

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

SECTION 1. IDENTIFICATION

Product name : Furosemide Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.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

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 dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P314 Get medical advice/ attention if you feel unwell.

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

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
 Date of first issue: 03.05.2016

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

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 : Causes damage to organs through prolonged or repeated exposure.
 Contact with dust can cause mechanical irritation or drying of the skin.
 Dust contact with the eyes can lead to mechanical irritation.

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 : 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.

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	658044-00016	Date of first issue: 03.05.2016

- Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Nitrogen oxides (NO_x)
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.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
-

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.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
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 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 : 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.

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
 Date of first issue: 03.05.2016

- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure 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 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL
		Further information: A4 - Not classifiable as a human carcinogen		
		TWA	10 mg/m ³	ACGIH
Furosemide	54-31-9	TWA	200 µg/m ³	Internal
		TWA	OEB 2 (>=100 - 1000 µg/m ³)	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 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 : 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

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

Skin and body protection : aerosols.
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

Appearance : powder
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 : 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

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

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.
Molecular weight : Not applicable
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : 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 available 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

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

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

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Starch:**

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin 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.

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	658044-00016	Date of first issue: 03.05.2016

Components:

Starch:

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

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

Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
 Date of first issue: 03.05.2016

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 : Mouse
 Application Route : Ingestion
 Exposure time : 2 Years
 LOAEL : 91 mg/kg body weight
 Result : positive

Cellulose:

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

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.

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	658044-00016	Date of first issue: 03.05.2016

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.

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: negative

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:

Starch:

Species : Rat
 NOAEL : >= 2.000 mg/kg
 Application Route : Skin contact
 Exposure time : 28 Days
 Method : OECD Test Guideline 410

Furosemide:

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

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

Cellulose:

Species : Rat
NOAEL : >= 9.000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

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

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Furosemide Solid Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 658044-00016 Date of last issue: 04.04.2023
Date of first issue: 03.05.2016

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.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	658044-00016	Date of first issue: 03.05.2016

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Further information

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/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

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 Substances Inventory; TDG - Transportation of Dangerous Goods; TECl - 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

Furosemide Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	658044-00016	Date of first issue: 03.05.2016

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.

AR / Z8