Amitriptyline Hydrochloride

sc-210801

Material Safety Data Sheet

Hazard Alert Code Key:
- EXTREME
- HIGH
- MODERATE
- LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Amitriptyline Hydrochloride

STATEMENT OF HAZARDOUS NATURE

SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
<tr>
<th></th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Reactivity</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>
CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW
RISK
Possible risk of harm to the unborn child.
Toxic by inhalation, in contact with skin and if swallowed.
Irritating to eyes, respiratory system and skin.
Very toxic to aquatic organisms.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED
- Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.
- Side effects of tricyclic antidepressants include dry mouth, sour or metallic taste, constipation, retention of urine, blurred vision and changes in focusing, palpitations, and fast heart beat.
- Gastrointestinal disturbances (including nausea and vomiting), drowsiness, tremor, low blood pressure when standing, dizziness, sweating, weakness and fatigue, inco-ordination, epilepsy-like seizures, and speech difficulties may occur.
- Patients of any age with Major Depressive Disorder may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs.
Patients should be closely monitored, especially at the beginning of therapy or when the dose is changed, until such improvement occurs.
- Serotonin syndrome (serious changes to how the brain, muscles and digestive system works due to high levels of serotonin in the body) may occur in therapy.
  Signs and symptoms of serotonin syndrome include · restlessness · fast heart beat · fast changes in blood pressure · diarrhoea and vomiting · nausea · hallucinations · increased body temperature · coma · loss of coordination · overactive reflexes General side effects of serotonin reuptake inhibitors (SSRIs) are mostly present during the first 1-4 weeks while the body adapts to the drug (with the exception of sexual side effects, which tend to occur later in treatment).
- As with the SSRIs, abrupt discontinuation of SNRI-medication usually leads to a discontinuation syndrome which could include states of anxiety and further symptoms.
Because one of the actions of the SNRIs is to block the reuptake of serotonin as the SSRIs do, it has many of the same side effects.

EYE
- There is evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation.
- Severe inflammation may be expected with pain.

SKIN
- Skin contact with the material may produce toxic effects; systemic effects may result following absorption.
- This material can cause inflammation of the skin on contact in some persons.
- The material may accentuate any pre-existing dermatitis condition.
- This material is a photosensitizer.
  Certain individuals working with this substance may show allergic reaction of the skin under sunlight.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED
- Inhalation of dusts, generated by the material, during the course of normal handling, may produce toxic effects.
- The material can cause respiratory irritation in some persons.
The body's response to such irritation can cause further lung damage.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS
- Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.
  Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.
  Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
  Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.
Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>amitriptyline hydrochloride</td>
<td>549-18-8</td>
<td>&gt;98</td>
</tr>
</tbody>
</table>

Section 4 - FIRST AID MEASURES

**SWALLOWED**
- If swallowed, refer for medical attention, where possible, without delay. Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
  - If skin or hair contact occurs: Quickly but gently, wipe material off skin with a dry, clean cloth. Immediately remove all contaminated clothing, including footwear.

**EYE**
- If this product comes in contact with the eyes: Immediately hold eyelids apart and flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

**SKIN**
- If skin or hair contact occurs: Quickly but gently, wipe material off skin with a dry, clean cloth. Immediately remove all contaminated clothing, including footwear.

**INAHALED**
- If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested.

**NOTES TO PHYSICIAN**
- For selective serotonin reuptake inhibitors (SSRIs):
  - Serotonin toxicity is more pronounced following supra-therapeutic doses and overdoses, and they merge in a continuum with the toxic effects of overdose. The serotonergic toxicity of SSRIs increases with dose, but even in over-dose it is insufficient to cause fatalities from serotonin syndrome in healthy adults. The syndrome occurs in approximately 14 to 16 percent of persons who overdose on SSRIs. It is usually only when drugs with different mechanisms of action are mixed together that elevations of central nervous system serotonin reach potentially fatal levels.
  - The symptoms are often described as a clinical triad of abnormalities:
    - Cognitive effects: mental confusion, hypomania, hallucinations, agitation, headache, coma.
    - Autonomic effects: shivering, sweating, fever, hypertension, tachycardia, nausea, diarrhea.
    - Somatic effects: myoclonus/clonus (muscle twitching), hyperreflexia, tremor.
  - Symptom onset is usually rapid, often occurring within minutes after self-poisoning or a change in medication. Serotonin syndrome encompasses a wide range of clinical findings. Mild symptoms may only consist of tachycardia, shivering, diaphoresis (sweating), mydriasis (dilated pupils), myoclonus (intermittent tremor or twitching), as well as overactive or over-responsive reflexes. Moderate intoxication includes additional abnormalities such as hyperactive bowel sounds, hypertension and hyperthermia; a temperature as high as 40 C (104 F) is common in moderate intoxication. The overactive reflexes and clonus in moderate cases may be greater in the lower limbs than in the upper limbs. Mental status changes include hyper-vigilance and agitation. Severe symptoms include severe hypertension and tachycardia that may lead to shock. Severe cases often have agitated delirium as well as muscular rigidity and high muscular tension. Temperature may rise to above 41.1 C (106.0 F) in life-threatening cases. Other abnormalities include metabolic acidosis, rhabdomyolysis, seizures, renal failure, and disseminated intravascular coagulation, these effects usually arise as a consequence of hyperthermia.
  - SSRIs appear to be safer in overdose when compared with traditional antidepressants such as the tricyclic antidepressants. This relative safety is supported both by case series and studies of deaths per numbers of prescriptions. However, case reports of SSRI poisoning have indicated that severe toxicity can occur and deaths have been reported following massive single ingestions, although this is exceedingly uncommon when compared to the tricyclic antidepressants. Because of the wide therapeutic index of the SSRIs, most patients will have mild or no symptoms following moderate overdoses. The most commonly reported severe effect following SSRI overdose is serotonin syndrome; serotonin toxicity is usually associated with very high overdoses or multiple drug ingestion. Other reported significant effects include coma, seizures, and cardiac toxicity.
  - Treatment for SSRI overdose is mainly based on symptomatic and supportive care. Medical care may be required for agitation, maintenance of the airways, and treatment for serotonin syndrome. ECG monitoring is usually indicated to detect any cardiac abnormalities.
  - Supportive care includes:
    - the control of agitation,
    - the administration of serotonin antagonists (cyproheptadine or methysergide),
    - the control of autonomic instability, and the control of hyperthermia.
  - The intensity of therapy depends on the severity of symptoms.
  - If the symptoms are mild, treatment may only consist of:
    - discontinuation of the offending medication or medications,
    - offering supportive measures,
    - giving benzodiazepines for myoclonus, and waiting for the symptoms to resolve.
  - Moderate cases should have:
    - all thermal and cardiorespiratory abnormalities corrected and
    - can benefit from serotonin antagonists such as cyproheptadine.
  - Critically ill patients should receive the above therapies as well as:
    - sedation, neuromuscular paralysis, and
    - intubation with artificial ventilation.
Upon initiation of therapy and the discontinuation of serotonergic drugs most cases of serotonin syndrome resolve within 24 hours although delirium may persist for a number of days. Cases have reported muscle pain and weakness persisting for months although antidepressant withdrawal may contribute to ongoing features. Following appropriate medical management, serotonin syndrome is generally associated with a favorable prognosis.

For tricyclic antidepressant poisonings: The stomach should be emptied by aspiration and lavage. Activated charcoal as an adjunct to gastric lavage may also be used. Readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring within 6 hours of oral administration. Because amitriptyline slows gastrointestinal transit time, absorption may be delayed especially in overdose. Extensively demethylated in the liver producing the primary active metabolite nortriptyline. Excreted in the urine mainly as free or conjugated metabolites. Reported plasma half-life range from 9 to 25 hours. Extensively bound to plasma and tissue protein.

### Section 5 - FIRE FIGHTING MEASURES

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<thead>
<tr>
<th>Vapour Pressure (mmHg):</th>
<th>Negligible</th>
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</thead>
<tbody>
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<td>Upper Explosive Limit (%):</td>
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</tr>
<tr>
<td>Specific Gravity (water=1):</td>
<td>Not available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%):</td>
<td>Not available</td>
</tr>
</tbody>
</table>

**EXTINGUISHING MEDIA**
- Water spray or fog.
- Foam.

**FIRE FIGHTING**
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.

**GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS**
- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

**FIRE INCOMPATIBILITY**
- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

**PERSONAL PROTECTION**
- Glasses: Chemical goggles.
- Gloves: Particulate
- Respirator:

### Section 6 - ACCIDENTAL RELEASE MEASURES

**MINOR SPILLS**
- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

**MAJOR SPILLS**
- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.

### Section 7 - HANDLING AND STORAGE

**PROCEDURE FOR HANDLING**
- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS
- Lined metal can, Lined metal pail/drum
- Plastic pail.
- For low viscosity materials
- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

STORAGE REQUIREMENTS
- Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS
The following materials had no OELs on our records
- amitriptyline hydrochloride: CAS:549-18-8

PERSONAL PROTECTION

RESPIRATOR
- particulate.

EYE
- For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
  - Chemical goggles
  - Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
  - Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET
- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
  - frequency and duration of contact,
  - chemical resistance of glove material,
  - glove thickness and
  - dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

OTHER
- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

ENGINEERING CONTROLS
- For potent pharmacological agents:
  - Powders
    - To prevent contamination and overexposure, no open handling of powder should be allowed.
    - Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
    - In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
    - Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
    - An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
    - Powder should be put into solution or a closed or covered container after handling.
    - If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
  - Solutions Handling:
    - Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.
    - Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.
    - In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
    - Ensure gloves are protective against solvents in use.

Unless written procedures, specific to the workplace are available, the following is intended as a guide:
- For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*,
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

### Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL PROPERTIES

Solid.
Mixes with water.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>State</td>
<td>Solid</td>
</tr>
<tr>
<td>Melting Range (°F)</td>
<td>383- 390</td>
</tr>
<tr>
<td>Boiling Range (°F)</td>
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</tr>
<tr>
<td>Flash Point (°F)</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition Temp (°F)</td>
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</tr>
<tr>
<td>Autoignition Temp (°F)</td>
<td>702</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
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</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
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</tr>
<tr>
<td>Volatile Component (%vol)</td>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>log Kow (Sangster 1997)</th>
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<tbody>
<tr>
<td>amitriptyline hydrochloride</td>
<td>5.04</td>
</tr>
</tbody>
</table>

#### APPEARANCE

Odourless, colourless or white powder with bitter, burning taste followed by sensation of numbness; mixes with water (1:1), alcohol
(1:1.5), acetone (1:56), chloroform (1:1.2) and methanol (1:1).

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**Section 10 - CHEMICAL STABILITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**
- Presence of incompatible materials.
- Product is considered stable.

**STORAGE INCOMPATIBILITY**
- Avoid strong bases.
- Avoid reaction with oxidizing agents.
- Reaction with alkali will produce toxic free amine. Thermally decomposes

For incompatible materials - refer to Section 7 - Handling and Storage.

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**Section 11 - TOXICOLOGICAL INFORMATION**

amitriptyline hydrochloride

**TOXICITY AND IRRITATION**

**AMITRIPYLNE HYDROCHLORIDE:**

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

<table>
<thead>
<tr>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (child) LDLo: 62.5 mg/kg</td>
<td>Eye (rabbit): SEVERE *</td>
</tr>
<tr>
<td>Oral (woman) LDLo: 19 mg/kg</td>
<td>Skin (rabbit): slight *</td>
</tr>
<tr>
<td>Oral (rat) LD50: 240 mg/kg</td>
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<tr>
<td>Oral (rat) LD50: 532 mg/kg *</td>
<td></td>
</tr>
<tr>
<td>Intraperitoneal (rat) LD50: 67 mg/kg</td>
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</tr>
<tr>
<td>Intraperitoneal (rat) LD50: 72 mg/kg *</td>
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<tr>
<td>Subcutaneous (rat) LD50: 385 mg/kg</td>
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</tr>
<tr>
<td>Subcutaneous (rat) LD50: 1293 mg/kg *</td>
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</tr>
<tr>
<td>Intravenous (rat) LD50: 14 mg/kg</td>
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</tr>
<tr>
<td>Oral (mouse) LD50: 140 mg/kg</td>
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</tr>
<tr>
<td>Oral (mouse) LD50: 289 mg/kg *</td>
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<tr>
<td>Intraperitoneal (mouse) LD50: 65 mg/kg</td>
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<td>Subcutaneous (mouse) LD50: 80 mg/kg</td>
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<td>Intravenous (mouse) LD50: 21 mg/kg</td>
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<tr>
<td>Oral (dog) LD50: 100 mg/kg *</td>
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<td>Intravenous (dog) LD50: &gt;27 mg/kg</td>
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<td>Intramuscular (dog) LD50: &gt;23 mg/kg</td>
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<tr>
<td>Oral (Human) TDL50: 10 mg/kg</td>
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<td>Oral (Human) TDL50: 200 mg/kg</td>
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<tr>
<td>Oral (Human) LD: 62.5 mg/kg</td>
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<tr>
<td>Oral (Dog) LD: 200 mg/kg</td>
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<tr>
<td>Oral (Human) TDL50: 58 mg/kg</td>
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<tr>
<td>Oral (Human) TDL50: 60 mg/kg</td>
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<tr>
<td>Oral (Human) LD: 19 mg/kg</td>
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<tr>
<td>Oral (Cat) LD50: 37 mg/kg</td>
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<tr>
<td>Intravenous (Rabbit) LD50: 9.9 mg/kg</td>
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<tr>
<td>Intravenous (Guinea pig) LD: 52 mg/kg</td>
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</table>

- Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A
reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production. The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Intravenous (rabbit): 9.9 mg/kg *

AD: 150 mg/day

Sleep, somnolence, hallucinations, convulsions, ataxia, muscle contraction, coma, cardiac changes, lowered blood pressure, dyspnea, cyanosis, respiratory depression, patemal effects, foetoxyticity, foetotolathcy, specific developmental abnormalities (central nervous system, craniofacial, body wall, musculoskeletal, effects on newborn recorded.

* Mercke, Sharp and Dohme

**CARCINOGEN**

<table>
<thead>
<tr>
<th>PBTC (PERS)</th>
<th>US - Maine Chemicals of High Concern List</th>
<th>Carcinogen</th>
</tr>
</thead>
</table>

**Section 12 - ECOLOGICAL INFORMATION**

Very toxic to aquatic organisms. This material and its container must be disposed of as hazardous waste. Avoid release to the environment. Refer to special instructions/ safety data sheets.

**Ecotoxicity**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
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<tr>
<td>amitriptyline hydrochloride</td>
<td>HIGH</td>
<td>No Data Available</td>
<td>HIGH</td>
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**GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles**

Name / EHS TRN A1a A1b A2 B1 B2 C1 C2 C3 D1 D2 D3 E1 E2 E3 Cas No / RTECS No

Poly(2+)c 224 574 4 4 4 NR (4) NI (1) (1) (1) (1) CM S 3 cyclic 6 aromatics / CAS:549-18-8 /

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acute aquatic toxicity LC50/EC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg), C2=Acute mammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation & corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lung injury, N=Neurotoxic, I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floaters, S=Sinking substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

**Section 13 - DISPOSAL CONSIDERATIONS**

**Disposal Instructions**

All waste must be handled in accordance with local, state and federal regulations. Puncture containers to prevent re-use and bury at an authorized landfill. Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.
· Recycle wherever possible.
· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

DOT:
Symbols: None Hazard class or Division: 6.1
Identification Numbers: UN3249 PG: II
Label Codes: 6.1 Special provisions: T3, TP33
Packaging: Exceptions: 153 Packaging: Non- bulk: 212
Packaging: Exceptions: 153 Quantity limitations: 5 kg
Passenger aircraft/rail:
Quantity Limitations: Cargo 5 kg Vessel stowage: Location: C
aircraft only:
Vessel stowage: Other: 40
Hazardous materials descriptions and proper shipping names:
Medicine, solid, toxic, n.o.s.

Air Transport IATA:
ICAO/IATA Class: 6.1 ICAO/IATA Subrisk: None
UN/ID Number: 3249 Packing Group: II
Special provisions: A3 Cargo Only
Packaging Instructions: 100 kg Maximum Qty/Pack: 676
Passenger and Cargo Passenger and Cargo
Packaging Instructions: 25 kg Maximum Qty/Pack: 669
Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity
Packaging Instructions: 1 kg Maximum Qty/Pack: Y644
Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(CONTAINS AMITRIPTYLINE HYDROCHLORIDE)

Maritime Transport IMDG:
IMDG Class: 6.1 IMDG Subrisk: None
UN Number: 3249 Packing Group: II
EMS Number: F-A , S-A Special provisions: 221
Limited Quantities: 500 g Marine Pollutant: Yes
Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(contains amitriptyline hydrochloride)

Section 15 - REGULATORY INFORMATION

amitriptyline hydrochloride (CAS: 549-18-8) is found on the following regulatory lists;
"Canada Domestic Substances List (DSL)","US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

ND
Substance CAS Suggested codes amitriptyline hydrochloride 549- 18- 8 Mut3; R68 Rep3; R63 Xn; R22 N; R50/53

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Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent
review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.
The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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