

MATERIAL SAFETY DATA SHEET

SECTION: 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY

COMPANY ADDRESS EMERGENCY TELEPHONE NUMBERS:

Manufacturer address:

GRAVITI PHARMACEUTICALS PVT. LTD

Plot No. 621/E, 621/EE, Isnapur village
Patancheru Mandal, Sangareddy (District)
Telangana- 502302

Emergency Telephone number +91 8455 248500

Fax: +91 8455 248500

Distributor address

Rising Pharma Holdings, Inc

East Brunswick, NJ 08816,
USA.

PRODUCT NAME: Furosemide Tablets USP 20 mg, 40 mg and 80 mg

CHEMICAL**NAME:**

Furosemide USP

PRODUCT USE: Pharmaceutical product used Treatment of edema associated with congestive heart failure, cirrhosis of the liver, an renal disease

SECTION- 2 HAZARDS IDENTIFICATION

Appearance: 20 mg: White, oval, biconvex tablets debossed with “16” on one side and plain on other side.

40 mg: White, round, flat face, beveled edge scored tablets debossed with “17” on one side and plain on other side.

80 mg: White, round, flat face, facettted edge scored tablets debossed with “19” on one side and plain on other side.

Explosion: Product does not present an explosion hazard.

Health: This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

SECTION-3: COMPOSITION/INFORMATION ON INGREDIENTS

Furosemide USP [#]	54-31-9
Lactose monohydrate USP-NF (Pharmatose 200 M)*	10039-26-6
Corn starch USP-NF (Purity 21A)	9005-25-8
Pregelatinized Starch (Partially pregelatinized maize starch)USP-NF (Starch 1500)	977050-93-3
Talc USP (Luzenac Pharma)	14807-96-6

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Colloidal silicon dioxide USP-NF
(Aerosil® 200 Pharma)
Magnesium stearate USP-NF
(Ligamed- MF-2V)

7631-86-9

557-04-0

SECTION-4: FIRST AID MEASURES

Eye Contact:	Rinse with water. Get medical attention if irritation develops and persists.
Skin Contact:	Wash off with soap and water. Get medical attention if irritation develops and persists.
Ingestion:	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately.
Inhalation:	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist
Protection of First-aiders:	Use personal protective equipment

SECTION-5: FIRE FIGHTING MEASURES

Special Exposure Hazards:	Use carbon dioxide, dry chemical, or water spray. Use fire extinguishing media appropriate for surrounding materials.
Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray. Use fire extinguishing media appropriate for surrounding materials.
<u>Advice for fire fighters</u>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. Use water spray to cool unopened containers. Use standard firefighting procedures and consider the hazards of other involved materials
Protective Equipment and Precautions for Firefighters:	

SECTION-6: ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited however; the following guidance may be used as needed.

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Protective equipment:	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection
Methods for Cleaning Up:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed

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Environmental Precautions:

to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the clean-up of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide.

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. Avoid discharge into drains, water courses or onto the ground.

SECTION-7: HANDLING AND STORAGE

Precautions for safe handling

Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities:

Store at Controlled Room Temperature: 20° to 25° C (68° to 77° F).
Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

Specific end use(s) Recommended use:

Pharmaceuticals

SECTION-8: EXPOSURES AND CONTROLS

Exposure Controls

Engineering controls:

General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

Respiratory Protection:

Use suitable respiratory protective device in case of insufficient ventilation.
If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Eyes protection:

Wear safety glasses or goggles if eye contact is possible

Gloves:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations- preferred, Maintain eyewash facilities in the work area.

Environmental Exposure Controls:

Not determined

SECTION-9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid	Odour Threshold: No data available
Odour: Not determined	Vapor Pressure (mm Hg): Not determined
Melting/Freezing Point (°C): Not determined	Vapor Density (Air = 1): Not determined
Lower Explosive Limit: Not determined	Specific Gravity: Not determined
Upper Explosive Limit: Not determined	Partition coefficient: n-octanol/water: Not determined
Molecular Formula: No data available	Autoignition Temp. (°C): Not determined
Solvent Solubility: Not determined	Decomposition temperature (°C): Not determined
Water Solubility: Not determined	Viscosity (centipoise): Not determined
pH: Not determined	Explosion Severity: Not determined
Boiling Point (°C): Not determined	Oxidizer Properties: Not determined

SECTION-10: STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	No dangerous reaction known under conditions of normal use.
Conditions to avoid:	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible materials:	Strong oxidizing agents
Hazardous decomposition products:	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x), Sulfur oxides

SECTION-11: TOXICOLOGICAL INFORMATION

Routes of Exposure: Oral: Clinical Route,
Dermal: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate skin.
Inhalation: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation
Acute toxicity:
 May be harmful if swallowed in large quantities. Product is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion.
 LD50 and LC50 data: Furosemide Rat Oral LD50 > 2600mg/kg
Skin corrosion/irritation: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate skin.
Serious eye damage/irritation: Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes

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Respiratory or skin sensitization: Not a respiratory sensitizer.

Germ cell mutagenicity: The product contains a substance which has demonstrated animal effects of mutagenicity.

Teratogenicity: Not available

Carcinogenicity: This product is not considered to be a carcinogen by NTP, IARC, or OSHA.

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Reproductive toxicity: Because there are no adequate and well-controlled studies in pregnant women, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women

This product passes into breast milk. Breast-feeding is not advised in mothers being treated.

Aspiration hazard: Not classified

Information on toxicological effects - ingredient(s)

SECTION-12: ECOLOGICAL INFORMATION

Ecotoxicity: Do not empty into drains.

Persistence and Degradability: No information available Bioaccumulation/ Accumulation No information available.

Mobility: No information available

SECTION-13: DISPOSAL CONSIDERATIONS

Waste disposal recommendations:	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations. The waste code should be assigned in discussion between the user, the producer and the waste disposal company
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

SECTION-14: TRANSPORTATION INFORMATION

IATA/ICAO- Not Regulated

IMDG - Not Regulated

DOT - Not Regulated

IMO – Not Regulated

SECTION-15: REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.

USA

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Furosemide	54-31-9	-	-	-

SECTION-16: OTHER INFORMATION

Graviti Pharmaceuticals Pvt Ltd believes that the information contained in this Material Safety DataSheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Graviti shall not be held liable for any damage resulting from handling or from contact with the above product. Graviti reserves the right to revise this MSDS