Ertugliflozin (< 5%) / Sitagliptin Formulation

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ertugliflozin (< 5%) / Sitagliptin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 1

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.
H402 Harmful to aquatic life.

Precautionary statements :

Prevention:

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

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.
P332 + P317 If skin irritation occurs: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sitagliptin	654671-77-9	>= 30 - < 50
Cellulose	9004-34-6	>= 20 - < 30
Ertugliflozin	1210344-83-4	>= 3 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5
Propyl 3,4,5-trihydroxybenzoate	121-79-9	>= 0.25 - < 1

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : 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 immediately.

If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Causes skin irritation. Causes serious eye damage.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Oxides of phosphorus
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-

leased 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.

7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Do not 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 Keep container tightly closed. 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.
Conditions for safe storage	:	Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (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
Ertugliflozin	1210344-83-4	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	100 µg/100 cm²	Internal
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH

		TWA (Respirable particulate matter)	3 mg/m3	ACGIH

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

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

Remarks : Consider double gloving.

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.
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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : No data available

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

Particle size	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Sitagliptin:

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

Cellulose:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Ertugliflozin:

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

Acute dermal toxicity : Remarks: No data available

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

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

Causes skin irritation.

Components:

Sitagliptin:

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

Ertugliflozin:

Result : Corrosive

Magnesium stearate:

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

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 damage.

Components:

Sitagliptin:

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

Ertugliflozin:

Result	:	Severe irritation

Magnesium stearate:

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

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.

Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

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
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

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

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

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

Cellulose:

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

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 Species: Rat Application Route: Oral Fertility: NOAEL Parent: 1,000 mg/kg body weight Result: Animal testing did not show any effects on fertility.
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Teratogenicity: LOAEL: 250 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects Test Type: Embryo-foetal development

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

Cellulose:

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

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

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

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 foetal development : Test Type: Embryo-foetal 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 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

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

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

Magnesium stearate:

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

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, Diarrhoea

Ertugliflozin:

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

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 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

Cellulose:

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

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

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

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

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.

Ertugliflozin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 40.8 %
Exposure time: 28 d

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

Ertugliflozin:

Partition coefficient: n-octanol/water : log Pow: 2.47

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

Ertugliflozin:

Distribution among environmental compartments : log Koc: 2.88

Other adverse effects

No data available

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.

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 IMO instruments
Not applicable for product as supplied.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	30.09.2023

Further information

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)

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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