

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### SECTION 1. IDENTIFICATION

Product name : Sitagliptin / Metformin Extended Release Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Acute toxicity (Oral) : Category 4

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.  
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 doctor if you feel unwell. Rinse mouth.  
**Disposal:**

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version 12.1      Revision Date: 08/11/2025      SDS Number: 29118-00027      Date of last issue: 04/14/2025  
Date of first issue: 11/07/2014

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
metformin hydrochloride	1115-70-4*	$\geq 40 - \leq 63$	-
Cellulose	9004-34-6*	$\geq 7 - \leq 13$	TSC
Sitagliptin Phosphate	654671-77-9*	$\geq 5 - \leq 10$	TSC
Kaolin	1332-58-7*	$\geq 1 - \leq 5$	TSC
Titanium dioxide	13463-67-7*	$\geq 0.1 - \leq 1$	TSC

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

### 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. FIRE-FIGHTING MEASURES

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                  | : | Carbon oxides<br>Metal oxides<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).   |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding |

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

- |                             |   |   |
|-----------------------------|---|---|
| Technical measures          | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>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.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>Strong oxidizing agents   |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

- |                                      |  |
|--------------------------------------|--|
| inert or nuisance dust               | 50 Million particles per cubic foot<br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3          |
|                                      | 15 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (total dust)<br>Basis: OSHA Z-3                         |
|                                      | 5 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3                 |
|                                      | 15 Million particles per cubic foot<br>Value type (Form of exposure): TWA (respirable fraction)<br>Basis: OSHA Z-3 |
| Dust, nuisance dust and particulates | 10 mg/m <sup>3</sup><br>Value type (Form of exposure): PEL (Total dust)  |

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version  
12.1

Revision Date:  
08/11/2025

SDS Number:  
29118-00027

Date of last issue: 04/14/2025  
Date of first issue: 11/07/2014

Basis: CAL PEL

5 mg/m<sup>3</sup>

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m <sup>3</sup> (OEB 2)	Internal
Kaolin	1332-58-7	TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
Titanium dioxide	13463-67-7	TWA (Respirable particulate matter)	2.5 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1

**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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version 12.1	Revision Date: 08/11/2025	SDS Number: 29118-00027	Date of last issue: 04/14/2025 Date of first issue: 11/07/2014
-----------------	------------------------------	----------------------------	---

concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection  
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  
Hygiene measures

: Work uniform or laboratory coat.  
: 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

: powder

Color

: blue green

Odor

: No data available

Odor 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,

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version 12.1	Revision Date: 08/11/2025	SDS Number: 29118-00027	Date of last issue: 04/14/2025 Date of first issue: 11/07/2014
-----------------	------------------------------	----------------------------	---

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
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

Hazardous decomposition products : No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,588 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

##### **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 Phosphate:**

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

##### **Kaolin:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

---

### 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

### 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

#### Kaolin:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### **Kaolin:**

Species	:	Rabbit
Result	:	No eye irritation

### **Titanium dioxide:**

Species	:	Rabbit
Result	:	No eye irritation

### **Respiratory or skin sensitization**

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

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.

#### **Titanium dioxide:**

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

### **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 test
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
----------------------	---	---

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

Result: negative

### Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### 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

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

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.

### Cellulose:

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

### 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

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version 12.1	Revision Date: 08/11/2025	SDS Number: 29118-00027	Date of last issue: 04/14/2025 Date of first issue: 11/07/2014
-----------------	------------------------------	----------------------------	---

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

**IARC** Group 2B: Possibly carcinogenic to humans  
Titanium dioxide 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### 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 fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 600 mg/kg body weight  
Result: No teratogenic effects.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-fetal toxicity: NOAEL: 140 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 fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Sitagliptin Phosphate:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

Fertility: NOAEL Parent: 1,000 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

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

### 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

##### **Cellulose:**

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### Sitagliptin Phosphate:

Species	:	Mouse
NOAEL	:	500 mg/kg
LOAEL	:	1,000 mg/kg
Application Route	:	Oral
Exposure time	:	> 2 y
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

### Titanium dioxide:

Species	:	Rat
NOAEL	:	24,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Species	:	Rat
NOAEL	:	10 mg/m <sup>3</sup>
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 y

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### 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: Diarrhea, 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, Diarrhea

## 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
----------------------------------	--

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

##### **Cellulose:**

Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h
------------------	---



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version 12.1	Revision Date: 08/11/2025	SDS Number: 29118-00027	Date of last issue: 04/14/2025 Date of first issue: 11/07/2014
-----------------	------------------------------	----------------------------	---

Remarks: Based on data from similar materials

### 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  
Test Type: Respiration inhibition

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

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

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

##### **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

### Bioaccumulative potential

#### Components:

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

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

##### **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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. 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

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

### SECTION 15. REGULATORY INFORMATION

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

#### SARA 311/312 Hazards

: Combustible dust  
Acute toxicity (any route of exposure)

#### SARA 313

: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

### US State Regulations

#### Pennsylvania Right To Know

metformin hydrochloride	1115-70-4
Hydroxypropyl methylcellulose	9004-65-3
Cellulose	9004-34-6
Sitagliptin Phosphate	654671-77-9
Polyvinyl pyrrolidone	9003-39-8
Kaolin	1332-58-7

#### California Prop. 65

WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### California List of Hazardous Substances

Polyvinyl pyrrolidone	9003-39-8
-----------------------	-----------

#### California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Kaolin	1332-58-7

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

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

## SECTION 16. OTHER INFORMATION

### Further information

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

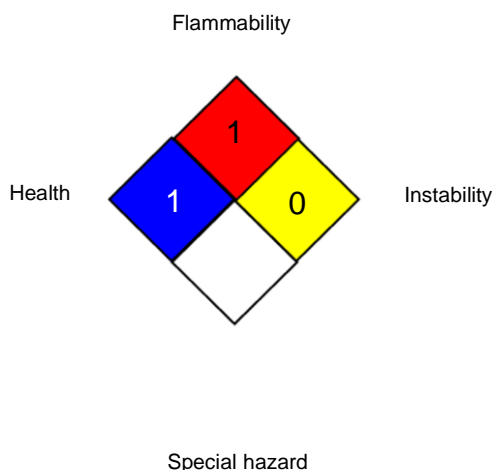
Version  
12.1

Revision Date:  
08/11/2025

SDS Number:  
29118-00027

Date of last issue: 04/14/2025  
Date of first issue: 11/07/2014

### NFPA 704:



### HMIS® IV:

HEALTH	/	1
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
12.1	08/11/2025	29118-00027	Date of first issue: 11/07/2014

50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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

Revision Date : 08/11/2025

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.

US / Z8