SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Sitagliptin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/26/2023
8.2	09/28/2024	17316-00025	Date of first issue: 09/30/2014

SECTION 1. IDENTIFICATION

Product name : Sitagliptin Formulation

Manufacturer or supplier's details

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

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

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

Combustible dust

Eye irritation : Category 2A

Skin sensitization : Category 1

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary Statements :

Prevention:

P261 Avoid breathing dust.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves, eye protection and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.
P363 Wash contaminated clothing before reuse.

Disposal:

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

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 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
Polyethylene glycol	25322-68-3	>= 1 - < 5
Magnesium stearate	557-04-0	>= 1 - < 5
Titanium dioxide	13463-67-7	>= 0.1 - < 1
Propyl 3,4,5-trihydroxybenzoate	121-79-9	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : 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 : May cause an allergic skin reaction.
Causes serious eye irritation.

delayed		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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) 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 fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

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. Avoid breathing 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. Take care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	:	Keep in properly labeled containers. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3 15 mg/m³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3 5 mg/m³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3

15 Million particles per cubic foot
Value type (Form of exposure): TWA (respirable fraction)
Basis: OSHA Z-3

Dust, nuisance dust and particulates

10 mg/m³
Value type (Form of exposure): PEL (Total dust)
Basis: CAL PEL

5 mg/m³
Value type (Form of exposure): PEL (respirable dust fraction)
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sitagliptin	654671-77-9	TWA	0.5 mg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	TWA	10 mg/m³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m³	US WEEL
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH
Titanium dioxide	13463-67-7	TWA (Respirable particulate matter)	2.5 mg/m³ (Titanium dioxide)	ACGIH
		TWA (total dust)	15 mg/m³	OSHA Z-1

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

Titanium dioxide

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

Personal protective equipment

Respiratory protection	:	General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.
Hand protection Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable

Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.

Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

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

Polyethylene glycol:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials

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.

Components:

Sitagliptin:

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

Polyethylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

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

Polyethylene glycol:

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405
Remarks	:	Based on data from similar materials

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

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

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.

Polyethylene glycol:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Magnesium stearate:

Test Type	:	Maximization Test
Routes of exposure	:	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)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	negative

Propyl 3,4,5-trihydroxybenzoate:

Test Type	:	Local lymph node assay (LLNA)
Routes of exposure	:	Skin contact
Species	:	Mouse
Result	:	positive
Assessment	:	Probability or evidence of skin sensitization in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Sitagliptin:

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

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

Polyethylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

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:

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

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

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

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

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

Reproductive toxicity

Not classified based on available information.

Components:

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

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

Cellulose:

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

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

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 fetal development : Test Type: Embryo-fetal 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 fetal development : Test Type: Embryo-fetal 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 y
Target Organs	:	Kidney

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

Species	:	Dog
NOAEL	:	10 mg/kg
LOAEL	:	50 mg/kg
Application Route	:	Oral
Exposure time	:	53 Weeks
Target Organs	:	Central nervous system
Symptoms	:	Loss of balance

Remarks	:	The mechanism or mode of action may not be relevant in humans.

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

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

Cellulose:

Species	:	Rat
NOAEL	:	>= 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
Application Route	:	Ingestion
Exposure time	:	28 Days

Species	:	Rat
NOAEL	:	10 mg/m³
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	2 y

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, Diarrhea

SECTION 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 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

Polyethylene glycol:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
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
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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l

aquatic invertebrates — 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: Neutralized 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: Neutralized product
Method: OECD Test Guideline 201

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

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

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.

Polyethylene glycol:

Biodegradability : Result: rapidly degradable
Remarks: Based on data from similar materials

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

Polyethylene glycol:

Partition coefficient: n-octanol/water : log Pow: < 3

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

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust
Respiratory or skin sensitization
Serious eye damage or eye irritation

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

US State Regulations

Pennsylvania Right To Know

Sitagliptin	654671-77-9
Cellulose	9004-34-6
Calcium hydrogenorthophosphate	7757-93-9

California Prop. 65
WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose	9004-34-6
Magnesium stearate	557-04-0

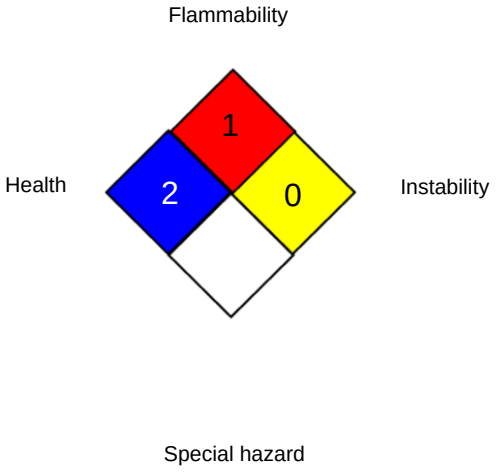
The ingredients of this product are reported in the following inventories:

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

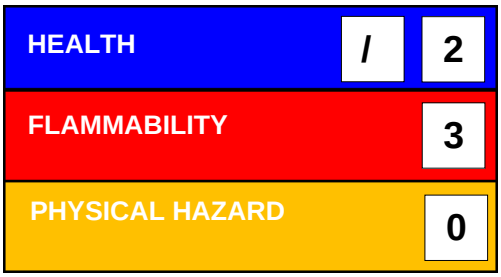
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



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

Full text of other abbreviations

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

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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

Revision Date : 09/28/2024

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.

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