Furosemide Injection Formulation

SECTION 1. IDENTIFICATION

Product name: Furosemide Injection Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc.
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATATESTeward@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Specific target organ toxicity - repeated exposure: Category 1 (Kidney, Liver)

GHS label elements
Hazard pictograms: 

Signal Word: Danger
Hazard Statements: H372 Causes damage to organs (Kidney, Liver) through prolonged or repeated exposure.
Precautionary Statements: Prevention:
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P314 Get medical attention if you feel unwell.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide</td>
<td>No data available</td>
<td>54-31-9</td>
<td>&gt;= 5 - &lt; 10 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water. Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Nitrogen oxides (NOx)
Carbon oxides
Sulfur oxides
Chlorine compounds

Specific extinguishing methods : 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.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment and emergency procedures**
Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**
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. Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**
Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

**Technical measures**
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

**Local/Total ventilation**
Use only with adequate ventilation.

**Advice on safe 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.

**Conditions for safe storage**
Keep in properly labeled containers.
Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide</td>
<td>54-31-9</td>
<td>TWA</td>
<td>200 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>OEB 2 (&gt;=100 - 1000 ug/m3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Particulates type
Hand protection Material : Chemical-resistant gloves
Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
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.
### Appearance
Aqueous solution

### Color
yellow

### Odor
No data available

### Odor Threshold
No data available

### pH
No data available

### Melting point/freezing point
No data available

### Initial boiling point and boiling range
No data available

### Flash point
No data available

### Evaporation rate
No data available

### Flammability (solid, gas)
Not applicable

### Flammability (liquids)
No data available

### Upper explosion limit / Upper flammability limit
No data available

### Lower explosion limit / Lower flammability limit
No data available

### Vapor pressure
No data available

### Relative vapor density
No data available

### Relative density
No data available

### Density
No data available

### Solubility(ies)
Water solubility
No data available

### Partition coefficient: n-octanol/water
No data available

### Autoignition temperature
No data available

### Decomposition temperature
No data available

### Viscosity
Viscosity, kinematic
No data available

### Explosive properties
Not explosive

### Oxidizing properties
The substance or mixture is not classified as oxidizing.
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SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
Furosemide:
Acute oral toxicity: LD50 (Rat): 2,600 mg/kg
LD50 (Dog): 2,000 mg/kg
LD50 (Rabbit): 800 mg/kg

Acute toxicity (other routes of administration): LD0 (Humans): 6 - 29 mg/kg
Application Route: Intravenous
LD50 (Rat): 800 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

Furosemide:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
                          Result: negative

                          Test Type: In vitro mammalian cell gene mutation test
                          Test system: mouse lymphoma cells
                          Result: positive

                          Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
                          Test system: mammalian liver cells
                          Result: negative

                          Test Type: Chromosome aberration test in vitro
                          Test system: Chinese hamster ovary cells
                          Result: positive

                          Test Type: In vitro sister chromatid exchange assay in mammalian cells
                          Test system: Chinese hamster cells
                          Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
                     Species: Mouse
                     Application Route: Ingestion
                     Result: negative

                     Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
                     Species: Chinese hamster
                     Application Route: Ingestion
                     Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Furosemide:
Species : Rat
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Reproductive toxicity
Not classified based on available information.

Components:

Furosemide:

Effects on fertility:
- Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - General Toxicity Parent: NOAEL: 90 mg/kg body weight
  - Result: No effects on reproduction parameters.

- Test Type: One-generation reproduction toxicity study
  - Species: Mouse
  - Application Route: Ingestion
  - General Toxicity Parent: NOAEL: 200 mg/kg body weight
  - Result: No effects on reproduction parameters.

Effects on fetal development:
- Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Ingestion
  - General Toxicity Maternal: LOAEL: 50 mg/kg body weight
  - Developmental Toxicity: NOAEL: 300 mg/kg body weight
  - Result: No embryotoxic effects., No teratogenic effects.

- Test Type: Fertility/early embryonic development
  - Species: Mouse
  - Application Route: Ingestion
  - General Toxicity Maternal: LOAEL: 25 mg/kg body weight
  - Result: Maternal toxicity observed., Fetal effects.

- Test Type: Fertility/early embryonic development
  - Species: Rabbit
  - Application Route: Ingestion
  - General Toxicity Maternal: LOAEL: <= 12 mg/kg body weight
  - Developmental Toxicity: LOAEL: 12.5 mg/kg body weight
  - Result: Maternal toxicity observed., Reduced number of viable fetuses.

- Test Type: Fertility/early embryonic development
  - Species: Rabbit
  - Application Route: Ingestion
  - General Toxicity Maternal: LOAEL: 15 mg/kg body weight
Result: Maternal toxicity observed., No effects on fetal development.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Components:

Furosemide:
Routes of exposure : Ingestion
Target Organs : Kidney
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Furosemide:
Species : Dog
NOAEL : 4 mg/kg
LOAEL : 8 mg/kg
Application Route : Ingestion
Exposure time : 12 Months
Target Organs : Kidney
Symptoms : Blood disorders
Remarks : Significant toxicity observed in testing

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Furosemide:
Inhalation : Remarks: May be harmful if inhaled.
Skin contact : Remarks: May irritate skin.
Eye contact : Remarks: May cause eye irritation.
Ingestion : Symptoms: Kidney disorders, Headache, electrolyte imbalance, dry mouth, hearing loss, Irregular cardiac activity, Gastrointestinal disturbance, hypotension

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Furosemide:
Toxicity to fish: LC50: 500 mg/l  
Exposure time: 96 h

Persistence and degradability:
No data available

Bioaccumulative potential:
Components:
Furosemide:
Partition coefficient: n-octanol/water: log Pow: 2.03

Mobility in soil:
No data available

Other adverse effects:
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods:
Waste from residues: Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste 
handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG:
Not regulated as a dangerous good

IATA-DGR:
Not regulated as a dangerous good

IMDG-Code:
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
Not applicable for product as supplied.

Domestic regulation
TDG:
Not regulated as a dangerous good

Special precautions for user:
Not applicable
SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations:

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System


Revision Date: 09/30/2023
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8