**SAFETY DATA SHEET**

**Ertugliflozin (< 2%) / Sitagliptin Formulation**

**SECTION 1. IDENTIFICATION**

**Product name**: Ertugliflozin (< 2%) / Sitagliptin Formulation  
**Other means of identification**: No data available

**Manufacturer or supplier’s details**

- **Company name of supplier**: Merck & Co., Inc  
- **Address**: 2000 Galloping Hill Road  
  Kenilworth - New Jersey - U.S.A. 07033  
- **Telephone**: 908-740-4000  
- **Telefax**: 908-735-1496  
- **Emergency telephone**: 1-908-423-6000  
- **E-mail address**: EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

**Recommended use**: Pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the Hazardous Products Regulations**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation</td>
<td>2</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>2A</td>
</tr>
<tr>
<td>Specific target organ toxicity</td>
<td>(Kidney, Stomach, Prostate)</td>
</tr>
<tr>
<td>- repeated exposure (Oral)</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

**GHS label elements**

**Hazard pictograms**: 

- ![](image)

**Signal Word**: Warning

**Hazard Statements**:  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H373 May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

**Precautionary Statements**

**Prevention**:  
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
P264 Wash skin thoroughly after handling.  
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 easy to do. Continue rinsing.  
P314 Get medical advice/ attention if you feel unwell.  
P332 + P313 If skin irritation occurs: Get medical advice/ atten-

1 / 20
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td></td>
<td>654671-77-9</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Cellulose</td>
<td></td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td></td>
<td>1210344-83-4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration or concentration range is withheld as a trade secret.

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact: 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 delayed: Causes skin irritation.
Causes serious eye irritation.
May cause damage to organs through prolonged or repeated exposure if swallowed.

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).
SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant 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.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

Version: 4.2
Revision Date: 09/13/2019
SDS Number: 595267-00010
Date of last issue: 04/24/2019
Date of first issue: 04/04/2016

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.
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.

Conditions for safe storage:
Keep in properly labeled containers.
Store in accordance with the particular national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</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

Hand protection: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
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 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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Sitagliptin:**
Test Type: Local lymph node assay (LLNA)  
Species: Mouse
**SAFETY DATA SHEET**

**Ertugliflozin (< 2%) / Sitagliptin Formulation**

<table>
<thead>
<tr>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 429</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Ertugliflozin:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Not a skin sensitizer.</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Sitagliptin:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Ames test</td>
<td>negative</td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>negative</td>
</tr>
<tr>
<td>Test system: Chinese hamster ovary cells</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
</tr>
<tr>
<td>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
</tr>
<tr>
<td>Test system: rat hepatocytes</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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
- **Exposure time:** 2 Years
- **Result:** negative

Species:  
- **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 fetal development: Test Type: Embryo-fetal 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 fetal 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 fetal development:

Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Remarks: Adverse developmental effects were observed

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

Magnesium stearate:

Effects on fertility:

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

Effects on fetal development:

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

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

Components:

Ertugliflozin:
Routes of exposure: Oral
Target Organs: Kidney, Stomach, Prostate
Assessment: May cause damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

**Components:**

**Sitagliptin:**
- **Species:** Mouse
- **NOAEL:** 500 mg/kg
- **LOAEL:** 1,000 mg/kg
- **Application Route:** Oral
- **Exposure time:** > 2 y
- **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:**
- **Species:** Rat
- **LOAEL:** 500 mg/kg
<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>30 d</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>LOAEL</td>
<td>250 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>30 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

| 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 |

**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, Diarrhea

Ertugliflozin:
Ingestion: Symptoms: The most common side effects are:, Headache, constipation, Diarrhea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

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

<table>
<thead>
<tr>
<th>Ertugliflozin:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to algae/aquatic plants:</td>
</tr>
<tr>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l detain time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposuertime: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials.</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity):</td>
</tr>
<tr>
<td>NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Detain time: 32 d Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):</td>
</tr>
<tr>
<td>NOEC (Daphnia magna (Water flea)): 2.14 mg/l Exposuertime: 21 d Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to microorganisms:</td>
</tr>
<tr>
<td>EC50: &gt; 1,000 mg/l Exposuertime: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td>NOEC: 1,000 mg/l Exposuertime: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Magnesium stearate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish:</td>
</tr>
<tr>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l Exposuertime: 48 h Method: DIN 38412</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials.</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates:</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants:</td>
</tr>
<tr>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l Exposuertime: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>
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: \( \log K_{oc} = 4.37 \)

Ertugliflozin:
Distribution among environmental compartments: \( \log K_{oc} = 2.88 \)

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

TDG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

AICS: not determined

DSL: not determined

IECSC: not determined
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

Version 4.2
Revision Date: 09/13/2019
SDS Number: 595267-00010
Date of last issue: 04/24/2019
Date of first issue: 04/04/2016

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals 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 - Transport 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


Revision Date: 09/13/2019
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.

CA / Z8