



Humco Holding Group, Inc.
7400 Alumax Dr
Texarkana TX 75501 USA
800-662-3435
cs@humco.com
www.humco.com

24-Hour Emergency Number (CHEMTREC)
USA- 800-424-9300

All non-emergency calls should be directed to
Customer Service at 800-662-3435

NAME: AMITRIPTYLINE HYDROCHLORIDE, USP **SDS NO. 8048**

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Amitriptyline Hydrochloride, USP

Synonyms: 1-Propanamine, 3-(10, 11-dihydro-5H-dibenzo [a, d] cyclohepten-5-ylidene)-N,N-dimethyl-, hydrochloride.

Recommended Use: Active Pharmaceutical Ingredient

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2. HAZARD IDENTIFICATION

| | |
|---------------------------|--|
| Pictogram: | |
| Classification: | Acute Toxicity - Oral (Category 3) Toxic to Reproduction (Category 1B) Chronic Aquatic Toxicity (Category 1) |
| Signal Word: | Danger |
| Hazard Statements: | Toxic if swallowed. Causes skin and eye irritation. May damage fertility or the unborn child. Very toxic to aquatic life with long lasting effects. The substance is a |

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| | powerful local anesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion. . |
| Precautionary Statements | <p>Prevention: Wash thoroughly after handling; Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment</p> <p>IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.</p> <p>IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.</p> <p>IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional.</p> <p>IF EXPOSED OR CONCERNED: Get medical advice/attention.</p> <p>Storage: Store locked up.</p> <p>Disposal: Dispose of contents and/or container in accordance with local regulations.</p> |

3. COMPOSITION / INGREDIENTS

| CHEMICAL NAME | CAS# |
|---------------------------------|----------|
| AMITIPTYLINE HYDROCHLORIDE, USP | 549-18-8 |

4. FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS: Not expected to present a significant hazard under anticipated conditions of normal use.

5. FIRE-FIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

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

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition.

Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Preserve in tight, light-resistant containers.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

National occupational exposure limits

United States

| Components | OSHA | NIOSH | ACGIH | AIHA WHEEL |
|------------|------|-------|-------|------------|
| | | | | |

| | | | | |
|---|-----|-----|-----|-----|
| Amitriptyline Hydrochloride 549-18-8 | N/L | N/L | N/L | N/L |
|---|-----|-----|-----|-----|

EXPOSURE GUIDELINES: Consult local authorities for provincial or state exposure limits

PERSONAL PROTECTIVE EQUIPMENT: Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS: Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

The substance is a powerful local anesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.

9. PHYSICAL AND CHEMICAL PROPERTIES

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|---------------------------------------|---|--|----------------|
| Appearance: | White to practically crystalline powder or small crystals | Upper/Lower Flammability: | Not determined |
| Odor: | Not determined | Vapor Pressure | Not determined |
| Odor Threshold: | Not determined | Vapor Density: | Not determined |
| pH: | 5 - 6 | Relative Density: | 0.1 - 0.2 |
| Melting point /Freezing Point: | >196 °C, 384.8 ° F | Solubilities: | Not determined |
| Boiling point/range: | Not determined | Partition coefficient: n-octanol/water: | Not determined |
| Flash point | Not determined | Auto-ignition temperature | Not determined |
| Evaporation rate | Not determined | Decomposition Temperature: | Not determined |
| Flammability: | Not determined | Viscosity | Not determined |

10. STABILITY AND RACTIVITY

REACTIVITY: Not established

STABILITY: Stable under recommended storage conditions

MATERIALS TO AVOID: Not determined

HAZARDOUS DECOMPOSITION PRODUCTS: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

HAZARDOUS POLYMERIZATION: Will not occur

POSSIBILITY OF HAZARDOUS REACTION: Not established

CONDITIONS TO AVOID: Moisture, sunlight and extreme temperatures

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Oral: Rat: LD50 (mg/Kg): 240 mg/kg

Dermal: Rabbit: LD50: Not available

Inhalation: Rat: LD50: Not available

SKIN CORROSION/IRRITATION: Not available

SERIOUS EYE DAMAGE/EYE IRRITATION: Not available

RESPIRATORY OR SKIN SENSITIZATION: Not available

GERM CELL MUTAGENICITY: Not available

CARCINOGENICITY

OSHA: Not listed.

NTP: Not listed.

IARC: Not listed.

California Proposition 65: No component of this product, present at $\geq 0.1\%$ is known to the State of California to cause cancer, birth defects, or any other reproductive harm.

REPRODUCTIVE TOXICITY: The substance administered subcutaneously in female mice during pregnancy (9 days after conception) at a dose of 60 mg/kg/day, caused craniofacial abnormalities and central nervous system defects, fetal toxicity and death of the fetus; administered orally in male mice before mating, at a dose of 70 mg/kg/day, the substance caused adverse effects in spermatogenesis. Studies on rats administered the substance at a dose of 220 mg/kg/day have shown adverse effects on the fetuses.

SPECIFIC TARGET ORGAN TOXICITY-SINGLE EXPOSURE: Not Available.

SPECIFIC TARGET ORGAN TOXICITY-REPEATED EXPOSURE: Not Available.

ASPIRATION HAZARDS: Not Available.

POTENTIAL HEALTH EFFECTS

Inhalation: Harmful if inhaled. May cause respiratory tract irritation.

Ingestion: Toxic if swallowed.

Skin: May be harmful if absorbed through skin. May cause skin irritation

Eyes: Causes eye irritation.

May cause dry mouth, constipation, urinary retention, blurred vision, increased intra-ocular pressure, hyperthermia; drowsiness, headache, nervousness, insomnia, tremor, ataxia, epileptiform seizures, tinnitus, dysarthria; confusion, hallucinations, mania; stomatitis, nausea, vomiting; hypersensitivity reactions as urticarial, angioedema, photosensitization, cholesteric jaundice, blood disorders, endocrine effects such as testicular enlargement, gynecomastia, breast enlargement; sexual dysfunction; over dosage may cause tachycardia, intestinal stasis, unconsciousness, convulsions, hyperreflexia, hypothermia, hypotension, metabolic acidosis, respiratory and cardiac depression.

12. ECOLOGICAL INFORMATION

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| Acute or chronic aquatic toxicity: | No specific information available, but material is not intended to be released to the environment. |
| Chemical degradation: | Not determined. |
| Biodegradation: | Not determined. |
| Bioaccumulation potential | Not determined. |
| Adsorption studies or leaching studies: | Not determined. |
| Other adverse effects | Not determined. |

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with federal, state and local laws and regulations. Avoid release into environment.

14. TRANSPORT INFORMATION

| | |
|------------------------------------|-----------------------------------|
| DOT Hazard Classification: | HAZARDOUS MATERIAL |
| UN number: | 2811 |
| UN proper shipping name: | TOXIC SOLID, ORGANIC, N.O.S. |
| Transport hazard class(es): | 6.1 |
| Packing group number: | III |
| Environmental hazards: | Not applicable |
| Special precautions: | Do not freeze, avoid extreme heat |

15. REGULATORY INFORMATION

Not determined

16. OTHER INFORMATION

The information in this SDS is considered current and reliable. However, the data is provided without any warranty, expressed or implied, regarding its correctness or accuracy. Since the conditions for use, handling, storage and disposal are beyond Humco's control, it is the responsibility of the user to determine safe conditions for use and to assume liability for loss, damage, or expenses arising from improper use. No warranty expressed or implied regarding the product described herein will be created by or inferred from any statement or omission. Various agencies may have specific regulations concerning the transportation, handling, storage, use or disposal of this product which may not be reflected in the SDS. The user should review these regulations to ensure full compliance.