SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Furosemide Solid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   Kilsheelan
   Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Specific target organ toxicity - repeated exposure, Category 1
   H372: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   
   Signal word : Danger
   Hazard statements : H372 Causes damage to organs 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.

Hazardous components which must be listed on the label:
Furosemide

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No. Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide</td>
<td>54-31-9</td>
<td>200-203-6</td>
<td>STOT RE 1; H372 (Kidney, Liver)</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: 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
Sulphur oxides
Chlorine compounds

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
- 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.

**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.

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers**

Keep in properly labelled containers. Store in accordance with the particular national regulations.

**Advice on common storage**

Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

### 7.3 Specific end use(s)

**Specific use(s)**

No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (inhalable dust)</td>
<td>10 mg/m³</td>
<td>IE OEL</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>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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
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.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: powder
Colour: yellow
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: 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
Flash point: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
pH: No data available
Viscosity
  Viscosity, kinematic : No data available

Solubilities
  Water solubility : No data available

Partition coefficient: n-octanol/water
  Vapour pressure : No data available

Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
  Particle size : No data available

9.2 Other information
  Explosives : Not explosive
  Oxidizing properties : The substance or mixture is not classified as oxidizing.
  Evaporation rate : No data available
  Molecular weight : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity
Not classified based on available information.

Components:

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

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:

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 syn-
thesis 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

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

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs 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:

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

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components consid-
ered to have endocrine disrupting properties according to
REACH Article 57(f) or Commission Delegated regulation
(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
levels of 0.1% or higher.

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 imbal-
ance, dry mouth, hearing loss, Irregular cardiac activity, Gas-
trointestinal disturbance, hypotension

SECTION 12: Ecological information

12.1 Toxicity

Components:

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

12.2 Persistence and degradability
No data available
Furosemide Solid Formulation

12.3 Bioaccumulative potential

**Components:**

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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**
- Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
- Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
- Dispose of in accordance with local regulations.
  - According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
  - Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**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

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Furosemide Solid Formulation

Version 3.5  Revision Date: 27.08.2021  SDS Number: 658059-00011  Date of last issue: 10.10.2020

Date of first issue: 03.05.2016

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Maritime transport in bulk according to IMO instruments
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):
Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59):
Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:
Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast):
Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:
Not applicable

REACH - List of substances subject to authorisation (Annex XIV):
Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information:
Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
Furosemide Solid Formulation

Full text of H-statements
H372 : Causes damage to organs through prolonged or repeated exposure.

Full text of other abbreviations
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; IECS - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Road; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
STOT RE 1 H372

Classification procedure:
Calculation method
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.

IE / EN