

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 14.04.2025 |
| 4.1 | 11.08.2025 | 17310-00028 | Date of first issue: 30.09.2014 |

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Sitagliptin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

| | |
|--|--|
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Long-term (chronic) aquatic hazard, Category 3 | H412: Harmful to aquatic life with long lasting effects. |

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements :

Prevention:

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

Response:

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

EUH208 Contains Propyl 3,4,5-trihydroxybenzoate. May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------------------------|---|---|--------------------------|
| Sitagliptin Phosphate | 654671-77-9 | Eye Irrit. 2; H319 | >= 30 - < 50 |
| Propyl 3,4,5-trihydroxybenzoate | 121-79-9 204-498-2 607-198-00-3 | Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 | >= 0,25 - < 1 |

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| | | | |
|--|--|--|--|
| | | M-Factor (Chronic aquatic toxicity): 1 | |
| | | Acute toxicity estimate | |
| | | Acute oral toxicity: 1.700 mg/kg | |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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. |
| 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). |
| 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. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed | : If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

- | | |
|-------|---|
| Risks | : Contact with dust can cause mechanical irritation or drying of the skin. May produce an allergic reaction. Causes serious eye irritation. |
|-------|---|

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4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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
Oxides of phosphorus

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

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6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

| | | |
|-------------------------|---|--|
| 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 get on skin or clothing. Avoid breathing dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. 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. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust 5 mg/m³
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-----------------------|-------------|-------------------------------|-------------------------------|----------|
| Sitagliptin Phosphate | 654671-77-9 | TWA | 0.6 mg/m ³ (OEB 2) | Internal |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|---------------------------------|-----------|-----------------|----------------------------|------------------------|
| Propyl 3,4,5-trihydroxybenzoate | Workers | Inhalation | Long-term systemic effects | 6,66 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 1,89 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1,17 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 0,675 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,675 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name | Environmental Compartment | Value |
|---------------------------------|-----------------------------|------------|
| Propyl 3,4,5-trihydroxybenzoate | Fresh water | 0,37 µg/l |
| | Freshwater - intermittent | 3,7 µg/l |
| | Marine water | 0,037 µg/l |
| | Marine water - intermittent | 0,37 µg/l |
| | Sewage treatment plant | 6,36 mg/l |

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| | | |
|--|----------------------|----------------------------------|
| | Fresh water sediment | 0,0045 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,00045 mg/kg dry weight (d.w.) |
| | Soil | 0,000688 mg/kg dry weight (d.w.) |

8.2 Exposure controls

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

| | | |
|--------------------------|---|--|
| Eye/face 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. |
| Hand protection | : | |
| Material | : | Chemical-resistant gloves |
| Skin and body protection | : | Work uniform or laboratory coat. |
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143 |
| Filter type | : | Particulates type (P) |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | powder |
| Colour | : | No data available |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper | : | No data available |

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flammability limit

Lower explosion limit / Lower
flammability limit : No data available

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-
octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Acute oral toxicity : LD50 (Rat): > 3.000 mg/kg
LD50 (Mouse): 3.000 mg/kg

Propyl 3,4,5-trihydroxybenzoate:

Acute oral toxicity : LD50 (Mouse): 1.700 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 Phosphate:

Species : Rabbit

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| | | |
|--------|---|--------------------|
| Method | : | Draize Test |
| 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 Phosphate:

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

Propyl 3,4,5-trihydroxybenzoate:

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

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. |

Propyl 3,4,5-trihydroxybenzoate:

| | | |
|-----------------|---|-------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Result | : | positive |

| | | |
|------------|---|---|
| Assessment | : | Probability or evidence of skin sensitisation in humans |
|------------|---|---|

Germ cell mutagenicity

Not classified based on available information.

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Components:

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

Propyl 3,4,5-trihydroxybenzoate:

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

Carcinogenicity

Not classified based on available information.

Components:

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 |

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 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 |

Propyl 3,4,5-trihydroxybenzoate:

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

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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 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. |

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

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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.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

| | | |
|------------|---|---|
| Assessment | : | The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. |
|------------|---|---|

Experience with human exposure

Components:

Sitagliptin Phosphate:

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 |

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- NOEC (Pseudokirchneriella subcapitata (green algae)): 2,2 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
- 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
- Toxicity to fish (Chronic toxicity) : NOEC: 9,2 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9,8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Propyl 3,4,5-trihydroxybenzoate:

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 19,6 mg/l
Exposure time: 48 h
Test substance: Neutralised product
Method: OECD Test Guideline 202
Remarks: The test was conducted according to guideline
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,22 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
- EC10 (Pseudokirchneriella subcapitata (green algae)): 0,096 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
- M-Factor (Acute aquatic toxicity) : 1
- Toxicity to microorganisms : EC50 (activated sludge): 636 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

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M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Components:

Sitagliptin Phosphate:

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

Stability in water : pH: 7
Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

Propyl 3,4,5-trihydroxybenzoate:

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

12.3 Bioaccumulative potential

Components:

Sitagliptin Phosphate:

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

Propyl 3,4,5-trihydroxybenzoate:

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

12.4 Mobility in soil

Components:

Sitagliptin Phosphate:

Distribution among environmental compartments : log Koc: 4,37

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

| | |
|------------------------|---|
| Product | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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. |

SECTION 14: Transport information

14.1 UN number or ID number

| | |
|------|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |
| RID | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

14.2 UN proper shipping name

| | |
|------|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |
| RID | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

14.3 Transport hazard class(es)

| | |
|-----|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
| ADR | : Not regulated as a dangerous good |

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| | | |
|-------------|---|-----------------------------------|
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

14.4 Packing group

| | | |
|-------------------------|---|-----------------------------------|
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA (Cargo) | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | Not regulated as a dangerous good |

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

| | | |
|---------|---|---|
| Remarks | : | Not applicable for product as supplied. |
|---------|---|---|

SECTION 15: Regulatory information

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

| | | |
|--|---|--|
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor. |
|--|---|--|

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

| | | |
|---|---|----------------|
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parliament | : | Not applicable |

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ment and the Council concerning the export and import
of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Skin Sens. : Skin sensitisation
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland
Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by
Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-
ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-
tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard
of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -
European Chemicals Agency; EC-Number - European Community number; ECx - Concentration
associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-
cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-
sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good La-

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boratory 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

| | |
|-------------------|------|
| Eye Irrit. 2 | H319 |
| Aquatic Chronic 3 | H412 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |

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.

NO / EN