

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Sitagliptin / Simvastatin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2

H319: Causes serious eye irritation.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Specific target organ toxicity - repeated
exposure, Category 2

H373: May cause damage to organs through pro-
longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-
egory 3

H412: Harmful to aquatic life with long lasting ef-
fects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

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

Precautionary statements : **Prevention:**
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
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.

Hazardous components which must be listed on the label:
Simvastatin

2.3 Other hazards

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

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Sitagliptin Phosphate	654671-77-9	Eye Irrit. 2; H319	>= 10 - < 20
Simvastatin	79902-63-9	Skin Irrit. 2; H315	>= 2,5 - < 10

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

		Skin Sens. 1; H317 STOT RE 1; H372 (Liver, muscle, optic nerve, Eye) Aquatic Chronic 2; H411	
Substances with a workplace exposure limit :			
Ascorbic acid	50-81-7 200-066-2		$\geq 1 - < 10$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- | | |
|----------------------------|---|
| General advice | : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| If inhaled | : If inhaled, remove to fresh air.
Get medical attention. |
| 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. |

4.2 Most important symptoms and effects, both acute and delayed

- | | |
|-------|--|
| Risks | : May cause an allergic skin reaction.
Causes serious eye irritation.
May cause damage to organs through prolonged or repeated exposure. |
|-------|--|

4.3 Indication of any immediate medical attention and special treatment needed

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides
Metal oxides
Oxides of phosphorus

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	: Static electricity may accumulate and ignite suspended dust 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.
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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust 5 mg/m³
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sitagliptin Phosphate	654671-77-9	TWA	0.6 mg/m ³ (OEB 2)	Internal
Simvastatin	79902-63-9	TWA	25 µg/m ³ (OEB 3)	Internal
Further information: DSEN				
		Wipe limit	250 µg/100 cm ²	Internal
Ascorbic acid	50-81-7	TWA	5000 µg/m ³ (OEB 1)	Internal

8.2 Exposure controls

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

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Hand protection		Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	pink
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

Sitagliptin Phosphate:

Acute oral toxicity : LD50 (Rat): > 3.000 mg/kg
LD50 (Mouse): 3.000 mg/kg

Simvastatin:

Acute oral toxicity : LD50 (Rat): 5.000 mg/kg
LD50 (Mouse): 3.800 mg/kg

Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11.900 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Sitagliptin Phosphate:

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

Simvastatin:

Species : Rabbit
Remarks : Moderate skin irritation

Ascorbic acid:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Sitagliptin Phosphate:

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

Simvastatin:

Species	:	Rabbit
Remarks	:	slight irritation

Ascorbic acid:

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

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Sitagliptin Phosphate:

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

Simvastatin:

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

Ascorbic acid:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

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 Species: Mouse Application Route: Oral 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.

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
		Test Type: Chromosome aberration test in vitro

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Result: negative

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

Simvastatin:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

mans.

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

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

Ascorbic acid:

Species	: Rat, male
NOAEL	: ≥ 8.100 mg/kg
Application Route	: Ingestion
Exposure time	: 13 Weeks

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
------------	---

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

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

SECTION 12: Ecological information

12.1 Toxicity

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 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
Toxicity to fish (Chronic toxicity)	:	NOEC: 9,2 mg/l Exposure time: 33 d

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9,8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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
Method: DIN 38 412 Part 8

12.2 Persistence and degradability

Components:

Sitagliptin Phosphate:

Biodegradability : Result: not rapidly degradable
Biodegradation: 39,7 %

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water : pH: 7
Hydrolysis: 50 %(401 d)
Method: OECD Test Guideline 111

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

12.3 Bioaccumulative potential

Components:

Sitagliptin Phosphate:

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

12.4 Mobility in soil

Components:

Sitagliptin Phosphate:

Distribution among environmental compartments : log Koc: 4,37

12.5 Results of PBT and vPvB assessment

Product:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.3 Transport hazard class(es)

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks	:	Not applicable for product as supplied.
---------	---	---

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.
--	---	--

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament	:	Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

ment and the Council concerning the export and import
of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of
major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of
children and young people.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H372 : Causes damage to organs through prolonged or repeated
exposure.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / : Long term exposure limit
TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland
Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by
Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-
ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-
tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard
of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -
European Chemicals Agency; EC-Number - European Community number; ECx - Concentration

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014

associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Eye Irrit. 2	H319
Skin Sens. 1	H317
STOT RE 2	H373
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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

NO / EN

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



Sitagliptin / Simvastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
7.3	11.08.2025	24509-00027	Date of first issue: 21.10.2014
