

Safety Data Sheet

1. Identification

Product name	Japanese Pharmacopoeia Azithromycin 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 Not classified.

Environmental hazards Hazardous to the aquatic environment - Short-term (Acute) hazard Category 1

Hazardous to the aquatic environment - Long-term (Chronic) hazard Category 1

Label elements

Pictograms



Signal word Warning.

Hazard statement Very toxic to aquatic life with long lasting effects

Precautionary statement **【Prevention】**

Avoid release to the environment.

【Response】

Collect spillage.

【Disposal】

Dispose of contents/container in accordance with local/regional/national/international regulations.

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Azithromycin dihydrate.
Synonym / common name	—
CAS No.	117772-70-0
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 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.
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. 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. Store in a place out of direct sunlight. Store in an appropriate container according to applicable laws and regulations.

8. Exposure Controls/Personal Protection

Occupational Exposure Limits	TWA-8 hours: 500 µg/m ³
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.
Odor	Odorless.
Melting point/Freezing point	110°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
	No data available.
	Other
	> 100 mg/mL: Ethanol. Isopropyl alcohol. Methanol. Acetonitrile. Acetone. Chloroform. Dimethylsulfoxide. Ethyl acetate. N,N-dimethylformamide.
Partition coefficient n-octanol/water (log value)	0.67 (pH 7)
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	
pKa	8.8
Dust Explosivity	Max. Explosion Pressure: 9.1 bar Max. Rate of Pressure rise: 962 bar/sec Kst Value: 281 bar m/s St Class: St 2 Min. Ignition Energy (mJ): 3 to 5 mJ Min. Ignition Temperature: 320°C Min. Explosion Concentration: 15 g/m ³ (anhydrous Azithromycin)
Electrostatic Risk	Charge Relaxation Time: 11.8 hours (Ambient Humidity), 110 hours (Low Humidity) Resistivity-Powder: 2.3e13 Ωm (Ambient), 4.0e14 Ωm (Low)

10 . Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Very high sensitivity to ignition, Strong dust explosion characteristic.
Conditions to avoid	Keep away from heat and other sources of ignition, including electrostatic discharge.
Incompatible materials	Strong oxidizing agents.
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	Mouse (female)	4000 mg/kg

Mouse (male)	3000 mg/kg
Rat	> 2000 mg/kg

Skin corrosion / irritation	No data available.
Serious eye damage / eye irritation	No data available.
Respiratory sensitization	No data available.
Skin sensitization	

Tests	Species	Results
Antigenicity - Active anaphylaxis test	Guinea pig	Negative
Antigenicity - Passive cutaneous anaphylaxis test	Rabbit	Negative
Antigenicity - Passive cutaneous anaphylaxis test	Mouse	Negative

Germ cell mutagenicity

Tests	Species	Results
Bacterial Mutagenicity (Ames) test	<i>Salmonella</i>	Negative
In vivo cytogenetics test	Mouse Lymphoma	Negative
In vitro cytogenetics test	Mouse	Negative
	Human Lymphocytes	Negative

Carcinogenicity	No data available.
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Reproductive toxicity

Tests	Species	Results
Reproductive & Fertility test (oral)	Rat	NOEL: 10 mg/kg/day Effect on fertility
Prenatal & Postnatal Development test (oral)	Rat	NOEL: 40 mg/kg/day Not teratogenic
Embryo / Fetal Developmen test (oral)	Mouse	NOAEL: 200 mg/kg/day Fetotoxicity, Maternal Toxicity
	Rat	NOAEL: 40 mg/kg/day Fetotoxicity, Maternal Toxicity
	Rabbit	LOAEL: 10 mg/kg/day Maternal Toxicity
		NOAEL: 40 mg/kg/day Fetotoxicity, Not Teratogenic

Specific target organ toxicity - Single exposure	No data available.
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Specific target organ toxicity - Repeated exposure	
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Tests	Species	Target organ	Results
1 Months oral administration test	Rat	Liver	LOAEL: 50 mg/kg/day
1 Months oral administration test	Dog	Liver	LOAEL: 25 mg/kg/day
6 Months oral administration test	Rat	Liver	LOAEL: 40 mg/kg/day
6 Months oral administration test	Dog	Liver	LOAEL: 10 mg/kg/day
1 Month intravenous administration test	Rat	Liver	NOAEL: 5 mg/kg/day
1 Month intravenous administration test	Dog	Liver	NOAEL: 5 mg/kg/day

Aspiration hazard	No data available.
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1 2 . Ecological Information
Ecotoxicity

Tests	Species	Results
Crustacea EC50	<i>Daphnia magna</i> (Water Flea)	120 mg/L, 48 hours
Crustacea LC50	<i>Hyalella azteca</i> (Freshwater Amphipod)	> 120 mg/L, 96 hours
Fish LC50	<i>Oncorhynchus mykiss</i> (Rainbow Trout)	> 84 mg/L, 96 hours
Algae EC50	Gleen Algae	0.0037 mg/L, 72 hours
Algae ErC50	<i>Microcystis aeruginosa</i> (Blue-green alga)	0.0018mg/L, 96 hours
Fungus MIC	<i>Aspergillus niger</i>	> 1000 mg/L
Fungus MIC	<i>Trichoderma viride</i>	> 1000 mg/L
Bacterium MIC	<i>Clostridium perfringens</i>	2.0 mg/L

Bacterium MIC	<i>Bacillus subtilis</i>	2.0 mg/L
Terrestrial NOEC	Earthworm	1000 mg/kg, 28 days
Fish NOEC	<i>Pimephales promelas</i> (Fathead Minnow)	4.6 mg/L, 32 days (Survival)
Crustacea NOEC	<i>Ceriodaphnia dubia</i>	0.0044 mg/L, 7 days (Reproduction)

Persistence and degradability	No data available.
Bioaccumulative potential	Partition coefficient n-octanol/water (log value): 0.67 (pH 7)
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	UN3077
Proper shipping name	Environmentally Hazardous Substance, Solid, N.O.S. (Azithromycin dihydrate)
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.

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	aAZM-01 :	Jun. 25, 2019
Revision date	aAZM-03 :	Jul. 01, 2023
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.