1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sitagliptin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Serious eye damage/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 + P317 If eye irritation persists: Get medical help.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<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>Magnesium stearate</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media
Water spray
Alcohol-resistant foam
SAFETY DATA SHEET

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Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal oxides
Oxides of phosphorus

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

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

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.

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 labelled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>TWA</td>
<td>0.5 mg/m³ (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>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</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

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.
SAFETY DATA SHEET

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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: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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.

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:
SAFETY DATA SHEET

Sitagliptin Formulation

<table>
<thead>
<tr>
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</tbody>
</table>

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

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  
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
- **Method:** Draize Test
- **Result:** Irritating to eyes.

**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 sensitisation**

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

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

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

**Magnesium stearate:**
- **Test Type:** Maximisation Test
- **Exposure routes:** 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)
- **Exposure routes:** 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
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Application Route: Oral
Fertility: NOAEL Parent: 1,000 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Oral
- Teratogenicity: LOAEL: 250 mg/kg body weight
- Result: Embryotoxic effects and adverse effects on the offspring were detected. No teratogenic effects

- Test Type: Embryo-foetal development
- Species: Rabbit
- Teratogenicity: NOAEL: 125 mg/kg body weight
- Result: No teratogenic effects

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

Effects on foetal 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 foetal development:
- Test Type: Embryo-foetal 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
- **Species**: Rat
- **NOAEL**: 500 mg/kg
- **LOAEL**: 1,000 mg/kg
- **Application Route**: Oral
- **Exposure time**: > 2 yr
- **Target Organs**: Kidney
- **Species**: Dog
- **NOAEL**: 10 mg/kg
- **LOAEL**: 50 mg/kg
- **Application Route**: Oral
- **Exposure time**: 14 Weeks
- **Target Organs**: Liver, Kidney, Heart, Teeth
- **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**: 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 yr

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, Diarrhoea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sitagliptin:
Toxicity to fish: \( LC_{50} \) (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: \( EC_{50} \) (Daphnia magna (Water flea)): 60 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: \( EC_{50} \) (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 microorganisms: \( EC_{50} \): > 150 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 150 mg/l
Exposure time: 3 h
**SAFETY DATA SHEET**

**Sitagliptin Formulation**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Substance</th>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiration inhibition</td>
<td>Water Accommodated Fraction</td>
<td>NOEC: 9.2 mg/l</td>
<td>Species: Pimephales promelas (fathead minnow)</td>
<td>OECD Test Guideline 210</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC: 9.8 mg/l</td>
<td>OECD Test Guideline 211</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Toxicity to fish</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium dioxide:</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout))</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials
- No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate:</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks:
- No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Toxicity to microorganisms</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

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<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose:</td>
<td>LC50 (Oryzias latipes (Japanese medaka))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

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<th>EL50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Daphnia magna (Water flea))</td>
<td>&gt; 1 mg/l</td>
<td>47 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
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<table>
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<tr>
<th>Test Substance</th>
<th>Toxicity to fish</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Leuciscus idus (Golden orfe))</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Water Accommodated Fraction</td>
<td>DIN 38412</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

<table>
<thead>
<tr>
<th>Test Substance</th>
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<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Toxicity to microorganisms</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC10 (Pseudomonas putida)</td>
<td>&gt; 100 mg/l</td>
<td>16 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Toxicity to microorganisms</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>72 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

Remarks:
- Based on data from similar materials

<table>
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<tr>
<th>Test Substance</th>
<th>Toxicity to fish</th>
<th>LC50</th>
<th>Exposure time</th>
<th>Test substance</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout))</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

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

**14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to IMO instruments**
Not applicable for product as supplied.

**Special precautions for user**
Not applicable

**15. REGULATORY INFORMATION**

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

**The components of this product are reported in the following inventories:**

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**16. OTHER INFORMATION**

**Further information**

- **Date format**: dd.mm.yyyy
SAFETY DATA SHEET

Sitagliptin Formulation

Version 1.18
Revision Date: 27.08.2021
SDS Number: 17302-00019
Date of last issue: 02.10.2020
Date of first issue: 30.09.2014

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

IN / EN