SAFETY DATA SHEET

Furosemide Solid Formulation

Chemical product name: Furosemide Solid 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

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. General Information

1.2. Supplier’s company name, address and phone number

1.3. Recommendations on first aid measures

1.4. Protective measures and guidance on first-aid measures

1.5. Fire-fighting measures

1.6. Accidental release measures

1.7. Handling and storage

1.8. Exposure controls/Personal protective equipment

1.9. Physical and chemical properties

1.10. Stability

1.11. Chemical stability

1.12. Hazardous decomposition products

1.13. Incompatibility

1.14. Reactions in the environment

1.15. Ecotoxicological data

1.16. Biological/fate information

1.17. Transport information

1.18. Regulatory information

1.19. Safety, health and environmental considerations

1.20. Other information

2. HAZARDS IDENTIFICATION

2.1. GHS classification of chemical product

2.2. Specific target organ toxicity - repeated exposure

2.3. GHS label elements

2.4. Hazard pictograms

2.5. Signal word

2.6. Hazard statements

2.7. Precautionary statements

2.8. Other hazards which do not result in classification

Important symptoms and out-
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Version 3.0 Revision Date: 2020/03/23 SDS Number: 645627-00009 Date of last issue: 2019/09/13
Date of first issue: 2016/05/03

lines of the emergency assumed

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 50 - &lt; 60</td>
<td>8-98</td>
</tr>
<tr>
<td></td>
<td>Furosemide</td>
<td>54-31-9</td>
<td>&gt;= 10 - &lt; 20</td>
<td>9-377</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
</tbody>
</table>

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.

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- : Avoid generating dust; fine dust dispersed in air in sufficient
fighting concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Nitrogen oxides (NOx) Carbon oxides Sulphur 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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. 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.

7. HANDLING AND STORAGE

Handling

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

Avoidance of contact
Hygiene measures

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Furosemide</td>
<td>54-31-9</td>
<td>TWA</td>
<td>200 µg/m3</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>OEB 2 (&gt;=100 - 1000 µg/m3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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
Hand protection
Material
Eye protection
Skin and body protection

Physical state
Colour
Odour
Odour Threshold
Melting point/freezing point
Boiling point, initial boiling point and boiling range
Flammability (solid, gas)
Flammability (liquids)
Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit
Lower explosion limit / Lower flammability limit
Flash point
Decomposition temperature
pH
Evaporation rate
Auto-ignition temperature
Viscosity
Viscosity, kinematic
Solubility(ies)
Water solubility
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
                                               Skin contact
                                               Ingestion
                                               Eye contact

Acute toxicity
Not classified based on available information.

Components:

Starch:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Furosemide:
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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 sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Starch:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Germ cell mutagenicity
Not classified based on available information.
### Components:

#### Starch:
- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

#### Furosemide:
- **Genotoxicity in vitro**:  
  - 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
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 foetal 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
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 development

**Cellulose:**

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

**Effects on foetal 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:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
<tr>
<td>Assessment</td>
<td>Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

**Components:**

**Starch:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 2,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 410</td>
</tr>
</tbody>
</table>

**Furosemide:**
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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

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

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.

Bioaccumulative potential

Components:

Furosemide:
Partition coefficient: n-octanol/water: log Pow: 2.03

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.
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.

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.

National Regulations
Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
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

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

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**

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

Date format: yyyy/mm/dd

**Full text of other abbreviations**
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; 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
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