

**Sitagliptin / Metformin Formulation**

Version 3.0      Revision Date: 2023/04/04      SDS Number: 27106-00023      Date of last issue: 2022/10/01  
Date of first issue: 2014/10/31

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Sitagliptin / Metformin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

Restrictions on use :  
Not applicable

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**2. HAZARDS IDENTIFICATION****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:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

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### 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

| Chemical name           | CAS-No.     | Concentration (% w/w)  |
|-------------------------|-------------|------------------------|
| metformin hydrochloride | 1115-70-4   | $\geq 60$ - $\leq 100$ |
| Sitagliptin             | 654671-77-9 | < 10                   |
| Cellulose               | 9004-34-6   | < 10                   |
| Titanium dioxide        | 13463-67-7  | < 1                    |

### 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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 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.

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- Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
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 (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.
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**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

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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 labelled containers.  
 Store in accordance with the particular national regulations.

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

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

| Components              | CAS-No.   | Value type<br>(Form of exposure)    | Control parameters / Permissible concentration | Basis    |
|-------------------------|---|-------------------------------------|--|----------|
| metformin hydrochloride | 1115-70-4   | TWA                                 | 1 mg/m <sup>3</sup> (OEB 1)                    | Internal |
| Sitagliptin             | 654671-77-9   | TWA                                 | 0.5 mg/m <sup>3</sup> (OEB 2)                  | Internal |
| Cellulose               | 9004-34-6   | NAB                                 | 10 mg/m <sup>3</sup>                           | ID OEL   |
|                         |   | TWA                                 | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Titanium dioxide        | 13463-67-7  | NAB                                 | 10 mg/m <sup>3</sup>                           | ID OEL   |
|                         | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |                                     |  |          |
|                         |   | TWA (Respirable particulate matter) | 2.5 mg/m <sup>3</sup> (Titanium dioxide)       | ACGIH    |

**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

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.

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|  |  |
|--|--|
| Skin and body protection<br>Hygiene measures | : Work uniform or laboratory coat.<br>: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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, 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   |

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|  |   |  |
|--|---|--|
| 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. |
| Molecular weight                       | : | No data available  |
| 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.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials             | : | Oxidizing agents   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.   |

**11. TOXICOLOGICAL INFORMATION**

|  |   |  |
|--|---|--|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|--|---|--|

**Acute toxicity**

Harmful if swallowed.

**Product:**

|                     |   |  |
|---------------------|---|--|
| Acute oral toxicity | : | Acute toxicity estimate: 1,380 mg/kg<br>Method: Calculation method |
|---------------------|---|--|

**Components:**

**metformin hydrochloride:**

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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

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### 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                                     |



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Genotoxicity in vivo : 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.

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**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. |

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

|| 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

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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

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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

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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 :  $\geq 9,000$  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/m<sup>3</sup>  
 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

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

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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

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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 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

**Sitagliptin:**

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

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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

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
 Do not dispose of waste into sewer.  
 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**

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable



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**IATA-DGR**

UN/ID No. : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Packing instruction (cargo aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

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Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**The components of this product are reported in the following inventories:**

|       |                  |
|-------|------------------|
| AICS  | : not determined |
| DSL   | : not determined |
| IECSC | : not determined |

## 16. OTHER INFORMATION

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**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**Full text of other abbreviations**

|              |   |
|--------------|---|
| ACGIH        | : USA. ACGIH Threshold Limit Values (TLV) |
| ID OEL       | : Indonesia. Occupational Exposure Limits |
| ACGIH / TWA  | : 8-hour, time-weighted average           |
| ID OEL / NAB | : Long term exposure limit                |

AIC - Australian Inventory of Industrial Chemicals; 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

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es; (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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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