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

Ertugliflozin (< 5%) / Sitagliptin Formulation

Version 1.4  Revision Date: 09/13/2019  SDS Number: 2400333-00005  Date of last issue: 2019/04/24

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>Mixture</td>
</tr>
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<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</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.
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 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 get on skin or clothing.
- 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
Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis
--- | --- | --- | --- | ---
Sitagliptin | 654671-77-9 | TWA | 0.5 mg/m³ (OEB 2) | Internal
Cellulose | 9004-34-6 | PC-TWA | 10 mg/m³ | GBZ 2.1-2007
| | | TWA | 10 mg/m³ | ACGIH
Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m³ (OEB 3) | Internal
| | | Wipe limit | 100 µg/100 cm² | Internal
Magnesium stearate | 557-04-0 | TWA (Inhalable fraction) | 10 mg/m³ | ACGIH
| | | TWA (Respirable fraction) | 3 mg/m³ | ACGIH

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>
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<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>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Relative vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
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<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Viscosity
Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : No data available

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

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
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
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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
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Sitagliptin:
Species: Mouse
Application Route: Oral
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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
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

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
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ment
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
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<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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</thead>
<tbody>
<tr>
<td>1.4</td>
<td>09/13/2019</td>
<td>2400333-00005</td>
<td>2019/04/24</td>
<td>2018/02/01</td>
</tr>
</tbody>
</table>

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

Date format: yyyy/mm/dd

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)


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

Ertugliflozin (< 5%) / Sitagliptin Formulation

Version 1.4
Revision Date: 09/13/2019
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Date of last issue: 2019/04/24
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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; 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.

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