SECTION 1. IDENTIFICATION

Product name: Sitagliptin / Metformin Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 doctor if you feel unwell. Rinse mouth.

Disposal:
P501 Dispose of contents and 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.
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>Chemical name</th>
<th>Chemical Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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<tbody>
<tr>
<td>Mixture</td>
<td>metformin hydrochloride</td>
<td>No data available</td>
<td>1115-70-4</td>
<td>&gt;= 60 - &lt; 80 *</td>
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<tr>
<td></td>
<td>Sitagliptin</td>
<td>No data available</td>
<td>654671-77-9</td>
<td>&gt;= 5 - &lt; 10 *</td>
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<tr>
<td></td>
<td>Cellulose</td>
<td>No data available</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5 *</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>Titanium anhydride</td>
<td>13463-67-7</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

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 : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Harmful if swallowed.

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 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 (see section 7) and personal protective equipment recommendations (see section 8).

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

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

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.
- 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.

**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>
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<tbody>
<tr>
<td>metformin hydrochloride</td>
<td>1115-70-4</td>
<td>TWA</td>
<td>1 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</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC 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>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (total dust)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2.5 mg/m³ (Titanium dioxide)</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

This substance(s) is not bioavailable and therefore does 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 protection**: Chemical-resistant gloves

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

**Skin and body protection**: Work uniform or laboratory coat.

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

**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
**SAFETY DATA SHEET**

**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>
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<tr>
<td>5.0</td>
<td>04/04/2023</td>
<td>27095-00022</td>
<td>10/01/2022</td>
<td>10/31/2014</td>
</tr>
</tbody>
</table>

- **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.
- **Molecular weight**: No data available
- **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:
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
- 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

**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.
  This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

### 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**:

<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>125 mg/kg</td>
<td>Oral</td>
<td>1 year</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<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>Rabbit</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>1 Year</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<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>Dog</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>2 year</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>
**Sitagliptin / Metformin Formulation**

<table>
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<th>Safety Data Sheet</th>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

**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
SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

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**: Pimelphales promelias (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**: Pimelphales promelias (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:

- **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
  - Biodegradation: 50%
  - Exposure time: 2 hrs

**Sitagliptin:**
- Biodegradability: Result: not rapidly degradable
  - Biodegradation: 39.7%
  - Exposure time: 28 d
  - Method: OECD Test Guideline 314

**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.
Do not dispose of waste into sewer. 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

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)


CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

ACGIH / TWA : 8-hour, time-weighted average

CA AB OEL / TWA : 8-hour Occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWA EV : Time-weighted average exposure value
SAFETY DATA SHEET

Sitagliptin / Metformin Formulation

Version: 5.0
Revision Date: 04/04/2023
SDS Number: 27095-00022
Date of last issue: 10/01/2022
Date of first issue: 10/31/2014


Revision Date: 04/04/2023
Date format: mm/dd/yyyy

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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