

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

SECTION 1. IDENTIFICATION

Product name : Sitagliptin / Metformin Extended Release Formulation
Other means of identification : No data available

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 Hazardous Products Regulations

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 doctor if you feel unwell. Rinse mouth.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS No./Unique ID	Concentration (% w/w)	Trade secret
metformin hydrochloride	No data available	1115-70-4*	>= 40 - <= 63	-
Cellulose	No data available	9004-34-6*	>= 7 - <= 13	TSC
Sitagliptin Phosphate	No data available	654671-77-9*	>= 5 - <= 10	TSC
Kaolin	Hydrated aluminum silicate	1332-58-7*	>= 1 - <= 5	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 : Harmful if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Metal oxides
Nitrogen oxides (NO_x)
- 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 fire-fighters : 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m ³ (OEB 1)	Internal
Cellulose	9004-34-6	TWA	10 mg/m ³	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m ³	CA BC OEL
		TWAEV (total dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³	ACGIH
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m ³ (OEB 2)	Internal
Kaolin	1332-58-7	TWA (Respirable)	2 mg/m ³	CA AB OEL
		TWA (Respirable)	2 mg/m ³	CA BC OEL
		TWAEV (respirable aerosol frac-	2 mg/m ³	CA QC OEL

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

		tion)		
		TWA (Respirable particulate matter)	2 mg/m ³	ACGIH

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

Personal protective equipment

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

Filter type : Particulates type

Hand protection
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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

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.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
7.0	05/09/2026	29090-00028	Date of first issue: 11/07/2014

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

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

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

Kaolin:

Species : Rabbit
Result : No eye irritation

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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.

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
Genotoxicity in vivo	: Test Type: Chromosomal aberration
	Test system: Human lymphocytes
	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
Genotoxicity in vitro	: 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:

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

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.

Cellulose:

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

Sitagliptin Phosphate:

Species : Mouse

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

Effects on fetal 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.

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 Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
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

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 dis-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

	comfort, 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 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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

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

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

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

Endocrine disrupting properties

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

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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version 7.0 Revision Date: 05/09/2026 SDS Number: 29090-00028 Date of last issue: 12/06/2025
Date of first issue: 11/07/2014

Domestic regulation

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined
CA. DSL : not determined
CN IECSC : not determined

Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL : Canada. British Columbia OEL
CA QC OEL : Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA QC OEL / TWAEV : Time-weighted average exposure value

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 Standardization; 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 Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
7.0	05/09/2026	29090-00028	Date of first issue: 11/07/2014

centration 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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, Authorization 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

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 : 05/09/2026
Date format : mm/dd/yyyy

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

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.

CA / Z8