

# **Furosemide Injection Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 632208-00018 Date of first issue: 2016/05/03

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Furosemide Injection Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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

repeated exposure

**GHS** label elements

Hazard pictograms :

Signal word : Warning

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:

P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.



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

None known.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

	CAS-No.	Concentration (% w/w)	ENCS No.
Furosemide	54-31-9	>= 1 - < 10	9-377

#### 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

delayed

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-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: : Nitrogen oxides (NOx)



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ucts Carbon oxides

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, protective 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

Handling

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 vapours.

Do not swallow.



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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

environment.

Avoidance of contact : Oxidizing agents

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 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

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Furosemide	54-31-9	TWA	200 μg/m3	Internal
		TWA	OEB 2 (>=100 - 1000 ug/m3)	Internal

**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



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If adequate local exhaust ventilation is not available or expo-Respiratory protection

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

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.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state Aqueous solution

Colour yellow

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

No data available Flash point

No data available Decomposition temperature

No data available pΗ

Evaporation rate No data available

No data available Auto-ignition temperature

Viscosity

Viscosity, kinematic No data available



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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle characteristics

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-

tions

Can react with strong oxidizing agents.

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:

exposure

Inhalation Skin contact Ingestion

Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### Components:

#### Furosemide:

Acute oral toxicity : LD50 (Rat): 2,600 mg/kg



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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.

## 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)



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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

Species: MouseApplication Route: IngestionExposure 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



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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

#### 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 : Dog NOAEL : 4 mg/kg LOAEL : 8 mg/kg Application Route : Ingestion : 12 Months : Kidney Exposure time Target Organs

Symptoms : Blood disorders

Remarks Significant toxicity observed in testing



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## **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

Persistence and degradability

No data available

**Bioaccumulative potential** 

**Components:** 

Furosemide:

Partition coefficient: n- : log Pow: 2.03

octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.



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Do not dispose of waste into sewer.

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** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

**IMDG-Code** 

UN number Not applicable Not applicable Proper shipping name : Not applicable Class : Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

# Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## **National Regulations**

Refer to section 15 for specific national regulation.

## Special precautions for user

Not applicable

#### 15. REGULATORY INFORMATION

# **Related Regulations**

Fire Service Law



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Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

### **Industrial Safety and Health Law**

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

## **Harmful Substances Required Permission for Manufacture**

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

## **Substances Subject to be Notified Names**

Not applicable

## **Substances Subject to be Indicated Names**

Not applicable

# Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

# Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### Ordinance on Prevention of Lead Poisoning

Not applicable

## Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

# Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### **Poisonous and Deleterious Substances Control Law**

Not applicable



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Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Not regulated as a dangerous good

**Aviation Law** 

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

**Further information** 

Sources of key data used to : compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Sheet cv. http://echa.europa.eu

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Internal technical data, data from raw material SDSs, OECD

Date format : yyyy/mm/dd

Full text of other abbreviations



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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 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.

JP / EN