SAFETY DATA SHEETS

This SDS packet was issued with item:

078933923

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078933925

LEADING
PHARMA

SAFETY DATA SHEET

Product: Furosemide Tablets USP 20 mg / 40 mg / 80 mg

SECTION 1 — PRODUCT AND COMPANY IDENTIFICATION

Distributed by:
Leading Pharma LLC
3 Oak Road,
Fairfield, NJ 07004
Phone: 973-276-9600
Fax: 973-276-9656

Manufactured by:
Leading Pharma, LLC
3 Oak Road
Fairfield, NJ 07004

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research and manufacture. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SMS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

Material Name: Furosemide Tablets USP 20 mg / 40 mg / 80 mg

Trade Name:	Not Applicable
Chemical Family:	Mixture

SECTION 2 — HAZARDS IDENTIFCATION

Classification in accordance with 29 CFR 1910.1200

Classification of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, furosemide:

Classification: Furosemide is not classified as a hazardous substance

Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, furosemide:

- Signal Word: None required
- Hazard Statement(s): None required
- Symbol(s): None required

Precautionary Statement(s)

- Prevention: None required
- Response: None required
- Storage: None required
- Disposal: None required

Hazards Not Otherwise Classified (HNOC): Not classified

SAFETY DATA SHEET
Product: Furosemide Tablets USP 20 mg / 40 mg / 80 mg

SECTION 3 — COMPOSITION / INFORMATION ON INGREDIENTS

COMPOSITION		
Chemical Name	**Identifiers**	**%**
Furosemide USP-Micronized	CAS: 54-31-9	10% - 30%
Pregelatinized Starch NF (1551)	CAS: 9057-07-2	2% - 10%
Sodium Starch Glycolate NF	CAS: 9063-38-1	1% - 5%
Corn Starch NF (Purity 826)	CAS: 9005-25-8	5% - 15%
Microcrystalline Cellulose, NF (102)	CAS: 9004-34-6	2% - 10%
Lactose Anhydrous, NF (DT)	CAS: 63-42-3	45% - 65%
Colloidal Silicon Dioxide, NF	CAS: 7631-86-9	<2%
Magnesium Stearate, NF	CAS: 557-04-0	<2%

SECTION 4 — FIRST AID MEASURES

First Aid Procedures:

Eye contact: In case of contact with dust from broken tab lets, immediately flush eyes with plenty of water for at least 1 5 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with broken tablets, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If dust from broken tablets is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

Most important symptoms and effects, both acute and delayed:

Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, arrhythmia, or gastrointestinal disturbances such as nausea and vomiting

Indication of any immediate medical attention and special treatment needed:

- Treat symptomatically and supportively

SECTION 5 — FIREFIGHTING MEASURES

Extinguishing Media:

Suitable extinguishing media: All means water, carbon dioxide, foam or dry chemical

Unsuitable Extinguishing Media: Strong water jet

Specific hazards arising from the chemical:

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

Special Protective Equipment and Precautions for Fire-fighters:

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire- control water for later disposal.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn if significant dust emissions are generated from broken or crushed tablets or capsules.

Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

Methods for containment:

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom.

Methods for clean-up:

Place material in suitable container for disposal. Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

SECTION 7 — HANDLING AND STORAGE

Precautions for Safe Handling:

Use with adequate ventilation. Avoid breathing dust if tablets are crushed or spilled. Do not get dust in eyes or on skin. Wash thoroughly after handling.

Conditions for Safe Storage:

Store at 25° C (77° F). Keep container tightly closed. Protect from light. Store in a cool, well- ventilated area.

SECTION 8 — EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

Leading Pharma occupational exposure limit, furosemide: 0.2 mg/m^3, 8-hour TWA.

Appropriate Engineering Controls:

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

Individual Protection Measures:

Eye/face protection:	Safety glasses or safety goggles should be worn if there is a potential for dust exposure from broken or crushed tablets.
Skin protection:	Suitable protective gloves should be worn if handling the unfinished product or broken or crushed tablets.
Respiratory protection:	None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations or from broken or crushed tablets.
General hygiene considerations:	Suitable work clothes. Wash hands before breaks and at the end of the work shift.

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: White round scored tablets
- Odor: No data available

- Odor threshold: No data available
- pH (furosemide): 5 at 21°C (suspension in water) Melting point (furosemide): 204 - 206 °C
- Initial boiling point /boiling point range.Not applicable.
- Flash point: Not applicable
- Evaporation rate: Not applicable.
- Flammability: No data available
- Upper /lower flammability or explosive limits: No data available
- Vapor pressure: Not applicable
- Vapor density: Not applicable. Relative density: No data available
- Solubility (furosemide): Virtually insoluble in water
- Partition coefficient: n-octanol/water (furosemide): Log Kow = 2.3 (experimental)
- Auto-ignition temperature (furosemide): from 200 - 300 °C
- Decomposition temperature (furosemide): from 200 °C Viscosity: No data available

SECTION 10 — STABILITY AND REACTIVITY

Reactivity:

Not a reactive material under normal handling conditions.

Chemical Stability:

Stable under normal handling conditions

Possibility of hazardous reactions:

None known

Conditions to Avoid:

Keep away from heat, sparks and flames

Incompatible materials:

Strong oxidizing and reducing agents.

Hazardous decomposition products:

Carbon monoxide, carbon dioxide, oxides of sulfur and nitrogen.

SECTION 11 — TOXICOLOGICAL INFORMATION

The following information is for the active ingredient furosemide unless otherwise noted:

Information on likely routes of exposure:

- Exposure not expected under normal use. Dust from broken or crushed tablets could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics:

- Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, arrhythmia, or gastrointestinal disturbances such as nausea and vomiting.

Effects of short-term (acute) exposure:

- Dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia and hypochloremic alkalosis, which are extensions of its diuretic action.

Effects of long-term (chronic) exposure:

- Dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia and hypochloremic alkalosis, which are extensions of its diuretic action.

Acute toxicity (LD50):

- Oral route, rat: 2,600 mg /kg
- Oral route, mouse: 2,000 mg/kg

Skin corrosion/irritation:

- Not a skin irritant

Serious eye damage /irritation:

- Not an eye irritant

Sensitization:

- Not determined

Specific target organ toxicity - single exposure (STOT-SE):

- Not determined

Specific target organ toxicity- repeated exposure (STOT-RE):

- Not determined

Carcinogenicity:

- Furosemide was tested for carcinogenicity by oral administration in one strain of mice and one strain of rats. A small but significantly increased incidence of mammary gland carcinomas occurred in female mice at a dose 17.5 times the maximum human dose of 600 mg.
- There were marginal increases in uncommon tumors in male rats at a dose of 15 mg /kg (slightly greater than the maximum human dose) but not at 30 mg/kg.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity:

- Furosemide has been shown to cause unexplained maternal deaths and abortions in rabbits at 2, 4 and 8 times the maximal recommended human dose. Produced no impairment of fertility in male or female rats, at 100 mg /kg/day.

Mutagenicity:

- No experimental advice for genotoxicity in vivo. Not mutagenic in Ames Test.

Aspiration hazard:

- Not applicable.

SECTION 12— ECOLOGICAL INFORMATION

The following information is for the active ingredient furosemide unless otherwise noted:

Ecotoxicity:

Fish toxicity (LC50): > 500 mg /1
Species: golden orfe
Exposure duration: 96 h
Method: OECD 203

Chronic aquatic toxicity: not determined

Toxicity on invertebrates (EC50): > 100 mg / 1
Species: Daphnia magna
Exposure duration: 48 h
Method: OECD 202

Toxicity on invertebrates (Chronic toxicity): not determined

Algae toxicity (EC50): 322.21 mg/1
Species: Desmodesmus subspicatus
Exposure duration: 72 h
Method: OECD 201

Bacteria toxicity (ECO): approx. 1,000 mg/1

Persistence and degradability:

Biological degradability: < 10 %, not readily degradable
Testing period: 15 days

Bio accumulative potential:

No data available.

Mobility in soil:

No data available.

Other adverse effects:

No data available.

SECTION 13 — DISPOSAL CONSIDERATIONS

Disposal of product waste:

Disposal should be in accordance with applicable reg ion al, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Disposal of packaging waste:

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

SECTION 14 — TRANSPORT INFORMATION

Basic shipping information, finished product:

U.S. DOT	Not a regulated material
ICAO / IATA	Not a regulated material
IMDG	Not a regulated material

SECTION 15— REGULATORY INFORMATION

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4):

Not listed

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):

Not listed

Clean Air Act (CAA) Section 1 12(r) Accidental Release Prevention (40 CFR 68.13 0):

Not listed

SARA Title III:

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):

Not listed.

Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations:

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

Not listed

Massachusetts Right-To-Know List:

Not listed

New Jersey Right-To-Know List:

Not listed

Pennsylvania Right-To-Know List:

Not listed

SECTION 16— OTHER INFORMATION

Other Information:

The information contained herein is based upon data considered true and accurate. Leading Pharma, LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein.
This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms:

CAS: Chemical Abstracts Service
DOT: U.S. Department of Transportation
EST: Eastern standard time (U.S.)
IATA: International Air Transport Association
IMDG: International Maritime Dangerous Goods Code
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
OEL: Occupational Exposure Limit PPE: Personal Protection Equipment
SDS: Safety Data Sheet
STEL: Short-term exposure limit
TWA: Time-weighted average
U.S.: United States