


Safety Data Sheet

1. Identification

Product name	Japanese Pharmacopoeia Lanoconazole 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		
	Acute toxicity (Oral)	Category 4
	Skin corrosion / irritation	Category 3
	Serious eye damage / eye irritation	Category 2B
	Reproductive toxicity	Category 2
	Specific target organ toxicity - Repeated exposure	Category 1 (liver)
Environmental hazards		Not classified.
Label elements	Pictograms	
	Signal word	Danger.
	Hazard statement	Harmful if swallowed Causes mild skin irritation Causes eye irritation Suspected of damaging fertility or the unborn child Causes damage to organs (liver) through prolonged or repeated exposure
	Precautionary statement	<p>【Prevention】 Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust/fume/gas/mist/vapours/spray.</p> <p>【Response】 If swallowed: Call a doctor/physician if you feel unwell. Rinse mouth. If skin irritation occurs: Get medical advice/attention. 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. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.</p> <p>【Storage】 Store locked up.</p> <p>【Disposal】 Dispose of contents/container in accordance with local/regional/national/international regulations.</p>

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
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Chemical name	Lanoconazole.
Synonym / common name	—
CAS No.	101530-10-3
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : — ISHL : 8-(2)-1559
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victims to fresh air and keep comfortable for breathing. Get medical attention if irritation develops and persists.
Skin contact	If skin irritation occurs: Get medical advice/attention.
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	Call a doctor/physician if you feel unwell. Rinse mouth.
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 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. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.
	Contact avoidance	See section 10 of the SDS.

Storage	Safe storage conditions	Keep container tightly closed. Store locked up.
	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: Crystals or Crystalline powder.
Colour	White.
Odor	No data available.
Melting point/Freezing point	141 ~ 146°C
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	Practically insoluble.
Other	Slightly soluble in ethanol. Sparingly soluble in ethanol. Soluble in acetone.
Partition coefficient n-octanol/water (log value)	1.29 (pH 2.33), 3.08 (pH 4.03), 3.88 (pH 7.16)
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	No data available.

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	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	male: 993 mg/kg female 652 mg/kg
Dermal-LD50	Rat	male and female: > 5000 mg/kg
Inhalation-LC50	Rat	male and female: > 4.314 mg/L/4 h

Skin corrosion / irritation

Tests	Species	Results
Skin irritation test	Rabbit	Mild irritation. Irritation disappeared after 48 hours.

Serious eye damage / eye irritation

Tests	Species	Results
Eye irritation test	Rabbit	Mild irritation. Irritation disappeared after 96 hours.

Respiratory sensitization No data available.

Skin sensitization

Tests	Species	Results
Maximization test	Guinea pig	Negative.

Germ cell mutagenicity

Tests	Results
Bacterial in vitro reverse mutation test	Negative.
Mouse bone marrow in vivo micronucleus test	Negative.
Mammalian cultured cell in vitro chromosome aberration test	Negative.

Carcinogenicity No data available.

Reproductive toxicity It has been reported to lower blood testosterone levels in rats. It is considered to be based on the steroid synthesis inhibitory action generally recognized for imidazole compounds.

Tests	Species	Results
Administration test prior and in the early stages of pregnancy	Rat	Decreased mating rate at doses that do not show general toxicity.
Administration test during the period of organogenesis	Rat	The effects were observed on fetal intrauterine growth at doses not generally toxic to mother animals.

Specific target organ toxicity - Single exposure No data available.

Specific target organ toxicity - Repeated exposure

Tests	Species	Results
Dermal administration test, 4 weeks	Rat	At the highest dose (40 mg/kg/day) for females, pathological findings were observed in the liver, that were considered to be the effects of sample administration. In males, no effect from sample administration was observed at

Aspiration hazard No data available.

Other information No data available.

1 2 . Ecological Information

Ecotoxicity	No data available.
Persistence and degradability	No data available.
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.

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.
Deleterious Substances / Exception		【32-33. excluded from organic cyanide compounds / (E)-[(4RS)-4-(2-Chlorophenyl)-1,3-dithiolane-2-ylidene](1H-imidazole-1-yl)acetonitrile and preparations containing it】
Industrial Safety and Health Act		Not regulated.
Fire Service Act		Not regulated.

1 6 . Other Information

Issued date	LNC-01 :	Mar. 11, 2019
Revision date	LNC-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.