

| Document Type:    |
|-------------------|
| Safety Data Sheet |
| Effective Date:   |

12 JAN 2024

Furosemide Injection, USP

SDS No.: SDS009 Revision No: **01** 

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**Section 1 - Identification** 

(a) **Product Identifier:** Furosemide Injection

**(b) NDC:** 83634-302

Common/Trade Name: Furosemide Injection, LASIX®

Chemical Name: 4-chloro-N-furfuryl-5-sulfamoylanthranilic acid

**Chemical Family:** Diuretic

(c) **Product Use:** Treatment of edema associated with congestive heart failure,

cirrhosis of the liver, and renal disease, including the

nephrotic syndrome.

**Product Type:** Regulated Prescription Drug

Container Information: Vial

(d) Distributor: Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL

60173, 847-773-4901

(e) Emergency Telephone: 855-283-6229

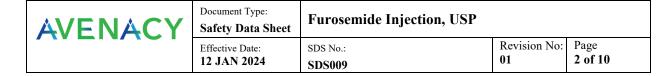
### **Section 2 - Hazards Identification**

Emergency Overview: Furosemide Injection is a solution containing furosemide, a loop diuretic with a rapid onset of action. It is used in the treatment of edema associated with heart failure, including pulmonary edema, with renal and hepatic disorders, and to treat hypertension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the gastrointestinal system, nervous system, blood and kidneys.

(a) Classification: U.S. OSHA GHS Classification

|                       | Hazard Class   | Hazard Category |
|-----------------------|----------------|-----------------|
| Physical Hazards      | Not classified | Not classified  |
| <b>Health Hazards</b> | STOT-RE        | 2               |

| (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards: |
|---|-----------------------------|
|   | Signal Word: Warning        |



| (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards:  |
|---|--|
| <u>Hazard Statements:</u>   | May cause damage to organs through   |
|   | prolonged or repeated exposure   |
| Precautionary Statements:   | Prevention   |
|   | Do not breathe vapor or spray.   |
|   | Wash hands thoroughly after handling.  |
|   | Response   |
|   | Get medical attention if you feel unwell.  |
|   | IF IN EYES: Rinse cautiously with water for several minutes.   |
|   | Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. |

# **Section 3 – Composition / Information on Ingredients**

| (a) Chemical Name        | (b) Common Name /<br>Synonym | %<br>Compositionor<br>other measure | (c) CAS No. | (d) Impurities /<br>Stabilizing<br>Additives |
|--------------------------|------------------------------|-------------------------------------|-------------|--|
| Furosemide USP           | Furosemide                   | 10.0 mg/mL                          | 54-31-9     | N/A  |
| Sodium chloride          | Sodium Chloride              | 7.5 mg/mL                           | 7647-14-5   | N/A  |
| Sodium hydroxide         | Sodium hydroxide             | q.s. to pH                          | 1310-73-2   | N/A  |
| Hydrochloric Acid        | Hydrochloric Acid            | q.s. to pH                          | 7647-01-0   | N/A  |
| Water for Injection, USP | Water for Injection,<br>USP  | q.s. to 1mL                         | 7732-18-5   | N/A  |
| Nitrogen                 | Nitrogen                     | q.s.                                | 7727-37-9   | N/A  |

### **Section 4 - First Aid Measures**

**Eye Exposure:** 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 Exposure:** Remove from source of exposure. Flush with copious

amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/



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supportive care as necessary.

**Ingestion:** Remove from source of exposure. If 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.

**Notes to Physician:** See patient package insert in shipping carton for complete

information.

## **Section 5 – Fire-fighting Measures**

(a) Extinguishing Media As with any fire, use extinguishing media appropriate for

primary cause of fire such as carbon dioxide, dry chemical

extinguishing powder or foam.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to

do so. Evacuate area.

(b) Hazardous Nitrogen oxides (NOx)

Combustion Carbon oxides
Products: Sulfur oxides

Chlorine compounds

(c) Special Protective

Equipment /
Precautions:

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**

Personal precautions, protective equipment andemergency procedures:

**Spill Cleanup and Disposal**: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control 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.

Release to Air: Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or oil

barriers).

Retain and dispose of contaminated wash water.



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Local authorities should be advised if significant spillages cannot be contained.

Release to Water: Prev

Prevent further leakage or spillage if safe to do so. Do not let

productenter drains.

### **Section 7 - Handling and Storage**

**General Handling:** 

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

**Hygiene Measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

When using do not eat, drink or smoke.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment,

appropriate degowning and decontamination procedures, industrial

hygiene monitoring, medical surveillance and the use of

administrative controls.

**Storage Conditions:** 

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room

Temperature.]

Do not store with strong oxidizing agents, organic peroxides,

explosives, or gasses.

# **Section 8 - Exposure Controls / Personal Protection**

# (a) Exposure Limits

| Compound   | Issuer | Type | Exposure Limit |
|------------|--------|------|----------------|
| Furosemide | OSHA   | PEL  | NE             |
|            | ACGIH  | TLV  | NE             |
|            | AIHA   | WEEL |                |

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### **Notes:**

OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

AIHA WEEL: Workplace Environmental Exposure Level

## (b) Engineering Controls

Engineering controls are normally not needed during the normal use of this product

# (c) Individual Protection Measures

| Respiratory Protection:     | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
|-----------------------------|--|
| Eye Protection:             | Safety goggles with side-shields or goggles.   |
| Skin Protection:            | Impervious clothing, uniform, or lab coat.   |
| Other Protective Equipment: | Chemical resistant gloves.   |

# **Section 9 - Physical and Chemical Properties**

| (a)        | Appearance                                   | Clear colorless, aqueous solution                            |
|------------|--|--|
| (b)        | Odor   | N/A  |
| (c)        | Odor Threshold                               | N/A  |
| (d)        | рН   | 8.0 - 9.3  |
| (e)        | Melting Point:                               | N/A  |
| (f)        | Initial Boiling Point:                       | N/A  |
| (g)        | Flash Point                                  | N/A  |
| (h)        | Evaporation Rate:                            | N/A  |
| (i)        | Flammability                                 | N/A  |
| <b>(j)</b> | Upper Lower Flammability or Explosion Limits | N/A  |
| (k)        | Vapor Pressure:                              | N/A  |
| <b>(l)</b> | Vapor Density:                               | N/A  |
| (m)        | Relative Density                             | N/A  |
| (n)        | Solubility(ies)                              | Practically insoluble in water, sparingly soluble in alcohol |
| <b>(0)</b> | Partition Coefficient: n-octanol/water       | N/A  |

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| <b>(p)</b> | Auto-ignition Temperature | N/A |
|------------|---------------------------|-----|
| (q)        | Decomposition Temperature | N/A |
| (r)        | Viscosity                 | N/A |

# Section 10 - Stability and Reactivity

| (a)        | Reactivity                              | Not classified as a reactivity hazard                   |
|------------|---|---|
| (b)        | Chemical Stability                      | Stable under standard use and storage conditions.       |
| (c)        | Possibility of Hazardous Reactions      | Can react with strong oxidizers.                        |
| (d)        | Conditions to Avoid                     | Strong oxidants.  |
| (e)        | Incompatible Materials                  | Strong acids/alkalis, strong oxidizing/reducing agents. |
| <b>(f)</b> | <b>Hazardous Decomposition Products</b> | No hazardous decomposition products are known.          |

# **Section 11 Toxicological Information**

| (a) | Likely Routes of Exposure  | Ingestion, Inhalation, skin, eye   |
|-----|--|--|
| (b) | Symptoms related to the physical, chemical and toxicological                             | None anticipated from normal handling of this product.   |
| (c) | Delayed and immediate effects and also chronic effects from short and long term exposure | Reproductive Effects  None anticipated from normal handling of this product. Furosemide produced no impairment of fertility in male or female rats, at 100 mg/kg/day (the maximum effective diuretic dose in the rat and 8 times the maximal human dose of 600 mg/day).  Mutagenicity  Furosemide was devoid of mutagenic activity in various strains of Salmonella typhimurium when tested in the presence or absence of an in vitro metabolic activation system, and questionably positive for gene mutation in mouse lymphoma cells in the presence of rat liver S9 at the highest dose tested. Furosemide did not induce sister chromatid exchange in human cells in vitro, but other studies on chromosomal aberrations in human cells in vitro gave conflicting results. In Chinese hamster cells it induced chromosomal damage but was questionably positive for sister chromatid |

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|                |                                  | exchange. Studies on the inconformosomal aberrations in The urine of rats treated with gene conversion in Sacchard Carcinogenicity Furosemide was tested for cadministration in one strain rats. A small but significantly mammary gland carcinomas at a dose 17.5 times the max | mice were incontinuous did<br>omyces cerevis<br>arcinogenicity<br>of mice and on<br>y increased incoccurred in fe | onclusive. not induce iae. by oral e strain of cidence of male mice |

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## (d) Acute Toxicity

Product formulation is not classified based on available information. Information for the active ingredient is as follows:

mg/kg.

mg. There were marginal increases in uncommon tumors in male rats at a dosage of 15 mg/kg (slightly greater than the maximum human dose) but not at 30

| Ingredient | Percent | Test Type | Route       | Value      | Species |
|------------|---------|-----------|-------------|------------|---------|
| Furosemide | 100     | LD50      | Oral        | 2600 mg/kg | Rat     |
|            |         |           |             | 2000 mg/kg | Mouse   |
|            |         |           |             | 800 mg/kg  | Rabbit  |
|            |         |           |             | 2000 mg/kg | Dog     |
| Furosemide | 100     | LD50      | Intravenous | 800        | Rat     |
|            |         |           |             | 308        | Mouse   |
|            |         |           |             | 400        | Rabbit  |
|            |         |           |             | >400       | Dog     |

### (e) Hazardous Chemical Listings

**NTP**: Not Listed **IARC**: Group 3 – Not classifiable **OSHA**: Not Listed as to carcinogenicity to humans

# **Section 12 - Ecological Information**

| (a)        | Ecotoxicity                   | No applicable ecological information found. |
|------------|-------------------------------|---|
| <b>(b)</b> | Persistence and degradability | No applicable ecological information found. |
| (c)        | Bioaccumulative potential     | No applicable ecological information found. |
| (d)        | Mobility in soil              | No applicable ecological information found. |
| (e)        | Other Adverse Effects         | No applicable ecological information found. |



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## **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.

### **Contaminated packaging**

Dispose of container and unused product in accordance with federal, state, and local regulations.

### **Section 14 - Transport Information**

| (a)        | UN Number  | N/A |
|------------|--|-----|
| (b)        | <b>UN Proper Shipping Name</b>   | N/A |
| (c)        | Transport Hazard Class(es)   | N/A |
| (d)        | Packing Group  | N/A |
| (e)        | Environmental Hazards  | N/A |
| <b>(f)</b> | Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code) | N/A |
| (g)        | <b>Special Precautions</b>   | N/A |

**DOT:** Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated IMDG: Not Regulated

### **Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Avenacy 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**:

TSCA – Exempt CERCLA - Not on this list SARA 313 - Not on this list SARA 302 – Not on this list RCRA listed – Not listed US PROP 65 (Calif.) – Not listed



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#### **Section 16 - Other Information**

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 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:

Avenacy 10 N. Martingale Road, Suite 225 Schaumburg, IL 60173 847-773-4901

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

| ACGIH      | American Conference of Governmental Industrial Hygienists               |
|------------|---|
| AICS       | Australian Inventory of Chemical Substances                             |
| AIHA       | American Industrial Hygiene Association                                 |
| ANSI       | American National Standards Institute                                   |
| 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  |
| DSL        | Domestic Substances List  |
| ECHA       | European Chemicals Agency   |
| EINECS     | European Inventory of Existing Commercial Chemical Substances           |
| ELINCS     | European List of Notified Chemical Substances                           |
| EPA        | Environmental Protection Agency   |
| GHS        | Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA       | High Efficiency Particulate Air (Filter)                                |
| HMIS       | Hazardous Materials Identification System                               |
| IARC       | International Agency for Research on Cancer                             |
| ICAO/IATA  | International Civil Aviation Organization/International Air Transport   |
|            | Association   |
| IMO        | International Maritime Organization                                     |
|            |   |
| KOW        | Octanol/Water Partition Coefficient                                     |



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|       | 32300   |
|-------|---|
| 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 |
| NE    | Not Established   |
| NADA  | New Animal Drug Application                                   |
| NAIF  | No Applicable Information Found                               |
| NCI   | National Cancer Institute                                     |
| NDSL  | Non-Domestic Substances List                                  |
| NFPA  | National Fire Protection Association                          |
| NIOSH | National Institute for Occupational Safety and Health         |
| NPDES | National Pollutant Discharge Elimination System               |
| NOS   | Not Otherwise Specified                                       |
| NTP   | National Toxicology Program                                   |
| OSHA  | Occupational Safety and Health Administration                 |
| OEL   | Occupational Exposure Limit                                   |
| 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                  |
| SDS   | Safety Data Sheet   |
| 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  |
| USP   | United States Pharmacopeia                                    |
| WEEL  | Workplace Environmental Exposure Level (AIHA)                 |
| WHMIS | Workplace Hazardous Materials Information System              |