SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin / Metformin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina  C1001AFB
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATATESTWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral) : Category 4

GHS label elements
Hazard pictograms :

Signal Word : Warning
Hazard Statements : H302 Harmful if swallowed.
Precautionary Statements :
Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>&gt;= 70 -&lt; 90</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>&gt;= 0,25 -&lt; 1</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.
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 : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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
- Nitrogen oxides (NOx)
- 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 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.
- Avoid contact with 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.
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.

Conditions for safe storage:
- Keep in properly labeled containers.
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1) Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>CMP</td>
<td>10 mg/m³ AR OEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³ AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP</td>
<td>10 mg/m³ AR OEL</td>
</tr>
</tbody>
</table>

Further information:
- A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories.
- Irritation

<table>
<thead>
<tr>
<th>Components</th>
<th>TWA (Inhalable fraction)</th>
<th>Control parameters / Permissible concentration Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>TWA (Respirable fraction)</th>
<th>Control parameters / Permissible concentration Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>TWA</th>
<th>Control parameters / Permissible concentration Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Wipe limit</th>
<th>Control parameters / Permissible concentration Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**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.
SAFETY DATA SHEET

Ertugliflozin / Metformin Formulation

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 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

### 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.
  - 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
Harmful if swallowed.

Product:
Acute oral toxicity : Acute toxicity estimate: 1.337 mg/kg
Method: Calculation method

Components:
metformin hydrochloride:
Acute oral toxicity : LD50 (Rat): 1.000 mg/kg
LD50 (Mouse): 1.450 - 3.500 mg/kg
LD50 (Monkey): 463 mg/kg
LD50 (Rabbit): 350 mg/kg
LD50 (Guinea pig): 500 mg/kg

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

Magnesium stearate:
Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Remarks: Based on data from similar materials

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
Not classified based on available information.

Components:
metformin hydrochloride:
SAFETY DATA SHEET

Ertugliflozin / Metformin Formulation

Species: Rabbit
Result: Mild skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Ertugliflozin:
Result: Corrosive

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

Components:
metformin hydrochloride:
Species: Rabbit
Result: Mild eye irritation

Magnesium stearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

Ertugliflozin:
Result: Severe irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Magnesium stearate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Ertugliflozin:
Test Type: Local lymph node assay (LLNA)
Result: Not a skin sensitizer.
Germ cell mutagenicity
Not classified based on available information.

**Components:**

**metformin hydrochloride:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: in vitro test
  Test system: mouse lymphoma cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative

**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

**Magnesium stearate:**

Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Remarks: Based on data from similar materials

**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:

metformin hydrochloride:
Species: Mouse  
Exposure time: 91 weeks  
Dose: 1500 mg/kg body weight  
Result: negative
Species: Rat, male  
Application Route: Oral  
Exposure time: 104 weeks  
Dose: 900 mg/kg body weight  
Result: negative
Species: Rat, female  
Application Route: Oral  
Exposure time: 104 weeks  
LOAEL: 900 mg/kg body weight  
Result: negative  
Target Organs: Uterus (including cervix)  
Remarks: The mechanism or mode of action may not be relevant in humans.

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
Reproductive toxicity
Not classified based on available information.

Components:

**Metformin hydrochloride:**
- **Effects on fertility**
  - Test Type: Fertility
  - Species: Rat
  - Application Route: Oral
  - Fertility: NOAEL: 600 mg/kg body weight
  - Result: No effects on fertility.

  **Effects on fetal development**
  - Test Type: Development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: NOAEL: 600 mg/kg body weight
  - Result: No teratogenic effects.

  - Test Type: Embryo-fetal development
    - Species: Rabbit
    - Application Route: Oral
    - Embryo-fetal toxicity: NOAEL: 140 mg/kg body weight
    - Result: No teratogenic effects.

**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

**Magnesium stearate:**
- **Effects on fertility**
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
    - Species: Rat
    - Application Route: Ingestion
    - Method: OECD Test Guideline 422
    - Result: negative
    - Remarks: Based on data from similar materials

  **Effects on fetal development**
  - Test Type: Embryo-fetal development
    - Species: Rat
    - Application Route: Ingestion
    - Result: negative
    - Remarks: Based on data from similar materials

**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:**

**metformin hydrochloride:**
- **Species:** Rat
  - **NOAEL:** 125 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 1 year
  - **Remarks:** No significant adverse effects were reported

- **Species:** Rabbit
  - **NOAEL:** 100 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 1 Year
  - **Remarks:** No significant adverse effects were reported
Species  :  Dog  
NOAEL  :  50 mg/kg  
Application Route  :  Subcutaneous  
Exposure time  :  2 year  
Remarks  :  No significant adverse effects were reported  

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

**Magnesium stearate:**
Species  :  Rat  
NOAEL  :  > 100 mg/kg  
Application Route  :  Ingestion  
Exposure time  :  90 Days  
Remarks  :  Based on data from similar materials  

**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

#### Aspiration toxicity
Not classified based on available information.

#### Experience with human exposure

### Components:

#### metformin hydrochloride:
- **Skin contact**: Remarks: May irritate skin.
- **Eye contact**: Remarks: May irritate eyes.
- **Ingestion**: Symptoms: Diarrhea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

### 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:

#### metformin hydrochloride:
- **Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): 10 mg/l
  - Exposure time: 33 d
  - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 40 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **Toxicity to microorganisms**: EC50: > 1.000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
**SAFETY DATA SHEET**

**Ertugliflozin / Metformin Formulation**

**Method:** OECD Test Guideline 209

**Cellulose:**

Toxicity to fish

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>LC50 (Oryzias latipes (Japanese medaka)):</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
</table>

Remarks: Based on data from similar materials

**Magnesium stearate:**

Toxicity to fish

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>LC50 (Leuciscus idus (Golden orfe)):</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
</table>

Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EL50 (Daphnia magna (Water flea)):</th>
<th>Exposure time: 47 h</th>
</tr>
</thead>
</table>

Test substance: Water Accommodated Fraction


Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
</table>

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC10 (Pseudomonas putida):</th>
<th>Exposure time: 16 h</th>
</tr>
</thead>
</table>

Test substance: Water Accommodated Fraction

Remarks: Based on data from similar materials

**Ertugliflozin:**

Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
</table>

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)

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>NOEC (Pimephales promelas (fathead minnow)):</th>
<th>Exposure time: 32 d</th>
</tr>
</thead>
</table>

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

Persistence and degradability

Components:

**metformin hydrochloride:**
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 2 hrs

**Cellulose:**
Biodegradability: Result: Readily biodegradable.

**Magnesium stearate:**
Biodegradability: Result: Not biodegradable.
Remarks: Based on data from similar materials

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

Bioaccumulative potential

Components:

**metformin hydrochloride:**
Partition coefficient: n-octanol/water: log Pow: -2

**Magnesium stearate:**
Partition coefficient: n-octanol/water: log Pow: > 4

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

Components:

**metformin hydrochloride:**
Distribution among environmental compartments: log Koc: 4,3
Method: OECD Test Guideline 106

**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**
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.

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

International Regulations

The ingredients of this product are reported in the following inventories:
SAFETY DATA SHEET

Ertugliflozin / Metformin Formulation

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
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)

AICS - Australian Inventory of Chemical Substances; 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; IMHO - 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; 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.

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