SAFETY DATA SHEET

Furosemide Solid Formulation

SECTION 1. IDENTIFICATION

Product name : Furosemide Solid Formulation
Other means of identification : No data available

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations
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 attention if you feel unwell.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
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**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>Sago starch</td>
<td>9005-25-8</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Furosemide</td>
<td>No data available</td>
<td>54-31-9</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
</tbody>
</table>

* 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:**
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.
Exposure to combustion products may be a hazard to health.

| Hazardous combustion products | Nitrogen oxides (NOx)  
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. |
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
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<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>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Furosemide</td>
<td>54-31-9</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>OEB 2 (&gt;=100 - 1000 µg/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
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<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</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.
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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

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.

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.

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
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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:
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.

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

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.

  **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:
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

SECTİON 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Furosemide:
Toxicity to fish: LC50: 500 mg/l
Exposure time: 96 h
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**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

**Other adverse effects**
- No data available

### SECTION 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.

### 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
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Revision Date: 08/27/2021
SDS Number: 645615-00011
Date of last issue: 10/10/2020
Date of first issue: 05/03/2016

Special precautions for user
Not applicable

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

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **CA AB OEL**: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
- **CA BC OEL**: Canada. British Columbia OEL
- **CA QC OEL**: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CA AB OEL / TWA**: 8-hour Occupational exposure limit
- **CA BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWA EV**: Time-weighted average exposure value

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;
Furosemide Solid Formulation

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 08/27/2021
Date format: mm/dd/yyyy

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