



## Furosemide Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.9	09/30/2023	632199-00016	Date of first issue: 05/03/2016

#### **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	:	EHSDATASTEWARD@merck.com
Telephone Emergency telephone	:	Rahway, New Jersey U.S.A. 07065 908-740-4000 1-908-423-6000

### 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 Regula	tions
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Specific target organ toxicity	:	Category 1 (Kidney, Liver)
<ul> <li>repeated exposure</li> </ul>		

:

#### **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.



according to the Hazardous Products Regulations

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#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Furosemide	No data availa- ble	54-31-9	>= 5 - < 10 *

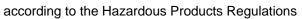
\* Actual concentration or concentration range is withheld as a trade secret

#### **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 prod- ucts	:	Nitrogen oxides (NOx) Carbon oxides Sulfur oxides Chlorine compounds
Specific extinguishing meth- ods	:	Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment.



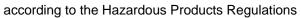


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	ial protective equipment e-fighters			ged containers from fire area if it is safe to do e, wear self-contained breathing apparatus.
SECTION	6. ACCIDENTAL RELE	AS	E MEASURES	
tive e	onal precautions, protec- equipment and emer- y procedures	:	Follow safe handl	ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).
Envir	onmental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or se of contaminated wash water. should be advised if significant spillages
	Methods and materials for containment and cleaning up		For large spills, pro- containment to kee can be pumped, so container. Clean up remaining absorbent. Local or national of disposal of this more employed in the of determine which to Sections 13 and 1	t absorbent material. rovide diking or other appropriate sep material from spreading. If diked material store recovered material in appropriate ng materials from spill with suitable regulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to regulations are applicable. 5 of this SDS provide information regarding tional requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures	0	ering measures under EXPOSURE S/PERSONAL PROTECTION section.
Local/Total ventilation Advice on safe handling	Do not brea Do not swal Avoid conta Avoid prolo Wash skin t Handle in a practice, ba assessmen Do not eat,	ct with eyes. nged or repeated contact with skin. horoughly after handling. ccordance with good industrial hygiene and safety sed on the results of the workplace exposure t drink or smoke when using this product. o prevent spills, waste and minimize release to the
Conditions for safe storage		perly labeled containers. ordance with the particular national regulations.





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Materia	als to avoid	Strong oxidizing a	stances and mixtures

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / 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 equipme	ent	
Respiratory protection Filter type	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. 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 Hygiene measures	:	Work uniform or laboratory coat. 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

according to the Hazardous Products Regulations



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	Appear	ance	:	Aqueous solution	I
	Color		:	yellow	
	Odor		:	No data available	)
	Odor Th	nreshold	:	No data available	)
	рН		:	No data available	)
	Melting	point/freezing point	:	No data available	)
	Initial bo range	oiling point and boiling	:	No data available	
	Flash p	oint	:	No data available	
	Evapora	ation rate	:	No data available	9
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available	)
	Relative	e vapor density	:	No data available	)
	Relative	e density	:	No data available	9
	Density		:	No data available	
	Solubili Wate	ty(ies) er solubility	:	No data available	9
	Partition octanol	n coefficient: n- /water	:	No data available	
		ition temperature	:	No data available	
	Decom	position temperature	:	No data available	
	Viscosit Visc	ty osity, kinematic	:	No data available	9
	Explosi	ve properties	:	Not explosive	
	Oxidizir	ng properties	:	The substance of	r mixture is not classified as oxidizing.

according to the Hazardous Products Regulations



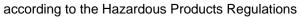
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Partic	le size	:	Not applicable	
ECTION	10. STABILITY AND RE	EAC	ΤΙΝΙΤΥ	
React		:		a reactivity hazard.
	ical stability bility of hazardous reac-	÷	Stable under nor	mai conditions. trong oxidizing agents.
tions		•	Carreact with 5	tiong oxidizing agents.
	tions to avoid	:	None known.	
	patible materials	:	Oxidizing agents	
produ	dous decomposition	:	No nazardous de	ecomposition products are known.
ECTION	11. TOXICOLOGICAL I			
	TI. TOXICOLOGICAL I			
Inform	nation on likely routes	of e	xnosure	
	nation on likely routes	of e	exposure	
Inhala	•	of e	exposure	
Inhala	ation contact	of e	exposure	
Inhala Skin o Inges	ation contact	of e	exposure	
Inhala Skin c Inges Eye c	tion contact tion	of e	exposure	
Inhala Skin o Inges Eye c <b>Acute</b>	ation contact tion ontact			
Inhala Skin o Inges Eye c <b>Acute</b>	ation contact tion ontact <b>e toxicity</b> assified based on availa			
Inhala Skin o Inges Eye c <b>Acute</b> Not cl	ation contact tion ontact <b>e toxicity</b> assified based on availa		nformation.	imate: > 2,000 mg/kg ion method
Inhala Skin c Inges Eye c <b>Acute</b> Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa		nformation.	
Inhala Skin c Inges Eye c <b>Acute</b> Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa <u>uct:</u> oral toxicity		nformation.	
Inhala Skin o Inges Eye c Acute Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa <u>uct:</u> oral toxicity	ble i :	nformation.	ion method
Inhala Skin o Inges Eye c Acute Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa <u>uct:</u> oral toxicity <u>conents:</u> semide:	ble i :	nformation. Acute toxicity est Method: Calculat	ion method D mg/kg
Inhala Skin o Inges Eye c Acute Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa <u>uct:</u> oral toxicity <u>conents:</u> semide:	ble i :	nformation. Acute toxicity est Method: Calculat LD50 (Rat): 2,600	ion method 0 mg/kg 10 mg/kg
Inhala Skin o Inges Eye c Acute Not cl <u>Produ</u> Acute	ation contact tion ontact <b>e toxicity</b> assified based on availa <u>uct:</u> oral toxicity <u>conents:</u> semide:	ble i :	nformation. Acute toxicity est Method: Calculat LD50 (Rat): 2,600 LD50 (Dog): 2,000	ion method D mg/kg 0 mg/kg 00 mg/kg - 29 mg/kg

Not classified based on available information.

## Serious eye damage/eye irritation

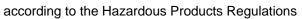
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Resp	iratory or skin sensit	ization	
-	sensitization assified based on ava	ilable information.	
Resp	iratory sensitization assified based on ava		
Germ	cell mutagenicity assified based on ava		
Com	oonents:		
Furos	semide:		
Geno	toxicity in vitro	: Test Type: Bao Result: negativ	cterial reverse mutation assay (AMES) /e
			ritro mammalian cell gene mutation test nouse lymphoma cells e
		thesis in mamr	A damage and repair, unscheduled DNA syn- nalian cells (in vitro) nammalian liver cells /e
			romosome aberration test in vitro Chinese hamster ovary cells e
		malian cells	ritro sister chromatid exchange assay in mam Chinese hamster cells re
Geno	toxicity in vivo	: Test Type: Ma cytogenetic as Species: Mous Application Ro Result: negativ	e ute: Ingestion
			ute: Ingestion
	<b>nogenicity</b> assified based on ava	ilable information.	
<u>Com</u>	<u>oonents:</u>		
	semide:		
Speci	es	: Rat	





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	Applica Exposu LOAEL Result		:	Ingestion 104 weeks 16 mg/kg body we equivocal	eight
	Species Applica Exposu LOAEL Result	tion Route ire time		Mouse Ingestion 2 Years 91 mg/kg body we positive	eight
	-	<b>luctive toxicity</b> ssified based on availa	ble	information.	
	Compo	onents:			
	Furose Effects	mide: on fertility	:	Test Type: One-ge Species: Rat	eneration reproduction toxicity study
				Application Route General Toxicity F	: Ingestion Parent: NOAEL: 90 mg/kg body weight on reproduction parameters.
				Species: Mouse Application Route General Toxicity F	eneration reproduction toxicity study : Ingestion Parent: NOAEL: 200 mg/kg body weight on reproduction parameters.
	Effects	on fetal development	:	Species: Rat Application Route General Toxicity M Developmental To	y/early embryonic development : Ingestion /aternal: LOAEL: 50 mg/kg body weight oxicity: NOAEL: 300 mg/kg body weight otoxic effects., No teratogenic effects.
				Species: Mouse Application Route General Toxicity N	y/early embryonic development : Ingestion /laternal: LOAEL: 25 mg/kg body weight oxicity observed., Fetal effects.
				Species: Rabbit Application Route General Toxicity M Developmental To	y/early embryonic development : Ingestion /laternal: LOAEL: <= 12 mg/kg body weight oxicity: LOAEL: 12.5 mg/kg body weight oxicity observed., Reduced number of viable
				Species: Rabbit Application Route	y/early embryonic development : Ingestion /laternal: LOAEL: 15 mg/kg body weight

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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 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
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:

Remarks: May be harmful if inhaled.
Remarks: May irritate skin.
Remarks: May cause eye irritation.

: Symptoms: Kidney disorders, Headache, electrolyte imbalance, dry mouth, hearing loss, Irregular cardiac activity, Gastrointestinal disturbance, hypotension

#### SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:** 

Furosemide:



according to the Hazardous Products Regulations

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Toxici	ty to fish	:	LC50 : 500 mg/l Exposure time: 9	6 h
No da	stence and degradal ta available cumulative potentia	-		
<u>Comp</u>	oonents:			
Partiti	e <b>mide:</b> on coefficient: n- bl/water	:	log Pow: 2.03	
	<b>ity in soil</b> ta available			
	<b>adverse effects</b> ta 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



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#### **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

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Povision Data		00/20/2022

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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