SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ertugliflozin Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090

Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin corrosion: Sub-category 1B
Serious eye damage: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Kidney, Stomach, Prostate)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H314 Causes severe skin burns and eye damage.
H373 May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

Precautionary Statements
Prevention:
P260 Do not breathe dusts or mists.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/ physician.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower. Immediately call a POISON CENTER or doctor/ physician.
P304 + P340 + P310 IF INHALED: Remove victim to fresh air
and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
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 or doctor/physician.
P314 Get medical advice/attention if you feel unwell.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 50 &lt; 70</td>
<td></td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>&gt;= 5 &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 &lt; 1</td>
<td></td>
</tr>
</tbody>
</table>

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. 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 center immediately. Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:
- Causes serious eye damage.
- May cause damage to organs through prolonged or repeated exposure if swallowed.
- Causes severe burns.
- Causes digestive tract burns.

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 (CO2)
- 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

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 and personal protective equipment recommendations.

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 spills 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: 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.
Conditions for safe storage: Keep in properly labeled containers. Store locked up. 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 Organic peroxides Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of Control parameters)</th>
<th>Basis</th>
</tr>
</thead>
</table>

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These substance(s) are inextricably bound in the product and therefore do 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

**Eye protection**

- **Remarks**: Consider double gloving.
- **Color**: No data available

**Skin and body protection**

- **Appearance**: powder
- **Material**: Chemical-resistant gloves

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.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility (water solubility)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**SECTION 10. STABILITY AND REACTIVITY**
SAFETY DATA SHEET

Ertugliflozin Formulation

Reactivity
: Not classified as a reactivity hazard.

Chemical stability
: Stable under normal conditions.

Possibility of hazardous reactions
: May form explosive dust-air mixture during processing, handling or other means.

: Can react with strong oxidizing agents.

Conditions to avoid
: Heat, flames and sparks.

: Avoid dust formation.

Incompatible materials
: Oxidizing agents

Hazardous decomposition products
: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation

Skin contact

Ingestion

Eye contact

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity
: Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

Cellulose:

Acute oral toxicity
: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity
: LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity
: LD50 (Rabbit): > 2,000 mg/kg

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
Causes severe burns.

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
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:

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.

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
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
May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

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:**
- 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
SAFETY DATA SHEET

Ertugliflozin Formulation

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

Species : Rat
NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat
NOAEL : 10 mg/m³
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
  - 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 : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
                      : If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1759
Proper shipping name : CORROSIVE SOLID, N.O.S.
(Ertugliflozin)
Class : 8
Packing group : II
Labels : 8

IATA-DGR
UN/ID No. : UN 1759
Proper shipping name : Corrosive solid, n.o.s.
(Ertugliflozin)
Class : 8
Packing group : II
Labels : Corrosive
Packing instruction (cargo aircraft) : 863
Packing instruction (passenger aircraft) : 859

IMDG-Code
UN number : UN 1759
Proper shipping name: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
Class: 8
Packing group: II
Labels: 8
EmS Code: F-A, S-B
Marine pollutant: no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation
NOM-002-SCT
UN number: UN 1759
Proper shipping name: CORROSIVE SOLID, N.O.S. (Ertugliflozin)
Class: 8
Packing group: II
Labels: 8

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: 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

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT: Time weighted average limit value
SAFETY DATA SHEET

Ertugliflozin Formulation

Version 3.2
Revision Date: 09/13/2019
SDS Number: 2337991-00006
Date of last issue: 24.04.2019
Date of first issue: 13.12.2017

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8