SAFETY DATA SHEET

Sitagliptin / Simvastatin Formulation

Version: 4.5  
Revision Date: 09/13/2019  
SDS Number: 24481-00013  
Date of last issue: 24.04.2019  
Date of first issue: 21.10.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sitagliptin / Simvastatin Formulation

Manufacturer or supplier's details

Company: MSD

Address: 26 Talavera Road, Talavera Corp Centre, Macquarie Park  
New South Wales, 2113 Australia

Telephone: (61)-02-8988-8000

Emergency telephone number: (61)-02-8988-8000

E-mail address: EHSDATASTEWARD@msd.com

Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Serious eye damage/eye irritation: Category 2A

Skin sensitisation: Category 1

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

GHS label elements

Hazard pictograms: 

Signal word: Warning

Hazard statements: H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H373 May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

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.  
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and 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.
P363 Wash contaminated clothing before reuse.

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

Other hazards which do not result in classification
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Sitagliptin</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Simvastatin</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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: May cause an allergic skin reaction.
and effects, both acute and delayed
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.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media
- None known.

Specific hazards during firefighting
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 firefighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions
- Discharge into the environment must be avoided.
- 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.
- 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.
  - Take care to prevent spills, waste and minimize release to the environment.

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.
  - 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.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (OEL 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>


**SAFETY DATA SHEET**

**Sitagliptin / Simvastatin Formulation**

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>25 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>250 µg/100 cm²</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA 10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA 10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: This value is for inhalable dust containing no asbestos and &lt; 1% crystalline silica</td>
<td></td>
</tr>
</tbody>
</table>

**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**: 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: powder

**Colour**: pink

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

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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes: 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

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

Titanium dioxide:
Acute oral toxicity: LD50 (Mouse): > 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:
Species: Rabbit
Method: Draize Test
Result: No skin irritation

Simvastatin:
Species: Rabbit
Remarks: Moderate 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

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:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.
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<thead>
<tr>
<th>Version</th>
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</tr>
</thead>
</table>

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

**Titanium dioxide:**
Test Type : Local lymph node assay (LLNA)  
Exposure routes : Skin contact  
Species : Mouse  
Result : negative

**Chronic toxicity**

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Sitagliptin:**
Genotoxicity in vitro : Test Type: Ames test  
Result: negative  
Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: negative  
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: rat hepatocytes  
Result: negative

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

**Cellulose:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytophenetic 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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**Sitagliptin / Simvastatin Formulation**

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<thead>
<tr>
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<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

### Genotoxicity in vitro

- **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.**

### 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:

- **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
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**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.

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

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: 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
### Sitagliptin / Simvastatin Formulation

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>1,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>&gt; 2 yr</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

Species | Rat
NOAEL | 500 mg/kg
LOAEL | 1,000 mg/kg
Application Route | Oral
Exposure time | 14 Weeks
Target Organs | Liver, Kidney, Heart, Teeth

Species | Dog
NOAEL | 10 mg/kg
LOAEL | 50 mg/kg
Application Route | Oral
Exposure time | 53 Weeks
Target Organs | Central nervous system
Symptoms | Loss of balance
Remarks | The mechanism or mode of action may not be relevant in humans.

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

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

**Cellulose:**
Species | Rat
NOAEL | >= 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
- **Sitagliptin**: Oral
- **Simvastatin**: Ingestion

## Exposure time
- **Sitagliptin**: 14 - 104 Weeks
- **Simvastatin**: 28 Days

## Target Organs
- **Sitagliptin**: Liver, Testis, Eye
- **Simvastatin**: Liver, Kidney

## Species and NOAEL/LOAEL
- **Sitagliptin**
  - Species: Rabbit
  - NOAEL: 30 mg/kg
  - LOAEL: 50 mg/kg
- **Simvastatin**
  - Species: Rat
  - NOAEL: 10 mg/m3

## Aspiration toxicity
Not classified based on available information.

## Experience with human exposure

### Components:

#### Sitagliptin:
- **Inhalation**
  - Symptoms: upper respiratory tract infection, pharyngitis, Headache

#### Simvastatin:
- **Skin contact**
  - Remarks: May produce an allergic reaction.
  - Target Organs: Liver
- **Ingestion**
  - Symptoms: upper respiratory tract infection, Headache, Abdominal pain, Diarrhoea
  - Target Organs: Musculo-skeletal system

## Ecotoxicity

### Components:

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

#### Simvastatin:
- **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
  - 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

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

Persistence and degradability

Components:

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

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

Cellulose:
Biodegradability: Result: Readily biodegradable.

Simvastatin:
Biodegradability: Result: rapidly degradable

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

Bioaccumulative potential

Components:

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

Simvastatin:
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Partition coefficient: n-octanol/water

Mobility in soil

Components:

Sitagliptin:
Distribution among environmental compartments

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
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.

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.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements
There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information
Revision Date : 09/13/2019
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; 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 Standardisation; 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; 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
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.

AU / EN