Safety Data Sheet

1. Identification

Product name		Japanese Pharmacopoeia Fenofibrate 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		
	Specific target organ toxicity - Repeated exposure	Category 2 (liver)
Environmental hazards		
	Hazardous to the aquatic environment - Long-term (Chronic) hazard	Category 4

Label elements

Pictograms

Signal word: Warning

Hazard statement:
May cause damage to organs (liver) through prolonged or repeated exposure
May cause long lasting harmful effects to aquatic life

Precautionary statement:
【Prevention】
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid release to the environment.
【Response】
Get medical advice/attention if you feel unwell.
【Disposal】
Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Fenofibrate.
Synonym / common name	－
CAS No.	49562-28-9
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : － ISHL : 7-(4)-955
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. 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		No set up.
Occupational Exposure Limits		Estimated Exposure Level TWA : 480 μg/m^3, 8 hours
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: Crystalline powder.
Colour		White.
Odour		No data available.
Melting point/Freezing point		80 to 83℃
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		540℃ (Godbert Greenwald)
Decomposition temperature		No data available.
pH		No data available.
Kinematic viscosity		No data available.
Solubility	Water	0.17 mg/L (20℃)
	Other	Soluble in organic solvents such as ethanol (1 mg/mL), DMF (30 mg/mL), DMSO (15 mg/mL). Soluble in acetone, ether, benzene, chloroform.
Partition coefficient n-octanol/water (log value)		Log Pow: 4.78
Vapor pressure		No data available.
Density and/or relative density		0.5 kg/L
Relative vapor density		No data available.
Particle characteristics		No data available.
Other information		
	Minimal energy of ignition	4.5 mJ < Median particle size 11.3 μm > 5.9 mJ
	Volume resistivity	1.2×10^{12} Ωm

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	Dust condition. Heat, Flame, spark.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Chlorydrate compounds. HCl.

１１．Toxicological Information

Acute toxicity

The maximum recommended human dose is 300 mg a day.
The lowest efficacious human clinical dose is 145 mg.
May be harmful by inhalation (after often repeated exposure).

Tests	Species	Results
Oral LD50	Rat	> 3200 mg/kg
		> 2000 mg/kg
	Mouse	1600 mg/kg
	Hamster	> 5000 mg/kg
	Dog	> 4000 mg/kg

Skin corrosion / irritation	No adverse effects are normally expected. In vitro study: no skin irritation.
Serious eye damage / eye irritation	In vitro study: no eye irritation. Mechanical irritation from the particulates generated by the product.
Respiratory sensitization	No data available.

Skin sensitization

Tests	Species	Results

0.4 g Sensitizing potential (modified Magnusson-Kligman method)	Guinea pig	No allergic (sensitizing) reaction.
Phototoxity study	—	Fenofibrate provoked neither phototoxicity nor photoallergenicity.
Persons sensitive to other benzophenones or fibrate agents		May also be sensitive to this material.

Germ cell mutagenicity

Tests	Results
Ames test	Negative.
Mouse lymphoma test	Negative.
Chromosomal aberration test	Negative.
unscheduled DNA synthesis test	Negative.

Carcinogenicity

Fenofibrate displays a tumorogenic tendency in rodents for 3 organ systems: the liver (nodules and hepatocellular carcinoma), the pancreas (acinar cell adenomas and adenocarcinomas) and the testis (interstitial Leydig cell tumors).
There is no evidence in man of any excess of hepatic tumors.
The carcinogenic effects observed in animals have not been demonstrated in humans.

Reproductive toxicity

Tests	Results
Studies in mice, rats and rabbits	Any teratogenic effect were not revealed.
High doses test in rats and rabbits.	Fenofibrate has been shown to be embryocidal.
Test in rats' female	Negative impact on fertility was noted.

Specific target organ toxicity - Single exposure: No data available.

Specific target organ toxicity - Repeated exposure: The STOT classification is based on liver effects that are observed in humans during use.

Tests	Results
Prolonged exposure test in rat's liver.	NOEL: 13 mg / kg.
Prolonged exposure test in dog	NOEL: 25 mg / kg.

Aspiration hazard: No data available.

Other information

Active pharmaceutical ingredient: Lipid-lowering drug.

Adverse effects: May include diarrhea, gas, nausea, vomiting, constipation, rash, itching, stuffy nose, muscle pain, chills and fever.
They were generally not severe and tended to resolve when treatment was stopped.

12. Ecological Information

Ecotoxicity

Substance lightly soluble in water, making irrelevant the acute toxicity studies.
No inhibitory effects observed in activated sludge (30 'and 3 hours).

Tests	Species	Results
Crustacea EC50	*Daphnia magna*	> 0.15 mg/L, 48 hours
Fish NOEC	*Brachydanio rerio*	0.047 mg/L, mortality, 30 days
Reproduction test in crustacea	*Daphnia magna*	EC50: > 0.12 mg/L, 21 days NOEC: 0.12 mg, 21 days
Algae EC50	*Selenastrum capricornutum*	> 0.102 mg/L, 72 hours

Persistence and degradability

Abiotic degradation: Aerobic degradation study concludes with a low risk of persistence in the environment.

Bioaccumulative potential

log Kow: Log Pow: 4.78 (20℃): potentially bioaccumulative.

BCF: Low to moderate potential to bioaccumulate.

Mobility in soil

	Distribution	Soil/ sediments: percolation non-significant Water/ soil: low solubility and mobility.
	Adsorption/Desorption	log KOC: 4.36
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	FEN-01 : 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.