SAFETY DATA SHEET

Sitagliptin / Metformin Extended Release Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
7.1	30.09.2023	29114-00024	Date of first issue: 07.11.2014

Section 1: Identification

Product name : Sitagliptin / Metformin Extended Release Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Acute toxicity (Oral) : Category 4

GHS label elements

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.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

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

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
metformin hydrochloride	1115-70-4	>= 50 -< 70
Cellulose	9004-34-6	>= 10 -< 20
Sitagliptin	654671-77-9	>= 1 -< 10
Kaolin	1332-58-7	>= 1 -< 10
Titanium dioxide	13463-67-7	>= 0.1 -< 1

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 : 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.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 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 Metal oxides Nitrogen oxides (NOx) Silicon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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 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.
Conditions for safe storage	:	Keep in properly labelled 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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
metformin hydrochloride	1115-70-4	TWA	1 mg/m3 (OEB 1)	Internal
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Sitagliptin	654671-77-9	TWA	0.5 mg/m3 (OEB 2)	Internal
Kaolin	1332-58-7	WES-TWA	10 mg/m3	NZ OEL

		WES-TWA (Respirable dust)	2 mg/m3	NZ OEL
		TWA (Respirable particulate matter)	2 mg/m3	ACGIH
Titanium dioxide	13463-67-7	WES-TWA	10 mg/m3	NZ OEL
		TWA (Respirable particulate matter)	2.5 mg/m3 (Titanium dioxide)	ACGIH

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

Titanium dioxide

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

Personal protective equipment

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

Filter type : Particulates type

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.

Section 9: Physical and chemical properties

Appearance : powder

Colour : blue green

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.
Molecular weight	:	No data available
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

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,588 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

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

Sitagliptin:

Acute oral toxicity	:	LD50 (Rat): > 3,000 mg/kg LD50 (Mouse): 3,000 mg/kg

Kaolin:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Remarks: Based on data from similar materials
Acute inhalation toxicity	:	LC50 (Rat): > 2.07 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 5,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity 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

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

Kaolin:

Species	:	Rabbit
Method	:	OECD Test Guideline 404

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

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
Result : Irritating to eyes.
Method : Draize Test

Kaolin:

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

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

Chronic toxicity

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

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

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

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.

Cellulose:

Species	:	Rat
Application Route	:	Ingestion

Exposure time	:	72 weeks
Result	:	negative

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.

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

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

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

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

Cellulose:

Species	:	Rat
NOAEL	:	>= 9,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

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

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

Ecotoxicity

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 fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 10 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)): 40 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition 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

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

Kaolin:

Toxicity to fish (Chronic toxicity)	:	NOELR (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 30 d

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

Persistence and degradability

Components:

metformin hydrochloride:

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

Cellulose:

Biodegradability : Result: Readily biodegradable.

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

Bioaccumulative potential

Components:

metformin hydrochloride:

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

Sitagliptin:

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

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

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

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

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

Section 14: Transport information

International Regulations

UNRTDG

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

IATA-DGR

UN/ID No.	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Packing instruction (cargo aircraft)	:	Not applicable
Packing instruction (passenger aircraft)	:	Not applicable

IMDG-Code

UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
EmS Code	:	Not applicable
Marine pollutant	:	Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

NZS 5433

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

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

HSW Controls

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Revision Date	:	30.09.2023

Further information

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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and

Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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