LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Bumetanide Injection**
Manufacturer	**Lupin Limited** Nagpur - 441108 Maharashtra, India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	Information on the absorption of this product via inhalation or skin contact is not available.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Composition:

Name	CAS No.
Bumetanide Injection	**28395-03-1**
Benzyl Alcohol	**100-51-6**
Sodium chloride	**7647-14-5**
Ammonium Acetate IH	**631-61-8**
Edetate disodium dihydrate USP	**6381-92-6**
Sodium Hydroxide NF	**1310-73-2**

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

General advice	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.
Eye contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Section 5: Fire-Fighting Measures

Flammability	None anticipated for this aqueous product.
Fire and Explosion Hazard	None anticipated for this aqueous product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire fighting procedure	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6: Accidental Release Measures

Spill cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Section 7: Handling and Storage

Precautions for safe handling:	No special handling required under conditions of normal product use.
Storage :	Store at 20 to 25°C (68 - 77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature]. Protect from light.
Special Precautions	No special precautions required for Hazard control.

Section 8: Exposure Controls/Personal Protection

Protective Measures	Not generally required. The use of personal protective equipment may be necessary as conditions warrant. Dust formation: dust mask. Gloves. Protective clothing. Protective goggles.
Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye Protection	Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eyes	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED	**Bumetanide Injection** Bumetanide injection USP 0.25mg/ml is sterile, clear , colourless to slightly yellow solution free from visible particulate matter supplied in amber vials. As follows 4ml single dose vial packaged in 10s (NDC 70748 -323-10) 10ml Multiple dose vial packaged in 10s (NDC 70748 -323-11) This container closure is not made with natural rubber latex. Store at 20 to 25°C (68 - 77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature]. Protect from light.

Appearance / Physical State	: Solid
Color	: Clear , Colorless to slightly yellow solution
Odor	: NA
Odor Threshold	: NA
pH	: 7.0
Melting Point / Freezing Point	: NA
Initial Boiling Point / Boiling Point	: NA
Evaporation Rate	: NA
Flammability (Solid, Gas)	: NA
Upper/Lower Flammability	:NA
Explosive Limit	: NA
Vapor Pressure	: NA

Vapor Density	: NA
Specific Gravity	: NA
Solubility	: Bumetanide is slightly soluble in water; soluble in alkaline solution.
Partition coefficient	: n-octonal /water : NA
Auto Ignition Temperature	: NA
Decomposition Temperature	: NA

Section 10: Stability and Reactivity

Reactivity	Not determined
Chemical stability	Stable under standard use and storage conditions.
Possibility of hazardous reactions	Not determined.
Condition to avoid	Not determined.
Incompatible Material	Not determined.
Hazardous decomposition products :	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization :	Not anticipated to occur with this product.

Section 11: Toxicological Information

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Bumetanide LD50 Oral >6000 , 4624, 350 mg/kg Rat,Mouse,Rabit

Benzyl Alcohol LD50 Oral 1040-2500 mg/kg Rat,Mouse,Rabit,Gunia Pig

Aspiration Hazard	**:** None anticipated from normal handling of this product
Skin Corrosion/Skin Irritation	**:** None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	**:** None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation.
Respiratory/ Skin Sensitization	**:** None anticipated from normal handling of this product. In clinical use, patients allergic to sulfonamides may show hypersensitivity to bumetanide.
Mutagenicity	: Bumetanide was not mutagenic in various strains of Salmonella typhimurium when tested in the presence or absence of an in vitro metabolic activation system.
Carcinogenicity	**:** An 18-month study showed an increase in mammary adenomas of questionable significance in female rats receiving oral dosages of 60 mg/kg/day (2000 times a 2 mg human dose). A repeat study at the same doses failed to duplicate this finding.
Specific Target Organ Toxicity	**:** Based on clinical use, possible target organs include the kidneys, cardiovascular system, and ears (hearing). In cats, dogs, and guinea pigs, bumetanide has been shown to produce ototoxicity. In these test animals bumetanide was 5 to 6 times more potent than furosemide and, since the diuretic potency of bumetanide is about 40 to 60 times furosemide, it is anticipated that blood levels necessary to produce ototoxicity in patients will rarely be achieved.

Section 12: Ecological Information

Acute Toxicity	**:** Not determined for product
Persistence and biodegradability	**:** Not determined for product.
Bioaccumulation	**:** Not determined for product.
Mobility in Soil	**:** Not determined for product.

Section 13: Disposal Considerations

Waste Disposal : All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements

Container Handling and Disposal : Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

No information available.

Section 16: Other Information

Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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