



AMITRIPTYLINE HYDROCHLORIDE TABLETS, USP

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Amitriptyline Hydrochloride Tablets, USP

Intended Use of the Product

Use of the substance/mixture: Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan N.V.
 Building 4
 Trident Place
 Mosquito Way
 Hatfield
 Hertfordshire
 AL10 9UL
 United Kingdom
www.mylan.com
 +44 (0)1707 853000

Emergency Telephone Number

Emergency number

: For Hazardous Materials Incident
 Spill, Leak, Fire, Exposure, or Accident
 Call CHEMTREC (24 Hours)
 Worldwide +1 703-741-5970

For adverse health events call:

+1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii) and in Canada's Hazardous Products Act.

Name	Product identifier	% (w/w)	Classification (GHS-US)
Amitriptyline	(CAS No) 50-48-6	7 - 13	Acute Tox. 4 (Oral), H302
Silica, amorphous	(CAS No) 7631-86-9	1 - 5	Not classified

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: Please refer to the package insert for more detailed information.

Inhalation: None expected under normal conditions of use.

Skin Contact: None expected under normal conditions of use.

Eye Contact: May cause minor eye irritation.

Ingestion: Potent pharmaceutical- may be harmful or have adverse effects if swallowed.

Chronic symptoms: Not available

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None known.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not flammable

Explosion hazard: Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Use water spray or fog for cooling exposed containers.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all contact with skin, eyes, or clothing. Avoid generating dust.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

Specific End Use(s) Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

Silica, amorphous (7631-86-9)		
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	6 mg/m
USA IDLH	US IDLH (mg/m ³)	3000 mg/m
Nunavut	OEL TWA (mg/m)	0.15 mg/m (regulated under Silica flour, total mass)
Northwest Territories	OEL TWA (mg/m)	0.15 mg/m (total mass, regulated under Silica flour)
Yukon	OEL TWA (mg/m)	2 mg/m

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Not generally required. Use may be necessary as conditions warrant.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	: Solid
Appearance	: Film-coated, unscored tablets
Odor and Odor Threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper/Lower flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density/Specific gravity	: Not available
Solubility	: Not available
Log Pow/Kow	: Not available
Viscosity (kinematic, dynamic)	: Not available
Explosion data	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.

Incompatible Materials Strong oxidizers. Strong bases. Strong acids.

Hazardous Decomposition Products Carbon oxides (CO, CO₂).

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified
Specific target organ toxicity (repeated exposure): Not classified
Reproductive toxicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Aspiration hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Silica, amorphous (7631-86-9)	
LD50 oral rat	> 5000 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 2.2 mg/l (Exposure time: 1 h)
Silica, amorphous (7631-86-9)	
IARC group	3

12. ECOLOGICAL INFORMATION

Toxicity

Silica, amorphous (7631-86-9)	
LC50 fish 1	5000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 Daphnia 1	7600 mg/l (Exposure time: 48 h - Species: Ceriodaphnia dubia)
EC50 other aquatic organisms 1	440 mg/l (Exposure time: 72 h - Species: Pseudokirchneriella subcapitata)

Persistence and Degradability Not available

Bioaccumulative Potential

Silica, amorphous (7631-86-9)	
BCF fish 1	(no bioaccumulation expected)

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations

Silica, amorphous (7631-86-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

US State Regulations

Silica, amorphous (7631-86-9)	
U.S. - California - Toxic Air Contaminant List (AB 1807, AB 2728)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

Canadian Regulations

Amitriptyline Hydrochloride Tablets, USP	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Silica, amorphous (7631-86-9)	
Listed on the Canadian DSL (Domestic Substances List) inventory and the Canadian Ingredient Disclosure List.	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION

- Indication of changes** : 24 May 2016 – Updated Section 1 information
Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.
Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H302	Harmful if swallowed

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department

Phone Number: 304-599-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Mylan NA GHS SDS