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
           Shotton Lane
           NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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.
Ertugliflozin Formulation

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td></td>
<td></td>
<td>Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT RE 2; H373 (Kidney, Stomach, Prostate)</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

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 (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.
Section 4: Transport Information

4.1 UN/MP number: 0
4.2 UN/MP class: 0
4.3 Special provisions: 0
4.4 Special precautions: 0
4.5 Advice for medical treatment: 0

Section 5: Health Effects

5.1 Acute effects: 0
5.2 Chronic effects: 0
5.3 Effects of exposure: 0
5.4 Symptoms of exposure: 0
5.5 Cautions: 0

Section 6: Biological Effects

6.1 Acute effects: 0
6.2 Chronic effects: 0
6.3 Effects of exposure: 0
6.4 Symptoms of exposure: 0
6.5 Cautions: 0

Section 7: MSDS History

7.1 Date of last issue: 23.03.2020
7.2 Date of first issue: 13.12.2017
7.3 Date of last amendment: 10.10.2020
7.4 Description of changes: 0

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

8.1.1 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>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Section 9: Physical and Chemical Properties

9.1 Physical properties: 0
9.2 Chemical properties: 0

Section 10: Stability and Reactivity

10.1 Stability: 0
10.2 Reactivity: 0

Section 11: Fire and Explosion Hazards

11.1 Fire: 0
11.2 Explosive: 0

Section 12: Spill/Fire/Firefighting

12.1 Spill procedures: 0
12.2 Fire-fighting procedures: 0

Section 13: Toxicological Information

13.1 Acute toxicity: 0
13.2 Chronic toxicity: 0
13.3 Mutagenicity: 0
13.4 Carcinogenicity: 0
13.5 Specific target organs: 0
13.6 Reactivity: 0

Section 14: Environmental Information

14.1 Persistence and bioaccumulation: 0
14.2 Mobility and bioaccumulation: 0
14.3 Toxicity: 0
14.4 Ecotoxicity: 0
14.5 Photochemical reactivity: 0

Section 15: Ecological Aspects

15.1 Effects on aquatic organisms: 0
15.2 Effects on terrestrial organisms: 0
15.3 Effects on soil organisms: 0
15.4 Effects on other organisms: 0
15.5 Persistence and bioaccumulation: 0
15.6 Mobility and bioaccumulation: 0
15.7 Toxicity: 0
15.8 Ecotoxicity: 0
15.9 Photochemical reactivity: 0

Section 16: Other Information

16.1 Additional information: 0

Section 17: Disposal Considerations

17.1 Disposal methods: 0

Section 18: Regulatory Information

18.1 National regulations: 0
18.2 International regulations: 0

Section 19: Other Information

19.1 Additional information: 0

Section 20: Certification

20.1 Certification date: 0
20.2 Certification body: 0
20.3 Certification number: 0
20.4 Certification status: 0

Section 21: References

21.1 Sources of information: 0

Section 22: Amendment History

22.1 Date of amendment: 0
22.2 Amendment description: 0

Section 23: Notes

23.1 Notes: 0

Section 24: Declarations

24.1 Declaration of content: 0
24.2 Declaration of accuracy: 0
24.3 Declaration of compliance: 0
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
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
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 NS EN 143

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

Ertugliflozin Formulation

Version 2.4  Revision Date: 10.10.2020  SDS Number: 2338804-00007  Date of last issue: 23.03.2020
Date of first issue: 13.12.2017

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

Species: Rat
Ertugliflozin Formulation

Version: 2.4
Revision Date: 10.10.2020
SDS Number: 2338804-00007
Date of last issue: 23.03.2020
Date of first issue: 13.12.2017

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

Species: Mouse
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Bone
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 plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.4 Revision Date: 10.10.2020 SDS Number: 2338804-00007 Date of last issue: 23.03.2020 Date of first issue: 13.12.2017

Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms:
EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity):
NOEC: 1 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 2,14 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

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

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

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1759</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 1759</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1759</td>
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<tr>
<td>IMDG</td>
<td>UN 1759</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1759</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>CORROSIVE SOLID, N.O.S. (Ertugliflozin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>CORROSIVE SOLID, N.O.S. (Ertugliflozin)</td>
</tr>
<tr>
<td>RID</td>
<td>CORROSIVE SOLID, N.O.S. (Ertugliflozin)</td>
</tr>
<tr>
<td>IMDG</td>
<td>CORROSIVE SOLID, N.O.S. (Ertugliflozin)</td>
</tr>
<tr>
<td>IATA</td>
<td>Corrosive solid, n.o.s. (Ertugliflozin)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>8</th>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
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<td>IMDG</td>
<td>8</td>
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<tr>
<td>IATA</td>
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</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group    : II</td>
</tr>
<tr>
<td>Classification Code : C10</td>
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</tbody>
</table>
## Ertugliflozin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>2.4</td>
<td>10.10.2020</td>
<td>2338804-00007</td>
<td>23.03.2020</td>
<td>13.12.2017</td>
</tr>
</tbody>
</table>

| 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.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

| Remarks |
| Not applicable for product as supplied. |
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ertugliflozin Formulation

Version 2.4 Revision Date: 10.10.2020 SDS Number: 2338804-00007 Date of last issue: 23.03.2020 Date of first issue: 13.12.2017

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
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 (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

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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
Acute Tox. : Acute toxicity
## SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

**Ertugliflozin Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<td>23.03.2020</td>
<td>13.12.2017</td>
</tr>
</tbody>
</table>

**Eye Dam.**: Serious eye damage  
**Skin Corr.**: Skin corrosion  
**STOT RE**: Specific target organ toxicity - repeated exposure

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; 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; 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 Rail; 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; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information


**Classification of the mixture:**

| Skin Corr. 1B | H314 | Calculation method |
| Eye Dam. 1 | H318 | 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 mate-
Ertugliflozin Formulation

Version | Revision Date: | SDS Number: | Date of last issue: 23.03.2020 | Date of first issue: 13.12.2017
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2.4 | 10.10.2020 | 2338804-00007 | |

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.

NO / EN