

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Sitagliptin Formulation

Version 8.0      Revision Date: 14.04.2025      SDS Number: 2160736-00012      Date of last issue: 28.09.2024  
Date of first issue: 09.11.2017

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

#### 1.1 Product identifier

Trade name : Sitagliptin Formulation

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

Use of the Substance/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

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848 and subsequent amendments

Eye irritation, Category 2 : H319: Causes serious eye irritation.

Long-term (chronic) aquatic hazard, Category 3 : H412: Harmful to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848 and subsequent amendments

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

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H412 Harmful to aquatic life with long lasting effects.

### 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.

### Additional Labelling:

EUH208 Contains Propyl 3,4,5-trihydroxybenzoate.  
May produce an allergic reaction.

## 2.3 Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.  
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. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Sitagliptin	654671-77-9	Eye Irrit. 2; H319	>= 30 - < 50
Titanium dioxide	13463-67-7 236-675-5 022-006-00-2	Carc. 2; H351	>= 0,1 - < 1
Propyl 3,4,5-trihydroxybenzoate	121-79-9 204-498-2 607-198-00-3	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic)	>= 0,25 - < 1

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		aquatic toxicity): 1	
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 20 - < 30

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 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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray

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Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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.

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## 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.

### 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 re-

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leased 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.

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## 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. 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.
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.

### 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

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### 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

15 mg/m<sup>3</sup>

Value type (Form of exposure): ZOAD/TWA (Total dust)

Basis: TR OEL DU

Further information: Allowable occupational exposure limit values of mineral dusts

5 mg/m<sup>3</sup>

Value type (Form of exposure): ZOAD/TWA (Respirable part)

Basis: TR OEL DU

Further information: Allowable occupational exposure limit values of mineral dusts

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Sitagliptin	654671-77-9	TWA	0.5 mg/m <sup>3</sup> (OEB 2)	Internal
Cellulose	9004-34-6	ZOAD/TWA (Total dust)	15 mg/m <sup>3</sup>	TR OEL DU
Further information: Allowable occupational exposure limit values of chemicals in dust form				
		ZOAD/TWA (Respirable dust)	5 mg/m <sup>3</sup>	TR OEL DU
		Further information: Allowable occupational exposure limit values of chemicals in dust form		
Titanium dioxide	13463-67-7	ZOAD/TWA (Total dust)	15 mg/m <sup>3</sup>	TR OEL DU
		Further information: Allowable occupational exposure limit values of chemicals in dust form		

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

Titanium dioxide

#### Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Propyl 3,4,5-trihydroxybenzoate	Workers	Inhalation	Long-term systemic effects	6,66 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	1,89 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,17 mg/m <sup>3</sup>

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	Consumers	Skin contact	Long-term systemic effects	0,675 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,675 mg/kg bw/day
Propyl 3,4,5-trihydroxybenzoate	Workers	Inhalation	Long-term systemic effects	6,66 mg/m3
	Workers	Skin contact	Long-term systemic effects	1,89 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,17 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,675 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,675 mg/kg bw/day

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Propyl 3,4,5-trihydroxybenzoate	Fresh water	0,37 µg/l
	Freshwater - intermittent	3,7 µg/l
	Marine water	0,037 µg/l
	Marine water - intermittent	0,37 µg/l
	Sewage treatment plant	6,36 mg/l
	Fresh water sediment	0,0045 mg/kg dry weight (d.w.)
	Marine sediment	0,00045 mg/kg dry weight (d.w.)
	Soil	0,000688 mg/kg dry weight (d.w.)

## 8.2 Exposure controls

### 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

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.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
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 TS EN 143
Filter type	: Particulates type (P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic 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
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.

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### 9.2 Other information

Molecular weight : No data available  
Particle size : No data available

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## 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.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

##### **Titanium dioxide:**

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

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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): 1.700 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

### 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

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Sitagliptin:

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

#### 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:

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

### Titanium dioxide:

Species	:	Rabbit
Result	:	No eye irritation

### Propyl 3,4,5-trihydroxybenzoate:

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

### 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.

##### 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
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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

### 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

### Cellulose:

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

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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

### 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

#### **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

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### Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 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

#### 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

### Cellulose:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative

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### 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
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

#### Titanium dioxide:

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Species	:	Rat
NOAEL	:	24.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days

Species	:	Rat
NOAEL	:	10 mg/m <sup>3</sup>
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

### Cellulose:

Species	:	Rat
NOAEL	:	>= 9.000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

### 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

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### 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	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 39

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plants	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 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

### 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)): 19,6 mg/l Exposure time: 48 h Test substance: Neutralised product Method: OECD Test Guideline 202 Remarks: The test was conducted according to guideline
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,22 mg/l

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	Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline
	EC10 (Pseudokirchneriella subcapitata (green algae)): 0,096 mg/l Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50 (activated sludge): 636 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	: 1
<b>Cellulose:</b>	
Toxicity to fish	: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

## 12.2 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	: pH: 7 Hydrolysis: 50 %(401 d) Method: OECD Test Guideline 111

#### **Propyl 3,4,5-trihydroxybenzoate:**

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 49,4 % Exposure time: 28 d Method: OECD Test Guideline 301F
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#### **Cellulose:**

Biodegradability	: Result: Readily biodegradable.
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### 12.3 Bioaccumulative potential

#### Components:

##### **Sitagliptin:**

Partition coefficient: n-octanol/water : log Pow: -0,03

##### **Propyl 3,4,5-trihydroxybenzoate:**

Partition coefficient: n-octanol/water : log Pow: 1,8  
Remarks: Calculation

### 12.4 Mobility in soil

#### Components:

##### **Sitagliptin:**

Distribution among environmental compartments : log Koc: 4,37

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced 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. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

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## SECTION 14: Transport information

### 14.1 UN number

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<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.2 UN proper shipping name

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.4 Packing group

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA (Cargo)</b>	:	Not regulated as a dangerous good
<b>IATA (Passenger)</b>	:	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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous

: Not applicable

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substances, mixtures and articles (Annex 17)  
Regulation on Persistent Organic Pollutants (Number : Not applicable  
30595 and subsequent amendments published)  
Regulation on prevention of major industrial accidents. Reg number 30702  
Not applicable

### Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.  
Regulation on Dust Control (No: 28812, 2013). Occupational Dust Exposure Limit Values (Annex 1)  
Regulation on Import and Export of Certain Hazardous : Not applicable Chemicals, No. 32087, 2023

### 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.

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## 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.  
The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

### Full text of H-Statements

H302 : Harmful if swallowed.  
H317 : May cause an allergic skin reaction.  
H318 : Causes serious eye damage.  
H319 : Causes serious eye irritation.  
H351 : Suspected of causing cancer if inhaled.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

### Full text of other abbreviations

Acute Tox. : Acute toxicity

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Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation
Skin Sens.	:	Skin sensitisation
TR OEL DU	:	Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
TR OEL DU / ZOAD/TWA	:	Time Weighted Average Value

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (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 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
Aquatic Chronic 3	H412

### Classification procedure:

Calculation method
Calculation method

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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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