

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Simvastatin Formulation

Version 13.1      Revision Date: 05/09/2026      SDS Number: 24515-00027      Date of last issue: 12/06/2025  
Date of first issue: 10/21/2014

### SECTION 1. IDENTIFICATION

Product name : Sitagliptin / Simvastatin 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)

##### Hazards for the product as supplied

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

##### Other hazards

None known.

##### Hazards associated with a change in physical form:

| Conditions  | Hazards  |
|---|--|
| If small particles are generated during further processing, handling or by other means. | May form combustible dust concentrations in air. |

##### GHS label elements

Hazard pictograms :

Signal Word : Danger

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

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### Precautionary Statements

#### : **Prevention:**

P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
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 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 attention if you feel unwell.  
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.

#### **Disposal:**

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

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name         | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|-----------------------|-------------------|-----------------------|--------------|
| Sitagliptin Phosphate | 654671-77-9*      | >= 10 - <= 30         | TSC          |
| Cellulose             | 9004-34-6*        | >= 5 - <= 10          | TSC          |
| Simvastatin           | 79902-63-9*       | >= 3 - <= 7           | TSC          |
| Starch                | 9005-25-8*        | >= 3 - <= 7           | TSC          |
| Ascorbic acid         | 50-81-7*          | >= 0.5 - <= 1.5       | TSC          |
| Titanium dioxide      | 13463-67-7*       | >= 0.1 - <= 1         | TSC          |
| Talc                  | 14807-96-6*       | >= 0.1 - <= 1         | TSC          |

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

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- 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.  
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.  
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.
- 

### SECTION 5. FIRE-FIGHTING 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 so.  
Evacuate area.
- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.
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for fire-fighters Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 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. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.

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Materials to avoid : Store in accordance with the particular national regulations.  
: Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 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>  
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 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     |
|                       |                           | 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  |
| 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>                           | ACGIH     |

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|                  |            |                                     |  |           |
|------------------|------------|-------------------------------------|--|-----------|
|                  |            | 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  |
| Ascorbic acid    | 50-81-7    | TWA                                 | 5000 µg/m <sup>3</sup> (OEB 1)           | Internal  |
| Titanium dioxide | 13463-67-7 | TWA (total dust)                    | 15 mg/m <sup>3</sup>                     | OSHA Z-1  |
|                  |            | TWA (Respirable particulate matter) | 2.5 mg/m <sup>3</sup> (Titanium dioxide) | ACGIH     |
| Talc             | 14807-96-6 | TWA (Dust)                          | 20 Million particles per cubic foot      | OSHA Z-3  |
|                  |            | TWA (Respirable)                    | 2 mg/m <sup>3</sup>                      | NIOSH REL |
|                  |            | TWA (Respirable particulate matter) | 2 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.

### 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.

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- 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.

### 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
- 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** : No data available

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flammability limit

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.  
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

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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

#### 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  
Method: OECD Test Guideline 425  
Remarks: The test was conducted according to guideline

Acute inhalation toxicity : LC50 (Rat): > 5.09 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: The test was conducted according to guideline

#### Talc:

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

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Remarks: Based on data from similar materials

### 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  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : The test was conducted equivalent or similar to guideline

##### Talc:

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

##### Simvastatin:

Species : Rabbit  
Remarks : slight irritation

##### Starch:

Species : Rabbit  
Result : No eye irritation

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### Ascorbic acid:

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

### Titanium dioxide:

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : The test was conducted according to guideline

### Talc:

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 Phosphate:

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 : Buehler Test

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Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : The test was conducted according to guideline

### **Talc:**

Routes of exposure : Skin contact  
Species : Humans  
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

#### **Simvastatin:**

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

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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)  
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)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: The test was conducted according to guideline

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Genotoxicity in vivo : Test Type: Transgenic rodent somatic cell gene mutation assay  
Species: Mouse (male)  
Application Route: Intravenous injection  
Method: OECD Test Guideline 488  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

### Talc:

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

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
Species: Rat  
Application Route: Ingestion  
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)  
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

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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

### Talc:

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

### IARC Group 2A: Probably carcinogenic to humans

Talc 14807-96-6

### Group 2B: Possibly carcinogenic to humans

Titanium dioxide 13463-67-7

**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 Phosphate:

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

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.

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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

### Titanium dioxide:

Effects on fertility : Test Type: Extended one-generation reproduction toxicity study  
Species: Rat

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Application Route: Ingestion  
Method: OECD Test Guideline 443  
Result: negative  
Remarks: The test was conducted according to guideline

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: The test was conducted according to guideline

### **Talc:**

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**

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 Phosphate:**

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

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LOAEL : 50 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Target Organs : Central nervous system  
Symptoms : Loss of balance  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Dog  
NOAEL : 2 mg/kg  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 27 Weeks  
Target Organs : Skeletal muscle, Central nervous system  
Symptoms : Loss of balance  
Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Monkey  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Remarks : No significant adverse effects were reported

### Cellulose:

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

### 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

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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 :  $\geq 1,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408  
Remarks : The test was conducted according to guideline

### 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, 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 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 : EC50 (Daphnia magna (Water flea)): 60 mg/l

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aquatic invertebrates      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  
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

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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 : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline  
Based on transformation/dissolution testing and data from  
soluble metal compounds

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : EL50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

NOELR (Raphidocelis subcapitata (freshwater green alga)): >= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline

Toxicity to microorganisms : NOEC (activated sludge): >= 1,000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline

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### Talc:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l  
Exposure time: 24 h

### 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:

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Distribution among environmental compartments : log K<sub>oc</sub>: 4.37

### Other adverse effects

No data available

### Endocrine disrupting properties

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : 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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## 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 IMO instruments

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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## 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** : Respiratory or skin sensitization  
Specific target organ toxicity (single or repeated exposure)  
Serious eye damage or eye irritation

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**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

|   |             |
|---|-------------|
| D-Glucose, 4-O- $\beta$ -D-galactopyranosyl-, monohydrate | 64044-51-5  |
| Calcium hydrogenorthophosphate                            | 7757-93-9   |
| Sitagliptin Phosphate                                     | 654671-77-9 |
| Cellulose   | 9004-34-6   |
| Starch  | 9005-25-8   |
| Simvastatin   | 79902-63-9  |

#### California Prop. 65

WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov). **California Permissible Exposure Limits for Chemical Contaminants**

|           |           |
|-----------|-----------|
| Cellulose | 9004-34-6 |
| Starch    | 9005-25-8 |

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

|          |                  |
|----------|------------------|
| AICS     | : not determined |
| CA. DSL  | : not determined |
| CN IECSC | : not determined |

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## SECTION 16. OTHER INFORMATION

### Further information

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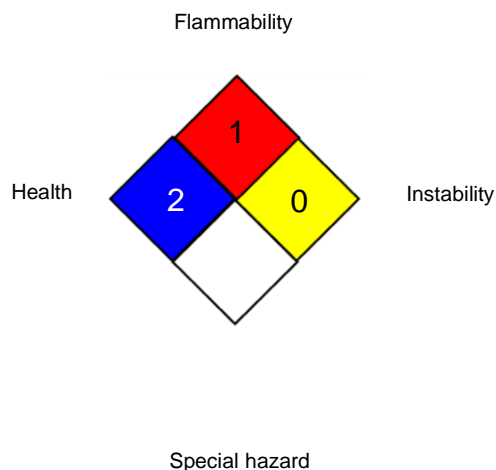
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### NFPA 704:



### HMIS® IV / CED:

|                 |   |   |
|-----------------|---|---|
| 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  |

AIIIC - 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 Standardization; 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 Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Pre-

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vention 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, Authorization 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/>

Revision Date : 05/09/2026

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.

US / Z8