1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin (< 5%) / Sitagliptin 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 |

Causes skin irritation. Causes serious eye damage. Harmful to aquatic life.

GHS Classification
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 1
Short-term (acute) aquatic hazard : Category 3

GHS label elements
Hazard pictograms

Signal word : Danger
Hazard statements : H315 Causes skin irritation.
                  H318 Causes serious eye damage.
                  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 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes skin irritation. Causes serious eye damage.

Environmental hazards
Harmful to aquatic life.

Other hazards which do not result in classification
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Sitagliptin</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Ertugliflozin</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</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 immediately.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Causes skin irritation. Causes serious eye damage.

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
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 spillages
Ertugliflozin (< 5%) / Sitagliptin Formulation

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 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.
  - Keep container tightly closed.
  - Minimize dust generation and accumulation.
  - Keep container closed when not in use.
  - Keep away from heat and sources of ignition.
  - Take precautionary measures against static discharges.
  - Take care to prevent spills, waste and minimize release to the environment.

- Avoidance of contact:
  - Oxidizing agents

Storage
- Conditions for safe storage:
  - Keep in properly labelled containers.
  - Keep tightly closed.
  - Store in accordance with the particular national regulations.

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

- 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>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td></td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ertuglifozin</td>
<td>1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td></td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td></td>
<td>3 mg/m³</td>
<td>ACGIH</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

Material: 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>
Ertugliflozin (< 5%) / Sitagliptin Formulation

Partition coefficient: n-octanol/water : Not applicable
Auto-ignition 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.
Molecular weight : No data available
Particle size : 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.
Conditions to avoid : Heat, flames and sparks.
  Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:
Sitagliptin:
Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
  LD50 (Mouse): 3,000 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

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

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

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 damage.
## 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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ertugliflozin (< 5%) / Sitagliptin Formulation

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

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

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
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

**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

  - 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**
    - Test Type: Embryo-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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ertugliflozin (< 5%) / 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>1.6</td>
<td>2020/09/28</td>
<td>2400333-00007</td>
<td>2020/03/23</td>
<td>2018/02/01</td>
</tr>
</tbody>
</table>

**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.

**Sitagliptin:**

**Species:**
- Mouse
- Rat
- Dog

**NOAEL:**
- 500 mg/kg
- 500 mg/kg
- 10 mg/kg

**LOAEL:**
- 1,000 mg/kg
- 1,000 mg/kg
- 50 mg/kg

**Application Route:**
- Oral
- Oral
- Oral

**Exposure time:**
- > 2 yr
- 14 Weeks
- 53 Weeks

**Target Organs:**
- Kidney
- Liver, Kidney, Heart, Teeth
## Ertugliflozin (< 5%) / Sitagliptin Formulation

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Central nervous system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>Loss of balance</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

### 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:

- **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
Ertugliflozin (< 5%) / Sitagliptin Formulation

**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

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

**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**: EC50 (Daphnia magna (Water flea)): 60 mg/l
**SAFETY DATA SHEET**

according to GB/T 16483 and GB/T 17519

**Ertugliflozin (< 5%) / 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>1.6</td>
<td>2020/09/28</td>
<td>2400333-00007</td>
<td>2020/03/23</td>
<td>2018/02/01</td>
</tr>
</tbody>
</table>

**Aquatic Invertebrates**

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

NOEC: 150 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

**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
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

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
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

Persistence and degradability

Components:

Sitagliptin:

Biodegradability: Result: not rapidly degradable
Biodegradation: 39.7 %
Exposure time: 28 d
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Ertugliflozin (< 5%) / Sitagliptin Formulation

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

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

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)
CN OEL: Occupational exposure limits for hazardous agents in the
workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AIC - 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 Standardisation; 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

Disclaimer
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.

CN / EN