Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Sitagliptin Phosphate Reference Standard
Supplier	Name	Pharmaceutical and Medical Device Regulatory Science Society of Japan
	Address	2-12-15, Shibuya, Shibuya-ku, Tokyo 150-0002, Japan
	Tel	+81-3-3400-5634
	Emergency contact	Pharmaceutical and Medical Device Regulatory Science Society of Japan, Pharmaceutical Reference Standards Center
	Tel	+81-6-6221-3444
	Fax	+81-6-6221-3445
Recommended use		This product is analytical reagent.
Restrictions on use		It is not a medicine or clinical diagnostic agent, so it can not be used for human or animals.

2. Hazard Identification

GHS Classification of chemicals

Physicochemical hazards	Not classified
Health hazards	
Serious eye damage / eye irritation	Category 2A
Environmental hazards	
Hazardous to the aquatic environment short-term (acute)	Category 3

Label elements

Pictograms

Signal word: Warning

Hazard statement:
Causes serious eye irritation
Harmful to aquatic life

Precautionary statement:
【Prevention】
Wash hands thoroughly after handling.
Wear eye protection/ face protection.
Avoid release to the environment.
【Response】
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/ attention.
【Disposal】
Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Sitagliptin monophosphate monohydrate.
Synonym / common name	－
CAS No.	654671-77-9
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : 8-(2)-2258
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victime to fresh air and keep comfortable for breathing. Get medical attention if irritation develops and persists.
Skin contact	Rinse skin with water/shower.

	Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes.
	Remove contact lenses, if present and easy to do. Continue rinsing.
	If eye irritation persists: Get medical advice/ attention.
Ingestion	Rinse mouth.
	If ingestion of a large amount dose occur, call a doctor/physician immediately.
Most important symptoms/effects, acute and delayed	No data available.
Protection of first-aiders	Wear personal protective equipment as required.
Indication of immediate medical attention and special treatment needed	Provide the symptomatic treatment.

5. Fire-Fighting Measures

Suitable extinguishing media	Water spray, foam, dry chemical, carbon dioxide.
Unsuitable extinguishing media	High volume water jet.
Specific hazards arising from the chemical product	Irritating, toxic or corrosive gases may be generated by a fire.
Special extinguishing method	Use standard firefighting procedures and consider the hazards of other involved materials.
	As with all fires, evacuate personnel to a safe area.
	Use water spray to cool unopened containers.
Protection of fire-fighters	Wear suitable protective equipment.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away.
	Ensure adequate ventilation.
	Avoid inhalation of dust or vapor etc from the spilled material.
	See section 8 of the SDS, wear suitable protective equipment.
	Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Avoid release to the environment.
Methods and materials for containment and cleaning up	Collect spillage in an appropriate way.
	Clean surface thoroughly to remove residual contamination.
	For waste disposal, see section 13 of the SDS.

7. Handling and Storage

Handling	Technical measures	See section 8 of the SDS, perform engineering controls and wear protective equipment.
		See section 8 of the SDS, perform local ventiration or general ventilation.
	Safety handling precautions	When handling Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.
		Wear personal protective equipment.
		After removing gloves, wash hands and other exposed skin thoroughly.
		Wash skin thoroughly after handling.
		Avoid release to the environment.
	Contact avoidance	See section 10 of the SDS.
Storage	Safe storage conditions	Keep container tightly closed.
	Safe packaging material	Store in an appropriate container according to applicable laws and regulations.

8. Exposure controls/personal protection

Administrative Control Levels	Not set up.
Occupational Exposure Limits	No data available.
Engineering controls	Install an eyewash facilities and a safety shower in the workplace where this material is stored or handled.
	Install general ventilation system and local exhaust ventilation.
	Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Personal protective equipment	
Respiratory protection	Wear appropriate respiratory protection (e.g., dust mask, gas mask).
Hand protection	Wear appropriate protective gloves (e.g., chemically compatible gloves).

Eye protection	Wear appropriate eye protection/face protection (e.g., safety glasses with side shields, goggle-type protective glasses).
Skin and body protection	Wear appropriate protective clothing (e.g., lab coat, long sleeve work clothes).

9. Physical and chemical properties and safety characteristics

Physical state		Solid: Powder.
Colour		White.
Odor		No data available.
Melting point/Freezing point		216 - 222℃
Flammability		No data available.
Boiling point or initial boiling point and boiling range		No data available.
Lower and upper explosion limit/ flammability limit		
	Lower limit(%)	No data available.
	Upper limit (%)	No data available.
Flash point		No data available.
Auto-ignition temperature		No data available.
Decomposition temperature		No data available.
pH		No data available.
Kinematic viscosity		No data available.
Solubility	Water	69,500 mg/L
	Other	No data available.
Partition coefficient n-octanol/water (log value)		-0.03
Vapor pressure		No data available.
Density and/or relative density		No data available.
Relative vapor density		No data available.
Particle characteristics		No data available.
Other information		
	Explosive properties	Not explosive.
	Dust deflagration index (Kst)	101 bar.m/s
	Minimum ignition energy	> 1 J

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Dust can form an explosive mixture in air.
	Can react with strong oxidizing agents.
Conditions to avoid	No data available.
Incompatible materials	Oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Acute toxicity

Tests	Species	Results
Oral-LD50	Rat	> 3000 mg/kg
	Mouse	> 3000 mg/kg

Skin corrosion / irritation

Tests	Species	Results
Draize test	Rabbit	No skin irritation.

Serious eye damage / eye irritation

Tests	Species	Results
Draize test	Rabbit	Irritating to eyes.

Respiratory sensitization No data available.

Skin sensitization

Tests	Species	Results
Local lymph node assay (LLNA)	Mouse	Not a skin sensitizer.

Germ cell mutagenicity

−in vitro

Tests	Test system	Results
Ames test	−	Negative.
Chromosome aberration test	Chinese hamster ovary cells	Negative.
DNA damage and repair, unscheduled DNA synthesis in mammalian cells	Rat hepatocytes	Negative.

−in vivo

Tests	Speices	Results
Oral-Micronucleus test	Mouse	Negative.

Carcinogenicity

Tests	Species	Period	Results
Oral administration test	Mouse	2 Years	Negative.
Oral administration test (drinking water)	Rat	2 Years	Positive (In liver, significant toxicity observed in testing).

Reproductive toxicity

Tests	Species	Results
Fertility/early embryonic development test	Rat(Oral)	NOAEL: 1000 mg/kg body weight No effects on fertility.
Embryo-fetal development test	Rat(Oral)	LOAEL: 250 mg/kg body weight Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.
Embryo-fetal development test	Rabbit(Oral)	NOAEL: 125 mg/kg body weight No teratogenic effects.

Specific target organ toxicity - Single exposure No data available.

Specific target organ toxicity - Repeated exposure

Tests	Species	Period	Results
Oral administration test	Mouse (Kidney)	>2 Years	NOAEL: 500 mg/kg, LOAEL: 1,000 mg/kg
Oral administration test	Rat (Liver, Kidney, Heart, Teeth)	14 Weeks	NOAEL: 500 mg/kg, LOAEL: 1,000 mg/kg
Oral administration test	Dog (Central nervous system)	53 Weeks	NOAEL: 10 mg/kg, LOAEL: 50 mg/kg Loss of balance.
Oral administration test	Dog (Central nervous system)	27 Weeks	NOAEL: 2 mg/kg, LOAEL: 10 mg/kg Loss of balance.
Oral administration test	Monkey (Skeletal muscle, Central nervous system)	14 Weeks	NOAEL: 100 mg/kg No significant adverse effects were reported.

Aspiration hazard

Tests	Species	Symptoms
Inhalation-exposure test	Human	Upper respiratory tract infection, pharyngitis, Headache
Ingestion-exposure test	Human	Upper respiratory tract infection, nasopharyngitis, Headache, Nausea, Abdominal pain, Diarrhea

Other information No data available.

12. Ecological information

Ecotoxicity

Tests	Species, Test type	Results
Fish-LC50	*Pimephales promelas* (fathead minnow)	> 100 mg/L, 96 h
Daphnia-EC50	*Daphnia magna* (Water flea)	60 mg/L, 48 h
Algae-EC50	*Pseudokirchneriella subcapitata* (green algae)	> 39 mg/L, 96h
Algae-EC50	*Pseudokirchneriella subcapitata* (green algae)	2.2 mg/L, 96 h
Fish-NOEC	*Pimephales promelas* (fathead minnow)	9.2 mg/L, 33 d
Daphnia-NOEC	*Daphnia magna* (Water flea)	9.8 mg/L, 21 d
Microorganisms-EC50	Respiration inhibition	> 150 mg/L, 3 h
Microorganisms-NOEC	Respiration inhibition	150 mg/L, 3 h

Persistence and degradability

Biodegradability:	Not rapidly degradable (Biodegradation: 39.7 % Exposure time: 28 d).
Stability in water:	Hydrolysis: 50 % (401 d)
Bioaccumulative potential	Partition coefficient: noctanol/water: log Pow: -0.03
Mobility in soil	No data available.
Hazard to the ozone layer	No data available.

13. Disposal considerations

Information on safe and environmentally desirable disposal or recycling of chemicals, contaminated containers and packaging.

Dispose in a safe manner in accordance with national and local regulations.

When empty containers are discarded, contents should be completely removed.

14. Transport information

UN Number		Not regulated.
Proper shipping name		
Hazard class		
Subsidiary hazard class		
Packing group		
Domestic restriction	Rail and road	Not regulated.
	Marine	Not regulated.
	Aviation	Not regulated.

15. Regulatory information

Japanese regulations

Pollutant Release and Transfer Register	Not regulated.
Poisonous and Deleterious Substances	Not regulated.
Industrial Safety and Health Act	Not regulated.
Fire Service Act	Not regulated.

16. Other information

Issued date	SIT-01 :	Mar. 07, 2019
Revision date	SIT-02 :	Apr. 01, 2021
References	Ministry of Health, Labour and Welfare : GHS model SDS information	
	Japan Science and Technology Agency. : J-GLOBAL	
	National Institute of Technology and Evaluation: NITE Chemical Risk Information Platform (NITE-CHRIP)	
	etc.	

The information in this Safety Data Sheet is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification of this product. The information provided is correct to the best of our knowledge, information and belief at the date of its publication and so on. However, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity.