



Nortriptyline Hydrochloride Capsules and Tablets

Eli Lilly and Company
Material Safety Data Sheet

Effective Date: 11-Sep-2001

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Nortriptyline Hydrochloride Capsules and Tablets

Chemical Name: 1-Propanamine, 3-(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ylidene)-N-methyl-, hydrochloride

Synonym(s): Nortriptyline; Nortriptyline Hydrochloride; Nortriptyline Hydrochloride Capsule Mix; Nortriptyline Hydrochloride Capsules; Nortriptyline Hydrochloride Tablet Mix; Nortriptyline Hydrochloride Tablets; H17; H19; 038489 Formulation

Trademarks(s): Acetexa; Branorflex; Paxtibi; Aventyl; Vividyl; Allegron

Lilly Item Code(s): DD1010; DD1011; PU0387; PU0389; PU3026; PU3027; QA446R; TA1010; TA1011; UC5372; UC5373; UE0003; UE0004; UE0005; UE0006; UF0008; UF0009; UF0010; UF0011; VF0062; VF0063; VF0073

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Nortriptyline Hydrochloride	894-71-3	4.9 - 16
Excipients	NA	84 - 95

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines: Nortriptyline hydrochloride - LEG 20 micrograms/m³ TWA for 12 hours.

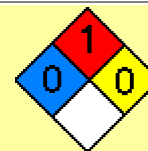
Section 3 - Hazards Identification

Appearance: White powder finished as capsules or coated tablets

Physical State: Solid

Odor: Odorless

Emergency Overview



Emergency Overview Effective Date: 11-Sep-2001

Lilly Laboratory Labeling Codes:

Health 0

Fire 1

Reactivity 0

Primary Physical and Health Hazards: Not hazardous if intact. Nervous System and Heart Effects.

Caution Statement: Intact Nortriptyline Hydrochloride Capsules and Tablets are not considered to be a health hazard. Effects of exposure to the contents of Nortriptyline Hydrochloride Capsules and Tablets may include drowsiness and change in heart rate/rhythm.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Capsules and tablets are intended for human consumption under guidance of a physician. Capsules and coated tablets are not considered hazardous under normal handling procedures. Based on clinical data, effects of exposure to contents of capsules or powder used to make tablets may include drowsiness, decreased blood pressure, irregular heartbeats, and blurred vision.

Medical Conditions Aggravated by Exposure: None known.

Carcinogenicity: Nortriptyline hydrochloride - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Controlled Room Temperature: 15 to 30 C (59 to 86 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Filled capsules and compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to contents may occur.

Respiratory Protection: Use an approved respirator.

Eye Protection: Chemical goggles and/or face shield.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: White powder finished as capsules or coated tablets

Odor: Odorless

Boiling Point: Not applicable

Melting Point: No applicable information found

Specific Gravity: No applicable information found
pH: No applicable information found
Evaporation Rate: No applicable information found
Water Solubility: Soluble
Vapor Density: No applicable information found
Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Oral: Nortriptyline hydrochloride - Rat, median lethal dose 502 mg/kg.

Skin: No applicable information found.

Inhalation: No applicable information found.

Intravenous: Nortriptyline hydrochloride - Rat, median lethal dose 22.3 mg/kg, increased activity, convulsions.

Skin Contact: No applicable information found.

Eye Contact: No applicable information found.

Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

Target Organ Effects: Nortriptyline hydrochloride - Various degrees of degenerative changes in liver and kidneys identified in rats administered up to 0.075% in diet for one year. Increase adrenal, thyroid, and ovarian weight (without abnormal tissue changes) reported in female rats administered 0.15% in diet for 13 months. No effects identified in male rats during this study. No target organ effects reported in dogs administered up to 10 mg/kg orally for one year or 20 mg/kg for 13 months.

Reproduction: Nortriptyline hydrochloride - No fetotoxic or developmental effects reported in rabbits administered 0.05% in diet from gestation day 5 to 20 or in rats administered 0.03% in diet from weaning through production of 2 litters. Delayed fetal development and resorption (along with maternal toxicity) reported in rabbits administered 25 mg/kg by gavage from gestation day 6 to 12.

Sensitization: No applicable information found.

Mutagenicity: No applicable information found.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Nortriptyline hydrochloride

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

EU Regulations

EC Classification

Not assigned an overall EC classification.

Section 16 - Other Information

MSDS Sections Revised: Sections 1, 2, 3, 7, 8, 11, and 15.

Emergency Overview Sections Revised: Caution statement.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company
Hazard Communication
317-277-6029

For additional copies contact:

Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association

BEI = Biological Exposure Index

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

CHAN = Chemical Hazard Alert Notice

CHEMTREC = Chemical Transportation Emergency Center

DOT = Department of Transportation

EC = European Community

EINECS = European Inventory of Existing Chemical Substances

ELINCS = European List of New Chemical Substances

EPA = Environmental Protection Agency

HEPA = High Efficiency Particulate Air (Filter)

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline

IMO = International Maritime Organization

Kow = Octanol/Water Partition Coefficient

LEG = Lilly Exposure Guideline

LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)