

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version 2.1 Revision Date: 2023/09/26 SDS Number: 17294-00024 Date of last issue: 2023/03/07
Date of first issue: 2014/09/30

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Sitagliptin Formulation

Manufacturer or supplier's details

Company : MSD

Address : 199 Wenhai North Road
HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone : 908-740-4000

Emergency telephone number : 86-571-87268110

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

Emergency Overview

Appearance : powder
Colour : No data available
Odour : No data available

Causes serious eye irritation. Harmful to aquatic life.

GHS Classification

Serious eye damage/eye irritation : Category 2A

Short-term (acute) aquatic hazard : Category 3

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H402 Harmful to aquatic life.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version 2.1 Revision Date: 2023/09/26 SDS Number: 17294-00024 Date of last issue: 2023/03/07
Date of first issue: 2014/09/30

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

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

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes serious eye irritation.

Environmental hazards

Harmful to aquatic life.

Other hazards which do not result in classification

Contact with dust can cause mechanical irritation or drying of the skin.
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	654671-77-9	>= 30 -< 50
Cellulose	9004-34-6	>= 20 -< 30
Magnesium stearate	557-04-0	>= 1 -< 10
Titanium dioxide	13463-67-7	>= 0.1 -< 1
Propyl 3,4,5-trihydroxybenzoate	121-79-9	>= 0.25 -< 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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

In case of skin contact	:	Get medical attention if symptoms occur. In case of contact, immediately flush skin with soap and 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	:	Causes serious eye irritation. Contact with dust can cause mechanical irritation or drying of the skin.
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

Personal precautions, protective equipment and emergency	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro-
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version 2.1 Revision Date: 2023/09/26 SDS Number: 17294-00024 Date of last issue: 2023/03/07
Date of first issue: 2014/09/30

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sitagliptin	654671-77-9	TWA	0.5 mg/m ³ (OEB 2)	Internal
Cellulose	9004-34-6	PC-TWA	10 mg/m ³	CN OEL
		TWA	10 mg/m ³	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Titanium dioxide	13463-67-7	PC-TWA (Total dust)	8 mg/m ³	CN OEL
Further information: G2B - Possibly carcinogenic to humans				
		TWA (Respirable particulate matter)	2.5 mg/m ³ (Titanium dioxide)	ACGIH

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

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

Personal protective equipment

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

Filter type : Particulates type

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Skin and body protection	:	Work uniform or laboratory coat.
Hand protection	:	
Material	:	Chemical-resistant gloves
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	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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 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

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Components:

Sitagliptin:

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

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

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

Propyl 3,4,5-trihydroxybenzoate:

Acute oral toxicity : LD50 (Mouse, female): > 1,000 - 2,000 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Components:

Sitagliptin:

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

Magnesium stearate:

Species : Rabbit
Result : No skin irritation
Remarks : Based on data from similar materials

Titanium dioxide:

Species : Rabbit
Result : No skin irritation

Propyl 3,4,5-trihydroxybenzoate:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Sitagliptin:

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

Magnesium stearate:

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Titanium dioxide:

Species : Rabbit
Result : No eye irritation

Propyl 3,4,5-trihydroxybenzoate:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sitagliptin:

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

Magnesium stearate:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

Titanium dioxide:

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

Propyl 3,4,5-trihydroxybenzoate:

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

Assessment	:	Probability or evidence of skin sensitisation in humans
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Germ cell mutagenicity

Not classified based on available information.

Components:

Sitagliptin:

Genotoxicity in vitro	:	Test Type: Ames test Result: negative
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	:	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells
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SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)

Test system: rat hepatocytes

Result: negative

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

Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

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

Propyl 3,4,5-trihydroxybenzoate:

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: positive

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

Carcinogenicity

Not classified based on available information.

Components:

Sitagliptin:

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

Species : Rat
Application Route : oral (drinking water)
Exposure time : 2 Years
Result : positive
Target Organs : Liver
Remarks : Significant toxicity observed in testing

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Cellulose:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.
This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

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

Propyl 3,4,5-trihydroxybenzoate:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Sitagliptin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL Parent: 1,000 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Teratogenicity: LOAEL: 250 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

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

Cellulose:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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

Magnesium stearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Propyl 3,4,5-trihydroxybenzoate:

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

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

Not classified based on available information.

Repeated dose toxicity

Components:

Sitagliptin:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version 2.1 Revision Date: 2023/09/26 SDS Number: 17294-00024 Date of last issue: 2023/03/07
Date of first issue: 2014/09/30

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

Cellulose:

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

Magnesium stearate:

Species : Rat
NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Titanium dioxide:

Species : Rat
NOAEL : 24,000 mg/kg

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Application Route	:	Ingestion
Exposure time	:	28 Days
Species	:	Rat
NOAEL	:	10 mg/m ³
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 yr

Propyl 3,4,5-trihydroxybenzoate:

Species	:	Rat
NOAEL	:	135 mg/kg
Application Route	:	Ingestion
Exposure time	:	13 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Sitagliptin:

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sitagliptin:

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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

Cellulose:

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

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Method: DIN 38412
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 47 h
Test substance: Water Accommodated Fraction
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (*Pseudomonas putida*): > 100 mg/l
Exposure time: 16 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

Propyl 3,4,5-trihydroxybenzoate:

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 19.06 mg/l
Exposure time: 48 h
Test substance: Neutralised product
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): 0.37 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201

EC10 (*Pseudokirchneriella subcapitata* (green algae)): 0.17 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50: 636 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

Persistence and degradability

Components:

Sitagliptin:

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.

Magnesium stearate:

Biodegradability : Result: Not biodegradable
Remarks: Based on data from similar materials

Propyl 3,4,5-trihydroxybenzoate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 49.4 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Sitagliptin:

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

Magnesium stearate:

Partition coefficient: n-octanol/water : log Pow: > 4

Propyl 3,4,5-trihydroxybenzoate:

Partition coefficient: n-octanol/water : log Pow: 1.8
Remarks: Calculation

Mobility in soil

Components:

Sitagliptin:

Distribution among environmental compartments : log Koc: 4.37

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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

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
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.

National Regulations

GB 6944/12268

SAFETY DATA SHEET

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Sitagliptin Formulation

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UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

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

16. OTHER INFORMATION

Revision Date : 2023/09/26

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AllC - 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;

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/07
2.1	2023/09/26	17294-00024	Date of first issue: 2014/09/30

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

Disclaimer

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.

CN / EN