

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Ertugliflozin (< 5%) / Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2025/04/14
4.1	2025/08/11	2400333-00016	Date of first issue: 2018/02/01

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin (< 5%) / Sitagliptin Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road  
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Appearance	: powder
Colour	: No data available
Odour	: No data available

Causes skin irritation. Causes serious eye damage. Harmful to aquatic life with long lasting effects.

#### GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 1

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

#### GHS label elements

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Hazard pictograms

:



Signal word

:

Danger

Hazard statements

:

H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

:

### Prevention:

P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.  
P332 + P317 If skin irritation occurs: Get medical help.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

Causes skin irritation. Causes serious eye damage.

### Environmental hazards

Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

### Other hazards which do not result in classification

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

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

:

Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sitagliptin Phosphate	654671-77-9	>= 30 -< 50
Cellulose	9004-34-6	>= 20 -< 30
Ertugliflozin	1210344-83-4	>= 3 -< 5
Magnesium stearate	557-04-0	>= 1 -< 10
Propyl 3,4,5-trihydroxybenzoate	121-79-9	>= 0.25 -< 1

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### 4. FIRST AID MEASURES

- |   |  |
|---|--|
| General advice  | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : If inhaled, remove to fresh air.<br>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.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately.   |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : Causes skin irritation.<br>Causes serious eye damage.  |
| 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.  |

### 5. FIREFIGHTING MEASURES

- |                                       |   |
|---------------------------------------|---|
| Suitable extinguishing media          | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products         | : Carbon oxides<br>Metal oxides<br>Oxides of phosphorus   |
| Specific extinguishing methods        | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.   |

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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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 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.

### 7. HANDLING AND STORAGE

#### Handling

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

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety

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practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
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.

Avoidance of contact : Oxidizing agents

### Storage

Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.  
Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL
		TWA	10 mg/m3	ACGIH
Ertugliflozin	1210344-83-4	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

**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.

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### 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  |
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.  |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Remarks                  | : | Consider double gloving.   |
| Hygiene measures         | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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. |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- |   |   |                   |
|---|---|-------------------|
| Appearance                              | : | powder            |
| Colour                                  | : | No data available |
| Odour                                   | : | No data available |
| Odour Threshold                         | : | No data available |
| pH                                      | : | No data available |
| Melting point/freezing point            | : | No data available |
| Initial boiling point and boiling range | : | No data available |

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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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.

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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.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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#### Acute toxicity

Not classified based on available information.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
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#### Components:

##### Sitagliptin Phosphate:

Acute oral toxicity	:	LD50 (Rat): > 3,000 mg/kg  LD50 (Mouse): 3,000 mg/kg
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##### 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
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Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral toxicity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: Based on data from similar materials

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

Acute oral toxicity : LD50 (Mouse): 1,700 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Causes skin irritation.

#### Components:

##### Sitagliptin Phosphate:

Species : Rabbit  
Method : Draize Test  
Result : No skin irritation

##### Ertugliflozin:

Result : Corrosive

##### Magnesium stearate:

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

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

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439

Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### Sitagliptin Phosphate:

Species : Rabbit  
Result : Irritating to eyes.

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Method : Draize Test

### Ertugliflozin:

Result : Severe irritation

### Magnesium stearate:

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

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

Species : Rabbit  
Result : Irreversible effects on the eye  
Method : OECD Test Guideline 405

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Sitagliptin Phosphate:

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 : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

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

Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse

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Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Sitagliptin Phosphate:

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

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Result: negative

### Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

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

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

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: positive

Test Type: Chromosome aberration test in vitro  
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Sitagliptin Phosphate:

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

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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

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

Species : Rat  
Application Route : Ingestion  
Exposure time : 103 weeks  
Result : negative

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Sitagliptin Phosphate:

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.

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Effects on foetal development : Test Type: Embryo-foetal 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-foetal development  
Species: Rabbit  
Teratogenicity: NOAEL: 125 mg/kg body weight  
Result: No teratogenic effects

### Cellulose:

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

Effects on foetal 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 foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Remarks: Adverse developmental effects were observed

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

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

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

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

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

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### Ertugliflozin:

Exposure routes : Oral  
Target Organs : Kidney, Stomach, Prostate  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Sitagliptin Phosphate:

Species : Mouse  
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Oral  
Exposure time : > 2 yr

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Target Organs : Kidney

Species : Rat

NOAEL : 500 mg/kg

LOAEL : 1,000 mg/kg

Application Route : Oral

Exposure time : 14 Weeks

Target Organs : Liver, Kidney, Heart, Teeth

Species : Dog

NOAEL : 10 mg/kg

LOAEL : 50 mg/kg

Application Route : Oral

Exposure time : 53 Weeks

Target Organs : Central nervous system

Symptoms : Loss of balance

Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Dog

NOAEL : 2 mg/kg

LOAEL : 10 mg/kg

Application Route : Oral

Exposure time : 27 Weeks

Target Organs : Skeletal muscle, Central nervous system

Symptoms : Loss of balance

Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Monkey

NOAEL : 100 mg/kg

Application Route : Oral

Exposure time : 14 Weeks

Remarks : No significant adverse effects were reported

### Cellulose:

Species : Rat

NOAEL :  $\geq 9,000$  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



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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

### Magnesium stearate:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

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

Species : Rat  
NOAEL : 135 mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

### Aspiration toxicity

Not classified based on available information.

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according to GB/T 16483 and GB/T 17519



## Ertugliflozin (< 5%) / Sitagliptin Formulation

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### Experience with human exposure

#### Components:

##### **Sitagliptin Phosphate:**

Inhalation	: Symptoms: upper respiratory tract infection, pharyngitis, Headache
Ingestion	: Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea

##### **Ertugliflozin:**

Ingestion	: Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection
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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Sitagliptin Phosphate:**

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 60 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l Exposure time: 96 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l Exposure time: 33 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 9.8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: EC50: > 150 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

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NOEC: 150 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition

### Cellulose:

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

### 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  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Magnesium stearate:

Toxicity to fish : LC50 (*Leuciscus idus* (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (*Daphnia magna* (Water flea)): > 1 mg/l  
Exposure time: 47 h  
Test substance: Water Accommodated Fraction

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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

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 19.6 mg/l  
Exposure time: 48 h  
Test substance: Neutralised product  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.22 mg/l  
Exposure time: 72 h  
Test substance: Neutralised product  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.096 mg/l  
Exposure time: 72 h  
Test substance: Neutralised product  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

M-Factor (Acute aquatic toxicity) : 1

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge): 636 mg/l  
Exposure time: 3 h

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Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Sitagliptin Phosphate:**

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

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

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 49.4 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

### Bioaccumulative potential

#### Components:

##### **Sitagliptin Phosphate:**

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

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

Partition coefficient: n-octanol/water	:	log Pow: 1.8
	:	Remarks: Calculation

### Mobility in soil

#### Components:

#### Sitagliptin Phosphate:

Distribution among environmental compartments	:	log Koc: 4.37
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#### Ertugliflozin:

Distribution among environmental compartments	:	log Koc: 2.88
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#### Other adverse effects

No data available

## 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.

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

#### IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

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ger aircraft)

### IMDG-Code

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
EmS Code	: Not applicable
Marine pollutant	: no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### GB 6944/12268

UN number	: Not applicable
Proper shipping name	: Not applicable
Class	: Not applicable
Subsidiary risk	: Not applicable
Packing group	: Not applicable
Labels	: Not applicable
Marine pollutant	: no

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### National regulatory information

#### Law on the Prevention and Control of Occupational Diseases

#### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals	: This product is not listed in the catalogue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of determination.
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Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)	: Not listed
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Hazardous Chemicals for Priority Management under SAWS	: Not listed
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Catalogue of Specially Controlled Hazardous Chemicals	: Not listed
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List of Explosive Precursors	: Not listed
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### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import and Export : Not listed

### Regulation on the Administration of Precursor Chemicals

Catalogue and Classification of Precursor Chemicals : Not listed

### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

### Regulations of Ozone Depleting Substances Management

List of Controlled Ozone Depleting Substances Import and Export : Not listed

List of Controlled Ozone Depleting Substances : Not listed

### Environmental Protection Law

List of Priority Controlled Chemicals : Not listed

List of Key Controlled New Pollutants : Not listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 16. OTHER INFORMATION

Revision Date : 2025/08/11

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.



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ACGIH / TWA : 8-hour, time-weighted average  
CN OEL / PC-TWA : Permissible concentration - time weighted average

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 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 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

### Disclaimer

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.

CN / EN