Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Glimepiride 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	Glimepiride.
Synonym / common name	－
CAS No.	93479-97-1
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : 8-(1)-3837
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 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.
Most important symptoms/effects, acute and delayed	Symptoms: Dizziness. Sweating. Nausea. Hazards: Danger of hypoglycemia.
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.
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.
	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		No set up.
Occupational Exposure Limits		OEL: 0.01 mg/m^3 (preliminary) OEB: 3 (preliminary)
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.
Odour	Odorless.
Melting point/Freezing point	201-213℃
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	> 400℃
Decomposition temperature	> 400℃ (DTA)

pH		No data available.
Kinematic viscosity		No data available.
Solubility	Water	< 1 g/L (20℃)
	Other	No data available.
Partition coefficient n-octanol/water (log value)		No data available.
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		
	Dust explosion class	St 1 (1 < Kst =< 200): Capable of weak to moderate dust explosion.
	Further information (pyhs. -chem.)	The product is capable of dust explosions.
	Impact sensitivity	Not impact-sensitive.
	Burning number	BZ1: No ignition - Non combustible.

１０．Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Accumulation of fine dust may entail the risk of a dust explosion in the presence of air.
Conditions to avoid	No data available.
Incompatible materials	No data available.
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	> 10000 mg/kg
	Mouse	> 10000 mg/kg

Skin corrosion / irritation

Tests	Species	Results
Irritation test (72 hours exposure) (OECD 404)	Rabbit	Non-irritant.

Serious eye damage / eye irritation

Tests	Species	Results
Irritation test (OECD 405)	Rabbit	Non-irritant.

Respiratory sensitization	No data available.
Skin sensitization	No data available.

Germ cell mutagenicity

Tests	Results
Ames test	Negative.
In vivo micronucleus test	Negative.

Carcinogenicity	No data available.
Reproductive toxicity	No data available.
Specific target organ toxicity - Single exposure	No data available.
Specific target organ toxicity - Repeated exposure	No data available.
Aspiration hazard	No data available.
Other information	No data available.

１２．Ecological Information

Ecotoxicity

Tests	Species	Results
Fish LC50	*Brachydanio rerio*	> 10 g/L, 96 hours
Crustaces EC50	*Daphnia magna*	> 100 mg/L, 48 hours
Algae EC50	*Desmodesmus subspicatus*	610.72 mg/L, 72 hours
Bacteria EC20	Activated sludge	> 1000 mg/L

Persistence and degradability	Biological degradabillity: Not readily degradable. (< 10%, 28 days)
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Hazard to the ozone layer	This substance is not listed in the Annex to the Montreal Protocol.

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 Control Act	Not regulated.
Industrial Safety and Health Act	Not regulated.
Fire Service Act	Not regulated.

１６．Other Information

Issued date	GLI-01 :	Feb. 04, 2020
Revision date	GLI-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.