Safety Data Sheet

Claris Lifesciences Inc.

SDS No. CLI/SDS/FUR/01/00

FUROSEMIDE INJECTION, USP 10 mg/mL

1. PRODUCT IDENTIFICATION

Common/Trade Name:	**Furosemide Injection, USP**
How Supplied: 2,4 & 10 mL in amber glass vial	**Strength:** 10 mg/mL
Chemical Class	Anthranilic acid derivative
Chemical Name	Benzoic acid, 5-(aminosulfonyl)-4-chloro-2- [(2-furanylmethyl) amino]-. 4-Chloro-N-furfuryl-5-sulfamoylanthranilic acid
Formula	$C_{12}H_{11}ClN_2O_5S$
Product Type	Prescription Drug
Product Use	Pharmaceutical, Injectable
Distributor Name	CLARIS LIFESCIENCES INC.
Distributor Address	1445 US HIGHWAY 130, North Brusnwick, NJ 08902
Manufacturer's Name	CLARIS INJECTABLES LIMITED
Address	CHACHARWADI- VASANA, AHMEDABAD - 382 213, INDIA.
Telephone Number For Information/ Medical Emergency	**1-877-7CLARIS (1-877-725-2747)**
Date Prepared	22 April, 2016

2. HAZARDOUS IDENTIFICATION

Appearance / Odor
Clear, colorless to slightly yellow, odorless solution.

Skin, eye and respiratory irritant
Causes slight irritation of the eyes, skin and respiratory tract.

Toxicity to fish/aquatic organisms
Product is not known to be toxic to fish.

Potential Health Effects: See Section 11 for more information

Likely Routes of Exposure
Eye contact, inhalation and ingestion.

Eye Causes irritation of the eye.

Skin May cause irritation of the skin.

Inhalation May cause irritation of the upper and lower respiratory tract.

Ingestion May cause irritation of the gastrointestinal tract.

Skin Absorption Not absorbed through the skin.

Medical Conditions Aggravated by Exposure

Workers with impaired cardiovascular, kidney or liver functions should minimize their exposure to this product. It is strongly recommended that pregnant workers not be exposed to this product.

Target Organs
Kidney, liver, cardiovascular systems.

Potential Environmental Effects:See Section 12 for more information

This product is not known to be toxic to fish.

This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

3. COMPOSITION INFORMATION

Component	Content mg/ml	CAS
Furosemide	10.00	54-31-9
Sodium Chloride	7.50	7647-14-5
Sodium Hydroxide	1.34	1310-73-2
Sodium Hydroxide	q.s. to pH	1310-73-2
Hydrochloric Acid	q.s. to pH	7647-01-0
Water for Injection	q.s. to 1mL	7732-18-5

q.s.: Quantity Sufficient

4. FIRST-AID MEASURES

Eye contact
Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.

Skin contact
May cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.

Inhalation
May cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

Ingestion
May cause nausea, vomiting and irritation of the gastrointestinal tract. Flush mouth out with water. Seek medical attention.

Injection
See prescribing information.

Note to Physicians
Exposure to this product may result in headache, tinnitus, electrolyte imbalance, dry mouth, weakness, lethargy, drowsiness and muscle pains. Dermatitis, urticaria, rash and photosensitivity could be observed. Tachycardia, arrhythmia, hypotension, hypocalemia, hypochloremic alkalosis, nausea and vomiting may be observed as well. See prescribing information.

Suitable Extinguishing Media
Water spray, foam, dry chemical or Carbon Dioxide (CO_2). **Caution**: CO_2 will displace air in confined spaces and may cause an Oxygen deficient atmosphere.

Unsuitable Extinguishing Media
None.

Hazardous Combustion Products
When heated, Furosemide solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides)

Protection for Firefighters: Furosemide solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.

5. FIRE-FIGHTING MEASURES:

Flammability
Nonflammable, noncombustible

Fire & Explosion Hazard
Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable Upper: Not applicable

Fire Extinguishing Equipment: Water spray, foam, dry chemical or Carbon Dioxide (CO_2).

Fire Fighting Equipment: Wear self-contained breathing apparatus and protective clothing.

Hazardous Combustion Products: When heated, Furosemide solution thermally decomposes to form toxic vapors. (I.e. Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides)

6. ACCIDENTAL RELEASE MEASURES

Personnel Precautions
Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Environmental Precautions
This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

Methods of Containment
Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.

Methods of Clean Up
Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled

material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

Other Information
A spill of this material does not need to be reported to the National Response Center.

7. HANDLING AND STORAGE

Handling:
As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.
Use in a well ventilated area. Wash thoroughly after handling.
Storage:
Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION INFORMATION

Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Furosemide	Not listed	Not listed	
Sodium Chloride	Not listed	Not listed	
Hydrochloric Acid	5 parts per million – Ceiling	2 parts per million - Ceiling	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Water for Injection	Not listed	Not listed	
Personal Protective Equipment		Description	
Ventilation		Local exhaust or general ventilation is recommended.	
Respiratory Protection		Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100 / organic vapor cartridges.	
Eye Protection		Wear ANSI approved chemical splash goggles or safety glasses.	
Skin Protection		When administering this product to patients, use nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.	

9.0 PHYSICAL AND CHEMICAL PROPERTIES

Color	:	Clear, colorless to slightly yellow solution.
Odor / Odor Threshold	:	Odorless
Physical State	:	Liquid
pH	:	8.0 to 9.3
Freezing Point	:	Approximately 32 degrees Fahrenheit
Boiling Point	:	Approximately 212 degrees Fahrenheit
Flash Point	:	Not applicable
Evaporation Rate	:	Not applicable
Flammability	:	Nonflammable, noncombustible
Upper Flammable Limit	:	Not applicable
Lower Flammable Limit	:	Not applicable
Vapor Pressure	:	Not applicable
Vapor Density	:	Not applicable
Specific Gravity	:	Approximately 1.0
Solubility (water)	:	Slightly soluble in water
Partition Coefficient	:	Not applicable
Auto-ignition Temperature	:	Not applicable
Percent Volatile	:	0 percent
Volatile Organic Compounds (%)	:	0 percent

10. STABILITY AND REACTIVITY

Stability	:	Stable
Conditions to Avoid	:	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	:	Reactive with oxidizers, metals and acids
Hazardous Decomposition Products	:	Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides may be released by thermal decomposition
Possibility of Hazardous Reactions	:	Hazardous polymerization will not occur

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Acute Effects

Oral (LD50)

LD50: 2600 mg/kg oral - rat
LD50: 4600 mg/kg oral - mouse
LD50: 800 mg/kg oral - rabbit
LD50: 1000 mg/kg oral - dog

Intravenous (LD50)

LD50: 800 mg/kg intravenous - rat
LD50: 308 mg/kg intravenous - mouse
LD50: 400 mg/kg intravenous - rabbit
LD50: 300 mg/kg intravenous - dog

Intraperitoneal (LD50)

LD50: 910 mg/kg intraperitoneal - rat

Dermal (LD50)

None Listed

Toxic Dose - Minimum (TDLo)

TDLo : 29 mg/kg intravenous - human

Inhalation	Respiratory irritation is possible
Eye Irritation	Eye irritation is possible
Skin Irritation	Skin irritation may be possible
Sensitization	Repeated exposures may lead to sensitivity to this product

Chronic Effects

Organ Systems	Prolonged or repeated exposure may lead to damage to the kidneys, liver and cardiovascular system
Carcinogenicity	At high doses, two animal studies illustrated that Furosemide is carcinogenic. No adequate and well controlled studies in humans have been conducted
Mutagenicity	One animal cell study illustrated Furosemide is mutagenic in somatic mammalian cells. No adequate and well controlled studies in humans regarding the mutagenic effects of Furosemide. Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast
Reproductive Effects	Animal studies have demonstrated that Furosemide is embryotoxic. No adequate and well controlled studies in humans have been conducted. Furosemide passes into breast milk of nursing mothers
Developmental Effects	Above prescribed doses, Furosemide was found to be teratogenic in animal studies. No adequate and well controlled studies in humans. Classified as Pregnancy Category C

12. ECOLOGICAL INFORMATION

Ecotoxicity	No data available
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products may arise
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment

Mobility in Environment — Appreciable volatilization is not expected into the air

13. DISPOSAL CONSIDERATIONS

Disposal — Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal

14. TRANSPORT INFORMATION

Regulatory Agency	**Shipping Description**
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for Shipment
Canadian TDG (ground)	See US DOT
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment

15. REGULATORY INFORMATION

STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	CB2625000
TSCA	8b Inventory - Not listed
NFPA Rating	Health - 2, Fire - 1, Reactivity – 0
WHMIS (Canada)	Not controlled

16. OTHER INFORMATION

Parenteral therapy should be reserved for patients unable to take oral medication or for patients in emergency clinical situations. **Edema**: Furosemide is indicated in adults and pediatric patients for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Furosemide is particularly useful when an agent with greater diuretic potential is desired.

Furosemide is indicated as adjunctive therapy in acute pulmonary edema. The intravenous administration of Furosemide is indicated when a rapid onset of diuresis is desired, e.g., in acute pulmonary edema.

If gastrointestinal absorption is impaired or oral medication is not practical for any reason, Furosemide is indicated by the intravenous or intramuscular route. Parenteral use should be replaced with oral Furosemide as soon as practical.

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