

SAFETY DATA SHEET

Revision Date 30-Mar-2024 Revision Number 3

1. Identification

Product Name Azithromycin dihydrate

Cat No. : J66740

CAS No 117772-70-0

Synonyms No information available

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Thermo Fisher Scientific Chemicals, Inc. 30 Bond Street Ward Hill, MA 01835-8099

Tel: 800-343-0660 Fax: 800-322-4757

Emergency Telephone Number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory Sensitization Category 1
Skin Sensitization Category 1

Label Elements

Signal Word

Danger

Hazard Statements

May cause an allergic skin reaction

May cause allergy or asthma symptoms or breathing difficulties if inhaled

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Precautionary Statements

Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves

Inhalation

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing

Skin

IF ON SKIN: Wash with plenty of soap and water

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

None identified

3. Composition/information on Ingredients

Component	CAS No	Weight %	
Azithromycin hydrate	117772-70-0	<=100	
Azithromycin	83905-01-5	0	

4. First-aid measures

General Advice If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Ingestion Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Most important symptoms and

effects

None reasonably foreseeable. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin reaction. Symptoms of allergic reaction may

include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Azithromycin dihydrate

Unsuitable Extinguishing Media No information available

Flash Point $> 110 \, ^{\circ}\text{C} \, / > 230 \, ^{\circ}\text{F}$

Method - No information available

Autoignition Temperature

No information available

Explosion Limits

Upper No data available
Lower No data available
Sensitivity to Mechanical Impact No information available

Sensitivity to Static Discharge No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NOx).

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health Flammability Instability Physical hazards
2 1 0 -

6. Accidental release measures

Personal Precautions Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust

formation.

Environmental Precautions Should not be released into the environment.

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed

p containers for disposal.

7. Handling and Storage

Handling Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid

ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

Storage. Keep refrigerated.

8. Exposure controls / personal protection

Exposure GuidelinesThis product does not contain any hazardous materials with occupational exposure

limitsestablished by the region specific regulatory bodies.

Engineering Measures None under normal use conditions.

Personal Protective Equipment

Eye/face Protection Wear appropriate protective eyeglasses or chemical safety goggles as described by

OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protectionWear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection No protective equipment is needed under normal use conditions.

Azithromycin dihydrate

Recommended Filter type: Particle filter.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State Solid Appearance White

Odor No information available Odor Threshold No information available

pH Not applicable Melting Point/Range 126 °C / 258.8 °F Boiling Point/Range 717 °C / 1322.6 °F Flash Point > 110 °C / > 230 °F

Evaporation Rate Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

Upper No data available
Lower No data available
Vapor Pressure No information available
Vapor Ponsitu

Vapor DensityNot applicableSpecific GravityNo information availableSolubilityNo information availablePartition coefficient; n-octanol/waterNo data available

Autoignition Temperature

No information available

No information available

No information available

Viscosity Not applicable

Molecular Formula C38 H72 N2 O12 .2H2 O

Molecular Weight 785.01

10. STABILITY AND REACTIVITY

Reactive Hazard None known, based on information available

Stability Air sensitive.

Conditions to Avoid Incompatible products.

Incompatible Materials Strong oxidizing agents

Hazardous Decomposition Products Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NOx)

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous ReactionsNone under normal processing.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation	
Azithromycin	LD50 > 2 g/kg (Rat)	Not listed	Not listed	

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Azithromycin dihydrate

Sensitization May cause sensitization by skin contact

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

IARC Component **CAS No** NTP **ACGIH OSHA** Mexico Azithromycin hydrate 117772-70-0 Not listed Not listed Not listed Not listed Not listed 83905-01-5 Not listed Not listed Not listed Azithromycin Not listed Not listed

Mutagenic Effects No information available

Reproductive Effects No information available.

Developmental EffectsNo information available.

Teratogenicity No information available.

STOT - single exposureSTOT - repeated exposure
None known
None known

Aspiration hazard No information available

Symptoms / effects,both acute and

delayed

Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing

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Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Do not empty into drains.

Persistence and Degradability No information available

Bioaccumulation/ Accumulation No information available.

Mobility No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

	14. TRANSPORT INFORMATION
DOT	Not regulated
TDG_	Not regulated
DOT TDG IATA	Not regulated
IMDG/IMO	Not regulated

15. Regulatory Information

United States of America Inventory

	Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags	
Ι	Azithromycin hydrate	117772-70-0	=	-	-	
Γ	Azithromycin	83905-01-5	=	=	-	

Leaend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

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X - Listed '-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT) Not applicable

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

X = listed, U.S.A. (TSCA), Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Australia (AICS), Korea (KECL), China (IECSC), Japan (ENCS), Philippines (PICCS), Taiwan (TCSI), Japan (ISHL), New Zealand (NZIoC), Japan (ISHL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Azithromycin hydrate	117772-70-0	-	-	-	-	-		-	-	-
Azithromycin	83905-01-5	-	-	-	-	-		-	-	-

KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Health Administration

Not applicable

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know

Regulations

Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): Ν **DOT Marine Pollutant** Ν **DOT Severe Marine Pollutant** Ν

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Azithromycin hydrate	117772-70-0	-	-	-
Azithromycin	83905-01-5	-	Use restricted. See entry 75.	-
			(see link for restriction details)	

REACH links

https://echa.europa.eu/substances-restricted-under-reach

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous
			Tonatant	1 otomai	Substances (RoHS)
Azithromycin hydrate	117772-70-0	Not applicable	Not applicable	Not applicable	Not applicable
Azithromycin	83905-01-5	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
Azithromycin hydrate	117772-70-0	Not applicable	Not applicable	Not applicable	Not applicable
Azithromycin	83905-01-5	Not applicable	Not applicable	Not applicable	Not applicable

16. Other Information

Prepared By Health, Safety and Environmental Department

Email: chem.techinfo@thermofisher.com

www.thermofisher.com

 Revision Date
 30-Mar-2024

 Print Date
 30-Mar-2024

Revision Summary New emergency telephone response service provider.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of SDS