SAFETY DATA SHEET
according to the Hazardous Products Regulations

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: 126 E. Lincoln Avenue
           Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Skin irritation: Category 2
Eye irritation: Category 2A
Skin sensitization: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Kidney, Stomach, Prostate)

GHS label elements
Hazard pictograms:

Signal Word: Warning

Hazard Statements:
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
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.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, eye protection and face protec-
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 attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Other hazards
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>No data available</td>
<td>654671-77-9</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>No data available</td>
<td>1210344-83-4</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Propyl 3,4,5-trihydroxybenzoate</td>
<td>Benzoic acid, 3,4,5-trihydroxy- propyl ester</td>
<td>121-79-9</td>
<td>&gt;= 0.1 - &lt; 1 *</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.
May cause an allergic skin reaction.
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).

**Notes to physician**: Treat symptomatically and supportively.

### 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 (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
Use only with adequate ventilation.

Advice on safe handling:
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

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</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 23
SAFETY DATA SHEET  
according to the Hazardous Products Regulations

Ertugliflozin (< 2%) / Sitagliptin Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>Exposure</th>
<th>Concentration</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin 654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose 9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td>Ertugliflozin 1210344-83-4</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate 557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></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>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

**Eye protection**: Consider double gloving.

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...
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. Contaminated work clothing should not be allowed out of the workplace. 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.
Molecular weight : No data available
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.
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.
**SAFETY DATA SHEET**
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**Ertugliflozin (< 2%) / Sitagliptin Formulation**

<table>
<thead>
<tr>
<th>Product:</th>
<th></th>
</tr>
</thead>
</table>
| Acute oral toxicity | Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method |

<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sitagliptin:</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Acute oral toxicity | LD50 (Rat): > 3,000 mg/kg  
LD50 (Mouse): 3,000 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 |

| **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 |

| **Propyl 3,4,5-trihydroxybenzoate:** |  |
| Acute oral toxicity | LD50 (Mouse, female): > 1,000 - 2,000 mg/kg |
| Acute dermal toxicity | LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity |

**Skin corrosion/irritation**
Causes skin irritation.
# SAFETY DATA SHEET

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<table>
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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>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>09/30/2023</td>
<td>595267-00020</td>
<td>03/06/2023</td>
<td>04/04/2016</td>
</tr>
</tbody>
</table>

### 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

**Propyl 3,4,5-trihydroxybenzoate:**
- **Species:** reconstructed human epidermis (RhE)
- **Method:** OECD Test Guideline 439
- **Result:** No skin irritation

### 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

**Propyl 3,4,5-trihydroxybenzoate:**
- **Species:** Rabbit
- **Result:** Irreversible effects on the eye
- **Method:** OECD Test Guideline 405

### Respiratory or skin sensitization

**Skin sensitization**
May cause an allergic skin reaction.
Respiratory sensitization
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:** Maximization Test
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Propyl 3,4,5-trihydroxybenzoate:**
- **Test Type:** Local lymph node assay (LLNA)
- **Species:** Mouse
- **Result:** positive
- **Assessment:** Probability or evidence of skin sensitization in humans

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

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

- **Genotoxicity in vivo:**
  - **Test Type:** Micronucleus test
    - Species: Mouse
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</tr>
</tbody>
</table>

**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

### Propyl 3,4,5-trihydroxybenzoate:

- **Genotoxicity in vitro**  
  Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative  
  Test Type: In vitro mammalian cell gene mutation test  
  Result: positive  
  Test Type: Chromosome aberration test in vitro  
  Result: positive
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: positive

Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Description</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA damage and repair</td>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Mouse</td>
<td>Oral injection</td>
<td>2 Years</td>
<td>negative</td>
<td>Significant toxicity observed in testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogenicity
Not classified based on available information.

Components:

**Sitagliptin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>oral (drinking water)</td>
<td>2 Years</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>72 weeks</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Ertugliflozin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>
Carcinogenicity - Assessment: Weight of evidence does not support classification as a carcinogen

Propyl 3,4,5-trihydroxybenzoate:
Species: Rat
Application Route: Ingestion
Exposure time: 103 weeks
Result: negative

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.

Test Type: Embryo-fetal 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 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:
Test Type: Embryo-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

**Propyl 3,4,5-trihydroxybenzoate:**

Effects on fertility
Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

**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**: \( \geq 9,000 \text{ mg/kg} \)
- **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
- **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

Propyl 3,4,5-trihydroxybenzoate:
Species : Rat
NOAEL : 135 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

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 tox- : 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

Exposure time: 21 d  
Method: OECD Test Guideline 211

Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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

Exposure time: 48 h  
Remarks: Based on data from similar materials

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

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.

Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility.

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

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

Propyl 3,4,5-trihydroxybenzoate:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 19.06 mg/l
   Exposure time: 48 h
   Test substance: Neutralized product
   Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.37 mg/l
   Exposure time: 72 h
   Test substance: Neutralized product
   Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.17 mg/l
   Exposure time: 72 h
   Test substance: Neutralized product
   Method: OECD Test Guideline 201

Toxicity to microorganisms: EC50: 636 mg/l
   Exposure time: 3 h
   Method: OECD Test Guideline 209
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

**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

**Propyl 3,4,5-trihydroxybenzoate:**
- Biodegradability: Result: Not readily biodegradable.
  - Biodegradation: 49.4 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301F

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

**Propyl 3,4,5-trihydroxybenzoate:**
- Partition coefficient: n-octanol/water: log Pow: 1.8
  - Remarks: Calculation
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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Do not dispose of waste into sewer.
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

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined
SAFETY DATA SHEET
generated by the Hazardous Products Regulations

Ertugliflozin (< 2%) / Sitagliptin Formulation

Version 5.1 Revision Date: 09/30/2023 SDS Number: 595267-00020 Date of last issue: 03/06/2023 Date of first issue: 04/04/2016

IECSC: not determined

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 / TWA EV : Time-weighted average exposure value

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

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET
according to the Hazardous Products Regulations

Ertugliflozin (< 2%) / Sitagliptin Formulation

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Revision Date: 09/30/2023
Date format: mm/dd/yyyy

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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