Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 09.16.2024

Furosimide Injection 80mg/2.67ml for Subcutaneous Use

SECTION 1: Identification

Product identifier

Product name: Furosimide Injection 80mg/2.67ml for Subcutaneous Use

Other means of identification

Product code: SQIN-01

Additional information: None

Recommended use of the chemical and restrictions on use

Recommended use: Diuretic for Congestive Heart Failure.

Restrictions on use: Not determined or not applicable.

Manufacturer or supplier details

Manufacturer:

United States

SQ Innovation, Inc.
20 Burlington Mall Road
Suite 220
Burlington, MA 01803
(781) 552-4990

Emergency telephone number:

United States

SQ Innovation, Inc.
(781) 552-4990 (Mon-Fri / 9am - 5pm)

SECTION 2: Hazard(s) identification

Classification in accordance with paragraph (d) (1)(i)(A) of §1910.1200, GHS Revision 7 and certain provision of GHS Revision 8:

Skin sensitization, category 1
Reproductive toxicity, category 1B

Label elements

Pictogram(s):

Signal Word: Danger

Hazard statements:

H317 May cause an allergic skin reaction

H360 May damage fertility or the unborn child

Precautionary statements:

P261 Avoid breathing dust, fumes, gas, mist, vapors or spray.

P272 Contaminated work clothing must not be allowed out of the workplace

P280 Wear protective gloves, protective clothing and eye protection.

P201 Obtain special instructions before use

P202 Do not handle until all safety precautions have been read and understood

P302+P352 IF ON SKIN: Wash with plenty of water.
P363 Wash contaminated clothing before reuse
P333+P313 If skin irritation or rash occurs: Get medical attention.
P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).
P308+P313 If exposed or concerned: Get medical attention.
P405 Store locked up
P501 Dispose of contents and container in accordance with local regulations.

Hazards not otherwise classified: None

Supplemental label elements: None

SECTION 3: Composition/information on ingredients

Identification	Name	Weight %
CAS Number: 7732-18-5	Water	70.5
CAS Number: 182410-00-0	Beta-cyclodextrin sulfobutyl ether, sodium salt	26.7
CAS Number: 54-31-9	Furosemide	2.7
CAS Number: 77-86-1	2-amino-2-(hydroxymethyl)propane-1,3-diol	0.2
CAS Number: 1310-73-2	Sodium hydroxide	**
CAS Number: 7647-01-0	Hydrogen chloride	**

Additional Information:
** to adjust pH
The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200).

SECTION 4: First-aid measures

Description of first-aid measures

General notes:
Show this Safety Data Sheet to the doctor in attendance.

After inhalation:
If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If experiencing respiratory symptoms, seek medical advice/attention.

After skin contact:
Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:
Rinse eyes with plenty of water for several minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After ingestion:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms/effects, acute and delayed

Acute symptoms and effects:

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

Long term exposure may affect fertility. Symptoms include, but are not limited to: menstrual problems, altered sexual behavior/fertility/ and pregnancy outcome. Long term exposure may also affect development of the unborn child. Symptoms include, but are not limited to: intrauterine growth retardation, pre-term birth, birth defects and postnatal death.

Indication of immediate medical attention and special treatment needed, if necessary

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards arising from the chemical:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment and precautions for fire-fighters

Special protective equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).
Recommended temperature range: 20°C - 25°C.

SECTION 8: Exposure controls/personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m³
	Hydrogen chloride	7647-01-0	Ceiling Limit: 2 ppm (TLV)
OSHA	Sodium hydroxide	1310-73-2	8-Hour TWA-PEL: 2 mg/m³
	Hydrogen chloride	7647-01-0	Ceiling Limit: 5 ppm (7 mg/m3)
	Hydrogen chloride	7647-01-0	PEL: 5 ppm (7 mg/m3)
NIOSH	Sodium hydroxide	1310-73-2	IDLH: 10 mg/m³
	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m³
	Hydrogen chloride	7647-01-0	IDLH: 50 ppm
	Hydrogen chloride	7647-01-0	Ceiling Limit: 5 ppm (7 mg/m3)
United States(California)	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m³
	Hydrogen chloride	7647-01-0	PEL: 0.3 ppm (0.45 mg/m3)
	Hydrogen chloride	7647-01-0	Ceiling Limit: 2 ppm

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable.

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Individual protection measures, such as personal protective equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygiene measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Color	Clear to slightly yellow
Odor	None
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flammability	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Flash point	Not determined or not available.
Auto-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
pH	7.1 - 7.8
Kinematic viscosity	Not determined or not available.
Solubility	Not determined or not available.
Partition coefficient — n-octanol/water	Not determined or not available.
Vapor pressure	Not determined or not available.
Density	Not determined or not available.
Relative density	1.1297 g/ml
Relative vapor density	Not determined or not available.
Particle characteristics	Not determined or not available.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:
Stable under recommended handling and storage conditions.

Possibility of hazardous reactions, including those associated with foreseeable emergencies:
Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:
Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible materials:
None known.

Hazardous decomposition products:
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Furosemide	oral	LD50 Rat: 2600 mg/kg
Sodium hydroxide	oral	LD50 Rat: 325 mg/kg
	dermal	LD50 Rabbit: 1350 mg/kg
Hydrogen chloride	Inhalation ATE	LC50 Rat: 700 ppmV (4 hr [gas])
Beta-cyclodextrin sulfobutyl ether, sodium salt	oral	LD50 Rat: >2000 mg/kg
	dermal	LD50 Rabbit: >2000 mg/kg
2-amino-2-(hydroxymethyl)propane-1,3- diol	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rat: >5000 mg/kg

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Sodium hydroxide	Causes severe skin burns.
Hydrogen chloride	Causes severe skin burns.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Sodium hydroxide	Causes serious eye damage.
Hydrogen chloride	Causes serious eye damage.

Respiratory or skin sensitization

Assessment:

May cause an allergic skin reaction.

Product data: No data available.

Substance data:

Name	Result
Beta-cyclodextrin sulfobutyl ether, sodium salt	May cause an allergic skin reaction.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data: No data available.

International Agency for Research on Cancer (IARC):

Name	Classification
Furosemide	Group 3
Hydrogen chloride	Group 3

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens: Not applicable.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data: No data available.

Reproductive toxicity

Assessment:
May damage fertility or the unborn child.
Product data: No data available.
Substance data:

Name	Result
Furosemide	May damage fertility or the unborn child.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data:

Name	Result
Hydrogen chloride	May cause respiratory irritation.
2-amino-2-(hydroxymethyl)propane-1,3- diol	May cause respiratory irritation.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data: No data available.

Interactive effects:

No data available.

Information on likely routes of exposure:

Skin contact, eye contact, ingestion and inhalation

Symptoms related to the physical, chemical and toxicological characteristics:
Refer to Section 4 of this SDS.

Other information:
No additional information.

SECTION 12: Ecological information

Acute (short-term) toxicity
Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data:

Name	Result
Sodium hydroxide	Aquatic Invertebrates EC50 Ceriodaphnia sp.: 40.4 mg/L (48 hr [immobilization])
	Fish LC50 Fish: 35 - 189 mg/L (96 hr)
Beta-cyclodextrin sulfobutyl ether, sodium salt	Fish LC50 Fish: 220 mg/L (96 hr)
	Aquatic Invertebrates EC50 Aquatic crustacea: >96 mg/L (48 hr [immobility])
	Aquatic Plants EC50 Algae: >100 mg/L (72 hr [biomass & growth rate])
2-amino-2-(hydroxymethyl)propane-1,3- diol	Aquatic Invertebrates EC50 Daphnia magna: >980 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Raphidocelis subcapitata: 397 mg/L (72 hr [cell number])
	Fish LC50 Freshwater fish: >4000 mg/L (96 hr)

Chronic (long-term) toxicity
Assessment: Based on available data, the classification criteria are not met.
Product data: No data available.
Substance data: No data available.

Persistence and degradability
Product data: No data available.
Substance data:

Name	Result
Sodium hydroxide	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.
Hydrogen chloride	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.
Beta-cyclodextrin sulfobutyl ether, sodium salt	The substance is not readily biodegradable. 2% degradation in water, after 28 days.
2-amino-2-(hydroxymethyl)propane-1,3- diol	The substance is readily biodegradable.100.7 % degradation in water, measured by O2 consumption, after 28 days.

Bioaccumulative potential
Product data: No data available.
Substance data:

Name	Result
Sodium hydroxide	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.
Hydrogen chloride	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.
2-amino-2-(hydroxymethyl)propane-1,3- diol	The substance is not expected to bioaccumulate (log Pow: -2.31 at 20 °C).

Mobility in soil

Product data: No data available.

Substance data:

Name	Result
Sodium hydroxide	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.
Hydrogen chloride	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.
2-amino-2-(hydroxymethyl)propane-1,3- diol	The substance is mobile, therefore, there is low potential for adsorption to soil and sediment (log Koc: 1.54 - 1.87, QSAR substance data).

Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

Sodium hydroxide	PBT assessment does not apply to inorganic compounds such as this substance.
Hydrogen chloride	PBT assessment does not apply to inorganic compounds such as this substance.
2-amino-2- (hydroxymethyl)propane-1,3- diol	The substance is not PBT.

vPvB assessment:

Sodium hydroxide	vPvB assessment does not apply to inorganic compounds such as this substance.
Hydrogen chloride	vPvB assessment does not apply to inorganic compounds such as this substance.
2-amino-2- (hydroxymethyl)propane-1,3- diol	The substance is not vPvB.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport information

United States Transportation of Dangerous Goods (49 CFR DOT)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Passenger Air/Rail	None
Cargo Aircraft Only	None
Stowage Category	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG) Code

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
EmS Number	None
Stowage Category	None
Excepted Quantities	None
Additional Information	None

International Air Transport Association (IATA) Dangerous Goods Regulations (DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None
ERG Code	None
Excepted Quantities	None
Limited Quantity	None

Transport in Bulk according to IMO Instruments

IMO hazard class	None
Environmental hazards	None
Material hazardous only in bulk	None
Cargo Group	None
Bulk Name	None

SECTION 15: Regulatory information

United States Regulations

Inventory Listing (TSCA):

CAS	Name	Status
54-31-9	Furosemide	Exempt
1310-73-2	Sodium hydroxide	Listed - Active
7647-01-0	Hydrogen chloride	Listed - Active
182410-00-0	Beta-cyclodextrin sulfobutyl ether, sodium salt	Not Listed
77-86-1	2-amino-2-(hydroxymethyl)propane-1,3-diol	Listed - Active

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export Notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 Extremely Hazardous Substances:

CAS	Name	SARA 302
7647-01-0	Hydrogen chloride	Listed

SARA Section 313 Toxic Chemicals:

CAS	Name	SARA 313
7647-01-0	Hydrogen chloride	Listed

CERCLA:

CAS	Name	Status	RQ
1310-73-2	Sodium hydroxide	Listed	1000 lb
7647-01-0	Hydrogen chloride	Listed	5000 lbs

RCRA: None of the ingredients are listed.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know:

CAS	Name	Status
1310-73-2	Sodium hydroxide	Listed
7647-01-0	Hydrogen chloride	Listed

New Jersey Right to Know:

CAS	Name	Status
1310-73-2	Sodium hydroxide	Listed
7647-01-0	Hydrogen chloride	Listed

New York Right to Know:

CAS	Name	Status
1310-73-2	Sodium hydroxide	Listed
7647-01-0	Hydrogen chloride	Listed

Pennsylvania Right to Know:

CAS	Name	Status
1310-73-2	Sodium hydroxide	Listed
7647-01-0	Hydrogen chloride	Listed

California Proposition 65: None of the ingredients are listed.

Additional information: Not determined.

SECTION 16: Other information

Disclaimer:

This product has been classified in accordance with paragraph (d) (1)(i)(A) of §1910.1200, GHS Revision 7 and certain provision of GHS Revision 8. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

Initial Preparation Date: 09.16.2024

End of Safety Data Sheet