SAFETY DATA SHEET

Sitagliptin Formulation

SECTION 1. IDENTIFICATION

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

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATATESTeward@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 Hazardous Products Regulations
Eye irritation : Category 2A

GHS label elements
Hazard pictograms :
Signal Word : Warning
Hazard Statements : H319 Causes serious eye irritation.
Precautionary Statements :
Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear eye protection and face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical attention.

Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
### SAFETY DATA SHEET

**Sitagliptin Formulation**

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>No data available</td>
<td>654671-77-9</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Titanic anhydride</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

* 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 advice.

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

**In case of skin contact**
- Wash with water and soap.
- Get medical attention if symptoms occur.

**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**
- Causes serious eye irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.

**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 (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 prod-**
- 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.

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 breathe dust.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- 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.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
Keep in properly labeled 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

Ingredients 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 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA</td>
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<td>CA AB OEL</td>
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<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
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<td>CA BC OEL</td>
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<tr>
<td></td>
<td></td>
<td>TWAEV (Total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

Titanium dioxide
SAFETY DATA SHEET

Sitagliptin Formulation

Engineering measures: Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: Not applicable

Evaporation rate: Not applicable

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

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

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

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

Titanium dioxide:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
                          Exposure time: 4 h
                          Test atmosphere: dust/mist
                          Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:

Sitagliptin:
Sitagliptin Formulation

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

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

**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

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

**Titanium dioxide:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**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.

**Magnesium stearate:**
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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
  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

Magnesium stearate:
Genotoxicity in vitro
  Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials
Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

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

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.
These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

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 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

Magnesium stearate:
Effects on fertility:
- Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
- Species: Rat
- Application Route: Ingestion
- Method: OECD Test Guideline 422
- Result: negative
- Remarks: Based on data from similar materials

Effects on fetal development:
- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
### STOT-singe exposure
Not classified based on available information.

### STOT-repeated exposure
Not classified based on available information.

### Repeated dose toxicity

#### Components:

**Sitagliptin**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
<th>500 mg/kg</th>
<th>1,000 mg/kg</th>
<th>Oral</th>
<th>&gt; 2 y</th>
<th>Kidney</th>
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<tr>
<td>NOAEL</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOAEL</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>&gt; 2 y</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
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<table>
<thead>
<tr>
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<th>Rat</th>
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<th>Oral</th>
<th>14 Weeks</th>
<th>Liver, Kidney, Heart, Teeth</th>
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<tbody>
<tr>
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<td>LOAEL</td>
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<td>14 Weeks</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Kidney, Heart, Teeth</td>
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<table>
<thead>
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<th>Species</th>
<th>Dog</th>
<th>10 mg/kg</th>
<th>50 mg/kg</th>
<th>Oral</th>
<th>53 Weeks</th>
<th>Central nervous system, Loss of balance, Loss of balance</th>
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<tbody>
<tr>
<td>NOAEL</td>
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<tr>
<td>Application Route</td>
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</tr>
<tr>
<td>Exposure time</td>
<td>53 Weeks</td>
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<tr>
<td>Target Organs</td>
<td>Central nervous system, Loss of balance</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
<th>2 mg/kg</th>
<th>10 mg/kg</th>
<th>Oral</th>
<th>27 Weeks</th>
<th>Skeletal muscle, Central nervous system, Loss of balance</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>LOAEL</td>
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</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
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<td></td>
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<tr>
<td>Exposure time</td>
<td>27 Weeks</td>
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</tr>
<tr>
<td>Target Organs</td>
<td>Skeletal muscle, Central nervous system, Loss of balance</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
<th>100 mg/kg</th>
<th>Oral</th>
<th>14 Weeks</th>
<th>No significant adverse effects were reported</th>
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</thead>
<tbody>
<tr>
<td>NOAEL</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cellulose:
Species : Rat
NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Magnesium stearate:
Species : Rat
NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Titanium dioxide:
Species : Rat
NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Species : Rat
NOAEL : 10 mg/m³
Application Route : inhalation (dust/mist/fume)
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

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 : EC50 (Pseudokirchneriella subcapitata (green algae)): > 39
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<th>Plants mg/l</th>
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<td></td>
<td></td>
<td>Exposure time: 96 h</td>
<td>Method: OECD Test Guideline 201</td>
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<td></td>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l</td>
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<td>Exposure time: 96 h</td>
<td>Method: OECD Test Guideline 201</td>
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<td></td>
<td></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l</td>
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<td></td>
<td>Exposure time: 33 d</td>
<td>Method: OECD Test Guideline 210</td>
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<td></td>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 9.8 mg/l</td>
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<td></td>
<td>Exposure time: 21 d</td>
<td>Method: OECD Test Guideline 211</td>
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<td>NOEC: 150 mg/l</td>
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<td>Exposure time: 3 h</td>
<td>Method: OECD Test Guideline 209</td>
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<td>Test Type: Respiration inhibition</td>
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<td>Remarks: Based on data from similar materials</td>
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<td>Cellulose:</td>
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<td></td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
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<td>Exposure time: 48 h</td>
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<td>Magnesium stearate:</td>
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<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
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<td>Exposure time: 48 h</td>
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<td>Method: DIN 38412</td>
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<td>Remarks: Based on data from similar materials</td>
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<td>Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
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<td>Exposure time: 47 h</td>
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<td>Test substance: Water Accommodated Fraction</td>
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<td>Remarks: Based on data from similar materials</td>
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<td>No toxicity at the limit of solubility.</td>
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<td>Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
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<td>Exposure time: 72 h</td>
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<td>Test substance: Water Accommodated Fraction</td>
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<td>Method: OECD Test Guideline 201</td>
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<td>Remarks: Based on data from similar materials</td>
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<td></td>
<td>No toxicity at the limit of solubility.</td>
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<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
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Remarks:
Based on data from similar materials
No toxicity at the limit of solubility.
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms  
EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

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.

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

Bioaccumulative potential

Components:

Sitagliptin:  
Partition coefficient: n-octanol/water  
log Pow: -0.03
Magnesium stearate:
Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil

Components:
Sitagliptin:
Distribution among environmental compartments: log Koc: 4.37

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.

Domestic regulation
TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
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


Revision Date : 08/27/2021
Date format : mm/dd/yyyy
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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