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

1.1 Product identifier
   Trade name : Ertugliflozin Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Innishannon
             County Cork - Ireland
   Telephone : 353 214329300
   Telefax : 908-735-1496
   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)
   Skin corrosion, Sub-category 1B : H314: Causes severe skin burns and eye damage.
   Serious eye damage, Category 1 : H318: Causes serious eye damage.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :

   Signal word : Danger
   Hazard statements : H314 Causes severe skin burns and eye damage.
   Precautionary statements : Prevention:
                            P260 Do not breathe dust or mist.
                            P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.2
Revision Date: 09/13/2019
SDS Number: 2338808-00005
Date of last issue: 24.04.2019
Date of first issue: 13.12.2017

Response:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/doctor.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
Ertugliflozin

2.3 Other hazards
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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT RE 2; H373</td>
<td>&gt;= 5 - &lt; 10</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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.
Get medical attention immediately.

In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention immediately.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

If swallowed: If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Causes serious eye damage.
Causes severe burns.
Causes digestive tract burns.

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: Carbon oxides
Metal oxides
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 and personal protective equipment recommendations.

6.2 Environmental precautions

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.

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: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- 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.

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 locked up. Keep tightly closed. 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

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>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2338808-00005  Date of last issue: 24.04.2019  Date of first issue: 13.12.2017

| Wipe limit | 100 µg/100 cm² | Internal |

8.2 Exposure controls

Engineering measures
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

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
Remarks: Consider double gloving.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: No data available
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: Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
  Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
  Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : No data available

Particle size : No data available

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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2338808-00005  Date of last issue: 24.04.2019
2.2  Revision Date: 09/13/2019  SDS Number: 2338808-00005  Date of last issue: 24.04.2019

Date of first issue: 13.12.2017

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 toxicological effects

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: > 2,000 mg/kg
   Method: Calculation method

Components:

Ertugliflozin:
Acute oral toxicity: LD50 (Rat): 500 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Causes severe burns.

Components:

Ertugliflozin:
Result: Corrosive

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Ertugliflozin:
Result: Severe irritation
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Ertugliflozin:
Test Type : Local lymph node assay (LLNA)
Result : Not a skin sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Ertugliflozin:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result : negative
Test Type: Chromosome aberration test in vitro
Result : negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Result : negative

Carcinogenicity
Not classified based on available information.

Components:

Ertugliflozin:
Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity
Not classified based on available information.
Components:

Ertugliflozin:

Effects on fertility:
- Test Type: Fertility/early embryonic development
  - Species: Rat
  - Application Route: Oral
  - Fertility: NOAEL: 250 mg/kg body weight
  - Remarks: Maternal toxicity observed.
  - No significant adverse effects were reported

  - Test Type: Fertility/early embryonic development
    - Species: Rabbit
    - Application Route: Oral
    - Fertility: NOAEL: 200 mg/kg body weight
    - Remarks: No significant adverse effects were reported

Effects on foetal development:
- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 50 mg/kg body weight
  - Remarks: Adverse developmental effects were observed

  - Test Type: Embryo-foetal development
    - Species: Rabbit
    - Application Route: Oral
    - Developmental Toxicity: NOAEL: 250 mg/kg body weight
    - Remarks: No significant adverse effects were reported

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Ertugliflozin:

Exposure routes: Oral
Target Organs: Kidney, Stomach, Prostate
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ertugliflozin:

Species: Rat
LOAEL: 500 mg/kg
Application Route: Oral
Exposure time: 30 d

Species: Rat
LOAEL: 250 mg/kg
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Application Route: Oral
Exposure time: 30 d
Target Organs: Kidney

Species: Rat
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 180 d
Target Organs: Kidney, Bone, Stomach

Species: Rat
LOAEL: 25 mg/kg
Exposure time: 90 d
Target Organs: Kidney, Gastrointestinal tract, Prostate

Species: Dog
NOAEL: 150 mg/kg
Application Route: Oral
Exposure time: 270 d
Remarks: No significant adverse effects were reported

Species: Mouse
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Ertugliflozin:
Ingestion: Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ertugliflozin:
Toxicity to algae/aquatic: EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l
12.2 Persistence and degradability

**Components:**

**Ertugliflozin:**
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40.8 %
Exposure time: 28 d

12.3 Bioaccumulative potential

**Components:**

**Ertugliflozin:**
Partition coefficient: n-octanol/water : log Pow: 2.47

12.4 Mobility in soil

**Components:**

**Ertugliflozin:**
Distribution among environmental compartments : log Koc: 2.88
SAFETY DATA SHEET 
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version: 2.2
Revision Date: 09/13/2019
SDS Number: 2338808-00005
Date of last issue: 24.04.2019
Date of first issue: 13.12.2017

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 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
ADN: UN 1759
ADR: UN 1759
RID: UN 1759
IMDG: UN 1759
IATA: UN 1759

14.2 UN proper shipping name
ADN: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
ADR: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
RID: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
IMDG: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
IATA: Corrosive solid, n.o.s. (Ertugliflozin)

14.3 Transport hazard class(es)
ADN: 8
ADR: 8
RID: 8
IMDG: 8
IATA: 8
14.4 Packing group

**ADN**
Packing group : II  
Classification Code : C10  
Hazard Identification Number : 80  
Labels : 8  

**ADR**
Packing group : II  
Classification Code : C10  
Hazard Identification Number : 80  
Labels : 8  
Tunnel restriction code : (E)  

**RID**
Packing group : II  
Classification Code : C10  
Hazard Identification Number : 80  
Labels : 8  

**IMDG**
Packing group : II  
Labels : 8  
EmS Code : F-A, S-B  

**IATA (Cargo)**
Packing instruction (cargo aircraft) : 863  
Packing instruction (LQ) : Y844  
Packing group : II  
Labels : Corrosive  

**IATA (Passenger)**
Packing instruction (passenger aircraft) : 859  
Packing instruction (LQ) : Y844  
Packing group : II  
Labels : Corrosive  

14.5 Environmental hazards

**ADN**
Environmentally hazardous : no  

**ADR**
Environmentally hazardous : no  

**RID**
Environmentally hazardous : no  

**IMDG**
Marine pollutant : no  

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
SAFETY DATA SHEET 
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 2338808-00005  Date of last issue: 24.04.2019
Date of first issue: 13.12.2017

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
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 - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
- REACH - List of substances subject to authorisation (Annex XIV): Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
- Regulation (EC) No 850/2004 on persistent organic pollutants: 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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): 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.

Full text of H-statements

- H302: Harmful if swallowed.
- H314: Causes severe skin burns and eye damage.
- H318: Causes serious eye damage.
- H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

Full text of other abbreviations
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.2
Revision Date: 09/13/2019
SDS Number: 2338808-00005
Date of last issue: 24.04.2019
Date of first issue: 13.12.2017

16 / 17

Acute Tox.: Acute toxicity
Eye Dam.: Serious eye damage
Skin Corr.: Skin corrosion
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)

Further information

Classification of the mixture: Skin Corr. 1B H314 Calculation method
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