# SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

## Sitagliptin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td>09/26/2023</td>
<td>17316-00024</td>
<td>03/07/2023</td>
<td>09/30/2014</td>
</tr>
</tbody>
</table>

## SECTION 1. IDENTIFICATION

**Product name**: Sitagliptin 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)**  
Combustible dust  
Eye irritation: Category 2A  
Skin sensitization: Category 1  
**GHS label elements**  
Hazard pictograms: ![Exclamation Mark]

**Signal Word**: Warning  
**Hazard Statements**: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

**Precautionary Statements**:  
**Prevention**:  
P261 Avoid breathing dust.  
P264 Wash skin thoroughly after handling.  
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 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.
P333 + P313 If skin irritation or rash occurs: Get medical atten-
tion.
P337 + P313 If eye irritation persists: Get medical attention.
P363 Wash contaminated clothing before reuse.

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

Other hazards
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
<tr>
<td>Propyl 3,4,5-trihydroxybenzoate</td>
<td>121-79-9</td>
</tr>
<tr>
<td>Actual concentration is withheld as a trade secret</td>
<td></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 if symptoms occur.
In case of skin contact : In case of contact, immediately flush skin with soap and 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 : May cause an allergic skin reaction. Causes serious eye irritation.
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</tr>
</tbody>
</table>

delayed

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 products

Carbon oxides
Metal oxides
Oxides of phosphorus

Specific extinguishing methods

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for fire-fighters

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 spills 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. Avoid breathing 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. 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

inert or nuisance dust
50 Million particles per cubic foot
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

15 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: OSHA Z-3

5 mg/m³
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/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

### Components

<table>
<thead>
<tr>
<th>Component</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>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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 (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter) (Titanium dioxide)</td>
<td>2.5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.**

Titanium dioxide

**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**: 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

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.
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 : 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.
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks. Avoid dust formation.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Sitagliptin:
Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
LD50 (Mouse): 3,000 mg/kg

Cellulose:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

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

Polyethylene glycol:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
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
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Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

**Propyl 3,4,5-trihydroxybenzoate:**

Acute oral toxicity : LD50 (Mouse, female): > 1,000 - 2,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

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

**Polyethylene glycol:**
Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

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

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

**Propyl 3,4,5-trihydroxybenzoate:**
Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Result : No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye irritation.
Components:

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

Polyethylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

Titanium dioxide:
Species: Rabbit
Result: No eye irritation

Propyl 3,4,5-trihydroxybenzoate:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

Respiratory sensitization
Not classified based on available information.

Components:

Sitagliptin:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Method: OECD Test Guideline 429
Result: Not a skin sensitizer.

Polyethylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials
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

Propyl 3,4,5-trihydroxybenzoate:
- **Test Type:** Local lymph node assay (LLNA)
- **Routes of exposure:** Skin contact
- **Species:** Mouse
- **Result:** positive
- **Assessment:** Probability or evidence of skin sensitization in humans

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
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<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**Polyethylene glycol:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Method: OECD Test Guideline 473</td>
</tr>
<tr>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: In vivo micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

**Propyl 3,4,5-trihydroxybenzoate:**

<table>
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<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
<tr>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td></td>
</tr>
<tr>
<td>Result: positive</td>
<td></td>
</tr>
<tr>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Result: positive</td>
</tr>
<tr>
<td>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Test Type: In vitro sister chromatid exchange assay in mammalian cells</td>
<td>Result: positive</td>
</tr>
</tbody>
</table>
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
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. This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

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

**Propyl 3,4,5-trihydroxybenzoate:**
- Species: Rat  
- Application Route: Ingestion
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<table>
<thead>
<tr>
<th>Components</th>
<th>Effects on fertility</th>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td></td>
<td>Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL Parent: 1,000 mg/kg body weight Animal testing did not show any effects on fertility.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Embryo-fetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 250 mg/kg body weight Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Embryo-fetal development</td>
<td>Rabbit</td>
<td></td>
<td>No teratogenic effects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Cellulose</td>
<td></td>
<td>Fertility</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td>Fertility</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>
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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
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Propyl 3,4,5-trihydroxybenzoate:**

**Effects on fertility**
- **Test Type:** Two-generation reproduction toxicity study
- **Species:** Rat
- **Application Route:** Ingestion
- **Result:** negative

**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**
Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**Sitagliptin:**
- **Species:** Mouse
- **NOAEL:** 500 mg/kg
- **LOAEL:** 1,000 mg/kg
- **Application Route:** Oral
- **Exposure time:** > 2 y
- **Target Organs:** Kidney

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

- **Species:** Dog
- **NOAEL:** 10 mg/kg
- **LOAEL:** 50 mg/kg
- **Application Route:** Oral
- **Exposure time:** 53 Weeks
- **Target Organs:** Central nervous system
- **Symptoms:** Loss of balance
## Sitagliptin Formulation

**Remarks**: The mechanism or mode of action may not be relevant in humans.

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>2 mg/kg</td>
<td>10 mg/kg</td>
<td>Oral</td>
<td>27 Weeks</td>
<td>Skeletal muscle, Central nervous system</td>
<td>Loss of balance</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
<tr>
<td>Monkey</td>
<td>100 mg/kg</td>
<td></td>
<td>Oral</td>
<td>14 Weeks</td>
<td></td>
<td></td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 9,000 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td></td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>24,000 mg/kg</td>
<td>Ingestion</td>
<td>28 Days</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>10 mg/m³</td>
<td>inhalation (dust/mist/fume)</td>
<td>2 y</td>
<td></td>
</tr>
</tbody>
</table>

**Propyl 3,4,5-trihydroxybenzoate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>135 mg/kg</td>
<td>Ingestion</td>
<td>13 Weeks</td>
<td></td>
</tr>
</tbody>
</table>
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 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

**Polyethylene glycol:**
Toxicity to fish: LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

**Magnesium stearate:**
Toxicity to fish: LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
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
aquatic invertebrates  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

Propyl 3,4,5-trihydroxybenzoate:

Toxicity to daphnia and other aquatic invertebrates :  EC50 (Daphnia magna (Water flea)): 19.06 mg/l
                                                     Exposure time: 48 h
                                                     Test substance: Neutralized product
                                                     Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants :  ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.37 mg/l
                                    Exposure time: 72 h
                                    Test substance: Neutralized product
                                    Method: OECD Test Guideline 201

                                    EC10 (Pseudokirchneriella subcapitata (green algae)): 0.17 mg/l
                                    Exposure time: 72 h
                                    Test substance: Neutralized product
                                    Method: OECD Test Guideline 201

Toxicity to microorganisms :  EC50: 636 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.

Polyethylene glycol:

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

Propyl 3,4,5-trihydroxybenzoate:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 49.4 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

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

Polyethylene glycol:
Partition coefficient: n-octanol/water : log Pow: < 3

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

Propyl 3,4,5-trihydroxybenzoate:
Partition coefficient: n-octanol/water : log Pow: 1.8
Remarks: Calculation

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.
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.
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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

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
- Combustible dust
- Respiratory or skin sensitization
- Serious eye damage or eye irritation

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

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Calcium hydrogenorthophosphate</td>
<td>7757-93-9</td>
</tr>
</tbody>
</table>

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.
SAFETY DATA SHEET according to the OSHA Hazard Communication Standard

Sitagliptin Formulation

Version 8.1  Revision Date: 09/26/2023  SDS Number: 17316-00024  Date of last issue: 03/07/2023  Date of first issue: 09/30/2014

California Permissible Exposure Limits for Chemical Contaminants

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
</tbody>
</table>

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

HMIS® IV:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Physical Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ 2</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

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

US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)

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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Sitagliptin Formulation

Version  Revision Date:  SDS Number:  Date of last issue: 03/07/2023
8.1    09/26/2023    17316-00024    Date of first issue: 09/30/2014

US WEEL / TWA :  8-hr TWA

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 Standardisation; 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 Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SAR - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TCSI - 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


Revision Date : 09/26/2023

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