SAFETY DATA SHEET

Sitagliptin / Simvastatin Formulation

Version: 3.3  
Revision Date: 16.10.2020  
SDS Number: 24516-00014  
Date of last issue: 13.09.2019  
Date of first issue: 21.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: Sitagliptin / Simvastatin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company: MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone: +27 11 655 3000
   Telefax: 908-735-1496
   E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Eye irritation, Category 2  
   Skin sensitisation, Category 1  
   Specific target organ toxicity - repeated exposure, Category 2  
   Long-term (chronic) aquatic hazard, Category 3  
   H319: Causes serious eye irritation.  
   H317: May cause an allergic skin reaction.  
   H373: May cause damage to organs through prolonged or repeated exposure.  
   H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms:
   Signal word: Warning  
   Hazard statements:
   H317 - May cause an allergic skin reaction.
   H319 - Causes serious eye irritation.
   H373 - May cause damage to organs through prolonged or repeated exposure.
   H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements:

Prevention:
P260  Do not breathe dust.
P273  Avoid release to the environment.
P280  Wear protective gloves/eye protection/face protection.

Response:
P314  Get medical advice/attention if you feel unwell.
P333 + P313  If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313  If eye irritation persists: Get medical advice/attention.

Hazardous components which must be listed on the label:
Simvastatin

2.3 Other hazards
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>79902-63-9</td>
<td>Skin Irrit. 2; H315 Skin Sens. 1; H317 STOT RE 1; H372 (Liver, muscle, optic nerve, Eye) Aquatic Chronic 2; H411</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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

In case of skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures

Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling

Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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 OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA OEL-RL (inhalable dust)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL OEL-RL (Dust)</td>
<td>20 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>
Further information: Recommended Limit

<table>
<thead>
<tr>
<th>Starch</th>
<th>TWA OEL-RL (Respirable dust)</th>
<th>5 mg/m³</th>
<th>ZA OEL</th>
</tr>
</thead>
</table>

Further information: Recommended Limit

| TWA OEL-RL (inhalable dust) | 10 mg/m³ | ZA OEL |

Further information: Recommended Limit

<table>
<thead>
<tr>
<th>Simvastatin</th>
<th>TWA</th>
<th>25 µg/m³ (OEB 3)</th>
<th>Internal</th>
</tr>
</thead>
</table>

Further information: DSEN

| Internal | Wipe limit | 250 µg/100 cm² |

### 8.2 Exposure controls

**Engineering measures**

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

**Personal protective equipment**

**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.

**Hand protection**

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

**Skin and body protection**

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**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 (P)

### SECTION 9: Physical and chemical properties

**9.1 Information on basic physical and chemical properties**

**Appearance**: powder

**Colour**: pink

**Odour**: No data available

**Odour Threshold**: No data available

**pH**: No data available
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<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>
</table>

- 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.
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapour pressure: Not applicable
- Relative vapour density: Not applicable
- Relative density: No data available
- Density: No data available
- Solubility(ies)
  - Water solubility: No data available
  - Partition coefficient: n-octanol/water: Not applicable
  - Auto-ignition temperature: No data available
  - Decomposition temperature: No data available
- Viscosity
  - Viscosity, kinematic: Not applicable
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids): No data available
- Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.
10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Simvastatin:
Acute oral toxicity : LD50 (Rat): 5.000 mg/kg
                  : LD50 (Mouse): 3.800 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

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

Simvastatin:
Species : Rabbit
Remarks : Moderate skin irritation
Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

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

Simvastatin:
Species: Rabbit
Remarks: slight irritation

Respiratory or skin sensitisation

Skin sensitisation
May cause an allergic skin reaction.

Respiratory sensitisation
Not classified based on available information.

Components:

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

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

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

Simvastatin:
Genotoxicity in vitro:
  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Alkaline elution assay
  Result: negative
  Test Type: Chromosomal aberration
  Result: negative
  Test Type: In vitro mammalian cell gene mutation test
  Result: negative

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

Germ cell mutagenicity - Assessment:
  Weight of evidence does not support classification as a germ cell mutagen.

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: < 92 weeks
Result: positive
Target Organs: Liver
Remarks: Significant toxicity observed in testing
Carcinogenicity - Assessment:
  Weight of evidence does not support classification as a carcinogen

Simvastatin:
Species: Mouse
Application Route: Oral
Exposure time: < 92 weeks
Target Organs: Harderian gland
Tumor Type: Liver, Lungs
Remarks: The significance of these findings for humans is not certain.
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Tumor Type: Liver, Thyroid
Remarks: The significance of these findings for humans is not certain.

Reproductive toxicity
Not classified based on available information.

Components:

Sitagliptin:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL Parent: 1.000 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development
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

Simvastatin:
Effects on fertility: Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight
Result: Teratogenic potential
Remarks: Based on data from similar materials
### STOT - single exposure
Not classified based on available information.

### STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

#### Components:

**Simvastatin:**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver, muscle, optic nerve, Eye</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

#### Repeated dose toxicity

#### Components:

**Sitagliptin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>&gt; 2 yr</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>500 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>1.000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>14 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Kidney, Heart, Teeth</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>100 mg/kg</td>
</tr>
</tbody>
</table>
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Application Route: Oral
Exposure time: 14 Weeks
Remarks: No significant adverse effects were reported

Simvastatin:
Species: Rat
NOAEL: 5 mg/kg
LOAEL: 30 mg/kg
Application Route: Oral
Exposure time: 14 - 104 Weeks
Target Organs: Liver, Testis, Musculo-skeletal system, Eye

Species: Dog
NOAEL: 10 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Exposure time: 14 - 104 Weeks
Target Organs: Liver, Testis, Eye

Species: Rabbit
NOAEL: 30 mg/kg
LOAEL: 50 mg/kg
Application Route: Oral
Target Organs: Liver, Kidney

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

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

SECTION 12: Ecological information

12.1 Toxicity
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 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

Toxicity to fish (Chronic toxicity): NOEC: 9.2 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 9.8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Simvastatin:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 3.5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l
Exposure time: 96 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l
Exposure time: 96 h

Toxicity to microorganisms: EC50: > 30 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 21 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

12.2 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:
-pH: 7
-Hydrolysis: 50% (401 d)
Method: OECD Test Guideline 111

Simvastatin:
Biodegradability: Result: rapidly degradable
Stability in water:
-Hydrolysis: 50% (3.2 d)

12.3 Bioaccumulative potential

Components:

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

Simvastatin:
Partition coefficient: n-octanol/water:
-log Pow: > 4.07

12.4 Mobility in soil

Components:

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

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Version: 3.3  Revision Date: 16.10.2020  SDS Number: 24516-00014  Date of last issue: 13.09.2019

Date of first issue: 21.10.2014

Full text of H-statements

H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H372 : Causes damage to organs through prolonged or repeated exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICL - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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 Bio-accumulative

Further information

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET

Sitagliptin / Simvastatin Formulation

Version 3.3
Revision Date: 16.10.2020
SDS Number: 24516-00014
Date of last issue: 13.09.2019
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Classification of the mixture:

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<th>Calculation method</th>
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<td>H319</td>
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<td>STOT RE 2</td>
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<td>Aquatic Chronic 3</td>
<td>H412</td>
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ZA / EN