

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Sitagliptin / Metformin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
4.5 11.08.2025 9371387-00010 Date of first issue: 27.08.2021

## SECTION 1: Identifi

**Relevant identified uses of the substance or mixture**

Recommended restrictions : Not applicable

#### 4.3 Details of the supplier of the safety data sheet

**Details of the supplier of the safety data sheet**

Company : MSD  
120 Moorgate  
EC2M 6UR, London, United Kingdom

Telephone : +44 (0) 2081548000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

---

## SECTION 2: Hazards identification

## 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Acute toxicity, Category 4 H302: Harmful if swallowed.

## 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

## Hazard pictograms



Signal word : Warning

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

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.

Hazardous components which must be listed on the label:

metformin hydrochloride

### 2.3 Other hazards

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

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

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
metformin hydrochloride	1115-70-4 214-230-6	Acute Tox. 4; H302	>= 70 - < 90
Sitagliptin Phosphate	654671-77-9	Eye Irrit. 2; H319	>= 1 - < 10
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 1 - < 10

For explanation of abbreviations see section 16.

---

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

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

In case of skin contact : 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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : 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.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version  
4.5

Revision Date:  
11.08.2025

SDS Number:  
9371387-00010

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

Metal oxides

### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

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

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

Local/Total ventilation	causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Advice on safe handling	: 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 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	: 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 engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: Keep in properly labelled containers. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s)	: No data available
-----------------	---------------------

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dust of any kind	10 mg/m <sup>3</sup> Value type (Form of exposure): TWA (Inhalable) Basis: GB EH40
------------------	--

4 mg/m <sup>3</sup> Value type (Form of exposure): TWA (Respirable fraction) Basis: GB EH40
---

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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 (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40

## 8.2 Exposure controls

### Engineering measures

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

Eye/face protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

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.

### 9.2 Other information

Molecular weight	: No data available
Particle size	: No data available

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

## SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Sitagliptin / Metformin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
4.5 11.08.2025 9371387-00010 Date of first issue: 27.08.2021

### 10.3 Possibility of hazardous reactions

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

## 10.4 Conditions to avoid

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

## 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects

Information on likely routes of exposure : 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

## Sitaagliptin Phosphate:

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

## Cellulose-

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

---

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

### 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

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **metformin hydrochloride:**

Species : Rabbit  
Result : Mild eye irritation

##### **Sitagliptin Phosphate:**

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

### Respiratory or skin sensitisation

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### Components:

##### **Sitagliptin Phosphate:**

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version  
4.5

Revision Date:  
11.08.2025

SDS Number:  
9371387-00010

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### 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

#### **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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version  
4.5

Revision Date:  
11.08.2025

SDS Number:  
9371387-00010

Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

Application Route: Ingestion  
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
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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### 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

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

## SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Sitagliptin / Metformin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
4.5 11.08.2025 9371387-00010 Date of first issue: 27.08.2021

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  
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:

Citagnipin 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

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

### **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**

### **12.1 Toxicity**

#### **Components:**

##### **metformin hydrochloride:**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 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
Toxicity to fish (Chronic toxicity)	: NOEC: 10 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: 40 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

### 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 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

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

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

### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

## 12.3 Bioaccumulative potential

### Components:

#### **metformin hydrochloride:**

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

#### **Sitagliptin Phosphate:**

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

Version 4.5      Revision Date: 11.08.2025      SDS Number: 9371387-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

---

### 12.4 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

### 12.5 Results of PBT and vPvB assessment

#### Product:

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

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## SECTION 14: Transport information

### 14.1 UN number

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

---

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

---

**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADN** : Not regulated as a dangerous good

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

---

## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

---

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

---

ain)

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)  
Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

---

## SECTION 16: Other information

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

### Full text of H-Statements

H302 : Harmful if swallowed.  
H319 : Causes serious eye irritation.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Irrit. : Eye irritation  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Sitagliptin / Metformin Formulation

---

Version 4.5	Revision Date: 11.08.2025	SDS Number: 9371387-00010	Date of last issue: 14.04.2025 Date of first issue: 27.08.2021
----------------	------------------------------	------------------------------	---

---

IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

Acute Tox. 4

H302

### Classification procedure:

Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN