

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Sitagliptin / Simvastatin Formulation

Version 8.0      Revision Date: 07/06/2024      SDS Number: 24487-00025      Date of last issue: 04/06/2024  
Date of first issue: 10/21/2014

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### SECTION 1. IDENTIFICATION

Product name : Sitagliptin / Simvastatin Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

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

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

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Eye irritation : Category 2A  
Skin sensitization : Category 1  
Carcinogenicity (Inhalation) : Category 2  
Specific target organ toxicity - repeated exposure : Category 1 (Liver, muscle, optic nerve, Eye)

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H351 Suspected of causing cancer if inhaled.  
H372 Causes damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and 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.  
P308 + P313 IF exposed or concerned: Get medical attention.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

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

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Sitagliptin	No data available	654671-77-9	$\geq 10 - < 30$ *
Cellulose	No data available	9004-34-6	$\geq 5 - < 10$ *
Simvastatin	No data available	79902-63-9	$\geq 1 - < 5$ *
Starch	Sago starch	9005-25-8	$\geq 1 - < 5$ *
Ascorbic acid	No data available	50-81-7	$\geq 1 - < 5$ *
Titanium dioxide	Titanic anhydride	13463-67-7	$\geq 0.1 - < 1$ *

\* Actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

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

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If inhaled	: advice. 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. Suspected of causing cancer if inhaled. Causes 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire 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 so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protection	: Use personal protective equipment.
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- |   |   |  |
|---|---|--|
| tive equipment and emergency procedures               | : | 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.  |
| Methods and materials for containment and cleaning up | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives   |

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

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>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Simvastatin	79902-63-9	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: DSEN				
		Wipe limit	250 µg/100 cm <sup>2</sup>	Internal
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m <sup>3</sup> (OEB 1)	Internal
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL

**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
- 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 : pink
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable

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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 characteristics Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks.

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Incompatible materials : Avoid dust formation.  
                                      : 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.

#### 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

##### Simvastatin:

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

##### Starch:

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

##### Ascorbic acid:

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



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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:**

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:**

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

#### **Simvastatin:**

Species : Rabbit  
Remarks : slight irritation

#### **Starch:**

Species : Rabbit  
Result : No eye irritation

#### **Ascorbic acid:**

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

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### Titanium dioxide:

Species : Rabbit  
Result : No eye irritation

### 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.

#### Simvastatin:

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

#### Starch:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Ascorbic acid:

Test Type : Maurer optimisation test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### Titanium dioxide:

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Sitagliptin:

Genotoxicity in vitro : Test Type: Ames test

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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

### Simvastatin:

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

Test Type: Alkaline elution assay  
Result: negative

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.

### Starch:

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

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||      Result: negative

### 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

Suspected of causing cancer if inhaled.

### 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

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

#### Cellulose:

|| Species      :    Rat  
|| Application Route      :    Ingestion  
|| Exposure time      :    72 weeks

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||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.

### 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.

||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

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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

### Simvastatin:

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

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

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

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

### Ascorbic acid:

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.

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### STOT-repeated exposure

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

#### Components:

##### Simvastatin:

Target Organs : Liver, muscle, optic nerve, Eye  
Assessment : Causes 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  
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

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||Remarks : No significant adverse effects were reported

### Cellulose:

||Species : Rat  
||NOAEL :  $\geq 9,000$  mg/kg  
||Application Route : Ingestion  
||Exposure time : 90 Days

### 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  
||Application Route : Oral  
||Target Organs : Liver, Kidney

### Starch:

||Species : Rat  
||NOAEL :  $\geq 2,000$  mg/kg  
||Application Route : Skin contact  
||Exposure time : 28 Days  
||Method : OECD Test Guideline 410

### 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)



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|| Exposure time : 2 y

### 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

##### 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

---

## 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

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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  
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

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### Titanium dioxide:

- |   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants                    | : | EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l<br>Exposure time: 72 h                                |
| Toxicity to microorganisms                          | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209                                      |

### Persistence and degradability

#### Components:

##### Sitagliptin:

- |                    |   |  |
|--------------------|---|--|
| Biodegradability   | : | Result: not rapidly degradable<br>Biodegradation: 39.7 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
| Stability in water | : | Hydrolysis: 50 %(401 d)<br>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.<br>Biodegradation: 97 %<br>Exposure time: 5 d<br>Method: OECD Test Guideline 302 |
|------------------|---|---|

### Bioaccumulative potential

#### Components:

##### Sitagliptin:

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

##### Simvastatin:

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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:

Distribution among environmental compartments : log Koc: 4.37

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

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DSL : not determined

IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)  
CA BC OEL : Canada. British Columbia OEL  
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
CA AB OEL / TWA : 8-hour Occupational exposure limit  
CA BC OEL / TWA : 8-hour time weighted average  
CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for 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; KECl - 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; TECl - 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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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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Date format : mm/dd/yyyy

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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