SAFETY DATA SHEET

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

Sitagliptin / Metformin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
8.1	14.04.2025	2044899-00019	Date of first issue: 05.10.2017

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

1.1 Product identifier

Trade name : Sitagliptin / Metformin 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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

Acute toxicity, Category 4 — H302: Harmful if swallowed.

2.2 Label elements

Labelling T.R. SEA No 28848 and subsequent amendments

Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Hazardous components which must be listed on the label:
metformin hydrochloride

2.3 Other hazards

Dust contact with the eyes can lead to mechanical irritation.
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)
metformin hydrochloride	1115-70-4 214-230-6	Acute Tox. 4; H302	>= 70 - < 90
Sitagliptin	654671-77-9	Eye Irrit. 2; H319	>= 1 - < 10
Titanium dioxide	13463-67-7 236-675-5 022-006-00-2	Carc. 2; H351	>= 0,1 - < 1
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

If inhaled	:	If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact	:	Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact	:	If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.Harmful if swallowed.

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 Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting	:	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 Nitrogen oxides (NOx) Metal oxides

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	Use only with adequate ventilation.

Advice on safe handling	:	Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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

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/m3 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/m3 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
metformin hydrochloride	1115-70-4	TWA	1 mg/m3 (OEB 1)	Internal
Sitagliptin	654671-77-9	TWA	0.5 mg/m3 (OEB 2)	Internal
Cellulose	9004-34-6	ZOAD/TWA (Total dust)	15 mg/m3	TR OEL DU
	Further information: Allowable occupational exposure limit values of chemicals in dust form			
		ZOAD/TWA (Respirable dust)	5 mg/m3	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/m3	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

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)

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.

9.2 Other information

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

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

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

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1.380 mg/kg
Method: Calculation method

Components:

metformin hydrochloride:

Acute oral toxicity : LD50 (Rat): 1.000 mg/kg

LD50 (Mouse): 1.450 - 3.500 mg/kg

LD50 (Monkey): 463 mg/kg

LD50 (Rabbit): 350 mg/kg

LD50 (Guinea pig): 500 mg/kg

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

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

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:

metformin hydrochloride:

Species : Rabbit
Result : Mild skin irritation

Sitagliptin:

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

Titanium dioxide:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

metformin hydrochloride:

Species	:	Rabbit
Result	:	Mild eye irritation

Sitagliptin:

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

Titanium dioxide:

Species	:	Rabbit
Result	:	No eye irritation

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

Germ cell mutagenicity

Not classified based on available information.

Components:

metformin hydrochloride:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro assay Test system: mouse lymphoma cells Result: negative Test Type: Chromosomal aberration

Test system: Human lymphocytes
Result: negative

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

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

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

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

Carcinogenicity

Not classified based on available information.

Components:

metformin hydrochloride:

Species	:	Mouse
Exposure time	:	91 weeks
Dose	:	1500 mg/kg body weight
Result	:	negative
Species	:	Rat, male
Application Route	:	Oral
Exposure time	:	104 weeks
Dose	:	900 mg/kg body weight
Result	:	negative
Species	:	Rat, female
Application Route	:	Oral
Exposure time	:	104 weeks
LOAEL	:	900 mg/kg body weight
Result	:	negative
Target Organs	:	Uterus (including cervix)
Remarks	:	The mechanism or mode of action may not be relevant in humans.

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.

Cellulose:

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

Reproductive toxicity

Not classified based on available information.

Components:

metformin hydrochloride:

Effects on fertility	:	Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 600 mg/kg body weight Result: No effects on fertility
Effects on foetal development	:	Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 600 mg/kg body weight Result: No teratogenic effects Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Embryo-foetal toxicity: NOAEL: 140 mg/kg body weight Result: No teratogenic effects

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
Effects on foetal development	:	Test Type: Fertility/early embryonic 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:

metformin hydrochloride:

Species	:	Rat
NOAEL	:	125 mg/kg
Application Route	:	Oral
Exposure time	:	1 year
Remarks	:	No significant adverse effects were reported

Species	:	Rabbit
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	1 Year
Remarks	:	No significant adverse effects were reported

Species	:	Dog
NOAEL	:	50 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	2 year
Remarks	:	No significant adverse effects were reported

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:

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 yr

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:

metformin hydrochloride:

Skin contact	:	Remarks: May irritate skin.
Eye contact	:	Remarks: May irritate eyes.
Ingestion	:	Symptoms: Diarrhoea, Nausea, Vomiting, Gastrointestinal discomfort, flatulence, asthenia, Fatigue, Headache

Sitagliptin:

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

metformin hydrochloride:

Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 10 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: 40 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

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 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

Cellulose:

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:

metformin hydrochloride:

Biodegradability : Result: rapidly degradable
Biodegradation: 50 %
Exposure time: 2 hrs

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

Cellulose:

Biodegradability : Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

metformin hydrochloride:

Partition coefficient: n-octanol/water : log Pow: -2

Sitagliptin:

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

12.4 Mobility in soil

Components:

metformin hydrochloride:

Distribution among environmental compartments : log Koc: 4,3
Method: OECD Test Guideline 106

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

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.

SECTION 14: Transport information

14.1 UN number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

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

14.4 Packing group

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

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable

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 Chemicals, No. 32087, 2023 : Not applicable

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

AICS	:	not determined
DSL	:	not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The SDS has been prepared by: Name: Gökhan Ardıç; 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.
H319 : Causes serious eye irritation.
H351 : Suspected of causing cancer if inhaled.

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
Carc. : Carcinogenicity
Eye Irrit. : Eye irritation
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) Ef-

fect 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:		**Classification procedure:**
Acute Tox. 4	H302	Calculation method

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

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