

Safety Data Sheet

1. Identification

Product name	Japanese Pharmacopoeia Cilostazol 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	Not classified.
Environmental hazards	Not classified.
Label elements	Pictograms: No symbol. Signal word: None. Hazard statement: — Precautionary statement: —

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Cilostazol
Synonym / common name	—
CAS No.	73963-72-1
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : — ISHL : 8-(1)-1777
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victim 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 with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount dose occur, call a doctor/physician immediately. No data available.
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	No data available.
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.
Wear suitable protective equipment.

Protection of fire-fighters

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 ventilation 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.
	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

Occupational Exposure Limits	OEEL: 0.5 mg/m ³ (8hr TWA)
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: Crystals or crystalline powder.
Colour	White to pale yellow-white.
Odor	Odorless.
Melting point/Freezing point	158 to 162°C
Flammability	Not highly flammable.
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	about 192°C
pH	No data available.
Kinematic viscosity	No data available.
Solubility	Water Other
	Practically insoluble. Slightly soluble in methanol, ethanol, acetonitrile.

Partition coefficient n-octanol/water (log value)	log Kow: 2.64 (shake-flask method)
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	
Lower dust explosive limit	50 g/m ³
Minimum ignition energy	0.3 < E ≤ 1 mJ
Volume resistivity (conductivity)	5.5×10 ¹³ Ω·m (highly charged object)

10. Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction under conditions of normal use.
Conditions to avoid	Generation of dust and static electricity.
Incompatible materials	No data available.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological Information

Acute toxicity

Tests	Species	Results
Oral LD50	Rat	> 5000 mg/kg
	Mouse	> 5000 mg/kg

Skin corrosion / irritation

Tests	Species	Results
Irritation test	Rabbit	Non-irritation.

Serious eye damage / eye irritation

Tests	Species	Results
Irritation test	Rabbit	Non-irritation.

Respiratory sensitization

Skin sensitization

Tests	Species	Results
Sensitization test	Guinea pig	Negative.

Germ cell mutagenicity

Tests	Results
Bacterial gene mutation test	Negative.
Cultured mouse cell gene mutation test	Negative.
Cultured hamster cell chromosomal damage test	Positive (nonspecific effects due to cytotoxicity) 70 mg/L.
Mouse oral administration chromosomal damage test	Negative 6000 mg/kg/day.
Bacterial DNA damage test	Negative.
Mouse oral administration DNA damage test	Negative.

Carcinogenicity

Reproductive toxicity

Tests	Results
1000 mg/kg/day, Teratogenicity test in rat	Body weight decreased, ossification retarded and the incidence of external, visceral or skeletal anomalies increased in fetuses.

Specific target organ toxicity - Single exposure

Specific target organ toxicity - Repeated exposure

Tests	Species	NOAEL
Subacute toxicity test (oral)	Rat	30 mg/kg/day
	Dog	30 mg/kg/day
Chronic toxicity/long-term toxicity test (oral)	Rat	6 mg/kg/day
	Dog	12 mg/kg/day

Aspiration hazard
Other information

1 2 . Ecological Information

Ecotoxicity

Tests	Species	Results
Fish NOEC	<i>Danio rerio</i> (zebrafish)	≥4.0 mg/L (early life stage)
Crustacea NOEC	<i>Daphnia magna</i>	≥4.0 mg/L (survival and reproduction)
Algae EC50	<i>Pseudokirchneriella subcapitata</i>	≥4.0 mg/L, 72 hours
Algae NOEC	<i>Pseudokirchneriella subcapitata</i>	1.3 mg/L

Persistence and degradability
Bioaccumulative potential
Mobility in soil
Hazard to the ozone layer

Ready biodegradation (28 days): 2.3%; Not Biodegradable - unlikely to undergo rapid biodegradation in the environment.

log Kow: 2.64

No data available.

This substance is not listed in the Annex to the Montreal Protocol.

1 3 . 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.

1 4 . 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.

1 5 . Regulatory Information

Japanese regulations

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

1 6 . Other Information

Issued date	CIL-01 :	Jun. 24, 2019
	CIL-03 :	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-CHRIPI) 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.