



# Nizatidine Capsules

Effective Date: 04-May-2000

Eli Lilly and Company  
Material Safety Data Sheet

## 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:** Nizatidine Capsules

**Chemical Name:** 1,1-Ethenediamine, N-[2-[[[2-[(dimethylamino)methyl]-4-thiazolyl]methyl]thio]ethyl]-N'-methyl-2-nitro-

**Chemical Name 2:** N-[2-[[[2-[(Dimethylamino)methyl]-4-thiazolyl]methyl]thio]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine

**Synonym(s):** Nizatidine Capsule Mix; Nizatidine Formulation; 139037 Formulation; 3144; 3145

**Trademarks(s):** Averati; Averaty; Averity; Nizatt; Nizatto; Naxidine; Bonaxid; Nizaxid; Axid; Acinon; Antizid; Axid AR; Bonacid; Calmaxid; Cronizat; Distaxid; Naxidin; Nizax; Nizid; Panaxid; Tazac; Zanizal

**Lilly Item Code(s):** B01975; CK0895; CK0897; CK0920; CK0921; CK0944; CK0974; ID0620; ND0896; ND0898; ND0904; ND0984; ND1051; PU3143; PU3144; PU3145; QA443K; QA447J; SA0905; SA0916; SA0935; SA0936; SA0953; SA0954; SA0961; UC5401; UC5402; UC5983; UC5984; UC7208; UC7209; UC9529; UC9530; UC9557; UC9558; VF0176; VF0177; VF0219; VF0220; VF0354

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Nizatidine	76963-41-2	45 - 82
Excipients	NA	18 - 55

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


**Exposure Guidelines:** Nizatidine - LEG <100 micrograms/m<sup>3</sup> TWA for 12 hours.

## Section 3 - Hazards Identification

**Appearance:** Capsules containing white to off-white powder

**Physical State:** Solid

**Odor:** Mild sulfur-like

<h2>Emergency Overview</h2> <p><b>Emergency Overview Effective Date:</b> 04-May-2000</p> <p><b>Lilly Laboratory Labeling Codes:</b> Health 2                      Fire 1                      Reactivity 0                      Special A</p> <p><b>Primary Physical and Health Hazards:</b> Not hazardous if intact. Irritant (eyes). Allergen.</p> <p><b>Caution Statement:</b> Intact Nizatidine Capsules are not considered to be a health hazard. The contents of Nizatidine Capsules may be irritating to the eyes and causes allergic reactions.</p>	 <p>Special A = Allergen</p>
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**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Capsules are intended for human consumption under guidance of a physician. Capsules are not considered hazardous under normal handling procedures. Allergic reaction has been reported with occupational exposure to nizatidine, including watery eyes, sneezing, congestion, and shortness of breath. Based on animal studies, nizatidine may be irritating to the eyes.

**Medical Conditions Aggravated by Exposure:** Known sensitization or allergy to nizatidine.

**Carcinogenicity:** Nizatidine - Not listed by IARC, NTP, ACGIH, or OSHA. Not considered carcinogenic in animal studies conducted by Lilly Research Laboratories.

## 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:** Not applicable

**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:** Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). 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.

## Section 7 - Handling and Storage

**Storage Conditions:** Controlled Room Temperature: 15 to 30 C (59 to 86 F). Warehouse: 10 to 40 C (50 to 104 F).

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Filled capsules 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.

**Additional Exposure Precautions:** In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

## Section 9 - Physical and Chemical Properties

**Appearance:** Capsules containing white to off-white powder

**Odor:** Mild sulfur-like

**Boiling Point:** Not applicable

**Melting Point:** No applicable information found

**Specific Gravity:** Not applicable

**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:** Will emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

Data for the active ingredient, nizatidine, are reported.

**Oral:** Nizatidine - Rat, median lethal dose 2109 mg/kg, convulsions, incoordination, tremors, diarrhea, reduced activity.

Monkey, 1200 mg/kg, no deaths or toxicity.

**Skin:** Nizatidine - Rabbit, 200 mg/kg, no deaths or toxicity.

**Inhalation:** Nizatidine - Rat, 1540 mg/m<sup>3</sup> for 4 hours, no deaths.

**Intravenous:** Nizatidine - Monkey, 200 mg/kg, no deaths, reduced activity, tremors, drooping eyelids, vasodilation, and salivation.

**Skin Contact:** Nizatidine - Rabbit, nonirritant

**Eye Contact:** Nizatidine - Rabbit, irritant

### Chronic Exposure

Data for the active ingredient, nizatidine, are reported.

**Target Organ Effects:** Nizatidine - Nervous system effects (reduced activity), heart effects (decreased heart rate), liver effects (liver enzyme changes, increased liver weight), kidney effects (increased kidney weight), digestive effects (reduced gastric acid secretion, nausea/vomiting, diarrhea), eye effects (contraction of pupils).

**Other Effects:** Nizatidine - Decreased body weight gain.

**Reproduction:** Nizatidine - No effects identified in animal studies.

**Sensitization:** No applicable information found.

**Mutagenicity:** Nizatidine - Not mutagenic in bacterial or mammalian cells.

## Section 12 - Ecological Information

Data for the active ingredient, nizatidine, are reported.

**Ecotoxicity Data:** Nizatidine

Rainbow trout 96-hour median lethal concentration: > 988 mg/L

Daphnia magna 48-hour median effective concentration: 2176 mg/L

Green algae (*S. capricornutum*) median effective concentration: > 1074 mg/L (average specific growth rate)

Microorganisms:

fungus (*Chaetomium globosum*): MIC > 1000 mg/L

mold (*Aspergillus flavus*): MIC > 1000 mg/L

soil bacteria (*Comamonas acidovorans*): MIC > 1000 mg/L

N-fixing bacteria (*Azotobacter chroococcum*): MIC > 1000 mg/L

blue-green algae (*Nostoc* sp.): MIC > 1000 mg/L

**Environmental Fate:** Nizatidine

Dissociation constants (pKa): 2.1, 6.52

Log Kow: -2.0, -0.6, -0.4 (pH 5, 7, 9)

Water solubility (g/L): > 100, 46.1, 26.7 (pH 5, 7, 9)

Light absorption (nm): 314 (pH 5, 7, 9)

Molar extinction coefficient (L/mole-cm): 16,546; 16,755; 18,380 (pH 5, 7, 9)

Hydrolysis: none measured after 5 days at 50 C (122 F) (pH 5, 7, and 9)

Aerobic biodegradation: none measured after 29 days

**Environmental Summary:** Nizatidine - Practically nontoxic to fish, invertebrates, green algae, and microorganisms. No volatility expected. Low potential to bioconcentrate in aquatic organisms. Persistence in the aquatic environment not expected due to the potential for photolysis.

## 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

Nizatidine

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

Xn (Harmful)

Xi (Irritant)

#### Risk Phrases

R 36 - Irritating to eyes.

R 42/43 - May cause sensitization by inhalation and skin contact.

#### Safety Phrases

S 36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## Section 16 - Other Information

**MSDS Sections Revised:** Section 1.

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)