

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sitagliptin / Simvastatin Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS Classification**

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : Category 1

Specific target organ toxicity - repeated exposure : Category 2 (Liver, muscle, optic nerve, Eye)

Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H373 May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Precautionary statements

:

Prevention:

P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sitagliptin Phosphate	654671-77-9	≥ 10 -< 30
Cellulose	9004-34-6	< 10
Simvastatin	79902-63-9	≥ 2.5 -< 10
Starch	9005-25-8	< 10
Ascorbic acid	50-81-7	< 10
Titanium dioxide	13463-67-7	< 1

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.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.1	2025/08/11	24498-00025	2024/07/06
			Date of first issue: 2014/10/21

In case of skin contact	:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	May cause an allergic skin reaction. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Metal oxides Oxides of phosphorus
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.1	2025/08/11	24498-00025	2024/07/06
			Date of first issue: 2014/10/21

- 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.

7. HANDLING AND STORAGE

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

Sitagliptin / Simvastatin Formulation

Version 8.1 Revision Date: 2025/08/11 SDS Number: 24498-00025 Date of last issue: 2024/07/06
Date of first issue: 2014/10/21

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m ³ (OEB 2)	Internal
Cellulose	9004-34-6	NAB	10 mg/m ³	ID OEL
		TWA	10 mg/m ³	ACGIH
Simvastatin	79902-63-9	TWA	25 µg/m ³ (OEB 3)	Internal
	Further information: DSEN			
		Wipe limit	250 µg/100 cm ²	Internal
Starch	9005-25-8	NAB	10 mg/m ³	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			
		TWA	10 mg/m ³	ACGIH
Ascorbic acid	50-81-7	TWA	5000 µg/m ³ (OEB 1)	Internal
Titanium dioxide	13463-67-7	NAB	10 mg/m ³	ID OEL
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

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

Remarks : Consider double gloving.
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.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.1	2025/08/11	24498-00025	2024/07/06
			Date of first issue: 2014/10/21

- Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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.
Contaminated work clothing should not be allowed out of the workplace.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Colour : pink
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : Not applicable

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
--	---	--

Acute toxicity

Not classified based on available information.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Components:**Sitagliptin Phosphate:**

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

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Simvastatin:

Acute oral toxicity : LD50 (Rat): 5,000 mg/kg
LD50 (Mouse): 3,800 mg/kg

Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11,900 mg/kg

Titanium dioxide:

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Sitagliptin Phosphate:**

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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Simvastatin:

Species	: Rabbit
Remarks	: Moderate skin irritation

Ascorbic acid:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

Titanium dioxide:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Sitagliptin Phosphate:**

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

Simvastatin:

Species	: Rabbit
Remarks	: slight irritation

Starch:

Species	: Rabbit
Result	: No eye irritation

Ascorbic acid:

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405

Titanium dioxide:

Species	: Rabbit
Result	: No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Components:**Sitagliptin Phosphate:**

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

Simvastatin:

Assessment	: Probability or evidence of skin sensitisation in humans
Result	: positive

Starch:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

Ascorbic acid:

Test Type	: Maurer optimisation test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

Titanium dioxide:

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

Germ cell mutagenicity

Not classified based on available information.

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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

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
Application Route: Ingestion
Result: negative

Simvastatin:

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

Test Type: Alkaline elution assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

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

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

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Starch:

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

Ascorbic acid:

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

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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Test Type: Chromosome aberration test in vitro
Result: negative

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

Titanium dioxide:

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

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

Carcinogenicity

Not classified based on available information.

Components:**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

Simvastatin:

Species : Mouse
Application Route : Oral
Exposure time : < 92 weeks
Target Organs : Harderian gland
Tumor Type : Liver, Lungs

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Remarks : The significance of these findings for humans is not certain.

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Tumor Type : Liver, Thyroid
Remarks : The significance of these findings for humans is not certain.

Ascorbic acid:

Species : Mouse
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.

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

Reproductive toxicity

Not classified based on available information.

Components:**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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.1	2025/08/11	24498-00025	2024/07/06
			Date of first issue: 2014/10/21

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Simvastatin:

Effects on fertility : Test Type: Fertility
Species: Rat, male
Application Route: Oral
Fertility: LOAEL: 25 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: NOAEL: 10 mg/kg body weight
Result: No teratogenic effects, No adverse effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 60 mg/kg body weight
Result: Teratogenic potential
Remarks: Based on data from similar materials

Ascorbic acid:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Liver, muscle, optic nerve, Eye) through prolonged or repeated exposure.

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Components:**Simvastatin:**

Target Organs	: Liver, muscle, optic nerve, Eye
Assessment	: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Sitagliptin Phosphate:**

Species	: Mouse
NOAEL	: 500 mg/kg
LOAEL	: 1,000 mg/kg
Application Route	: Oral
Exposure time	: > 2 yr
Target Organs	: Kidney

Species	: Rat
NOAEL	: 500 mg/kg
LOAEL	: 1,000 mg/kg
Application Route	: Oral
Exposure time	: 14 Weeks
Target Organs	: Liver, Kidney, Heart, Teeth

Species	: Dog
NOAEL	: 10 mg/kg
LOAEL	: 50 mg/kg
Application Route	: Oral
Exposure time	: 53 Weeks
Target Organs	: Central nervous system
Symptoms	: Loss of balance
Remarks	: The mechanism or mode of action may not be relevant in humans.

Species	: Dog
NOAEL	: 2 mg/kg
LOAEL	: 10 mg/kg
Application Route	: Oral
Exposure time	: 27 Weeks
Target Organs	: Skeletal muscle, Central nervous system
Symptoms	: Loss of balance
Remarks	: The mechanism or mode of action may not be relevant in humans.

Species	: Monkey
NOAEL	: 100 mg/kg
Application Route	: Oral
Exposure time	: 14 Weeks
Remarks	: No significant adverse effects were reported

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Cellulose:

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

Simvastatin:

Species	: Rat
NOAEL	: 5 mg/kg
LOAEL	: 30 mg/kg
Application Route	: Oral
Exposure time	: 14 - 104 Weeks
Target Organs	: Liver, Testis, Musculo-skeletal system, Eye

Species	: Dog
LOAEL	: 10 mg/kg
Application Route	: Oral
Exposure time	: 14 - 104 Weeks
Target Organs	: Liver, Testis, Eye

Species	: Rabbit
NOAEL	: 30 mg/kg
LOAEL	: 50 mg/kg
Application Route	: Oral
Target Organs	: Liver, Kidney

Starch:

Species	: Rat
NOAEL	: $\geq 2,000$ mg/kg
Application Route	: Skin contact
Exposure time	: 28 Days
Method	: OECD Test Guideline 410

Ascorbic acid:

Species	: Rat, male
NOAEL	: $\geq 8,100$ mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

Titanium dioxide:

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

Species	: Rat
NOAEL	: 10 mg/m ³
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 yr

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Sitagliptin Phosphate:**

Inhalation	:	Symptoms: upper respiratory tract infection, pharyngitis, Headache
Ingestion	:	Symptoms: upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhoea

Simvastatin:

Skin contact	:	Remarks: May produce an allergic reaction.
Ingestion	:	Target Organs: Liver Symptoms: upper respiratory tract infection, Headache, Abdominal pain, constipation, Nausea Target Organs: Musculo-skeletal system

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****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)	:	NOEC (Daphnia magna (Water flea)): 9.8 mg/l Exposure time: 21 d

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
8.1	2025/08/11	24498-00025	2024/07/06
			Date of first issue: 2014/10/21

ic toxicity) 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

Cellulose:

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

Simvastatin:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.91 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 25 mg/l
Exposure time: 96 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50: > 30 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 21 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50: 140 mg/l
Exposure time: 16 h

Sitagliptin / Simvastatin Formulation

Version 8.1	Revision Date: 2025/08/11	SDS Number: 24498-00025	Date of last issue: 2024/07/06 Date of first issue: 2014/10/21
----------------	------------------------------	----------------------------	---

Method: DIN 38 412 Part 8

Titanium dioxide:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability**Components:****Sitagliptin Phosphate:**

- Biodegradability : Result: not rapidly degradable
Biodegradation: 39.7 %
Exposure time: 28 d
Method: OECD Test Guideline 314
- Stability in water : Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

Cellulose:

- Biodegradability : Result: Readily biodegradable.

Simvastatin:

- Biodegradability : Result: rapidly degradable
- Stability in water : Hydrolysis: 50 %(3.2 d)

Ascorbic acid:

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 5 d
Method: OECD Test Guideline 302

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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

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

Simvastatin:

Partition coefficient: n-octanol/water : log Pow: > 4.07

Ascorbic acid:

Partition coefficient: n-octanol/water : log Pow: -1.85

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

Distribution among environmental compartments : log Koc: 4.37

Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

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

IATA-DGR

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

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

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

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

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

16. OTHER INFORMATION

Revision Date : 2025/08/11

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ID OEL : Indonesia. Occupational Exposure Limits

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

ID OEL / NAB : Long term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only

Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/07/06
8.1	2025/08/11	24498-00025	Date of first issue: 2014/10/21

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.

ID / EN