# SAFETY DATA SHEET

# Sitagliptin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 07.03.2023 |
|---|---|---|---|
| 4.1 | 26.09.2023 | 17287-00024 | Date of first issue: 30.09.2014 |

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sitagliptin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 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

## SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification in accordance with ABNT NBR 14725 Standard**

Eye irritation : Category 2A

Short-term (acute) aquatic hazard : Category 3

**GHS label elements in accordance with ABNT NBR 14725 Standard**

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H319 Causes serious eye irritation.
H402 Harmful to aquatic life.

Precautionary Statements :

**Prevention:**

P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.

**Response:**

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

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

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. | Classification | Concentration (% w/w) |
|---|---|---|---|
| Sitagliptin | 654671-77-9 | Eye irritation, Category 2A<br>Short-term (acute) aquatic hazard, Category 3 | >= 30 -< 50 |
| Cellulose | 9004-34-6 | | >= 20 -< 30 |
| Magnesium stearate | 557-04-0 | | >= 1 -< 5 |
| Titanium dioxide | 13463-67-7 | Carcinogenicity (Inhalation), Category 2 | >= 0,1 -< 1 |
| Propyl 3,4,5-trihydroxybenzoate | 121-79-9 | Acute toxicity (Oral), Category 4<br>Serious eye damage, Category 1<br>Skin sensitization, Category 1<br>Short-term (acute) aquatic hazard, Category 1<br>Long-term (chronic) aquatic hazard, Category 2 | >= 0,25 -< 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 : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

| | | |
|---|---|---|
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.<br>Contact with dust can cause mechanical irritation or drying of the skin. |
| 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Metal oxides<br>Oxides of phosphorus |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<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 get on skin or clothing.<br>Avoid breathing dust.<br>Do not swallow.<br>Do not get in eyes.<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>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>Contaminated work clothing should not be allowed out of the workplace.<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 labeled 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

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Sitagliptin | 654671-77-9 | TWA | 0.5 mg/m3 (OEB 2) | Internal |
| Cellulose | 9004-34-6 | TWA | 10 mg/m³ | ACGIH |
| Magnesium stearate | 557-04-0 | TWA (Inhalable particulate matter) | 10 mg/m³ | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m³ | ACGIH |
| Titanium dioxide | 13463-67-7 | TWA (Respirable particulate matter) | 2,5 mg/m³ (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

Color : No data available

Odor : No data available

Odor Threshold : No data available

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

## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:**

**Sitagliptin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 3.000 mg/kg<br><br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg |

**Magnesium stearate:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 423<br>Assessment: The substance or mixture has no acute oral toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg<br>Remarks: Based on data from similar materials |

**Titanium dioxide:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5.000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 6,82 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |

Assessment: The substance or mixture has no acute inhalation toxicity

**Propyl 3,4,5-trihydroxybenzoate:**

Acute oral toxicity : LD50 (Mouse, female): > 1.000 - 2.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Sitagliptin:**

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

**Magnesium stearate:**

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

**Titanium dioxide:**

Species : Rabbit
Result : No skin irritation

**Propyl 3,4,5-trihydroxybenzoate:**

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439

Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**Sitagliptin:**

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

**Magnesium stearate:**

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

**Titanium dioxide:**

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

**Propyl 3,4,5-trihydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Irreversible effects on the eye |
| Method | : | OECD Test Guideline 405 |

**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. |

**Magnesium stearate:**

| | | |
|---|---|---|
| Test Type | : | Maximization Test |
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |
| Method | : | OECD Test Guideline 406 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

**Titanium dioxide:**

| | | |
|---|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| Routes of exposure | : | Skin contact |
| Species | : | Mouse |
| Result | : | negative |

**Propyl 3,4,5-trihydroxybenzoate:**

| | | |
|---|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| Routes of exposure | : | Skin contact |
| Species | : | Mouse |
| Result | : | positive |
| Assessment | : | Probability or evidence of skin sensitization in humans |

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**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

**Magnesium stearate:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

**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

**Propyl 3,4,5-trihydroxybenzoate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: positive<br><br>Test Type: Chromosome aberration test in vitro<br>Result: positive<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative<br><br>Test Type: In vitro sister chromatid exchange assay in mammalian cells<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**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.<br>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. |

**Propyl 3,4,5-trihydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 103 weeks |
| Result | : | negative |

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**Sitagliptin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL Parent: 1.000 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility. |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Oral<br>Teratogenicity: LOAEL: 250 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.<br><br>Test Type: Embryo-fetal development<br>Species: Rabbit<br>Teratogenicity: NOAEL: 125 mg/kg body weight<br>Result: No teratogenic effects. |

**Cellulose:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion |

Result: negative

**Magnesium stearate:**

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

**Propyl 3,4,5-trihydroxybenzoate:**

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

Effects on fetal development : Test Type: Embryo-fetal 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:**

**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 |

**Magnesium stearate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | > 100 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Remarks | : | Based on data from similar materials |

**Titanium dioxide:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 24.000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 28 Days |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 10 mg/m³ |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 y |

**Propyl 3,4,5-trihydroxybenzoate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 135 mg/kg |

Application Route : Ingestion
Exposure time : 13 Weeks

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**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:**

**Sitagliptin:**

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

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

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 2,2 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9,2 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9,8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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

NOEC: 150 mg/l

Exposure time: 3 h
Test Type: Respiration inhibition

**Cellulose:**

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

**Magnesium stearate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
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

**Propyl 3,4,5-trihydroxybenzoate:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 19,06 mg/l
Exposure time: 48 h
Test substance: Neutralized product
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,37 mg/l
Exposure time: 72 h
Test substance: Neutralized product
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0,17 mg/l
Exposure time: 72 h
Test substance: Neutralized product
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50: 636 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**

**Sitagliptin:**

Biodegradability : Result: not rapidly degradable
Biodegradation: 39,7 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

**Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Magnesium stearate:**

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

**Propyl 3,4,5-trihydroxybenzoate:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 49,4 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

**Bioaccumulative potential**

**Components:**

**Sitagliptin:**

Partition coefficient: n-octanol/water : log Pow: -0,03

**Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

**Propyl 3,4,5-trihydroxybenzoate:**

Partition coefficient: n-octanol/water : log Pow: 1,8
Remarks: Calculation

**Mobility in soil**

**Components:**

**Sitagliptin:**

Distribution among environmental compartments : log Koc: 4,37

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

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

Not applicable for product as supplied.

**Domestic regulation**

**ANTT**

Not regulated as a dangerous good

**Special precautions for user**

Not applicable

## SECTION 15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH)

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

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

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

## SECTION 16. OTHER INFORMATION

| | | |
|---|---|---|
| Revision Date | : | 26.09.2023 |
| Date format | : | dd.mm.yyyy |

**Further information**

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

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH / TWA | : | 8-hour, 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 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.

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