according to the Globally Harmonized System



# **Furosemide Injection Formulation**

Revision Date: Date of last issue: 04.04.2023 Version SDS Number: 3.8 30.09.2023 657930-00015 Date of first issue: 03.05.2016

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name Furosemide Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Veterinary product Recommended use Restrictions on use Not applicable

## 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Specific target organ toxicity - : Category 2 (Kidney, Liver)

repeated exposure

**GHS** label elements

Hazard pictograms

Signal word

Hazard statements H373 May cause damage to organs (Kidney, Liver) through

prolonged or repeated exposure.

Precautionary statements **Prevention:** 

P260 Do not breathe mist or vapours.

Response:

P319 Get medical help if you feel unwell.

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### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Furosemide	54-31-9	>= 5 - < 10

#### 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 contact, immediately flush skin with soap and plenty In case of skin contact

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

delaved

May cause 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).

Treat symptomatically and supportively. Notes to physician

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

Exposure to combustion products may be a hazard to health.

fighting

Hazardous combustion prod-

ucts

Nitrogen oxides (NOx)

Carbon oxides

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Sulphur oxides Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not breathe mist or vapours.

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 as-

sessment

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

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

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environment.

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
54-31-9	TWA	200 μg/m3	Internal
	TWA	OEB 2 (>=100 -	Internal
		(Form of exposure) 54-31-9 TWA	(Form of exposure) ters / Permissible concentration  54-31-9 TWA 200 μg/m3

**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance : Aqueous solution

Colour : yellow

Odour : No data available

Odour 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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition 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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Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

## 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5,000 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 sensitisation

Skin sensitisation

Not classified based on available information.

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### Respiratory sensitisation

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 syn-

thesis 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 mam-

malian 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
Application Route : Ingestion
Exposure time : 104 weeks

LOAEL : 16 mg/kg body weight

Result : equivocal

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Species : Mouse
Application Route : Ingestion
Exposure time : 2 Years

LOAEL : 91 mg/kg body weight

Result : positive

#### 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 foetal develop-

ment

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 foetal de-

velopment

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## STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs (Kidney, Liver) through prolonged or repeated exposure.

### **Components:**

#### Furosemide:

Exposure routes : Ingestion Target Organs : Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

### Repeated dose toxicity

### **Components:**

#### Furosemide:

Species: DogNOAEL: 4 mg/kgLOAEL: 8 mg/kgApplication Route: IngestionExposure time: 12 MonthsTarget 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 imbal-

ance, dry mouth, hearing loss, Irregular cardiac activity, Gas-

trointestinal disturbance, hypotension

## 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

#### **Components:**

#### **Furosemide:**

Toxicity to fish : LC50: 500 mg/l

Exposure time: 96 h

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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

### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## 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 IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

AICS : not determined

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DSL not determined

**IECSC** not determined

#### 16. OTHER INFORMATION

**Revision Date** 30.09.2023

**Further information** 

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agen-Sheet cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

Date format dd.mm.yyyy

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

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 mate-

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rial 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.

IN / EN