1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Sitagliptin / Metformin Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: powder
Colour: No data available
Odour: No data available
Harmful if swallowed.

GHS Classification
Acute toxicity (Oral): Category 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/doctor if you feel unwell. Rinse mouth.
Disposal:
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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Date of last issue: 2019/04/24
Date of first issue: 2014/10/31

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
Harmful if swallowed.

Environmental hazards
Not classified based on available information.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1</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 : 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).
5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- 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
- 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.

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 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 re-leased 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

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 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 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.

Avoidance of contact: Oxidizing agents

Storage
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

Packaging material: Unsuitable material: None known.

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>PC-TWA</td>
<td>10 mg/m3</td>
<td>GBZ 2.1-2007</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>PC-TWA (Total dust)</td>
<td>8 mg/m3</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m3</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
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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Date of first issue: 2014/10/31

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

Eye/face 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.

Hand protection
Material
: Chemical-resistant gloves

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, han-
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
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

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

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
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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:
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

Germ cell mutagenicity
Not classified based on available information.

Components:
metformin hydrochloride:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: in vitro assay
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
Sitagliptin / Metformin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.13</td>
<td>27101-00014</td>
<td>2019/04/24</td>
<td>2014/10/31</td>
</tr>
</tbody>
</table>

Effects on fertility:
- **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-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.
- **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 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
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<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutaneous</td>
<td>2 year</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Sitagliptin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>500 mg/kg</td>
<td>1,000 mg/kg</td>
<td>Oral</td>
<td>&gt; 2 yr</td>
<td>Kidney</td>
</tr>
<tr>
<td>Rat</td>
<td>500 mg/kg</td>
<td>1,000 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>Liver, Kidney, Heart, Teeth</td>
</tr>
<tr>
<td>Dog</td>
<td>10 mg/kg</td>
<td>50 mg/kg</td>
<td>Oral</td>
<td>53 Weeks</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>Dog</td>
<td>2 mg/kg</td>
<td>10 mg/kg</td>
<td>Oral</td>
<td>27 Weeks</td>
<td>Skeletal muscle, Central nervous system</td>
</tr>
<tr>
<td>Monkey</td>
<td>100 mg/kg</td>
<td>&gt;= 9,000 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 9,000 mg/kg</td>
<td>Oral</td>
<td>90 Days</td>
<td></td>
</tr>
</tbody>
</table>

**Titanium dioxide:**

No adverse effects reported.
Sitagliptin / Metformin Formulation

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

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
### Sitagliptin / Metformin Formulation

#### 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 (Chronic toxicity)**
- **NOEC** (Daphnia magna (Water flea)): 9.8 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

**Toxicity to microorganisms**
- **EC50**: > 150 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - **NOEC**: 150 mg/l
    - Exposure time: 3 h
    - Test Type: Respiration inhibition

#### Cellulose:

**Toxicity to fish**
- **LC50** (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

#### 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**
- **EC50** (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates
Exposure time: 48 h

Toxicity to algae/aquatic plants
EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

Toxicity to microorganisms
EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

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

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.

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 environ-
mental compartments

Other adverse effects
No data available

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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations
GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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
SAFETY DATA SHEET
corresponding to GB/T 16483 and GB/T 17519

Sitagliptin / Metformin Formulation

Sources of key data used to compile the Safety Data Sheet


Date format

yyyymm/dd

Full text of other abbreviations

ACGIH
GBZ 2.1-2007

USA. ACGIH Threshold Limit Values (TLV)
Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA
GBZ 2.1-2007 / PC-TWA

8-hour, time-weighted average
Permissible concentration - 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 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; 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; 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

Disclaimer

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