

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)
according to Regulation (EU) No. 2020/878



Trade name : 101421 - Azithromycin dihydrate, Ph. Eur.
Revision date : 04/11/2022 **Version (Revision) :** 2.0.0 (1.0.0)
Print date : 08/05/2023

SECTION 1: Identification of the substance/mixture and of the company/ undertaking

1.1 Product identifier

Azithromycin dihydrate, Ph. Eur. (101421)
Azithromycin dihydrate ; CAS No. : 117772-70-0 ; REACH No. : N/D

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

For manufacturing, processing, laboratory or repacking use only.

Uses advised against

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor)

DC Fine Chemicals Ltd

Street : 88 Hill Top

Postal code/City : NW11 6DY London United Kingdom

Telephone : +44 (0)20 7586 6800

Telefax : +44 (0)20 7504 1701

Information contact : info@dcfinechemicals.com

1.4 Emergency telephone number

(Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Resp. Sens. 1 ; H334 - Sensitisation to the respiratory tract : Category 1 ; May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 ; H317 - Skin sensitisation : Category 1 ; May cause an allergic skin reaction.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms



Health hazard (GHS08)

Signal word

DANGER

Hazard statements

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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H317 May cause an allergic skin reaction.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

2.3 Other hazards

This substance/mixture contains no components considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name : Azithromycin dihydrate

REACH No. : N/D

CAS No. : 117772-70-0

Purity : 100 % [mass]

SECTION 4: First aid measures

4.1 Description of first aid measures

Remove contaminated, saturated clothing immediately. After contact with skin, wash immediately with plenty of water and soap. In case of skin reactions, consult a physician. After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately. If accidentally ingested, seek immediate medical attention, NEVER induce vomiting. Remove victim out of the danger area. In case of inhalation take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

4.2 Most important symptoms and effects, both acute and delayed

Accidental contact may result in serious respiratory difficulties, alteration of the central nervous system and in extreme cases, unconsciousness.

4.3 Indication of any immediate medical attention and special treatment needed

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: Firefighting measures

The product does not present any particular risk in case of fire.

5.1 Extinguishing media

Suitable extinguishing media

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

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5.2 Special hazards arising from the substance or mixture

In case of fire may be liberated: Pyrolysis products, toxic

5.3 Advice for firefighters

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Special protective equipment for firefighters

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Clear spills immediately.

For non-emergency personnel

Wear a self-contained breathing apparatus and chemical protective clothing. Remove persons to safety.

For emergency responders

Eliminate possible ignition points and ventilate the area. No smoking. Avoid breathing fumes. For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions

Do not allow to enter into surface water or drains. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities. Retain contaminated washing water and dispose it.

6.3 Methods and material for containment and cleaning up

For containment

Collect in closed and suitable containers for disposal.

For cleaning up

The contaminated area should be cleaned up immediately with: Water Soak up inert absorbent and dispose as waste requiring special attention. Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Avoid dust formation.

6.4 Reference to other sections

Reference to other sections Disposal: see section 13 Personal protection equipment: see section 8

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures



When using do not eat, drink, smoke, sniff. Wear personal protection equipment (refer to section 8).

Measures to prevent aerosol and dust generation

Use only in well-ventilated areas. Do not breathe gas/fumes/vapour/spray. Do not breathe dust.

Environmental precautions

Use appropriate container to avoid environmental contamination.

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Specific requirements or handling rules

Handle and open container with care.

Advices on general occupational hygiene

Handle and open container with care.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Storage temperature : +2 - +8°C

Keep in a cool, well-ventilated place. Protect against UV-radiation/sunlight Humidity.

Requirements for storage rooms and vessels

Only use containers specifically approved for the substance/product.

Hints on joint storage

Store at least 3 metres apart from: Chemicals/products that react together readily

Storage class (TRGS 510) : 13

7.3 Specific end use(s)

None

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Only wear fitting, comfortable and clean protective clothing.

Personal protection equipment

Eye/face protection



Eye glasses with side protection Face protection shield EN 166

Skin protection

Hand protection



Tested protective gloves must be worn EN ISO 374
chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

The quality of the protective gloves resistant to

Body protection



Full protection suit Wash contaminated clothing prior to re-use.

Respiratory protection

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If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.



The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Particle filter device (EN 143).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Safety characteristics

Melting point/freezing point : (1013 hPa) No data available

Initial boiling point and boiling range : (1013 hPa) No data available

Decomposition temperature : (1013 hPa) No data available

Flash point : No data available

Auto-ignition temperature : No data available

Lower explosion limit : No data available

Upper explosion limit : No data available

Vapour pressure : (50 °C) No data available

Density : (20 °C) No data available

Solvent separation test : (20 °C) not applicable

Water solubility : (20 °C) No data available

Fat solubility : (20 °C) No data available.

pH : No data available

log P O/W : No data available

Flow time : (20 °C) No data available

DIN-
cup 4
mm

Viscosity : (20 °C) No data available

Relative vapour density : (20 °C) No data available

Evaporation rate : No data available

Flammable solids : No data available.

Flammable gases : No data available.

Explosive properties : No data available.

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

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The product does not present hazards by their reactivity.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature. Safe handling: see section 7

10.3 Possibility of hazardous reactions

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid

Avoid any improper handling.

10.5 Incompatible materials

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products

In case of fire may be liberated: Hazardous combustion products

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

No information available.

Corrosion

Skin corrosion/irritation

No information available.

Serious eye damage/eye irritation

No information available.

Respiratory or skin sensitisation

No information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

No information available.

Germ cell mutagenicity

No information available.

Reproductive toxicity

No information available.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Aspiration hazard

No information available.

11.2 Information on other hazards

No information available.

SECTION 12: Ecological information

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12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

12.6 Endocrine disrupting properties

No information available.

12.7 Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation. Follow the provisions of Directive 2008/98/EC regarding waste management.

Product/Packaging disposal

Waste treatment options

Recycle according to official regulations. Evidence for disposal must be provided.

Appropriate disposal / Product

Dispose of waste according to applicable legislation.

Appropriate disposal / Package

Contaminated packages must be completely emptied and can be re-used following proper cleaning. Packing which cannot be properly cleaned must be disposed of. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 UN number

No information available.

14.2 UN proper shipping name

No information available.

14.3 Transport hazard class(es)

No information available.

14.4 Packing group

No information available.

14.5 Environmental hazards

No information available.

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14.6 Special precautions for user

None

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

No information available.

SECTION 15: Regulatory information

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

Safety Data Sheet According to Regulation (EC) No. 1907/2006 (REACH) Classification according to Regulation (EC) No 1272/2008 [CLP] according to Regulation (EU) No. 2020/878

EU legislation

Authorisations and/or restrictions on use

Restrictions on use

Regulation (EC) No. 1907/2006 (REACH), Annex XVII (restrictions)

Use restriction according to REACH annex XVII, no. : 3

National regulations

Water hazard class

Class : nwg (Non-hazardous to water)

15.2 Chemical Safety Assessment

No information available.

SECTION 16: Other information

16.1 Indication of changes

None

16.2 Abbreviations and acronyms

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM:	ASTM International, originally known as American Society for Testing and Materials (ASTM)
EINECS:	European Inventory of Existing Commercial Chemical Substances
EC50:	Effective Concentration 50 (Maximum Effective Concentration for 0% of Individuals)
LC50:	Lethal Concentration 50 (Lethal Concentration for 50% of Individuals)
IC50:	Inhibitor Concentration 50 (Inhibitory Concentration for 50% of Individuals)
NOEL:	No Observed Effect Level (Maximum dose without effect)
DNEL:	Derived No Effect Level (Derived no-effect dose)
DMEL:	Derived Minimum Effect Level (Derived dose of minimal effect)
CLP:	Classification, Labelling and Packaging
CSR:	Chemical Safety Report
LD50:	Lethal Dose 50 (Lethal Dose for 50% of Individuals)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
Codice IMDG:	International Maritime Dangerous Goods code
PBT:	Persistent, bioaccumulative and toxic
RID:	Regulations concerning the international rail transport of Dangerous Goods
STEL:	Short term exposure limit

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TLV:	Threshold limit value
TWA:	Time Weighted Average
UE:	European Union
vPvB:	Very persistent very bioaccumulative
N.D.:	Unavailable
N.A.:	Not applicable
VwVwS.:	Text of Administrative Regulation on the Classification of Substances hazardous to waters into Water Hazard Classes

16.3 Key literature references and sources for data

None

16.4 Relevant H- and EUH-phrases (Number and full text)

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

16.5 Training advice

None

16.6 Additional information

None

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.
