SAFETY DATA SHEET

Ertugliflozin / Metformin Formulation

SECTION 1. IDENTIFICATION

Product name: Ertugliflozin / Metformin 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
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
Acute toxicity (Oral): Category 4

GHS label elements
Hazard pictograms:

Signal Word: Warning
Hazard Statements: H302 Harmful if swallowed.
Precautionary Statements:
Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.

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

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture**: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>metformin hydrochloride</td>
<td>No data available</td>
<td>1115-70-4</td>
<td>&gt;= 60 - &lt; 80 *</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td></td>
<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></td>
<td>Ertugliflozin</td>
<td>No data available</td>
<td>1210344-83-4</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**: Wash with water and soap. Get medical attention if symptoms occur.

**In case of eye contact**: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

**If swallowed**: If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed**: Harmful if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

**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**: Avoid generating dust; fine dust dispersed in air in sufficient
fighting 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
- Nitrogen oxides (NOx)
- Metal oxides

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 spillages cannot be contained.

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

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 breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
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. Do not eat, drink or smoke when using this product. 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>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>1 mg/m³ (OEB 1)</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>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></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 particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</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>
</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: 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

Harmful if swallowed.

Product:

Acute oral toxicity: Acute toxicity estimate: 1,337 mg/kg
Method: Calculation method

Components:

metformin hydrochloride:
Acute oral toxicity: LD50 (Rat): 1,000 mg/kg
LD50 (Mouse): 1,450 - 3,500 mg/kg
LD50 (Monkey): 463 mg/kg
LD50 (Rabbit): 350 mg/kg
LD50 (Guinea pig): 500 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

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

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

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**metformin hydrochloride:**
Species: Rabbit
Result: Mild skin irritation

**Magnesium stearate:**
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

**Ertugliflozin:**
Result: Corrosive

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**metformin hydrochloride:**
Species: Rabbit
Result: Mild eye irritation

**Magnesium stearate:**
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

**Ertugliflozin:**
Result: Severe irritation

**Respiratory or skin sensitization**

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

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

**Components:**

**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

**Ertugliflozin:**

Test Type: Local lymph node assay (LLNA)
Result: Not a skin sensitizer.

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

**Components:**

**metformin hydrochloride:**

Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro test
  Test system: mouse lymphoma cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  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

**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
Ertugliflozin:  
Genotoxicity in vitro:  
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo:  
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Result: negative

Carcinogenicity  
Not classified based on available information.

Components:

metformin hydrochloride:
Species: Mouse  
Exposure time: 91 weeks  
Dose: 1500 mg/kg body weight  
Result: negative

Species: Rat, male  
Application Route: Oral  
Exposure time: 104 weeks  
Dose: 900 mg/kg body weight  
Result: negative

Species: Rat, female  
Application Route: Oral  
Exposure time: 104 weeks  
LOAEL: 900 mg/kg body weight  
Result: negative  
Target Organs: Uterus (including cervix)  
Remarks: The mechanism or mode of action may not be relevant in humans.

Cellulose:
Species: Rat  
Application Route: Ingestion  
Exposure time: 72 weeks  
Result: negative

Ertugliflozin:  
Species: Mouse  
Application Route: Oral  
Exposure time: 2 Years
### Reproductive toxicity

Not classified based on available information.

### Components:

**metformin hydrochloride:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
<th>Species: Rat</th>
<th>Application Route: Oral</th>
<th>Fertility: NOAEL: 600 mg/kg body weight</th>
<th>Result: No effects on fertility.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Development</th>
<th>Species: Rat</th>
<th>Application Route: Oral</th>
<th>Developmental Toxicity: NOAEL: 600 mg/kg body weight</th>
<th>Result: No teratogenic effects.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Test Type: Embryo-fetal development</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Species: Rabbit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Embryo-fetal toxicity.: NOAEL: 140 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Result: No teratogenic effects.</td>
<td></td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: One-generation reproduction toxicity study</th>
<th>Species: Rat</th>
<th>Application Route: Ingestion</th>
<th>Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Fertility/early embryonic development</th>
<th>Species: Rat</th>
<th>Application Route: Ingestion</th>
<th>Result: negative</th>
</tr>
</thead>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</th>
<th>Species: Rat</th>
<th>Application Route: Ingestion</th>
<th>Method: OECD Test Guideline 422</th>
<th>Result: negative</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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

Effects on fertility: 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

Effects on fetal development: 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

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

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:

metformin hydrochloride:
Species: Rat
NOAEL: 125 mg/kg
<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>Rat</td>
<td>500 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>250 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>180 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>25 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>26 mg/kg</td>
<td>Oral</td>
<td>180 d</td>
<td></td>
</tr>
</tbody>
</table>

**Remarks**: Based on data from similar materials

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ertugliflozin</td>
<td>Rat</td>
<td>500 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
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</tr>
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<td>25 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>26 mg/kg</td>
<td>Oral</td>
<td>180 d</td>
<td></td>
</tr>
</tbody>
</table>

**Remarks**: Based on data from similar materials
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

**Aspiration toxicity**
Not classified based on available information.

**Experience with human exposure**

**Components:**

**metformin hydrochloride:**
Skin contact: Remarks: May irritate skin.
Eye contact: Remarks: May irritate eyes.
Ingestion: Symptoms: Diarrhea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

**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:**

**metformin hydrochloride:**
Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 10 mg/l
Exposure time: 33 d

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### Ertugliflozin / Metformin Formulation

<table>
<thead>
<tr>
<th>Method</th>
<th>Test Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD Test Guideline 210</td>
<td>NOEC (Daphnia magna (Water flea)): 40 mg/l Exposure time: 21 d</td>
</tr>
<tr>
<td>OECD Test Guideline 211</td>
<td>EC50: &gt; 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td>OECD Test Guideline 209</td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>DIN 38412</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>EC10 (Pseudomonas putida): &gt; 100 mg/l Exposure time: 16 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>OECD Test Guideline 201</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>
NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
  NOEC (Pimephales promelas (fathead minnow)): 1 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210
  Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
  NOEC (Daphnia magna (Water flea)): 2.14 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
  Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms:
  EC50: > 1,000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Persistence and degradability
Components:

metformin hydrochloride:
Biodegradability: Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 2 hrs

Cellulose:
Biodegradability: Result: Readily biodegradable.

Magnesium stearate:
Biodegradability: Result: Not biodegradable
Remarks: Based on data from similar materials

Ertugliflozin:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 40.8 %
Exposure time: 28 d

Bioaccumulative potential
Components:
metformin hydrochloride:
Partition coefficient: n-octanol/water:

- **Magnesium stearate:**
  - log Pow: > 4

- **Ertugliflozin:**
  - log Pow: 2.47

**Mobility in soil**

**Components:**

- **metformin hydrochloride:**
  - Distribution among environmental compartments: log Koc: 4.3
  - Method: OECD Test Guideline 106

- **Ertugliflozin:**
  - Distribution among environmental compartments: log Koc: 2.88

**Other adverse effects**

No data available

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**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.

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**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
SAFETY DATA SHEET

Ertugliflozin / Metformin Formulation

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SDS Number: 590547-00014
Date of last issue: 04/09/2021
Date of first issue: 04/01/2016

SECTION 15. REGULATORY INFORMATION

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

AICS: not determined
DSL: not determined
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 / TWAEV: Time-weighted average exposure value

AIIIC - 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) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-
SAFETY DATA SHEET

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stances 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 compile the Material Safety Data Sheet:

Revision Date: 08/27/2021
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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