



### **SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	<b>Furosemide Injection USP, 20 mg/2 mL, 40 mg/4 mL and 100 mg/10 mL (10 mg/mL)</b>
<b>Recommended Use</b>	Pharmaceutical product used as loop diuretic
<b>Manufacturer</b>	<b>Aspiro Pharma Limited,</b> Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.,</b> Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Hazard statements</b>	Suspected of damaging the unborn child
<b>Precautionary Statements</b>	Obtain special instructions before use Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required IF exposed or concerned: Get medical attention/advice Store locked up. Dispose of contents/container in accordance with all local and national regulations
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	<b>CAS</b>
Furosemide	54-31-9
Hydrochloric acid	7647-01-0
Sodium Hydroxide	1310-73-2
Nitrogen NF	7727-37-9
Sodium Chloride USP	7647-14-5
Section 4: First-Aid Measures	
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately



## Section 5: Fire-Fighting Measures

<b>Extinguishing Media</b>	Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water.
<b>Special Hazards Arising from the Substance or Mixture</b>	
<b>Hazardous Combustion Products</b>	May include oxides of nitrogen and sulfur and products of chlorine
<b>Fire / Explosion Hazards</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Advice for Fire-Fighters:</b> During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus	

## Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release
<b>Methods and Material for Containment and Cleaning Up</b>	
<b>Measures for Cleaning /Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## Section 7: Handling and Storage

<b>Precautions for Safe Handling</b> Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls	
<b>Conditions for Safe Storage, Including any Incompatibilities</b>	
<b>Storage Conditions</b>	Store as directed by product packaging.
<b>Specific end use(s):</b>	Pharmaceutical drug product

## Section 8: Exposure Controls/Personal Protection

<b>Engineering Controls</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for



	assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
<b>Hands</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
<b>Respiratory protection</b>	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

## Section 9: Physical and Chemical Properties

<b>Physical Form</b>	Injection
<b>Colour</b>	A Clear colour less solution
<b>Description</b>	<p><b>Furosemide Injection, USP (10 mg/mL)</b></p> <p>2 mL single dose amber colored vials Boxes of 25 NDC 31722-309-32</p> <p>4 mL single dose amber colored vials Boxes of 25 NDC 31722-310-32</p> <p>10 mL single dose amber colored vials Boxes of 25 NDC 31722-311-31</p> <p>Do not use if solution is discolored.</p> <p>Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) [see USP Controlled Room Temperature]</p> <p>Protect from light.</p>

## Section 10: Stability and Reactivity

<b>Reactivity</b>	No data available
<b>Chemical stability</b>	Stable at normal conditions



Possibility of Hazardous Reactions	
<b>Oxidizing Properties</b>	No data available
<b>Conditions to Avoid</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products</b>	No data available
Section 11: Toxicological Information	
<b>Information on Toxicological Effects Short Term</b>	Ingestion may cause lowering of blood pressure. Accidental or incidental ingestion of large amounts may cause nausea, abdominal discomfort, headache or dizziness. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.
<b><u>Acute Toxicity: (Species, Route, End Point, Dose)</u></b> <b>Furosemide</b> Rat Oral LD 50 2600 mg/kg Mouse Sub-tenon injection (eye) Minimum Symptomatic Dose 400mg/kg <b>HYDROCHLORIC ACID</b> Rat Oral LD 50 238-277 mg/kg	
<b><u>Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)</u></b> <b>Furosemide</b> 13 Week(s) Rat Oral 300 mg/kg LOAEL 13 Week(s) Mouse Oral 600 mg/kg LOAEL 6 Month(s) Dog Oral 10 mg/kg/day LOAEL 2 Year(s) Rat Oral 30 mg/kg/day LOAEL	
<b><u>Reproduction &amp; Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))</u></b> <b>Furosemide</b> Reproductive & Fertility Rat Oral 2.9 mg/kg/day LOAEL Fertility Embryo / Fetal Development Rabbit Oral 25 mg/kg LOAEL Maternal Toxicity, Fetotoxicity Embryo / Fetal Development Rat Oral 12.5 mg/kg/day LOAEL Teratogenic Embryo / Fetal Development Mouse Oral 1250 mg/kg/day LOAEL Fetotoxicity, Teratogenic	
<b><u>Genetic Toxicity: (Study Type, Cell Type/Organism, Result)</u></b> <b>Furosemide</b> Bacterial Mutagenicity (Ames) Negative In Vitro Micronucleus Human Lymphocytes Positive Mammalian Cell Mutagenicity Mouse Lymphoma Positive	
<b>HYDROCHLORIC ACID</b> Bacterial Mutagenicity (Ames) Salmonella Negative In Vivo Micronucleus Rat Negative	
<b><u>Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u></b> <b>Furosemide</b> 2 Year(s) Male Rat Oral 15 mg/kg/day LOEL Tumors 104 Month(s) Female Mouse Oral 17.5 LOEL Tumors 2 Year(s) Female Rat Oral, in feed 700 ppm NOEL Not carcinogenic 104 Month(s) Male Mouse Oral, in feed 1400 ppm NOEL Not carcinogenic	



Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA

**Furosemide**

IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

**Section 12: Ecological Information**

<b>Environmental Overview</b>	Environmental properties have not been thoroughly investigated
<b>Toxicity</b>	No data available
<b>Persistence and Degradability</b>	No data available
<b>Bio-accumulative Potential</b>	No data available
<b>Mobility in Soil</b>	No data available

**Section 13: Disposal Considerations**

<b>Waste Treatment Methods</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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**Section 14: Transport Information**

**The following refers to all modes of transportation unless specified below.**  
This material is not regulated for transportation / carriage.

**Section 15: Regulatory Information**

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Furosemide**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-203-6



#### Section 16: Other Information

**Issue Date : 19-01-2026**

**Version : 01**

**Further information**

**Revision date: 19-01-2026**

**Revision note:** 1. Typo error corrected in Recommended Use.

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

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