skin and eye irritation
May cause irritation of respiratory tract

<table>
<thead>
<tr>
<th>Odor:</th>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
</tr>
</thead>
</table>

**OSHA Regulatory Status**
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

**POTENTIAL HEALTH EFFECTS**

Principal Routes of Exposure:
Ingestion. Inhalation.

**Acute Potential Health Effects:**

**Skin Contact:**
May cause skin irritation.

**Eye Contact:**
Contact with eyes may cause irritation.

**Inhalation:**
May cause irritation of respiratory tract.

**Ingestion:**
Harmful if swallowed. May cause nausea and vomiting. May cause stomach cramping. May cause central nervous system effects. May affect the cardiovascular system. May affect respiration. It may affect the urinary system. May affect the liver. May affect the blood. May cause hyperglycemia. It may affect the thyroid.

**Chronic Potential Health Effects:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Carcinogen Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>No information available</td>
</tr>
<tr>
<td>549-18-8 (100)</td>
<td></td>
</tr>
</tbody>
</table>

**Target Organs:**
Central nervous system. Cardiovascular system.

**Mutagenic Effects:**
May affect genetic material
Animal experiments showed mutagenic effects

**Teratogenic Effects:**
May cause birth defects (teratogenic effects)
Possible risk of harm to the unborn child

See Section 11 for additional Toxicological Information

POTENTIAL ENVIRONMENTAL EFFECTS

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>549-18-8</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General Advice: Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126). 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 clothes and shoes. Get medical attention if irritation develops.

Eye Contact: Flush eye 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 Centre immediately.

Notes to Physician: Treat symptomatically

5. FIRE-FIGHTING MEASURES

Flammable Properties

Flashpoint (°C/°F): Not applicable

Flash Point Tested according to: Not applicable

Lower Explosion Limit (%): Not applicable

Upper Explosion Limit (%): Not applicable

Product code: A1322  Product name: AMITRIPTYLINE HYDROCHLORIDE, USP
Autoignition Temperature (°C/°F): Not applicable.

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

Unsuitable Extinguishing Media: No information available.

Hazardous Combustion Products: Carbon monoxide; Carbon dioxide; Nitrogen oxides

Specific hazards: May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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.

Specific Methods: Dike fire-control water for later disposal; do not scatter the material. For larger fires, use water spray or fog. Cool containers with flooding quantities of water until well after fire is out.

6. ACCIDENTAL RELEASE MEASURES

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 for Cleaning Up: Sweep up and shovel into suitable containers for disposal. Use a suitable vacuum cleaner. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

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. Avoid dust formation. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

Storage

Product code: A1322  Product name: AMITRIPTYLINE HYDROCHLORIDE, USP
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

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.

Personal Protective Equipment

Eye protection: Safety glasses with side-shields
Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.
Respiratory protection: Wear respirator with dust filter.
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.

National occupational exposure limits

United States
U.S Occupational Exposure Limits: Not determined

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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<tbody>
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<td>None</td>
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<td>None</td>
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</table>

Canada
Canada Occupational Exposure Limits: Not determined

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
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<tr>
<td>Amitriptyline Hydrochloride 549-18-8</td>
<td>None</td>
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</table>

Australia and Mexico
Occupational Exposure Limits for Australia and Mexico: Not determined

<table>
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<tr>
<th>Components</th>
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<th>Mexico</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride 549-18-8</td>
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<td>None</td>
</tr>
</tbody>
</table>

9. PHYSICAL AND CHEMICAL PROPERTIES

Product code: A1322  Product name: AMITRIPTYLINE HYDROCHLORIDE, USP 5 / 12
## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
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<table>
<thead>
<tr>
<th>Odor:</th>
<th>Molecular/Formula weight:</th>
<th>Taste</th>
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<tbody>
<tr>
<td>None.</td>
<td>313.86</td>
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<table>
<thead>
<tr>
<th>Flash point (°C):</th>
<th>Lower Explosion Limit (%):</th>
<th>Upper Explosion Limit (%):</th>
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<tbody>
<tr>
<td>Not applicable</td>
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<td>No information available</td>
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<table>
<thead>
<tr>
<th>Autoignition Temperature (°C/°F):</th>
<th>Melting point/range(°C/°F):</th>
<th>Boiling point/range(°C/°F):</th>
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<tbody>
<tr>
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<td>196-197 °C/384.8-386.6 °F</td>
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<table>
<thead>
<tr>
<th>pH:</th>
<th>Decomposition temperature(°C/°F):</th>
<th>Specific gravity:</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Density (g/cm³):</th>
<th>Bulk density:</th>
<th>Vapor pressure @ 20°C (kPa):</th>
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</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Evaporation rate:</th>
<th>Vapor density:</th>
<th>VOC content (g/L):</th>
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<tbody>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Odor threshold (ppm):</th>
<th>Partition coefficient</th>
<th>Miscibility:</th>
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</thead>
<tbody>
<tr>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>

**Solubility:**
- Freely soluble in Chloroform
- Freely soluble in alcohol
- Solubility in Water: 10.84 mg/l @ 25 °C

## 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Stability:</th>
<th>Conditions to avoid:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable at normal conditions</td>
<td>Heat. Ignition sources. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incompatible Materials:</th>
<th>Hazardous decomposition products:</th>
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</thead>
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<table>
<thead>
<tr>
<th>Possibility of Hazardous Reactions:</th>
<th>Polymerization:</th>
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<tr>
<td>No information available</td>
<td>Hazardous polymerisation does not occur</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrosivity:</th>
<th>Special Remarks on Corrosivity:</th>
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</thead>
<tbody>
<tr>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

**Component Information**
Amitriptyline Hydrochloride - 549-18-8
   LD50/oral/rat = 240 mg/kg
   LD50/oral/mouse = 140 mg/kg
   LD50/dermal/rat = No information available
   LD50/dermal/rabbit = 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

LC50/inhalation/rat No information available
LC50/inhalation/mouse No information available
LD50/dermal/rabbit No information available
LD50/dermal/rat No information available
LD50/oral/mouse = 140mg/kg
LD50/oral/rat = 240 mg/kg

Local Effects

Skin irritation: May cause skin irritation.

Eye irritation: Contact with eyes may cause irritation.

Inhalation: May cause irritation of respiratory tract.
Ingestion:
Harmful if swallowed
May cause dry mouth, thirst
Ingestion may cause nausea, vomiting
May cause constipation
May cause diarrhea
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 (respiratory depression)
May cause mydriasis (dilated pupils)
May cause urinary retention
May cause headache
May cause blurred 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 conciousness, 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-parkinonism). They may include: mask-like facies, shuffling gait, cogwheel rigidity, pillrolling motion, drooling, tremors
May affect the peripheral nervous system ( 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

Sensitization:
No information available

Chronic Toxicity:
May cause Tardive Dyskinesia. It most commonly occurs in patients which 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. 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.

Carcinogenic effects:
Not considered carcinogenic

Product code: A1322
Product name: AMITRIPTYLINE HYDROCHLORIDE, USP
Mutagenic Effects: May affect genetic material
Animal experiments showed mutagenic effects

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.

Teratogenic Effects: May cause birth defects (teratogenic effects). Possible risk of harm to the unborn child.

Target Organs: Central nervous system. Cardiovascular system.

12. ECOLOGICAL INFORMATION

ECOTOXICITY

Toxicity to terrestrial and aquatic plants and animals: No information available

Ecotoxicity effects: No data available.

Aquatic toxicity: No information available

Mobility: No information available

Persistence and degradability: No information available

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

13. DISPOSAL CONSIDERATIONS

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811

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

Hazard Class: 6.1

Packing Group: III

Subsidiary Risk: Not applicable

Marine Pollutant: No data available

ERG No: 154

DOT RQ (lbs): No information available
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<thead>
<tr>
<th>Mode</th>
<th>UN-No:</th>
<th>Proper Shipping Name:</th>
<th>Hazard Class:</th>
<th>Packing Group:</th>
<th>Subsidiary Risk:</th>
<th>Classification Code:</th>
<th>Description:</th>
<th>CEFIC Tremcard No:</th>
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<tbody>
<tr>
<td>TDG (Canada)</td>
<td>UN2811</td>
<td>Toxic solid, organic, n.o.s.</td>
<td>6.1</td>
<td>III</td>
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<tr>
<td>ADR</td>
<td>UN2811</td>
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<td>III</td>
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<tr>
<td>IMO / IMDG</td>
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</tr>
<tr>
<td>ICAO</td>
<td>UN2811</td>
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<td>6.1</td>
<td>III</td>
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<tr>
<td>IATA</td>
<td>UN2811</td>
<td>Toxic solid, organic, n.o.s.</td>
<td>6.1</td>
<td>III</td>
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<td>6L</td>
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</table>
15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>Philippines (PICCS)</th>
<th>KOREA KECL</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>Present</td>
<td>Present KE-10614</td>
<td>Not present</td>
<td>Not present</td>
<td>Present</td>
<td>Present 208-964-6</td>
<td></td>
</tr>
</tbody>
</table>

U.S. Regulations


**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)

<table>
<thead>
<tr>
<th>Components</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
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<td>Not Listed</td>
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CERCLA/SARA

<table>
<thead>
<tr>
<th>Components</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
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<td>None</td>
<td>None</td>
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U.S. TSCA

<table>
<thead>
<tr>
<th>Components</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Canada

**WHMIS hazard class:**
D1B Toxic materials

**Canada Controlled Products Regulation:**
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

<table>
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<tr>
<th>Components</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
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<tbody>
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</tbody>
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<table>
<thead>
<tr>
<th>Components</th>
<th>CEPA Schedule I - Toxic Substances</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
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</thead>
<tbody>
<tr>
<td>Amitriptyline Hydrochloride</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>
EU Classification

R-phrase(s)
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

S-phrase(s)
S46 - If swallowed, seek medical advice immediately and show this container or label.

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

Indication of danger:
Xn - Harmful.

Xn

16. OTHER INFORMATION

The MSDS format complies with ANSI Z400.1/Z129.1-2010 standards.

Preparation Date: 19-Aug-2013
Reason for revision: Not applicable
Prepared by: Sonia Owen
Literature reference: No information available

All chemicals may pose unknown hazards and should be used with caution. This Material Safety Data Sheet (MSDS) 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 MSDS. The physical properties reported in this MSDS 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 MSDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.