SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ertugliflozin / Metformin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin / Metformin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | powder |
| Colour | No data available |
| Odour | No data available |

Harmful if swallowed.

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:
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according to GB/T 16483 and GB/T 17519

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Version: 2.7
Revision Date: 09/13/2019
SDS Number: 590550-00009
Date of last issue: 2019/04/24
Date of first issue: 2016/04/01

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Harmful if swallowed.

Environmental hazards
Not classified based on available information.

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.

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; 10</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>&gt;= 0.25 -&lt; 1</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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
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 firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.
7. HANDLING AND STORAGE

Handling
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling: Do not breathe dust.
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 assessment.
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.
Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers.
Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</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.

**Filter type**
- Particulates type

**Eye/face 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.

**Hand protection**
- Chemical-resistant gloves

**Remarks**
- Consider double gloving.

**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.

### 9. 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
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.
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: No data available.
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11. TOXICOLOGICAL INFORMATION

**Exposure routes:** 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

**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
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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:
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 sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.
Components:

Magnesium stearate:
Test Type: Maximisation Test
Exposure routes: 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 assay
  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
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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 foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 600 mg/kg body weight
Result: No teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal 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 foetal 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 foetal 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 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:

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
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<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>180 d</td>
<td>Kidney, Bone, Stomach</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>Kidney, Gastrointestinal tract, Prostate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>150 mg/kg</td>
<td>Oral</td>
<td>270 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>28 d</td>
<td>Bone</td>
</tr>
</tbody>
</table>

**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: Diarrhoea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

**Ertugliflozin:**

- **Ingestion**: Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection
### Ecological Information

**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
  - Method: OECD Test Guideline 209

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

**Magnesium stearate:**
- **Toxicity to fish:** LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
  - Exposure time: 48 h
  - Method: DIN 38412
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:** EL50 (Daphnia magna (Water flea)): > 1 mg/l
  - Exposure time: 47 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials
  - No toxicity at the limit of solubility

- **Toxicity to algae/aquatic plants:** EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
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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: EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
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

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

**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.

**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.

**National Regulations**

**GB 6944/12268**  
Not regulated as a dangerous good

**Special precautions for user**  
Not applicable

**15. REGULATORY INFORMATION**

**National regulatory information**

Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**16. OTHER INFORMATION**

**Further information**


Date format: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA, ACGIH Threshold Limit Values (TLV)
- **GBZ 2.1-2007**: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ertugliflozin / Metformin Formulation

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ACGIH / TWA : 8-hour, time-weighted average
GBZ 2.1-2007 / PC-TWA : Permissible concentration - time weighted average

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 Sys-
tem; 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 con-
centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chem-
ical 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 Con-
centration 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 Develop-
ment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-
lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-
es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-
tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tem-
perature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Trans-
portation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - Unit-
ed Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials In-
formation System

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, infor-
mation 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-
rial is used in combination with any other materials or in any process, unless specified in the text.
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