

**Sitagliptin / Metformin Extended Release Formulation**

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 14.04.2025  |
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**Section 1: Identification**

Product name : Sitagliptin / Metformin Extended Release Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)

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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**Section 2: Hazard 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:**

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

**Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

**Section 3: Composition/information on ingredients**

Substance / Mixture : Mixture

**Components**

| Chemical name           | CAS-No.     | Concentration (% w/w) |
|-------------------------|-------------|-----------------------|
| metformin hydrochloride | 1115-70-4   | $\geq 50$ -< 70       |
| Cellulose               | 9004-34-6   | $\geq 10$ -< 20       |
| Sitagliptin Phosphate   | 654671-77-9 | $\geq 1$ -< 10        |
| Kaolin                  | 1332-58-7   | $\geq 1$ -< 10        |
| Titanium dioxide        | 13463-67-7  | $\geq 0.1$ -< 1       |

**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

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- 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.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Metal oxides  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
- 

**Section 6: Accidental release measures**

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

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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.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures            | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<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.                                                                                                                                  |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

**Section 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/m3 (OEB 1)                                | Internal |
| Cellulose               | 9004-34-6 | WES-TWA                          | 10 mg/m3                                       | NZ OEL   |

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|                       |             |                                     |                                          |          |
|-----------------------|-------------|-------------------------------------|------------------------------------------|----------|
|                       |             | TWA                                 | 10 mg/m <sup>3</sup>                     | ACGIH    |
| Sitagliptin Phosphate | 654671-77-9 | TWA                                 | 0.6 mg/m <sup>3</sup> (OEB 2)            | Internal |
| Kaolin                | 1332-58-7   | WES-TWA                             | 10 mg/m <sup>3</sup>                     | NZ OEL   |
|                       |             | WES-TWA (Respirable dust)           | 2 mg/m <sup>3</sup>                      | NZ OEL   |
|                       |             | TWA (Respirable particulate matter) | 2 mg/m <sup>3</sup>                      | ACGIH    |
| Titanium dioxide      | 13463-67-7  | WES-TWA                             | 10 mg/m <sup>3</sup>                     | NZ OEL   |
|                       |             | 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.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection

: Work uniform or laboratory coat.

### Section 9: Physical and chemical properties

Appearance : powder

Colour : blue green

Odour : No data available

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|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Odour Threshold                                  | : | No data available                                                               |
| pH                                               | : | No data available                                                               |
| Melting point/freezing point                     | : | No data available                                                               |
| Initial boiling point and boiling range          | : | No data available                                                               |
| Flash point                                      | : | Not applicable                                                                  |
| Evaporation rate                                 | : | Not applicable                                                                  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available                                                               |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| Lower explosion limit / Lower flammability limit | : | No data available                                                               |
| Vapour pressure                                  | : | Not applicable                                                                  |
| Relative vapour density                          | : | Not applicable                                                                  |
| Relative density                                 | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)<br>Water solubility              | : | No data available                                                               |
| Partition coefficient: n-octanol/water           | : | Not applicable                                                                  |
| Auto-ignition temperature                        | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable                                                                  |
| Explosive properties                             | : | Not explosive                                                                   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |
| Molecular weight                                 | : | No data available                                                               |

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Particle characteristics  
Particle size : No data available

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**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.<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.                                                                             |

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**Section 11: Toxicological information**

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,588 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

**Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

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Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Sitagliptin Phosphate:**

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg

LD50 (Mouse): 3,000 mg/kg

**Kaolin:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 5,000 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 Phosphate:**

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

**Kaolin:**

Species : Rabbit  
Method : OECD Test Guideline 404  
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 Phosphate:**

|         |   |                     |
|---------|---|---------------------|
| Species | : | Rabbit              |
| Result  | : | Irritating to eyes. |
| Method  | : | Draize Test         |

**Kaolin:**

|         |   |                   |
|---------|---|-------------------|
| Species | : | Rabbit            |
| Result  | : | No eye irritation |

**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 Phosphate:**

|           |   |                               |
|-----------|---|-------------------------------|
| 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                      |

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**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****metformin hydrochloride:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: negative

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

**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

**Sitagliptin Phosphate:**

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

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Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
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.

**Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

**Sitagliptin Phosphate:**

Species : Mouse  
Application Route : Oral

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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

**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.

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

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**Cellulose:**

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

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

**Sitagliptin Phosphate:**

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

**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

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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

**Cellulose:**

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Sitagliptin Phosphate:**

Species : Mouse  
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Oral  
Exposure time :  $> 2$  yr  
Target Organs : Kidney

Species : Rat  
NOAEL : 500 mg/kg  
LOAEL : 1,000 mg/kg  
Application Route : Oral  
Exposure time : 14 Weeks  
Target Organs : Liver, Kidney, Heart, Teeth

Species : Dog  
NOAEL : 10 mg/kg  
LOAEL : 50 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Target Organs : Central nervous system  
Symptoms : Loss of balance  
Remarks : The mechanism or mode of action may not be relevant in 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.

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|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Monkey                                       |
| NOAEL             | : 100 mg/kg                                    |
| Application Route | : Oral                                         |
| Exposure time     | : 14 Weeks                                     |
| Remarks           | : No significant adverse effects were reported |

**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 |

**Sitagliptin Phosphate:**

|            |                                                                                                             |
|------------|-------------------------------------------------------------------------------------------------------------|
| Inhalation | : Symptoms: upper respiratory tract infection, pharyngitis, Headache                                        |
| Ingestion  | : Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea |

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**Section 12: Ecological information****Ecotoxicity****Components:****metformin hydrochloride:**

|                                  |                                                                                                                              |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to algae/aquatic plants | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------|

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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

### Cellulose:

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

### Sitagliptin Phosphate:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 60 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 39 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 201

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 2.2 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 9.2 mg/l  
Exposure time: 33 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 9.8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

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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

**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

**Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Sitagliptin Phosphate:**

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

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**Bioaccumulative potential****Components:****metformin hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: -2

**Sitagliptin Phosphate:**

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 Phosphate:**

Distribution among environmental compartments : log Koc: 4.37

**Other adverse effects**

No data available

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**Section 13: Disposal considerations****Disposal methods**

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

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**Section 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 |
| Environmentally hazardous | : no             |

**IATA-DGR**

|           |                  |
|-----------|------------------|
| UN/ID No. | : Not applicable |
|-----------|------------------|

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|                                          |                  |
|------------------------------------------|------------------|
| 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.

**National Regulations****NZS 5433**

|                      |                  |
|----------------------|------------------|
| UN number            | : Not applicable |
| Proper shipping name | : Not applicable |
| Class                | : Not applicable |
| Subsidiary risk      | : Not applicable |
| Packing group        | : Not applicable |
| Labels               | : Not applicable |
| Hazchem Code         | : Not applicable |

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information****Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard

**Tolerable Exposure Limits (TEL)**

Not applicable

**Environmental Exposure Limits (EEL)**

Not applicable

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**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

**Section 16: Other information**

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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/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - 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

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Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.

NZ / EN