1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Ertugliflozin (< 2%) / Sitagliptin Formulation

Supplier's company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

- Skin corrosion/irritation: Category 2
- Serious eye damage/eye irritation: Category 2A
- Short-term (acute) aquatic hazard: Category 3

GHS label elements

- Hazard pictograms: ![Warning]
- Signal word: Warning
- Hazard statements: H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H402 Harmful to aquatic life.
- Precautionary statements: Prevention:
  P264 Wash skin thoroughly after handling.
  P273 Avoid release to the environment.
  P280 Wear protective gloves/ eye protection/ face protection.
  Response:
  P302 + P352 IF ON SKIN: Wash with plenty of water.
  P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

Version: 6.0
Revision Date: 2021/04/09
SDS Number: 595276-00014
Date of last issue: 2020/10/01
Date of first issue: 2016/04/04

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:
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.
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.

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:
Causes skin irritation.
Causes serious eye irritation.

Other hazards which do not result in classification:
Important symptoms and outlines of the emergency assumed:
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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 40</td>
<td></td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>121034-83-4</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</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:
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.
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.

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:
Causes skin irritation.
Causes serious eye irritation.
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

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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  Metal oxides  Oxides of phosphorus

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 (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 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.
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

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 get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. 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

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.

**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

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m3 (OEB)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

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 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available
Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: Not applicable

Decomposition temperature: No data available

pH: No data available

Evaporation rate: Not applicable

Auto-ignition temperature: No data available

Viscosity
Viscosity, kinematic: Not applicable

Solubility(ies)
Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Vapour pressure: Not applicable

Density and / or relative density
Relative density: No data available

Density: No data available

Relative vapour density: Not applicable

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle characteristics
Particle size: No data available
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Conditions to avoid</th>
<th>Heat, flames and sparks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th>Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Skin contact</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
<tr>
<td></td>
<td>Eye contact</td>
</tr>
</tbody>
</table>

Acute toxicity

Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>Acute toxicity estimate: &gt; 2,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method:</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

**Sitagliptin:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 3,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Mouse): 3,000 mg/kg</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5.8 mg/l</td>
</tr>
<tr>
<td>Exposure time: 4 h</td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

**Ertugruliflozin:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 500 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Remarks: No data available</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

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

Skin corrosion/irritation
Causes skin irritation.

Components:

Sitagliptin:
- Species: Rabbit
- Method: Draize Test
- Result: No skin irritation

Ertugliflozin:
- Result: Corrosive

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Sitagliptin:
- Species: Rabbit
- Result: Irritating to eyes.
- Method: Draize Test

Ertugliflozin:
- Result: Severe irritation

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:

Sitagliptin:
- Test Type: Local lymph node assay (LLNA)
- Species: Mouse
- Method: OECD Test Guideline 429
- Result: Not a skin sensitizer.

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

Sitagliptin:
- Genotoxicity in vitro: Test Type: Ames test
  - Result: negative
- Test Type: Chromosome aberration test in vitro
  - Test system: Chinese hamster ovary cells
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Test system: rat hepatocytes
  - 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

Ertugliflozin:

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
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

Carcinogenicity: Not classified based on available information.

Components:

Sitagliptin:

Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years  
Result: negative

Species: Rat  
Application Route: oral (drinking water)  
Exposure time: 2 Years  
Result: positive  
Target Organs: Liver  
Remarks: Significant toxicity observed in testing

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen
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Ertugliflozin (< 2%) / Sitagliptin Formulation

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**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:**

**Sitagliptin:**
- **Effects on fertility:** Test Type: Fertility/early embryonic development  
  Species: Rat  
  Application Route: Oral  
  Fertility: NOAEL Parent: 1,000 mg/kg body weight  
  Result: Animal testing did not show any effects on fertility.

- **Effects on foetal development:** Test Type: Embryo-foetal development  
  Species: Rat  
  Application Route: Oral  
  Teratogenicity: LOAEL: 250 mg/kg body weight  
  Result: Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects

  Test Type: Embryo-foetal development  
  Species: Rabbit  
  Teratogenicity: NOAEL: 125 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

**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

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

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

**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:

Sitagliptin:
Species: Mouse
NOAEL: 500 mg/kg
LOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: > 2 yr
Target Organs: Kidney

Species: Rat
NOAEL: 500 mg/kg
LOAEL: 1,000 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Target Organs: Liver, Kidney, Heart, Teeth

Species: Dog
NOAEL: 10 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 53 Weeks
Target Organs: Central nervous system
Symptoms: Loss of balance
Remarks: The mechanism or mode of action may not be relevant in humans.

Species: Dog
NOAEL: 2 mg/kg
LOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 27 Weeks
Target Organs: Skeletal muscle, Central nervous system
Symptoms: Loss of balance
Remarks: The mechanism or mode of action may not be relevant in humans.

Species: Monkey
NOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 14 Weeks
Remarks: No significant adverse effects were reported

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
# Ertugliflozin (< 2%) / Sitagliptin Formulation

**Version:** 6.0  
**Revision Date:** 2021/04/09  
**SDS Number:** 595276-00014  
**Date of last issue:** 2020/10/01  
**Date of first issue:** 2016/04/04

<table>
<thead>
<tr>
<th><strong>Ertugliflozin:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td>500 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>30 d</td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td></td>
</tr>
</tbody>
</table>

| **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 |
| **Application Route** | Oral |
| **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 |

<table>
<thead>
<tr>
<th><strong>Magnesium stearate:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Rat</td>
</tr>
<tr>
<td><strong>NOAEL</strong></td>
<td>&gt; 100 mg/kg</td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Ingestion</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>90 Days</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.
Experience with human exposure

**Components:**

**Sitagliptin:**

- **Inhalation:** Symptoms: upper respiratory tract infection, pharyngitis, Headache
- **Ingestion:** Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea

**Ertugliflozin:**

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

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Sitagliptin:**

- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 60 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
- **Toxicity to algae/aquatic plants:** EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201
- **Toxicity to fish (Chronic toxicity):** NOEC (Pimephales promelas (fathead minnow)): 9.2 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)): 9.8 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
- **Toxicity to microorganisms:** EC50: > 150 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0</td>
<td>2021/04/09</td>
<td>595276-00014</td>
<td>2020/10/01</td>
<td>2016/04/04</td>
</tr>
</tbody>
</table>

**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

**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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)):</th>
<th>&gt; 1 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)):</td>
<td>&gt; 1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

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>Substance</th>
<th>EC10 (Pseudomonas putida):</th>
<th>&gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 16 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

Persistence and degradability

**Components:**

**Sitagliptin:**

- **Biodegradability:** Result: not rapidly degradable
- **Biodegradation:** 39.7 %
- **Exposure time:** 28 d
- **Method:** OECD Test Guideline 314

**Stability in water:**

- **Hydrolysis:** 50 % (401 d)
- **Method:** OECD Test Guideline 111

**Cellulose:**

- **Biodegradability:** Result: Readily biodegradable.

**Ertugliflozin:**

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

**Magnesium stearate:**

- **Biodegradability:** Result: Not biodegradable
- **Remarks:** Based on data from similar materials

Bioaccumulative potential

**Components:**

**Sitagliptin:**

- **Partition coefficient: n-octanol/water:** log Pow: -0.03
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

Version 6.0  Revision Date: 2021/04/09  SDS Number: 595276-00014  Date of last issue: 2020/10/01  Date of first issue: 2016/04/04

11. PHYSICAL AND CHEMICAL PROPERTIES

Ertugliflozin:
Partition coefficient: n-octanol/water: log Pow: 2.47

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

Mobility in soil

Components:

Sitagliptin:
Distribution among environmental compartments: log Koc: 4.37

Ertugliflozin:
Distribution among environmental compartments: log Koc: 2.88

Hazardous to the ozone layer
Not applicable

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
Refer to section 15 for specific national regulation.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable
16. OTHER INFORMATION

Further information

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AllIC - 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; 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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