

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Ertugliflozin / Metformin Formulation

Version 7.0      Revision Date: 05/09/2026      SDS Number: 590547-00023      Date of last issue: 12/13/2025  
Date of first issue: 04/01/2016

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### 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 : 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

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### 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.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
metformin hydrochloride	No data available	1115-70-4*	>= 65 - <= 85	TSC
Cellulose	No data available	9004-34-6*	>= 10 - <= 30	TSC
Magnesium stearate	Octadecanoic acid, magnesium salt (2:1)	557-04-0*	>= 0.5 - <= 1.5	TSC
Ertugliflozin	No data available	1210344-83-4*	>= 0.1 - <= 1	TSC

\* Indicates that the identifier is a CAS No.

TSC- the 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 (CO<sub>2</sub>)  
Dry chemical

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- 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  
Nitrogen oxides (NO<sub>x</sub>)  
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.

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### 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.

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### SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust

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- 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (inhalable dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWAEV (respirable aerosol fraction)	3 mg/m <sup>3</sup>	CA QC OEL

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		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Ertugliflozin	1210344-83-4	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**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

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.

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### 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

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

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### 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.

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### 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

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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

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### **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

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### 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  
  
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

### 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

### 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

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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  
Result : negative

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

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

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **metformin hydrochloride:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 600 mg/kg body weight  
Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 600 mg/kg body weight  
Result: No teratogenic effects.

Test Type: Embryo-fetal development

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Species: Rabbit  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 140 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

### 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

### 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

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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  
Application Route : Oral  
Exposure time : 1 year  
Remarks : No significant adverse effects were reported

Species : Rabbit  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 1 Year  
Remarks : No significant adverse effects were reported

Species : Dog  
NOAEL : 50 mg/kg  
Application Route : Subcutaneous  
Exposure time : 2 year  
Remarks : No significant adverse effects were reported

#### Cellulose:

Species : Rat  
NOAEL : >= 9,000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### Magnesium stearate:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion

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Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Ertugliflozin:

Species : Rat  
LOAEL : 500 mg/kg  
Application Route : Oral  
Exposure time : 30 d

Species : Rat  
LOAEL : 250 mg/kg  
Application Route : Oral  
Exposure time : 30 d  
Target Organs : Kidney

Species : Rat  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 180 d  
Target Organs : Kidney, Bone, Stomach

Species : Rat  
LOAEL : 25 mg/kg  
Exposure time : 90 d  
Target Organs : Kidney, Gastrointestinal tract, Prostate

Species : Dog  
NOAEL : 150 mg/kg  
Application Route : Oral  
Exposure time : 270 d  
Remarks : No significant adverse effects were reported

Species : Mouse  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Remarks : No significant adverse effects were reported

Species : Mouse  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Target Organs : Bone  
Remarks : No significant adverse effects were reported

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

**metformin hydrochloride:**

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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  
Method: OECD Test Guideline 210  
  
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 40 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
  
Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

##### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

##### 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 : EL50 (Daphnia magna (Water flea)): > 1 mg/l

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aquatic invertebrates	Exposure time: 47 h Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. 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

### Ertugliflozin:

Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 1 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 2.14 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility.
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  NOEC: 1,000 mg/l Exposure time: 3 h

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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 : log Pow: -2

##### Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

##### Ertugliflozin:

Partition coefficient: n-octanol/water : 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

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### Other adverse effects

No data available

### Endocrine disrupting properties

No data available

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## 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.

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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

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## SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

CA. DSL : not determined

CN IECSC : not determined

### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
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	:	Time-weighted average exposure value

AIIC - 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 Standardization; 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 Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization 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 compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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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