



## Azithromycin

### Neo Biotech

Part Number: NB-42-00091

Version No: 2.2

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Chemwatch Hazard Alert Code: 2

Issue Date: 28/07/2023

Print Date: 28/07/2023

S.REACH.GBR.EN

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

### 1.1. Product Identifier

Product name	Azithromycin
Chemical Name	azithromycin
Synonyms	Not Available
Chemical formula	C38-H72-N2-O12
Other means of identification	Not Available
CAS number	83905-01-5*

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

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

### 1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Neo Biotech
Address	74 rue des Suisses 92000 Nanterre France
Telephone	+33977400909
Fax	+33 9 77 40 10 11
Website	<a href="https://www.neo-biotech.com">https://www.neo-biotech.com</a>
Email	<a href="mailto:info@neo-biotech.com">info@neo-biotech.com</a>

### 1.4. Emergency telephone number


Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

## SECTION 2 Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	H317 - Sensitisation (Skin) Category 1B, H334 - Sensitisation (Respiratory) Category 1B
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

## 2.2. Label elements

Hazard pictogram(s)	
Signal word	<b>Danger</b>

### Hazard statement(s)

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

### Supplementary statement(s)

Not Applicable

### Precautionary statement(s) Prevention

<b>P261</b>	Avoid breathing dust/fumes.
<b>P280</b>	Wear protective gloves and protective clothing.
<b>P284</b>	[In case of inadequate ventilation] wear respiratory protection.
<b>P272</b>	Contaminated work clothing should not be allowed out of the workplace.

### Precautionary statement(s) Response

<b>P304+P340</b>	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
<b>P342+P311</b>	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
<b>P302+P352</b>	IF ON SKIN: Wash with plenty of water.
<b>P333+P313</b>	If skin irritation or rash occurs: Get medical advice/attention.
<b>P362+P364</b>	Take off contaminated clothing and wash it before reuse.

### Precautionary statement(s) Storage

Not Applicable

### Precautionary statement(s) Disposal

<b>P501</b>	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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## 2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

## SECTION 3 Composition / information on ingredients

### 3.1. Substances

1. CAS No 2. EC No 3. Index No 4. REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 83905-01-5 2. Not Available 3. Not Available 4. Not Available	100	<u>Azithromycin</u>	Sensitisation (Skin) Category 1B, Sensitisation (Respiratory) Category 1B; H317, H334 <sup>[1]</sup>	0	Not Available

**Legend:** 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; \* EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

### 3.2. Mixtures

See 'Information on ingredients' in section 3.1

## SECTION 4 First aid measures

#### 4.1. Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▸ Wash out immediately with water.</li> <li>▸ If irritation continues, seek medical attention.</li> <li>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▸ Immediately remove all contaminated clothing, including footwear.</li> <li>▸ Flush skin and hair with running water (and soap if available).</li> <li>▸ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▸ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▸ Immediately give a glass of water.</li> <li>▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.</li> </ul>

#### 4.2 Most important symptoms and effects, both acute and delayed

See Section 11

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5 Firefighting measures

#### 5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

#### 5.2. Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	None known.
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#### 5.3. Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▸ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▸ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▸ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▸ Use fire fighting procedures suitable for surrounding area.</li> <li>▸ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▸ Cool fire exposed containers with water spray from a protected location.</li> <li>▸ If safe to do so, remove containers from path of fire.</li> <li>▸ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▸ Non combustible.</li> <li>▸ Not considered a significant fire risk, however containers may burn.</li> </ul> <p>May emit poisonous fumes. May emit corrosive fumes.</p>

### SECTION 6 Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

See section 8

#### 6.2. Environmental precautions

See section 12

#### 6.3. Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▸ Clean up all spills immediately.</li> <li>▸ Avoid breathing dust and contact with skin and eyes.</li> <li>▸ Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>▸ Use dry clean up procedures and avoid generating dust.</li> <li>▸ Sweep up, shovel up or</li> <li>▸ Vacuum up (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>▸ Place spilled material in clean, dry, sealable, labelled container.</li> </ul>
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<b>Major Spills</b>	<p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ <b>CAUTION:</b> Advise personnel in area.</li> <li>▶ Alert Emergency Services and tell them location and nature of hazard.</li> <li>▶ Control personal contact by wearing protective clothing.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Recover product wherever possible.</li> <li>▶ <b>IF DRY:</b> Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. <b>IF WET:</b> Vacuum/shovel up and place in labelled containers for disposal.</li> <li>▶ <b>ALWAYS:</b> Wash area down with large amounts of water and prevent runoff into drains.</li> <li>▶ If contamination of drains or waterways occurs, advise Emergency Services.</li> </ul>
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#### 6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

### SECTION 7 Handling and storage

#### 7.1. Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Fire and explosion protection</b>	See section 5
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry area protected from environmental extremes.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul> <p>For major quantities:</p> <ul style="list-style-type: none"> <li>▶ Consider storage in bunded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).</li> <li>▶ Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul>

#### 7.2. Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	None known
<b>Hazard categories in accordance with Regulation (EC) No 1272/2008</b>	Not Available
<b>Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of</b>	Not Available

#### 7.3. Specific end use(s)

See section 1.2

## SECTION 8 Exposure controls / personal protection

### 8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

\* Values for General Population

#### Occupational Exposure Limits (OEL)

##### INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

Not Applicable

#### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Azithromycin	Not Available	Not Available	Not Available


Ingredient	Original IDLH	Revised IDLH
Azithromycin	Not Available	Not Available

#### Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
Azithromycin	E	≤ 0.01 mg/m <sup>3</sup>
<b>Notes:</b>	<i>Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.</i>	

### 8.2. Exposure controls

8.2.1. Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.</p> <p>An approved self contained breathing apparatus (SCBA) may be required in some situations.</p> <p>Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p>					
	Type of Contaminant:	Air Speed:				
	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min.)				
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)				
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)				
	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)				
<p>Within each range the appropriate value depends on:</p> <table border="1"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> </tbody> </table>			Lower end of the range	Upper end of the range	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
Lower end of the range	Upper end of the range					
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents					

	<p>2: Contaminants of low toxicity or of nuisance value only.</p> <p>3: Intermittent, low production.</p> <p>4: Large hood or large air mass in motion</p>	<p>2: Contaminants of high toxicity</p> <p>3: High production, heavy use</p> <p>4: Small hood-local control only</p> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>
<p><b>8.2.2. Individual protection measures, such as personal protective equipment</b></p>		
<p><b>Eye and face protection</b></p>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].</li> </ul>	
<p><b>Skin protection</b></p>	<p>See Hand protection below</p>	
<p><b>Hands/feet protection</b></p>	<p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.</li> <li>▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.</li> </ul> <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none"> <li>· frequency and duration of contact,</li> <li>· chemical resistance of glove material,</li> <li>· glove thickness and</li> <li>· dexterity</li> </ul> <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none"> <li>· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.</li> <li>· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.</li> <li>· Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.</li> <li>· Contaminated gloves should be replaced.</li> </ul> <p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> <li>· Excellent when breakthrough time &gt; 480 min</li> <li>· Good when breakthrough time &gt; 20 min</li> <li>· Fair when breakthrough time &lt; 20 min</li> <li>· Poor when glove material degrades</li> </ul> <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> <li>· Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.</li> <li>· Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential</li> </ul> <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> <li>▶ polychloroprene.</li> </ul>	

	<ul style="list-style-type: none"> <li>▸ nitrile rubber.</li> <li>▸ butyl rubber.</li> <li>▸ fluoroacoutchouc.</li> <li>▸ polyvinyl chloride.</li> </ul> <p>Gloves should be examined for wear and/ or degradation constantly.</p>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▸ Overalls.</li> <li>▸ P.V.C apron.</li> <li>▸ Barrier cream.</li> <li>▸ Skin cleansing cream.</li> <li>▸ Eye wash unit.</li> </ul>

## Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

### 8.2.3. Environmental exposure controls

See section 12

## SECTION 9 Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance	White		
<b>Physical state</b>	Divided Solid	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Available	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Available
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available

Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

## 9.2. Other information

Not Available

## SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

## SECTION 11 Toxicological information

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

Inhaled	<p>The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.</p> <p>Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p>
Ingestion	<p>The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.</p>
Skin Contact	<p>The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	<p>Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.</p>
Chronic	<p>Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.</p>

**Legend:** 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances



<b>Azithromycin</b>	<p>Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.</p> <p>Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p>
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<b>Acute Toxicity</b>	✘	<b>Carcinogenicity</b>	✘
<b>Skin Irritation/Corrosion</b>	✘	<b>Reproductivity</b>	✘
<b>Serious Eye Damage/Irritation</b>	✘	<b>STOT - Single Exposure</b>	✘
<b>Respiratory or Skin sensitisation</b>	✔	<b>STOT - Repeated Exposure</b>	✘
<b>Mutagenicity</b>	✘	<b>Aspiration Hazard</b>	✘

**Legend:** ✘ – Data either not available or does not fill the criteria for classification  
 ✔ – Data available to make classification

## 11.2 Information on other hazards

### 11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

### 11.2.2. Other information

See Section 11.1

## SECTION 12 Ecological information

### 12.1. Toxicity

<b>Legend:</b>	<p>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data</p>
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**DO NOT** discharge into sewer or waterways.

### 12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

### 12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

### 12.4. Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

### 12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✘	✘	✘

	<b>P</b>	<b>B</b>	<b>T</b>
vPvB	<b>X</b>	<b>X</b>	<b>X</b>
PBT Criteria fulfilled?			No
vPvB			No

### 12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

### 12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

## SECTION 13 Disposal considerations

### 13.1. Waste treatment methods

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▸ Containers may still present a chemical hazard/ danger when empty.</li> <li>▸ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▸ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> </ul> <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▸ Reduction</li> <li>▸ Reuse</li> <li>▸ Recycling</li> <li>▸ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. In most instances the supplier of the material should be consulted.</p> <ul style="list-style-type: none"> <li>▸ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▸ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▸ Where in doubt contact the responsible authority.</li> <li>▸ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▸ Consult State Land Waste Management Authority for disposal.</li> <li>▸ Bury residue in an authorised landfill.</li> <li>▸ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
<b>Waste treatment options</b>	Not Available
<b>Sewage disposal options</b>	Not Available

## SECTION 14 Transport information

### Labels Required

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

### Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. <b>UN number or ID number</b>	Not Applicable				
14.2. <b>UN proper shipping name</b>	Not Applicable				
14.3. <b>Transport hazard class(es)</b>	<table border="1"> <tbody> <tr> <td>Class</td> <td>Not Applicable</td> </tr> <tr> <td>Subsidiary risk</td> <td>Not Applicable</td> </tr> </tbody> </table>	Class	Not Applicable	Subsidiary risk	Not Applicable
Class	Not Applicable				
Subsidiary risk	Not Applicable				
14.4. <b>Packing group</b>	Not Applicable				
14.5. <b>Environmental hazard</b>	Not Applicable				

**Azithromycin**

<b>14.6. Special precautions for user</b>	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable
	Hazard Label	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Tunnel Restriction Code	Not Applicable

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

<b>14.1. UN number</b>	Not Applicable	
<b>14.2. UN proper shipping name</b>	Not Applicable	
<b>14.3. Transport hazard class(es)</b>	ICAO/IATA Class	Not Applicable
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	Not Applicable
<b>14.4. Packing group</b>	Not Applicable	
<b>14.5. Environmental hazard</b>	Not Applicable	
<b>14.6. Special precautions for user</b>	Special provisions	Not Applicable
	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

<b>14.1. UN number</b>	Not Applicable	
<b>14.2. UN proper shipping name</b>	Not Applicable	
<b>14.3. Transport hazard class(es)</b>	IMDG Class	Not Applicable
	IMDG Subrisk	Not Applicable
<b>14.4. Packing group</b>	Not Applicable	
<b>14.5. Environmental hazard</b>	Not Applicable	
<b>14.6. Special precautions for user</b>	EMS Number	Not Applicable
	Special provisions	Not Applicable
	Limited Quantities	Not Applicable

**Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

<b>14.1. UN number</b>	Not Applicable	
<b>14.2. UN proper shipping name</b>	Not Applicable	
<b>14.3. Transport hazard class(es)</b>	Not Applicable	Not Applicable
<b>14.4. Packing group</b>	Not Applicable	
<b>14.5. Environmental hazard</b>	Not Applicable	
<b>14.6. Special precautions for user</b>	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable

Equipment required	Not Applicable
Fire cones number	Not Applicable

#### 14.7. Maritime transport in bulk according to IMO instruments

##### 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

##### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
Azithromycin	Not Available

##### 14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
Azithromycin	Not Available

### SECTION 15 Regulatory information

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

Azithromycin is found on the following regulatory lists

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

#### Information according to 2012/18/EU (Seveso III):

Seveso Category	Status
	Not Available

#### 15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

#### ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
Azithromycin	83905-01-5	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Sens. 1; Resp. Sens. 1	GHS08; Dgr	H317; H334
2	Skin Sens. 1; Resp. Sens. 1; STOT RE 1; Aquatic Acute 1; Aquatic Chronic 1; Skin Irrit. 2; Eye Irrit. 2; STOT SE 3	GHS08; Dgr; GHS09	H317; H334; H372; H400; H410; H315; H319; H335; H302

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

#### National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (Azithromycin)
Canada - DSL	No (Azithromycin)
Canada - NDSL	No (Azithromycin)
China - IECSC	No (Azithromycin)
Europe - EINEC / ELINCS / NLP	No (Azithromycin)
Japan - ENCS	No (Azithromycin)
Korea - KECI	No (Azithromycin)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (Azithromycin)
USA - TSCA	No (Azithromycin)

National Inventory	Status
Taiwan - TCSI	Yes
Mexico - INSQ	No (Azithromycin)
Vietnam - NCI	Yes
Russia - FBEPH	No (Azithromycin)
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

## SECTION 16 Other information

<b>Revision Date</b>	28/07/2023
<b>Initial Date</b>	16/09/2022

### Full text Risk and Hazard codes

<b>H302</b>	Harmful if swallowed.
<b>H315</b>	Causes skin irritation.
<b>H319</b>	Causes serious eye irritation.
<b>H335</b>	May cause respiratory irritation.
<b>H372</b>	Causes damage to organs through prolonged or repeated exposure.
<b>H400</b>	Very toxic to aquatic life.
<b>H410</b>	Very toxic to aquatic life with long lasting effects.

### SDS Version Summary

Version	Date of Update	Sections Updated
1.2	28/07/2023	Toxicological information - Acute Health (skin), CAS Number, Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Exposure controls / personal protection - Engineering Control, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (fire/explosion hazard), First Aid measures - First Aid (skin), Handling and storage - Handling Procedure, Composition / information on ingredients - Ingredients, Stability and reactivity - Instability Condition, Exposure controls / personal protection - Personal Protection (other), Exposure controls / personal protection - Personal Protection (eye), Exposure controls / personal protection - Personal Protection (hands/feet), Accidental release measures - Spills (major), Accidental release measures - Spills (minor), Handling and storage - Storage (storage incompatibility), Handling and storage - Storage (suitable container), Identification of the substance / mixture and of the company / undertaking - Use

### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

### Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average PC
- STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard

OSF: Odour Safety Factor  
NOAEL :No Observed Adverse Effect Level  
LOAEL: Lowest Observed Adverse Effect Level  
TLV: Threshold Limit Value  
LOD: Limit Of Detection  
OTV: Odour Threshold Value  
BCF: BioConcentration Factors  
BEI: Biological Exposure Index  
AIIIC: Australian Inventory of Industrial Chemicals  
DSL: Domestic Substances List  
NDSL: Non-Domestic Substances List  
IECSC: Inventory of Existing Chemical Substance in China  
EINECS: European INventory of Existing Commercial chemical Substances  
ELINCS: European List of Notified Chemical Substances  
NLP: No-Longer Polymers  
ENCS: Existing and New Chemical Substances Inventory  
KECI: Korea Existing Chemicals Inventory  
NZIoC: New Zealand Inventory of Chemicals  
PICCS: Philippine Inventory of Chemicals and Chemical Substances  
TSCA: Toxic Substances Control Act  
TCSI: Taiwan Chemical Substance Inventory  
INSQ: Inventario Nacional de Sustancias Químicas  
NCI: National Chemical Inventory  
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

**Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]**

<b>Classification according to regulation (EC) No 1272/2008 [CLP] and amendments</b>	<b>Classification Procedure</b>
Sensitisation (Skin) Category 1B, H317	Expert judgement
Sensitisation (Respiratory) Category 1B, H334	Expert judgement

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