

# SAFETY DATA SHEET



## Sitagliptin / Simvastatin Formulation

Version 14.3 Revision Date: 2025/08/11 SDS Number: 24504-00029 Date of last issue: 2025/04/14  
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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Sitagliptin / Simvastatin Formulation

#### Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : Category 1

Specific target organ toxicity - repeated exposure : Category 2 (Liver, muscle, optic nerve, Eye)

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 3

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

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H373 May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

### Precautionary statements

#### : Prevention:

P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
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 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P314 Get medical advice/ attention if you feel unwell.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

#### : Disposal:

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

### Other hazards which do not result in classification

Important symptoms and out-  
lines of the emergency as-  
sumed : May form explosive dust-air mixture during processing, han-  
dling or other means.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Sitagliptin Phosphate	654671-77-9	>= 10 - < 20	
Cellulose	9004-34-6	>= 1 - < 10	
Starch	9005-25-8	>= 1 - < 10	8-98
Simvastatin	79902-63-9	>= 2.5 - < 10	
Ascorbic acid	50-81-7	>= 1 - < 10	5-62
Titanium dioxide	13463-67-7	>= 0.1 - < 1	1-558, 5-5225

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### 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.
In case of skin contact	: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.
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 Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides Oxides of phosphorus
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do

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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  
Advice on safe handling

: Use only with adequate ventilation.  
: 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  
Minimize dust generation and accumulation.

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Avoidance of contact Hygiene measures	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. : Oxidizing agents : 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.
<b>Storage</b>	
Conditions for safe storage	: Keep in properly labelled containers. 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

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m <sup>3</sup> (OEB 2)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Simvastatin	79902-63-9	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: DSEN				
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m <sup>3</sup> (OEB 1)	Internal
Titanium dioxide	13463-67-7	OEL-M (Respirable particulate matter)	1.5 mg/m <sup>3</sup> (Titanium)	JP OEL JSOH
	Further information: Group 2B: possibly carcinogenic to humans			

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	OEL-M (Total particulate matter)	2 mg/m <sup>3</sup> (Titanium)	JP OEL JSOH
Further information: Group 2B: possibly carcinogenic to humans			

**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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : pink

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

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Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: No data available
Lower explosion limit and upper explosion limit / flammability limit	
Upper explosion limit / Up- per flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Flash point	: Not applicable
Decomposition temperature	: No data available
pH	: No data available
Evaporation rate	: Not applicable
Auto-ignition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n- octanol/water	: Not applicable
Vapour pressure	: Not applicable
Density and / or relative density	
Relative density	: No data available
Density	: No data available
Relative vapour density	: 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

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## 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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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

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

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

##### **Starch:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **Simvastatin:**

Acute oral toxicity : LD50 (Rat): 5,000 mg/kg  
LD50 (Mouse): 3,800 mg/kg

##### **Ascorbic acid:**

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Acute oral toxicity : LD50 (Rat): 11,900 mg/kg

**Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Sitagliptin Phosphate:**

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

**Simvastatin:**

Species : Rabbit  
Remarks : Moderate skin irritation

**Ascorbic acid:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

**Titanium dioxide:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Sitagliptin Phosphate:**

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

**Starch:**

Species : Rabbit  
Result : No eye irritation

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### **Simvastatin:**

Species : Rabbit  
Remarks : slight irritation

### **Ascorbic acid:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

### **Titanium dioxide:**

Species : Rabbit  
Result : No eye irritation

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

May cause an allergic skin reaction.

#### **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.

#### **Starch:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

#### **Simvastatin:**

Assessment : Probability or evidence of skin sensitisation in humans  
Result : positive

#### **Ascorbic acid:**

Test Type : Maurer optimisation test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

#### **Titanium dioxide:**

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

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Species : Mouse  
Result : negative

### 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

#### **Starch:**

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

#### **Simvastatin:**

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

Test Type: Alkaline elution assay  
Result: negative

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Test Type: Chromosomal aberration  
Result: negative

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

Genotoxicity in vivo :

- Test Type: Micronucleus test
- Species: Mouse
- Application Route: Oral
- Result: negative

Germ cell mutagenicity - Assessment :

- Weight of evidence does not support classification as a germ cell mutagen.

### Ascorbic acid:

Genotoxicity in vitro :

- Test Type: Bacterial reverse mutation assay (AMES)
- Result: negative

Test Type: In vitro mammalian cell gene mutation test  
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: Mouse
- Application Route: Ingestion
- Result: negative

### Titanium dioxide:

Genotoxicity in vitro :

- Test Type: Bacterial reverse mutation assay (AMES)
- Result: negative

Genotoxicity in vivo :

- Test Type: In vivo micronucleus test
- Species: Mouse
- Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### **Sitagliptin Phosphate:**

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

  

Species	:	Rat
Application Route	:	oral (drinking water)

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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

### **Simvastatin:**

Species : Mouse  
Application Route : Oral  
Exposure time : < 92 weeks  
Target Organs : Harderian gland  
Tumor Type : Liver, Lungs  
Remarks : The significance of these findings for humans is not certain.

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Tumor Type : Liver, Thyroid  
Remarks : The significance of these findings for humans is not certain.

### **Ascorbic acid:**

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

### **Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

### **Reproductive toxicity**

Not classified based on available information.

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Effects on fertility

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

Effects on 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

**Simvastatin:**

Effects on fertility

: Test Type: Fertility  
Species: Rat, male  
Application Route: Oral  
Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal development

: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight  
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight  
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development

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Species: Rat  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight  
Result: Teratogenic potential  
Remarks: Based on data from similar materials

**Ascorbic acid:**

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**

May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

**Components:****Simvastatin:**Target Organs  
Assessment: Liver, muscle, optic nerve, Eye  
: Causes 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  
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

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**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

### Starch:

**Species** : Rat  
**NOAEL** : >= 2,000 mg/kg  
**Application Route** : Skin contact  
**Exposure time** : 28 Days  
**Method** : OECD Test Guideline 410

### Simvastatin:

**Species** : Rat  
**NOAEL** : 5 mg/kg  
**LOAEL** : 30 mg/kg  
**Application Route** : Oral  
**Exposure time** : 14 - 104 Weeks  
**Target Organs** : Liver, Testis, Musculo-skeletal system, Eye

**Species** : Dog  
**LOAEL** : 10 mg/kg  
**Application Route** : Oral  
**Exposure time** : 14 - 104 Weeks  
**Target Organs** : Liver, Testis, Eye

**Species** : Rabbit  
**NOAEL** : 30 mg/kg  
**LOAEL** : 50 mg/kg

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Application Route : Oral  
Target Organs : Liver, Kidney

## Ascorbic acid:

Species : Rat, male  
NOAEL :  $\geq 8,100$  mg/kg  
Application Route : Ingestion  
Exposure time : 13 Weeks

## Titanium dioxide:

Species : Rat  
NOAEL : 24,000 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days

Species : Rat  
NOAEL : 10 mg/m<sup>3</sup>  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 yr

## Aspiration toxicity

Not classified based on available information.

## 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

## Simvastatin:

Skin contact : Remarks: May produce an allergic reaction.

Ingestion : Target Organs: Liver  
Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea

Target Organs: Musculo-skeletal system

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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

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

**Simvastatin:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l  
Exposure time: 96 h

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Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.5 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l  
Exposure time: 96 h  
NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l  
Exposure time: 96 h

Toxicity to microorganisms : EC50: > 30 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
NOEC: 21 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Ascorbic acid:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50: 140 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8

**Titanium dioxide:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l  
Exposure time: 72 h

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

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### 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.

##### **Simvastatin:**

Biodegradability : Result: rapidly degradable

Stability in water : Hydrolysis: 50 %(3.2 d)

##### **Ascorbic acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 5 d  
Method: OECD Test Guideline 302

### Bioaccumulative potential

#### Components:

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

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

##### **Simvastatin:**

Partition coefficient: n-octanol/water : log Pow: > 4.07

##### **Ascorbic acid:**

Partition coefficient: n-octanol/water : log Pow: -1.85

### Mobility in soil

#### Components:

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

Distribution among environmental compartments : log Koc: 4.37

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### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

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

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## 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

#### 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 : Not applicable

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

Not applicable for product as supplied.

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### National Regulations

Refer to section 15 for specific national regulation.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

### Related Regulations

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

##### Substances Subject to be Notified Names

Law Article 57-2 (Ministerial Order Article 34-2 Appended Table 2)

Chemical name	Concentration (%)	Remarks
Titanium(IV) oxide	>=0.1 - <1	-

##### Substances Subject to be Indicated Names

Not applicable

##### Skin and Eye Damage Substances (ISHL MO Art. 594-2)

Not applicable

##### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

##### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

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### Ordinance on Prevention of Lead Poisoning

Not applicable

### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

### Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

### Poisonous and Deleterious Substances Control Law

Not applicable

### Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

### High Pressure Gas Safety Act

Not applicable

### Explosive Control Law

Not applicable

### Vessel Safety Law

Not regulated as a dangerous good

### Aviation Law

Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

### Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION**

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**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)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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

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JP / EN