Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Pioglitazone Hydrochloride 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 an 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		
	Carcinogenicity	Category 1B
	Reproductive toxicity	Category 2
	Specific target organ toxicity - Repeated exposure	Category 2 (Heart)
Environmental hazards		
	Hazardous to the aquatic environment - Long-term (Chronic) hazard	Category 1

Label elements

Pictograms

Signal word: Danger

Hazard statement:
May cause cancer
Suspected of damaging fertility or the unborn child
May cause damage to organs (Heart) through prolonged or repeated exposure
Very toxic to aquatic life with long lasting effects

Precautionary statement:
【Prevention】
Obtain special instructions before use.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid release to the environment.
【Response】
If exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.
Collect spillage.
【Storage】
Store locked up.
【Disposal】
Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Pioglitazone hydrochloride.
Synonym / common name	—
CAS No.	112529-15-4

Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : －
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	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.
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.
		Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
		Wash hands thoroughly after handling.
		Do not eat, drink or smoke when using this product.
		Use only outdoors or in a well-ventilated area.
		Obtain special instructions before use.

		Do not handle until all safety precautions have been read and understood.
		Avoid contact during pregnancy and while nursing.
		Avoid release to the environment.
	Contact avoidance	See section 10 of the SDS.
Storage	Safe storage conditions	Keep container tightly closed.
		Store in a well-ventilated place. Keep it in a cool place.
	Safe packaging material	Store in an appropriate container according to applicable laws and regulations.

8. Exposure Controls/Personal Protection

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: Crystals or crystalline powder.
Colour		White.
Odour		No data available.
Melting point/Freezing point		193°C (with decomposition)
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(%)	50 g/m^3 (particle size < 75 μm; Hartmann-type dust explosion tube; JIS Z 8818)
	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	Practically insoluble.
	Other	Very slightly soluble in acetonitrile (0.84 mg/mL at 20°C); slightly soluble in dehydrated ethanol (8.1mg/mL at 20°C); soluble in methanol (79 mg/mL at 20°C); freely soluble in dimethyl sulfoxide (335 mg/mL at 20°C)
Partition coefficient n-octanol/water (log value)		Log Pow -0.4 (pH 1.0), 3.1 (pH 5.0), 3.3 (pH 7.0), 1.7 (pH 9.0)
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		
	Limiting Oxygen Concentration	14 vol% (particle size < 75 μm; Hartmann-type dust explosion tube)
	Minimum ignition energy	1.7 mJ (particle size < 75 μm; Hartmann-type dust explosion tube and a resistance probe with 100 k Ω in the electric discharge circuit)
	Volume resistivity	5.5×10^{12} Ω・m

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	Static discharge.
Incompatible materials	Strong oxidizing agent, strong acid or strong alkali.
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, mouse	> 2000 mg/kg
	Monkey	> 240 mg/kg

Skin corrosion / irritation	No data available.
Serious eye damage / eye irritation	No data available.
Respiratory sensitization	No data available.
Skin sensitization	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	IARC: Group 2A (Probably carcinogenic to humans) No increased incidence of tumour was observed in mice and female rats. Male rat specific tumours in the urinary bladder were seen.
Reproductive toxicity	Delayed parturition and embryotoxicity were observed in rats at 40 mg/kg/day and above. In rabbits, embryotoxicity was observed at an oral dose of 160 mg/kg. Delayed postnatal development was observed in offspring of rats at 10 mg/kg and above during late gestation and lactation periods. No adverse effects upon fertility were observed in rats at doses up to 40 mg/kg/day prior to and throughout mating and gestation.
Specific target organ toxicity - Single exposure	No adverse effects were observed at doses up to 2000 mg/kg in rat oral study.
Specific target organ toxicity - Repeated exposure	Hypertrophy of the heart and/or slight decreases in red blood cell parameters were reported at 3.6 mg/kg/day and above in rats and 3 mg/kg/day and above in dogs in a 52-week oral studies.
Aspiration hazard	No data available.

１２．Ecological Information

Ecotoxicity

Tests	Species	Results
Fish NOEC	Fathead minnow	58.53* µg/L (early life stage; OECD TG210), 28 days
Crustacea NOEC	*Daphnia magna*	75.3* µg/L, 21 days
Algae NOECr (EC_{10})	Green algae	189* µg/L (OECD TG201), 72 hours

(* concentration value as pioglitazone (free form))

Persistence and degradability	Not readily biodegradable with 10.6% of biodegradation after 28 days incubation (OECD TG 301B)
Bioaccumulative potential	Log Pow -0.4 (pH 1.0), 3.1 (pH 5.0), 3.3 (pH 7.0), 1.7 (pH 9.0)
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	UN 3077
Proper shipping name	Environmentally Hazardous Substance, Solid, N.O.S. (Pioglitazone hydrochloride)

Hazard class		9
Subsidiary hazard class		—
Packing group		Ⅲ
Domestic restriction	Rail and road	Not regulated.
	Marine	Comply with Ship Safety Act.
	Aviation	Comply with Civil Aeronautics Act.

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	PIO-01：	Apr. 13, 2020
Revision date	PIO-03：	Oct. 13, 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.