Section 1: Identification

Product name : Sitagliptin / Metformin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

Section 2: Hazard identification

GHS Classification
Acute toxicity (Oral) : Acute Tox.4

GHS label elements
Hazard pictograms :

Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
Precautionary statements :
Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.
Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>metformin hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sitagliptin</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</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
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
If swallowed
If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed
Harmful if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
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, Nitrogen oxides (NOx), Metal oxides

**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.

### Section 6: Accidental release measures

**Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions:** Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### Section 7: Handling and storage

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

**Local/Total ventilation Advice on safe handling**

Use only with adequate ventilation. Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
SAFETY DATA SHEET
Sitagliptin / Metformin Formulation

Version: 3.9
Revision Date: 09/13/2019
SDS Number: 27119-00014
Date of last issue: 24.04.2019
Date of first issue: 31.10.2014

section 7: Risk 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.

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.

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

Section 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>Metformin hydrochloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>2 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<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>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>WES-TWA</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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

Titanium dioxide

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 type:
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.

Section 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

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
SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

Version: 3.9  Revision Date: 09/13/2019  SDS Number: 27119-00014  Date of last issue: 24.04.2019
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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.
Particle size: No data available

Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions
  May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
  Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes
  Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,380 mg/kg
  Method: Calculation method

Components:
metformin hydrochloride:
Acute oral toxicity: LD50 (Rat): 1,000 mg/kg
  LD50 (Mouse): 1,450 - 3,500 mg/kg
  LD50 (Monkey): 463 mg/kg
  LD50 (Rabbit): 350 mg/kg
  LD50 (Guinea pig): 500 mg/kg
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

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:
metformin hydrochloride:
Species : Rabbit
Result : Mild skin irritation

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

Titanium dioxide:
Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
metformin hydrochloride:
Species : Rabbit
Result : Mild eye irritation
**Sitagliptin / Metformin 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>
</table>

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

### 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.

#### Titanium dioxide:
**Test Type**: Local lymph node assay (LLNA)  
**Exposure routes**: Skin contact  
**Species**: Mouse  
**Result**: negative

**Chronic toxicity**

**Germ cell mutagenicity**  
Not classified based on available information.

**Components**:

#### metformin hydrochloride:
**Genotoxicity in vitro**  
**Result**: negative
- Test Type: Bacterial reverse mutation assay (AMES)  
  **Test system**: mouse lymphoma cells  
  **Result**: negative
- Test Type: Chromosomal aberration  
  **Test system**: Human lymphocytes  
  **Result**: negative

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

**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

**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:**

**metformin hydrochloride:**
- **Species:** Mouse
- **Exposure time:** 91 weeks
- **Dose:** 1500 mg/kg body weight
- **Result:** negative
Species: Rat, male  
Application Route: Oral  
Exposure time: 104 weeks  
Dose: 900 mg/kg body weight  
Result: negative

Species: Rat, female  
Application Route: Oral  
Exposure time: 104 weeks  
LOAEL: 900 mg/kg body weight  
Result: negative  
Target Organs: Uterus (including cervix)  
Remarks: The mechanism or mode of action may not be relevant in humans.

**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:

metformin hydrochloride:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 600 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 600 mg/kg body weight
Result: No teratogenic effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 140 mg/kg body weight
Result: No teratogenic effects

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: 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

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

Repeated dose toxicity

Components:

metformin hydrochloride:
Species : Rat
NOAEL : 125 mg/kg
Application Route : Oral
Exposure time : 1 year
Remarks : No significant adverse effects were reported

Species : Rabbit
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 1 year
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 50 mg/kg
Application Route : Subcutaneous
Exposure time : 2 year
Remarks : No significant adverse effects were reported

Sitagliptin:
Species : Mouse
NOAEL : 500 mg/kg
LOAEL : 1,000 mg/kg
Application Route : Oral
Exposure time : > 2 yr
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 hu-
mans.

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

**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:**

**metformin hydrochloride:**
Skin contact: Remarks: May irritate skin.
Eye contact: Remarks: May irritate eyes.
Ingestion: Symptoms: Diarrhoea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

**Sitagliptin:**
Inhalation: Symptoms: upper respiratory tract infection, pharyngitis, Headache
Ingestion: Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea
Section 12: Ecological information

**Ecotoxicity**

**Components:**

- **metformin hydrochloride:**
  - Toxicity to algae/aquatic plants:
    - EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
    - NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
  - Toxicity to fish (Chronic toxicity):
    - NOEC (Pimephales promelas (fathead minnow)): 10 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)): 40 mg/l
    - Exposure time: 21 d
    - Method: OECD Test Guideline 211
  - Toxicity to microorganisms:
    - EC50: > 1,000 mg/l
    - Exposure time: 3 h
    - Test Type: Respiration inhibition
    - Method: OECD Test Guideline 209

- **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:
    - NOEC (Daphnia magna (Water flea)): 9.8 mg/l
## aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d  
Method: OECD Test Guideline 211

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiration inhibition</td>
<td>&gt; 150 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

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

### 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

### metformin hydrochloride

Biodegradability  
Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 2 hrs

### Sitaglptin

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.
Bioaccumulative potential

**Components:**

**metformin hydrochloride:**
Partition coefficient: n-octanol/water : log Pow: -2

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

Mobility in soil

**Components:**

**metformin hydrochloride:**
Distribution among environmental compartments : log Koc: 4.3
   Method: OECD Test Guideline 106

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

Other adverse effects
No data available

---

**Section 13: Disposal considerations**

**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
   If not otherwise specified: Dispose of as unused product.

---

**Section 14: Transport information**

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

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

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

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**

**NZS 5433**
Not regulated as a dangerous good
Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

Section 16: Other information

Further information
Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AICS - Australian Inventory of Chemical Substances; 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-
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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.

NZ / EN