

Versi 4.1	on Revision Date: 30.09.2023		S Number: 3044-00016	Date of last issue: 04.04.2023 Date of first issue: 03.05.2016			
SEC	TION 1. IDENTIFICATION						
I	Product name	:	: Furosemide Solid Formulation				
I	Manufacturer or supplier's	deta	ils				
(Company	:	MSD				
/	Address	:		6th floor, Ciudad Autonoma gentina C1013AAP			
-	Telephone	:	908-740-4000				
I	Emergency telephone	:	1-908-423-6000				
I	E-mail address	:	EHSDATASTEW	/ARD@msd.com			
I	Recommended use of the c	hem	ical and restriction	ons on use			
-	Recommended use Restrictions on use	:	Veterinary produ Not applicable	ct			
SEC	TION 2. HAZARDS IDENTIFI	ICAT	ION				
(GHS Classification						
	Specific target organ toxicity - repeated exposure	- :	Category 1 (Kidr	ey, Liver)			
(GHS label elements						
I	Hazard pictograms	:					

auses damage to organs (Kidney, Liver) through pro- or repeated exposure.
ion: o not breathe dust. ash skin thoroughly after handling. o not eat, drink or smoke when using this product.
se: et medical advice/ attention if you feel unwell. II: spose of contents/ container to an approved waste plant.



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Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 50 -< 70
Furosemide	54-31-9	>= 10 -< 20
Cellulose	9004-34-6	>= 1 -< 5

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 eye contact	:	If in eyes, rinse well with water. 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	:	
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation. 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	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.



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	lazardo icts	ous combustion prod-	:	Exposure to comb Nitrogen oxides (I Carbon oxides Sulfur oxides Chlorine compour		
0	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 fire-fighters		:	: In the event of fire, wear self-contained breathing appara Use personal protective equipment.		
SECT	ION 6.	ACCIDENTAL RELE	ASI	E MEASURES		
tiv	ive equ	al precautions, protec- ipment and emer- rocedures	:		ective equipment. ing advice (see section 7) and personal ent recommendations (see section 8).	
E	Environ	mental precautions	:	Retain and dispos	akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages	
		s and materials for ment and cleaning up	:	container for disp	ⁱ dust in the air (i.e., clearing dust surfaces air).	

SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion.
		Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not breathe dust.
		Do not swallow.
		Avoid contact with eyes.
		Avoid prolonged or repeated contact with skin.
		Wash skin thoroughly after handling.

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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

Sections 13 and 15 of this SDS provide information regarding

determine which regulations are applicable.

certain local or national requirements.



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		Handle in accordance with good industrial hygiene and practice, based on the results of the workplace exposu assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release environment.				
Conc	litions for safe storage	: Keep in properly labeled containers. Store in accordance with the particular national regula				
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

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL
	Further information	ation: A4 - Not cl	lassifiable as a huma	n carcinogen
		TWA	10 mg/m ³	ACGIH
Furosemide	54-31-9	TWA	200 µg/m³	Internal
		TWA	OEB 2 (>=100 - 1000 ug/m3)	Internal
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH

Engineering measures :	Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Personal protective equipmen	t
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



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	and body protection ene measures	eye flushing sy working place. When using do Wash contamin The effective o engineering co appropriate de industrial hygie	or laboratory coat. chemical is likely during typical use, provide ystems and safety showers close to the o not eat, drink or smoke. nated clothing before re-use. operation of a facility should include review of introls, proper personal protective equipment, gowning and decontamination procedures, ene monitoring, medical surveillance and the trative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	yellow
Odor	:	No data available
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
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

SAFETY DATA SHEET



Furosemide Solid Formulation

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octa Auto Deco Visc V	tion coefficient: n- nol/water ignition temperature omposition temperature osity 'iscosity, kinematic osive properties	 No data avai 	lable lable	
Mole	izing properties ecular weight cle size	The substandNot applicableNo data avai		

SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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 availa	ıble	information.
Product:		
Acute oral toxicity	:	Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method
Components:		
Starch:		
Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 2.000 mg/kg
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	emide:			
Acute	oral toxicity	:	LD50 (Rat): 2.600) mg/kg
			LD50 (Dog): 2.00	0 mg/kg
			LD50 (Rabbit): 80	00 mg/kg
	toxicity (other routes of istration)	:	LD0 (Humans): 6 Application Route	
			LD50 (Rat): 800 r Application Route	
Cellul	ose:			
Acute	oral toxicity	:	LD50 (Rat): > 5.0	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 5,8 Exposure time: 4 Test atmosphere:	h
Acute	dermal toxicity	:	LD50 (Rabbit): > 2	2.000 mg/kg
	corrosion/irritation assified based on availa	ble	information.	
	us eye damage/eye irri			
	assified based on availa	ble	information.	
Comp	oonents:			
Starc				
Specie Result		:	Rabbit No eye irritation	
Respi	ratory or skin sensitiz	atio	on	
-	sensitization			

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Starch:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.



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<u>Com</u>	ponents:		
Stard Geno	ch: ptoxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) tive
Furo	semide:		
Geno	otoxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) tive
			vitro mammalian cell gene mutation test mouse lymphoma cells ve
		thesis in man	NA damage and repair, unscheduled DNA syn- nmalian cells (in vitro) mammalian liver cells tive
			hromosome aberration test in vitro Chinese hamster ovary cells ve
		malian cells	vitro sister chromatid exchange assay in mam- Chinese hamster cells tive
Gend	otoxicity in vivo	cytogenetic a Species: Mou	use coute: Ingestion
		cytogenetic to Species: Chi	utagenicity (in vivo mammalian bone-marrow est, chromosomal analysis) nese hamster oute: Ingestion tive
Cellu	ılose:		
Geno	ptoxicity in vitro	: Test Type: Ba Result: negat	acterial reverse mutation assay (AMES) iive
		Test Type: In Result: negat	vitro mammalian cell gene mutation test tive
Geno	otoxicity in vivo	cytogenetic a Species: Mou	use coute: Ingestion





Vers 4.1	sion	Revision Date: 30.09.2023		OS Number: 8044-00016	Date of last issue: 04.04.2023 Date of first issue: 03.05.2016
	Carcin	nogenicity			
	Not cla	assified based on availa	ble	information.	
	<u>Comp</u>	onents:			
	Furos	emide:			
		ation Route ure time L	: :	Rat Ingestion 104 weeks 16 mg/kg body equivocal	weight
		ation Route ure time L	:	Mouse Ingestion 2 Years 91 mg/kg body positive	weight
	Cellul	ose:			
		ation Route ure time		Rat Ingestion 72 weeks negative	
	-	ductive toxicity assified based on availa	ble	information.	
	<u>Comp</u>	onents:			
	Furos	emide:			
	Effects	s on fertility	:	Species: Rat Application Rou General Toxicit	e-generation reproduction toxicity study ute: Ingestion y Parent: NOAEL: 90 mg/kg body weight cts on reproduction parameters.
				Species: Mouse Application Rou General Toxicit	
	Effects	s on fetal development	:	Species: Rat Application Rou General Toxicit Developmental Result: No emb Test Type: Fert	y Maternal: LOAEL: 50 mg/kg body weight Toxicity: NOAEL: 300 mg/kg body weight rryotoxic effects., No teratogenic effects. ility/early embryonic development



ersion 1	Revision Date: 30.09.2023		S Number: 8044-00016	Date of last issue: 04.04.2023 Date of first issue: 03.05.2016
			Species: Rabbi Application Rou General Toxicit Developmental	
			Species: Rabbi Application Rou General Toxicit	
Cellul	ose.			
	s on fertility	:	Test Type: One Species: Rat Application Rou Result: negative	
Effects	s on fetal development	:	Test Type: Fert Species: Rat Application Rou Result: negative	
	-single exposure assified based on availa	blo	information	
	-repeated exposure	DIE	information.	
	• •	idne	ey, Liver) through	prolonged or repeated exposure.
	onents:			
	emide:			
Routes	s of exposure Organs	:		ice significant health effects in animals at cor 0 mg/kg bw or less.
Repea	nted dose toxicity			
<u>Comp</u>	onents:			
Starch	ו:			
		:	Rat >= 2.000 mg/kg Skin contact 28 Days	I

Furosemide:



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Expos	EL EL sution Route sure time t Organs toms	: Dog : 4 mg/kg : 8 mg/kg : Ingestion : 12 Months : Kidney : Blood disord : Significant to	ers oxicity observed in testing
Expos	es	: Rat : >= 9.000 mg : Ingestion : 90 Days	ı/kg
-	assified based on ava	ilable information.	
Expe	rience with human e	cposure	
Comp	oonents:		
Inhala Skin o	contact ontact	: Remarks: M : Remarks: M : Symptoms: ance, dry me	ay be harmful if inhaled. ay irritate skin. ay cause eye irritation. Kidney disorders, Headache, electrolyte imbal- buth, hearing loss, Irregular cardiac activity, Gas- disturbance, hypotension
SECTION	12. ECOLOGICAL IN	FORMATION	
Fcoto	oxicity		
	oonents:		
Furos	semide: ity to fish	: LC50 : 500 r Exposure tir	
Cellu Toxici	lose: ity to fish	Exposure tir	as latipes (Japanese medaka)): > 100 mg/l ne: 48 h ased on data from similar materials
Persi	stence and degradab	bility	
Comp	oonents:		
Cellu Biode	lose: gradability	: Result: Read	dily biodegradable.



Versic 4.1	on	Revision Date: 30.09.2023	SDS Number: 658044-00016	Date of last issue: 04.04.2023 Date of first issue: 03.05.2016
В	Bioacc	umulative potential		
<u>C</u>	Compo	onents:		
Р	Partitio	e mide: n coefficient: n- /water	: log Pow: 2,03	
		r y in soil a available		
		adverse effects a available		
SECT	TION 1	3. DISPOSAL CONSI	DERATIONS	
D	Dispos	al methods		
	-	from residues		of waste into sewer.
С	Contan	ninated packaging	: Empty container handling site for	cordance with local regulations. s should be taken to an approved waste recycling or disposal. specified: Dispose of as unused product.
SECT	TION 1	4. TRANSPORT INFO	RMATION	
l.	ntorna	tional Regulations		
	JNRTE	-		
-		julated as a dangerous	s good	
	ATA-D	OGR julated as a dangerous	s good	
	MDG-0 Not reg	Code julated as a dangerous	s good	
	-	oort in bulk according		POL 73/78 and the IBC Code
	•	I precautions for use	er	
SECT	TION 1	5. REGULATORY INF	FORMATION	
	Safety, nixtur		nental regulations/le	gislation specific for the substance or
	Argenti Registr	na. Carcinogenic Sub y.	stances and Agents	: Not applicable
		of precursors and ess ation of drugs.	sential chemicals for th	e : Not applicable

The ingredients of this product are reported in the following inventories: AICS : not determined



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	DSL		:	not determined	
	IECSC		:	not determined	
SEC	TION 1	6. OTHER INFORMAT	ΓΙΟΙ	N	
	Revisic Date fo		:	30.09.2023 dd.mm.yyyy	
	Furthe	r information			
	Source	s of key data used to the Material Safety	:		data, data from raw material SDSs, OECD arch results and European Chemicals Agen- ropa.eu/
	Full tex	xt of other abbreviation	ons		
	ACGIH AR OE		:		eshold Limit Values (TLV) ational Exposure Limits
		/ TWA L / CMP	:	8-hour, time-weig TLV (Threshold L	
	AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport b 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 wit x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated wit x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys tem; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction an Equipment of Ships carrying Dangerous Chemicals in Bulk: IC50 - Half maximal inhibitory cor				

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



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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 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.

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