

**Ertugliflozin Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
Date of first issue: 13.12.2017

---

**SECTION 1. IDENTIFICATION**

Product name : Ertugliflozin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Serious eye damage/eye irritation : Category 1

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

Precautionary Statements : **Prevention:**  
P280 Wear eye protection/ face protection.

**Response:**  
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.

**Other hazards which do not result in classification**

Contact with dust can cause mechanical irritation or drying of the skin.

## Ertugliflozin Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
 Date of first issue: 13.12.2017

May form explosive dust-air mixture during processing, handling or other means.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name    | CAS-No.      | Concentration (% w/w) |
|------------------|--------------|-----------------------|
| Cellulose        | 9004-34-6    | >= 50 -< 70           |
| Ertugliflozin    | 1210344-83-4 | >= 5 -< 10            |
| Titanium dioxide | 13463-67-7   | >= 0,1 -< 1           |

**SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
 Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.  
 Get medical attention if symptoms occur.

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.  
 Get medical attention if symptoms occur.  
 Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes serious eye damage.  
 Contact with dust can cause mechanical irritation or drying of the skin.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
 Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
 Metal oxides

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**SECTION 7. HANDLING AND STORAGE**

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
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.

## Ertugliflozin Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
Date of first issue: 13.12.2017

Conditions for safe storage : Take care to prevent spills, waste and minimize release to the environment.  
Keep in properly labeled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

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

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

| Components   | CAS-No.      | Value type (Form of exposure)       | Control parameters / Permissible concentration | Basis    |
|--|--------------|-------------------------------------|--|----------|
| Cellulose  | 9004-34-6    | CMP                                 | 10 mg/m <sup>3</sup>                           | AR OEL   |
|  |              | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Ertugliflozin  | 1210344-83-4 | TWA                                 | 10 µg/m <sup>3</sup> (OEB 3)                   | Internal |
|  |              | Wipe limit                          | 100 µg/100 cm <sup>2</sup>                     | Internal |
| Titanium dioxide   | 13463-67-7   | CMP                                 | 10 mg/m <sup>3</sup>                           | AR OEL   |
| Further information: A4 - Not classifiable as a human carcinogen |              |                                     |  |          |
|  |              | TWA (Respirable particulate matter) | 2,5 mg/m <sup>3</sup> (Titanium dioxide)       | ACGIH    |

**This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.**

Titanium dioxide

**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**

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

Remarks : Consider double gloving.  
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

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

- potential for direct contact to the face with dusts, mists, or aerosols.
- 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.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance** : powder
- Color** : No data available
- Odor** : No data available
- Odor Threshold** : No data available
- pH** : No data available
- Melting point/freezing point** : No data available
- Initial boiling point and boiling range** : No data available
- Flash point** : Not applicable
- Evaporation rate** : Not applicable
- 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
- Vapor pressure** : Not applicable
- Relative vapor density** : Not applicable

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

|  |   |  |
|--|---|--|
| Relative density                       | : | No data available  |
| Density                                | : | No data available  |
| Solubility(ies)                        | : |  |
| Water solubility                       | : | No data available  |
| Partition coefficient: n-octanol/water | : | Not applicable   |
| Autoignition 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. |
| Particle size                          | : | No data available  |

---

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |  |
|------------------------------------|---|--|
| Reactivity                         | : | Not classified as a reactivity hazard.   |
| Chemical stability                 | : | Stable under normal conditions.  |
| Possibility of hazardous reactions | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

---

**SECTION 11. TOXICOLOGICAL INFORMATION**

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

**Acute toxicity**

Not classified based on available information.

**Product:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: > 5.000 mg/kg<br>Method: Calculation method |
|---------------------|---|--|

**Components:**

**Cellulose:**

**Ertugliflozin Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
Date of first issue: 13.12.2017

---

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

**Ertugliflozin:**

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

**Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Assessment : No skin irritation  
Method : EpiDerm  
Result : Not corrosive

**Components:****Ertugliflozin:**

Result : Corrosive

**Titanium dioxide:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Ertugliflozin:**

Result : Severe irritation

**Titanium dioxide:**

Species : Rabbit

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

Result : No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Ertugliflozin:**

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

**Titanium dioxide:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****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

**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

**Titanium dioxide:**



## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

**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

**Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.  
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

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

Test Type: Embryo-fetal 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:**

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

**Repeated dose toxicity****Components:****Cellulose:**

## Ertugliflozin Formulation

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
 Date of first issue: 13.12.2017

---

Species : Rat  
 NOAEL : >= 9.000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days

**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  
 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

**Titanium dioxide:**

Species : Rat  
 NOAEL : 24.000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 28 Days

Species : Rat

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

NOAEL : 10 mg/m<sup>3</sup>  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 2 y

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Ertugliflozin:**

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

---

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l  
 Exposure time: 48 h  
 Remarks: Based on data from similar materials

**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  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

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

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

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

**Ertugliflozin Formulation**

Version 4.1      Revision Date: 30.09.2023      SDS Number: 2338800-00016      Date of last issue: 04.04.2023  
Date of first issue: 13.12.2017

---

Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Titanium dioxide:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l  
Exposure time: 72 h
- Toxicity to microorganisms : EC50: > 1.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Ertugliflozin:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 40,8 %  
Exposure time: 28 d

**Bioaccumulative potential****Components:****Ertugliflozin:**

Partition coefficient: n-octanol/water : log Pow: 2,47

**Mobility in soil****Components:****Ertugliflozin:**

Distribution among environmental compartments : log Koc: 2,88

**Other adverse effects**

No data available

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

---

Contaminated packaging : Dispose of in accordance with local regulations.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**Revision Date : 30.09.2023  
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>**Full text of other abbreviations**

## Ertugliflozin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04.04.2023  |
| 4.1     | 30.09.2023     | 2338800-00016 | Date of first issue: 13.12.2017 |

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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.

AR / Z8