SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

SECTION 1. IDENTIFICATION

Product name : Sitagliptin / Metformin Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEW@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Combustible dust

Acute toxicity (Oral) : Category 4

GHS label elements
Hazard pictograms : ⚠

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
节3. 组成/信息的成分

<table>
<thead>
<tr>
<th>成分</th>
<th>化学名</th>
<th>CAS号</th>
<th>浓度（% w/w）</th>
</tr>
</thead>
<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>&gt;= 70 - &lt; 90</td>
<td></td>
</tr>
<tr>
<td>Sitagliptin</td>
<td>654671-77-9</td>
<td>&gt;= 5 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5</td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td></td>
</tr>
</tbody>
</table>

实际浓度被保密为商业秘密

节4. 急救措施

总则：如果事故发生或感觉不适，立即寻求医疗帮助。在症状持续或有疑问的情况下寻求医疗帮助。

吸入：如吸入，移至新鲜空气。

皮肤接触：用清水和肥皂清洗。

眼睛接触：如眼睛接触，用清水充分冲洗。

吞咽：如吞咽，切勿诱导呕吐，除非医疗人员指示。

最重要的症状和效应，包括急性和延迟性：有害于吞咽。

暴露于灰尘的急救人员：急救人员应关注自我保护，并在可能存在暴露的情况下使用规定个人防护设备（见第8节）。

医疗人员注意事项：对症治疗和支持。

节5. 灭火措施

合适的灭火介质：水喷雾
酒精耐受泡沫
二氧化碳（CO2）
干化学

不合适的灭火介质：无

特定的灭火危害：避免产生灰尘；在足够大的灰尘浓度下，灰尘在空气中的散射可能成为爆炸性粉尘。接触燃烧产物可能对健康有害。

有害的燃烧产物：碳氧化物
氮氧化物（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 fire-fighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice 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 : 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.
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Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
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<tr>
<td></td>
<td></td>
<td>(Titanium dioxide)</td>
<td></td>
<td></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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Titanium dioxide

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

Titanium dioxide
Hand protection
Material : Chemical-resistant gloves

Eye protection
: Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

Hygiene measures
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder
Color : No data available
Odor : No data available
Odor Threshold : No data available
pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : Not applicable
Relative vapor 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
Autoignition 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

Information on likely routes of exposure
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:**
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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 sensitization**

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

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

**Components:**

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

**Titanium dioxide:**
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

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

**Components:**

**metformin hydrochloride:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
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Test Type: in vitro test
  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.

IARC Group 2B: Possibly carcinogenic to humans
Titanium dioxide 13463-67-7

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Teratogenicity: LOAEL: 250 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.
Test Type: Embryo-fetal development  
Species: Rabbit  
Teratogenicity: NOAEL: 125 mg/kg body weight  
Result: No teratogenic effects.

**Cellulose:**

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

Effects on fetal development: Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**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 y  
Target Organs: Kidney

Species: Rat
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Target Organs : Liver, Kidney, Heart, Teeth  
Species : Dog  
NOAEL : 10 mg/kg  
LOAEL : 50 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Target Organs : Central nervous system  
Symptoms : Loss of balance  
Remarks : The mechanism or mode of action may not be relevant in humans.  
Species : Dog  
NOAEL : 2 mg/kg  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 27 Weeks  
Target Organs : Skeletal muscle, Central nervous system  
Symptoms : Loss of balance  
Remarks : The mechanism or mode of action may not be relevant in humans.  
Species : Monkey  
NOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Remarks : No significant adverse effects were reported  
Species : Rat  
NOAEL : >= 9,000 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
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 y  
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: Diarrhea, 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, Diarrhea

### 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:

<table>
<thead>
<tr>
<th>EC50</th>
<th>Pseudokirchneriella subcapitata (green algae)</th>
<th>&gt; 39 mg/l</th>
<th>Exposure time: 96 h</th>
<th>Method: OECD Test Guideline 201</th>
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</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>2.2 mg/l</td>
<td>Exposure time: 96 h</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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:

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

Cellulose:

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

Titanium dioxide:

| LC50 | Oncorhynchus mykiss (rainbow trout) | > 100 mg/l | Exposure time: 96 h | Method: OECD Test Guideline 203 |

| EC50 | Daphnia magna (Water flea) | > 100 mg/l | Exposure time: 48 h |

| EC50 | Skeletonema costatum (marine diatom) | > 10,000 mg/l | Exposure time: 72 h |

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

### Persistence and degradability

**Components**:

**metformin hydrochloride**

Biodegradability: Result: rapidly degradable
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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 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.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: Combustible dust
Acute toxicity (any route of exposure)

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know
metformin hydrochloride 1115-70-4
Sitagliptin 654671-77-9
Polyvinyl pyrrolidone 9003-39-8
Cellulose 9004-34-6

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6

The ingredients of this product are reported in the following inventories:
SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

Version: 8.1
Revision Date: 09/13/2019
SDS Number: 27123-00014
Date of last issue: 04/24/2019
Date of first issue: 10/31/2014

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:
Flammability
Health
1
0
Instability
Special hazard

HMIS® IV:
HEALTH / 1
FLAMMABILITY 3
PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Chemi-
SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

<table>
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<tr>
<th>Version</th>
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<th>SDS Number:</th>
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

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.

US / Z8