SECTION 1. IDENTIFICATION

Product name : Ertugliflozin (< 2%) / Sitagliptin Formulation

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 29 CFR 1910.1200
Combustible dust

Skin irritation : Category 2
Eye irritation : Category 2A

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, Stomach, Prostate)

GHS label elements
Hazard pictograms :

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy
SAFETY DATA SHEET

Ertugliflozin (< 2%) / Sitagliptin Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<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;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>1210344-83-4</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

Actual concentration 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.

to do. Continue rinsing. P314 Get medical advice/ attention if you feel unwell. P332 + P313 If skin irritation occurs: Get medical advice/ attention. P337 + P313 If eye irritation persists: 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.

Other hazards
None known.
**SAFETY DATA SHEET**

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td>09/13/2019</td>
<td>595282-00010</td>
<td>04/24/2019</td>
<td>04/04/2016</td>
</tr>
</tbody>
</table>

**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 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...
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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.
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>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</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 (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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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

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

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.

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.

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
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
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Cellulose:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative
### Genotoxicity in vivo
- **Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- **Species:** Mouse
- **Application Route:** Ingestion
- **Result:** negative

### Ertugliflozin:
- **Genotoxicity in vitro**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
  - **Result:** negative
  - **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:** 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

IARC : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA : No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP : No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.
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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
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
<table>
<thead>
<tr>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**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**: 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: NOEC (Daphnia magna (Water flea)): 9.8 mg/l
<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to fish</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>EC50: &gt; 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</td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ertugliflozin</td>
<td>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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
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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

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

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards
- Combustible dust
- Skin corrosion or irritation
- Serious eye damage or eye irritation
- Specific target organ toxicity (single or repeated exposure)

SARA 313
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
- Sitagliptin: 654671-77-9
- Cellulose: 9004-34-6
- Calcium hydrogenorthophosphate: 7757-93-9
- Sodium octadecyl fumarate: 4070-80-8

California Permissible Exposure Limits for Chemical Contaminants
- Cellulose: 9004-34-6
- Magnesium stearate: 557-04-0

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

- AICS: not determined
- DSL: not determined
- IECSC: not determined
SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>0</td>
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</tbody>
</table>

**HMIS® IV:**

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA Z-1 / TWA: 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-
SAFETY DATA SHEET

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

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.

US / Z8