

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

SECTION 1: IDENTIFICATION

Product name : Sitagliptin / Metformin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements :

Prevention:
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Disposal:

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025 Date of first issue: 31.10.2014

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
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)
metformin hydrochloride	1115-70-4	>= 60 -<= 100
Sitagliptin Phosphate	654671-77-9	< 10
Cellulose	9004-34-6	< 10
Titanium dioxide	13463-67-7	< 1

SECTION 4. FIRST AID MEASURES

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

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

In case of skin contact : Wash with water and soap.
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
Harmful if swallowed.

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. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

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 Nitrogen oxides (NOx) 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

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.
--------------------	---

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025

SDS Number:
27089-00025

Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

Local/Total ventilation	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Advice on safe handling	<ul style="list-style-type: none">Use only with adequate ventilation.Do not breathe dust.Do not swallow.Avoid contact with 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
	<ul style="list-style-type: none">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.Do not eat, drink or smoke when using this product.Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	<ul style="list-style-type: none">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. <p>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.</p>
Conditions for safe storage	<ul style="list-style-type: none">Keep in properly labelled containers.Store in accordance with the particular national regulations.
Materials to avoid	<ul style="list-style-type: none">Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m3 (OEB 1)	Internal
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	TWA	10 mg/m3	AU OEL
		TWA	10 mg/m3	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m3	AU OEL
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

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

Personal protective equipment

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

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

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 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.

Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,380 mg/kg
Method: Calculation method

Components:**metformin hydrochloride:**

Acute oral toxicity : LD50 (Rat): 1,000 mg/kg
LD50 (Mouse): 1,450 - 3,500 mg/kg
LD50 (Monkey): 463 mg/kg
LD50 (Rabbit): 350 mg/kg
LD50 (Guinea pig): 500 mg/kg

Sitagliptin Phosphate:

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

Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

Skin corrosion/irritation

Not classified based on available information.

Components:

metformin hydrochloride:

Species : Rabbit
Result : Mild skin irritation

Sitagliptin Phosphate:

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

Titanium dioxide:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

metformin hydrochloride:

Species : Rabbit
Result : Mild eye irritation

Sitagliptin Phosphate:

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

Titanium dioxide:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Test Type : Local lymph node assay (LLNA)
Species : Mouse

Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

Method : OECD Test Guideline 429
Result : Not a skin sensitizer.

Titanium dioxide:

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

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**metformin hydrochloride:**

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

Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

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

Titanium dioxide:

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

metformin hydrochloride:

Species : Mouse
Exposure time : 91 weeks
Dose : 1500 mg/kg body weight
Result : negative

Species : Rat, male
Application Route : Oral
Exposure time : 104 weeks
Dose : 900 mg/kg body weight
Result : negative

Species : Rat, female
Application Route : Oral
Exposure time : 104 weeks
LOAEL : 900 mg/kg body weight
Result : negative
Target Organs : Uterus (including cervix)
Remarks : The mechanism or mode of action may not be relevant in humans.

Sitagliptin Phosphate:

Species : Mouse
Application Route : Oral

Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : oral (drinking water)
Exposure time : 2 Years
Result : positive
Target Organs : Liver
Remarks : Significant toxicity observed in testing

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Cellulose:

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

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

Reproductive toxicity

Not classified based on available information.

Components:**metformin hydrochloride:**

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 600 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 600 mg/kg body weight
Result: No teratogenic effects

Sitagliptin / Metformin FormulationVersion
4.4Revision Date:
11.08.2025SDS Number:
27089-00025Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 140 mg/kg body weight
Result: No teratogenic effects

Sitagliptin Phosphate:

Effects on fertility

: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL Parent: 1,000 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Teratogenicity: LOAEL: 250 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:****metformin hydrochloride:**

Species : Rat
NOAEL : 125 mg/kg
Application Route : Oral
Exposure time : 1 year

Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

Remarks	: No significant adverse effects were reported
Species	: Rabbit
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 1 Year
Remarks	: No significant adverse effects were reported
Species	: Dog
NOAEL	: 50 mg/kg
Application Route	: Subcutaneous
Exposure time	: 2 year
Remarks	: No significant adverse effects were reported

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

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

Titanium dioxide:

Species : Rat
NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

metformin hydrochloride:

Skin contact : Remarks: May irritate skin.
Eye contact : Remarks: May irritate eyes.
Ingestion : Symptoms: Diarrhoea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

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:

metformin hydrochloride:

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 10 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)): 40 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Sitagliptin Phosphate:

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

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

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

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

Test Type: Respiration inhibition

Cellulose:

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

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

metformin hydrochloride:

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 2 hrs

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

Cellulose:

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential

Components:

metformin hydrochloride:

Partition coefficient: n- : log Pow: -2

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

octanol/water

Sitagliptin Phosphate:

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

Mobility in soil

Components:

metformin hydrochloride:

Distribution among environmental compartments : log Koc: 4.3
Method: OECD Test Guideline 106

Sitagliptin Phosphate:

Distribution among environmental compartments : log Koc: 4.37

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4 Revision Date: 11.08.2025 SDS Number: 27089-00025 Date of last issue: 14.04.2025
Date of first issue: 31.10.2014

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

ADG

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

Therapeutic Goods (Poisons Standard) Instrument : Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date	:	11.08.2025
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)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - 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

SAFETY DATA SHEET



Sitagliptin / Metformin Formulation

Version 4.4	Revision Date: 11.08.2025	SDS Number: 27089-00025	Date of last issue: 14.04.2025 Date of first issue: 31.10.2014
----------------	------------------------------	----------------------------	---

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.

AU / EN