

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Section 1: Identification

Product name : Sitagliptin / Ipragliflozin L-Proline Formulation

Manufacturer or supplier's details

Company : MSD

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

Telephone : 0800 800 543

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

Section 2: Hazard identification**GHS Classification**

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 2 (Kidney, Liver)

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Kidney, Liver) through
prolonged or repeated exposure.

Precautionary statements : **Prevention:**

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 18.9 %

Other hazards which do not result in classification

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

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 30 -< 50
Ipragliflozin L-proline	951382-34-6	>= 10 -< 20
Sitagliptin Phosphate	654671-77-9	>= 10 -< 20
Magnesium stearate	557-04-0	>= 1 -< 10

Section 4: First-aid measures

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

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

		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. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Section 6: Accidental release measures

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
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.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.1	11.08.2025	3121444-00014	14.04.2025
			Date of first issue: 28.08.2018

engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.

Materials to avoid : Do not store with the particular national regulations.
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
Ipragliflozin L-proline	951382-34-6	TWA	0.4 mg/m ³ (OEB 2)	Internal
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m ³ (OEB 2)	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m ³	NZ OEL
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Engineering measures : Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Skin and body protection : aerosols.
: Work uniform or laboratory coat.

Section 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	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. 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.

Section 11: Toxicological information

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
---------------------	---	--

Components:**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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Ipragliflozin L-proline:

Acute oral toxicity : LD50 (Rat): < 1,000 mg/kg
LDLo (Monkey): >= 1,000 mg/kg

Sitagliptin Phosphate:

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

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Sitagliptin Phosphate:**

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

Magnesium stearate:

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Ipragliflozin L-proline:**

Species : Rabbit
Result : Mild eye irritation

Sitagliptin Phosphate:

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Magnesium stearate:

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

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Ipragliflozin L-proline:**

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Result	:	Not a skin sensitizer.

Sitagliptin Phosphate:

Test Type	:	Local lymph node assay (LLNA)
Species	:	Mouse
Method	:	OECD Test Guideline 429
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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**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)
----------------------	---	--

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Ipragliflozin L-proline:

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

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow
Result: negative

Sitagliptin Phosphate:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Carcinogenicity

Not classified based on available information.

Components:**Cellulose:**

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

Ipragliflozin L-proline:

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 years
NOAEL	:	500 mg/kg body weight
Result	:	negative

Species	:	Rat, male
Application Route	:	Oral
Exposure time	:	2 years
NOAEL	:	12.5 mg/kg body weight
LOAEL	:	40 mg/kg body weight
Result	:	positive
Remarks	:	The mechanism or mode of action is not relevant in humans.

Species	:	Rat, female
Application Route	:	Oral
Exposure time	:	2 years
LOAEL	:	> 125 mg/kg body weight
Result	:	positive
Remarks	:	The mechanism or mode of action is not relevant in humans.

Sitagliptin Phosphate:

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
------------------------------	---	--

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Reproductive toxicity

Suspected of damaging the unborn child.

Components:**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

Ipragliflozin L-proline:

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 300 mg/kg body weight
Result: Maternal toxicity observed., Reduced foetal weight

Test Type: Development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: 300 mg/kg body weight
Result: Maternal toxicity observed., Reduced foetal weight

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Effects on postnatal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Test Type: Embryo-foetal development
Species: Rabbit
Teratogenicity: NOAEL: 125 mg/kg body weight
Result: No teratogenic effects

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Kidney, Liver) through prolonged or repeated exposure.

Components:**Ipragliflozin L-proline:**

Target Organs : Kidney, Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Cellulose:**

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

Ipragliflozin L-proline:

Species : Rat
NOAEL : 0.1 mg/kg
Application Route : Oral
Exposure time : 26 weeks
Target Organs : Kidney, Liver, Gastrointestinal tract

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Species : Monkey, male and female
NOAEL : 1 - 10 mg/kg
LOAEL : 10 - 300 mg/kg
Application Route : Oral
Exposure time : 52 weeks
Target Organs : Kidney, Liver

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

Magnesium stearate:

Species : Rat

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Ipragliflozin L-proline:**

Skin contact	:	Target Organs: Skin Symptoms: Eczema
Ingestion	:	Target Organs: Kidney Symptoms: constipation, Thirst

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**Ecotoxicity****Components:****Cellulose:**

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

Ipragliflozin L-proline:**Ecotoxicology Assessment**

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

Sitagliptin Phosphate:

Toxicity to fish	:	LC50 (<i>Pimephales promelas</i> (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): 60 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

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

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

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

NOEC: 150 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

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

Persistence and degradability**Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

Sitagliptin Phosphate:

Biodegradability : Result: not rapidly degradable
Biodegradation: 39.7 %
Exposure time: 28 d
Method: OECD Test Guideline 314

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

Magnesium stearate:

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

Bioaccumulative potential**Components:****Sitagliptin Phosphate:**

Partition coefficient: n-octanol/water : log Pow: -0.03

Magnesium stearate:

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

Mobility in soil**Components:****Sitagliptin Phosphate:**

Distribution among environmental compartments : log Koc: 4.37

Other adverse effects

No data available

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Section 13: Disposal considerations**Disposal methods**

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

Section 14: Transport information**International Regulations****UNRTDG**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

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

Not applicable for product as supplied.

National Regulations**NZS 5433**

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Hazchem Code	:	Not applicable

Special precautions for user

Not applicable

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

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 11.08.2025

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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

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

Sitagliptin / Ipragliflozin L-Proline Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
4.1	11.08.2025	3121444-00014	Date of first issue: 28.08.2018

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.

NZ / EN