# SAFETY DATA SHEET

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

# Ertugliflozin (< 2%) / Sitagliptin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.03.2023 |
|---|---|---|---|
| 5.1 | 30.09.2023 | 599444-00019 | Date of first issue: 04.04.2016 |

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

### 1.1 Product identifier

Trade name : Ertugliflozin (< 2%) / Sitagliptin Formulation

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

Use of the Substance/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)**

| | |
|---|---|
| Skin irritation, Category 2 | H315: Causes skin irritation. |
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :

Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements :

**Prevention:**

P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

**Response:**

P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Additional Labelling**

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.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|
| Sitagliptin | 654671-77-9 | Eye Irrit. 2; H319 | >= 30 - < 50 |
| Ertugliflozin | 1210344-83-4 | Acute Tox. 4; H302<br>Skin Corr. 1B; H314<br>Eye Dam. 1; H318<br>STOT RE 2; H373 (Kidney, Stomach, Prostate) | >= 1 - < 3 |

| | | | |
|---|---|---|---|
| Propyl 3,4,5-trihydroxybenzoate | 121-79-9<br>204-498-2<br>607-198-00-3 | Acute Tox. 4; H302<br>Eye Dam. 1; H318<br>Skin Sens. 1; H317<br>Aquatic Acute 1; H400<br>Aquatic Chronic 2; H411<br>_____<br>M-Factor (Acute aquatic toxicity): 1 | >= 0,25 - < 1 |

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 plenty of water for at least 15 minutes while removing 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 : Causes skin irritation.
Causes serious eye irritation.

May produce an allergic reaction.

### 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.

### 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.
Do not breathe 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.

### 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 | 654671-77-9 | TWA | 0.5 mg/m3 (OEB 2) | Internal |
| Ertugliflozin | 1210344-83-4 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm² | 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/m3 |
| | Workers | Skin contact | Long-term systemic effects | 1,89 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1,17 mg/m3 |
| | 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 |
| | 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**

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**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

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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 flammability limit | : | No data available |
| 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.

### 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.<br>Can react with strong oxidizing agents. |

### 10.4 Conditions to avoid

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>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<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2.000 mg/kg<br>Method: Calculation method |

**Components:**

**Sitagliptin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 3.000 mg/kg<br><br>LD50 (Mouse): 3.000 mg/kg |

**Ertugliflozin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 500 mg/kg |
| Acute inhalation toxicity | : | Remarks: No data available |
| Acute dermal toxicity | : | Remarks: No data available |

**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<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Skin corrosion/irritation**

Causes skin irritation.

**Components:**

**Sitagliptin:**

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

**Ertugliflozin:**

| | | |
|---|---|---|
| Result | : | Corrosive |

**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 |
| Method | : | Draize Test |
| Result | : | Irritating to eyes. |

**Ertugliflozin:**

| | | |
|---|---|---|
| Result | : | Severe irritation |

**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:**

| | | |
|---|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| Species | : | Mouse |
| Method | : | OECD Test Guideline 429 |
| Result | : | Not a skin sensitizer. |

**Ertugliflozin:**

| | | |
|---|---|---|
| Test Type | : | Local lymph node assay (LLNA) |
| 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.

**Components:**

**Sitagliptin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Ames test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: Chinese hamster ovary cells<br>Result: negative<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Test system: rat hepatocytes<br>Result: negative |

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

**Ertugliflozin:**

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
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:**

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 |

**Ertugliflozin:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| Result | : | negative |
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| Result | : | negative |
| 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:**

| | | |
|---|---|---|
| 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 foetal development | : | Test Type: Embryo-foetal 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-foetal development |

Species: Rabbit
Teratogenicity: NOAEL: 125 mg/kg body weight
Result: No teratogenic effects

**Ertugliflozin:**

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 250 mg/kg body weight
Remarks: Maternal toxicity observed.
No significant adverse effects were reported

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 200 mg/kg body weight
Remarks: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight
Remarks: No significant adverse effects were reported

**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
Application Route: Ingestion
Result: negative

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Ertugliflozin:**

Exposure routes : Oral

| | | |
|---|---|---|
| Target Organs | : | Kidney, Stomach, Prostate |
| Assessment | : | May cause damage to organs through prolonged or repeated exposure. |

**Repeated dose toxicity**

**Components:**

**Sitagliptin:**

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

**Ertugliflozin:**

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 500 mg/kg |

| | | |
|---|---|---|
| Application Route | : | Oral |
| Exposure time | : | 30 d |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 250 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |
| Target Organs | : | Kidney |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 25 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 180 d |
| Target Organs | : | Kidney, Bone, Stomach |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 25 mg/kg |
| Exposure time | : | 90 d |
| Target Organs | : | Kidney, Gastrointestinal tract, Prostate |

| | | |
|---|---|---|
| Species | : | Dog |
| NOAEL | : | 150 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 270 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Mouse |
| NOAEL | : | 100 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Mouse |
| NOAEL | : | 100 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 28 d |
| Target Organs | : | Bone |
| Remarks | : | No significant adverse effects were reported |

**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**

**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:**

Inhalation : Symptoms: upper respiratory tract infection, pharyngitis, Headache

Ingestion : Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea

**Ertugliflozin:**

Ingestion : Symptoms: The most common side effects are:, Headache, constipation, Diarrhoea, Nausea, urinary tract infection, muscle pain, upper respiratory tract infection

## SECTION 12: Ecological information

### 12.1 Toxicity

**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 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

**Ertugliflozin:**

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 77 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC : 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 1 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 2,14 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

**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: Neutralised 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: Neutralised product
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0,17 mg/l
Exposure time: 72 h
Test substance: Neutralised 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

### 12.2 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 : pH: 7
Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

**Ertugliflozin:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 40,8 %
Exposure time: 28 d

**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:**

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

**Ertugliflozin:**

Partition coefficient: n-octanol/water : log Pow: 2,47

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

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

### 12.4 Mobility in soil

**Components:**

**Sitagliptin:**

Distribution among environmental compartments : log Koc: 4,37

**Ertugliflozin:**

Distribution among environmental compartments : log Koc: 2,88

### 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.

### 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 |
| **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:<br>Number on list 75<br>If you intend to use this product as tattoo ink, please contact your vendor.<br><br>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 (EC) No 1005/2009 on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollutants (recast) | : | Not applicable |
| Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals | : | Not applicable |

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. |
| H314 | : | Causes severe skin burns and eye damage. |
| H317 | : | May cause an allergic skin reaction. |
| H318 | : | Causes serious eye damage. |
| H319 | : | Causes serious eye irritation. |
| H373 | : | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400 | : | Very toxic to aquatic life. |
| H411 | : | 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 Corr. | : | Skin corrosion |
| Skin Sens. | : | Skin sensitisation |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| FOR-2011-12-06-1358 | : | Norway. Occupational Exposure limits |
| FOR-2011-12-06-1358 / TWA | : | Long term exposure limit |

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 Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (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 - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; 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; 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:** | | **Classification procedure:** |
|---|---|---|
| Skin Irrit. 2 | H315 | Calculation method |
| Eye Irrit. 2 | H319 | 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