

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Ertugliflozin (< 5%) / Sitagliptin Formulation

Version 5.1      Revision Date: 09/30/2023      SDS Number: 2400342-00013      Date of last issue: 03/06/2023  
Date of first issue: 02/01/2018

### SECTION 1. IDENTIFICATION

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

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin irritation : Category 2  
Serious eye damage : Category 1  
Skin sensitization : Category 1  
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Kidney, Stomach, Prostate)

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H373 May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust.

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P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves, eye protection and face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.

P314 Get medical attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Sitagliptin	654671-77-9	>= 30 - < 50
Cellulose	9004-34-6	>= 20 - < 30
Ertugliflozin	1210344-83-4	>= 1 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5
Propyl 3,4,5-trihydroxybenzoate	121-79-9	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

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- |   |   |  |
|---|---|--|
| 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>May cause an allergic skin reaction.<br>Causes serious eye damage.<br>May cause damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).      |
| Notes to physician  | : | Treat symptomatically and supportively.  |
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### SECTION 5. FIRE-FIGHTING 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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |   |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |

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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 causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
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.

Conditions for safe storage : Keep in properly labeled 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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m <sup>3</sup>

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Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sitagliptin	654671-77-9	TWA	0.5 mg/m <sup>3</sup> (OEB 2)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Ertugliflozin	1210344-83-4	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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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

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

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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

Not classified based on available information.

#### Product:

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

#### Components:

##### Sitagliptin:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg  
LD50 (Mouse): 3,000 mg/kg

##### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### Ertugliflozin:

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

##### Magnesium stearate:



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Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: Based on data from similar materials

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

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

Acute oral toxicity : LD50 (Mouse, female): > 1,000 - 2,000 mg/kg

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

### Skin corrosion/irritation

Causes skin irritation.

### Components:

#### Sitagliptin:

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

#### Ertugliflozin:

Result : Corrosive

#### Magnesium stearate:

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

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

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

Result : No skin irritation

### Serious eye damage/eye irritation

Causes serious eye damage.

### Components:

#### Sitagliptin:

Species : Rabbit  
Result : Irritating to eyes.  
Method : Draize Test

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### Ertugliflozin:

Result : Severe irritation

### Magnesium stearate:

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

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

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

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Sitagliptin:

Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : Not a skin sensitizer.

#### Ertugliflozin:

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

#### Magnesium stearate:

Test Type : Maximization Test  
Routes of exposure : 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)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : positive

Assessment : Probability or evidence of skin sensitization in humans

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Sitagliptin:

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: negative

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

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

#### Cellulose:

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

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

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

#### Ertugliflozin:

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

Test Type: Chromosome aberration test in vitro  
Result: negative

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

#### Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

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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:

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

Species : Rat  
Application Route : oral (drinking water)  
Exposure time : 2 Years  
Result : positive  
Target Organs : Liver  
Remarks : Significant toxicity observed in testing

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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

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

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

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

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Sitagliptin:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL Parent: 1,000 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

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Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Teratogenicity: LOAEL: 250 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.

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

### Cellulose:

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

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Ertugliflozin:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 250 mg/kg body weight  
Remarks: Maternal toxicity observed.  
No significant adverse effects were reported

Test Type: Fertility/early embryonic development  
Species: Rabbit  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Remarks: No significant adverse effects were reported

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

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

### Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test

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Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

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

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

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

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

### **STOT-single exposure**

Not classified based on available information.

### **STOT-repeated exposure**

May cause damage to organs (Kidney, Stomach, Prostate) through prolonged or repeated exposure if swallowed.

### **Components:**

#### **Ertugliflozin:**

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

### **Repeated dose toxicity**

#### **Components:**

#### **Sitagliptin:**

Species : Mouse  
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Oral  
Exposure time : > 2 y  
Target Organs : Kidney

Species : Rat  
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg

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

### Ertugliflozin:

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

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

Species : Rat  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 180 d



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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.

### **Experience with human exposure**

#### **Components:**

##### **Sitagliptin:**

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

##### **Ertugliflozin:**

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Ingestion : Symptoms: The most common side effects are:, Headache, constipation, Diarrhea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection

### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Sitagliptin:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 60 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 39 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l  
Exposure time: 33 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (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

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:**

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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  
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

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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)): 19.06 mg/l  
Exposure time: 48 h  
Test substance: Neutralized product  
Method: OECD Test Guideline 202

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

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

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

### Persistence and degradability

#### Components:

##### **Sitagliptin:**

Biodegradability : Result: not rapidly degradable  
Biodegradation: 39.7 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(401 d)  
Method: OECD Test Guideline 111

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **Ertugliflozin:**

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

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### Magnesium stearate:

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

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

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

### Bioaccumulative potential

#### Components:

##### Sitagliptin:

Partition coefficient: n-octanol/water : log Pow: -0.03

##### Ertugliflozin:

Partition coefficient: n-octanol/water : log Pow: 2.47

##### Magnesium stearate:

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

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

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

### Mobility in soil

#### Components:

##### Sitagliptin:

Distribution among environmental compartments : log Koc: 4.37

##### Ertugliflozin:

Distribution among environmental compartments : log Koc: 2.88

#### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste

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handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

Not regulated as a dangerous good

##### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

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

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Combustible dust  
Respiratory or skin sensitization  
Specific target organ toxicity (single or repeated exposure)  
Skin corrosion or irritation  
Serious eye damage or eye irritation

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

#### US State Regulations

##### Pennsylvania Right To Know

Sitagliptin	654671-77-9
Cellulose	9004-34-6
Calcium hydrogenorthophosphate	7757-93-9
Ertugliflozin	1210344-83-4

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Sodium octadecyl fumarate 4070-80-8

### California Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6  
Magnesium stearate 557-04-0

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

AICS : not determined

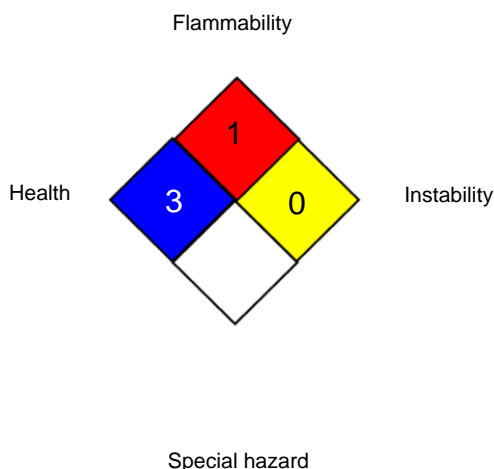
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

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

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CAL PEL : California permissible exposure limits for chemical contaminants (Title 8, Article 107)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts  
ACGIH / TWA : 8-hour, time-weighted average  
CAL PEL / PEL : Permissible exposure limit  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
OSHA Z-1 / TWA : 8-hour time weighted average  
OSHA Z-3 / TWA : 8-hour time weighted average

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AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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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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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