SAFETY DATA SHEET

Sitagliptin Formulation

Section 1. Product and Company Identification

Product name: Sitagliptin Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

Section 2. Hazards Identification

GHS Classification

Eye irritation: Category 2A
Short-term (acute) aquatic hazard: Category 3

GHS label elements

Hazard pictograms:

Signal Word: Warning
Hazard Statements: H319 Causes serious eye irritation.
H402 Harmful to aquatic life.

Precautionary Statements:

Prevention:
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/ 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 advice/ attention.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 20 -&lt; 30</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 -&lt; 5</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0,1 -&lt; 1</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: 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 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 Advice on safe handling: Use only with adequate ventilation.
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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td>titanium dioxide</td>
<td>13463-67-7</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information:
- A4 - Not classifiable as a human carcinogen, irritation
- A4 - Not classifiable as a human carcinogen, lung

These substance(s) are inextricably bound in the product and therefore do 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: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection Material: Chemical-resistant gloves

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

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.

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**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**: No data available
flammbility limit

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</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.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Avoid dust formation.</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td></td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

SECTION 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Information on likely routes of exposure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inhalation</td>
</tr>
<tr>
<td></td>
<td>Skin contact</td>
</tr>
<tr>
<td></td>
<td>Ingestion</td>
</tr>
<tr>
<td></td>
<td>Eye contact</td>
</tr>
</tbody>
</table>
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:**
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.

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
    Result: negative
    Remarks: Based on data from similar materials

**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
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

Magnesium stearate:

Species: Rat
NOAEL: > 100 mg/kg
### Application Route

<table>
<thead>
<tr>
<th>Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Titanium dioxide:

<table>
<thead>
<tr>
<th>Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Based on data from similar materials</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 tox-)**: NOEC (Pimephales promelas (fathead minnow)): 9,2 mg/l

---

**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>
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<tbody>
<tr>
<td>3.11</td>
<td>02.10.2020</td>
<td>17279-00018</td>
<td>23.03.2020</td>
<td>30.09.2014</td>
</tr>
</tbody>
</table>
## Toxicity to microorganisms

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 209

**NOEC**: 150 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

**Remarks**: Based on data from similar materials

## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guidelines 210

**NOEC** (Daphnia magna (Water flea)): 9.8 mg/l
Exposure time: 21 d

**Remarks**: Based on data from similar materials

## Toxicity to algae/aquatic plants

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**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

**Remarks**: Based on data from similar materials

## Toxicity to fish

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**Remarks**: Based on data from similar materials

## Cellulose

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**Remarks**: Based on data from similar materials

## Magnesium stearate

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**Remarks**: Based on data from similar materials

## Toxicity to fish

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**Remarks**: Based on data from similar materials

## Toxicity to algae/aquatic plants

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**Remarks**: Based on data from similar materials

## Toxicity to microorganisms

**Test substance**: Water Accommodated Fraction

**Method**: OECD Test Guideline 201

**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
**SAFETY DATA SHEET**

**Sitagliptin Formulation**

**Version** 3.11  
**Revision Date:** 02.10.2020  
**SDS Number:** 17279-00018  
**Date of last issue:** 23.03.2020  
**Date of first issue:** 30.09.2014

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**Other adverse effects**  
No data available

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**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.

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**
- **UNRTDG**  
  Not regulated as a dangerous good
- **IATA-DGR**  
  Not regulated as a dangerous good
- **IMDG-Code**  
  Not regulated as a dangerous good
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  
  Not applicable for product as supplied.

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**SECTION 15. REGULATORY INFORMATION**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Argentina. Carcinogenic Substances and Agents Registry.**  
  Not applicable
- **Control of precursors and essential chemicals for the preparation of drugs.**  
  Not applicable

**International Regulations**

**The ingredients of this product are reported in the following inventories:**
- **AICS**  
  Not determined
- **DSL**  
  Not determined
- **IECSC**  
  Not determined

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**SECTION 16. OTHER INFORMATION**

**Further information**
- **Sources of key data used to compile the Material Safety**  
  Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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