1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Furosemide Solid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Specific target organ toxicity - repeated exposure : Category 1 (Kidney, Liver)

GHS label elements
Hazard pictograms : [Icon]
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:
P319 Get medical help if you feel unwell.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Furosemide</td>
<td>54-31-9</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5</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-
### 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 (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.

### 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 and Advice on safe handling:**
- Use only with adequate ventilation.
- 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 labelled containers.
- Store in accordance with the particular national regulations.

**Materials to avoid**
- Do not store with the following product types:
  - Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

<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></td>
<td></td>
<td>TWA</td>
<td>OEB 2 (&gt;=100 - 1000 ug/m³)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</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.

**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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: yellow
Odour: No data available
Odour 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
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition 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

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.

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 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 Solid Formulation

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
Furosemide Solid Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>LOAEL</td>
<td>16 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
</tbody>
</table>

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

**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 eggs
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:
Exposure routes : 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

**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
SAFETY DATA SHEET

Furosemide Solid Formulation

Mobility in soil
No data available

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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.

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