



ANUH PHARMA LTD.

3-A, Shivsagar Estate, North Wing,
Dr. Annie Besant Road, Worli, **MUMBAI** - 400 018. **INDIA**
Tel. : 91-22-6622 7575 • Fax : 91-22-6622 7600 / 7500
E-Mail : anuh@sk1932.com • CIN: L24230MH1960PLC011586

MATERIAL SAFETY DATA SHEET AZITHROMYCIN IP/BP/EP/USP

Section 1: Chemical Product And Company Identification

1.1 Product Identifiers

Product Name : Azithromycin IP/BP/EP/USP

REACH Registration Number: A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

1.2.1 Relevant identified uses : Antibacterial

1.3 Details of the supplier of the safety data sheet

Company Identification: Anuh Pharma Ltd.

Head Office:
M/S Anuh Pharma Ltd
A-3 Shivsagar Estate, North wing,
Dr. Annie Besant Road, Worli
Mumbai 400018
State: Maharashtra
Country: - India

Tel. No: (91-22-) 66227575
66227600/ 66227500 (Fax)
E-mail: anuh@sk1932.com

Timing: 10.30 am to 5.00pm
(Indian Standard Time)

Factory:
M/S Anuh Pharma Ltd
E-17/3, E17/4 & E-18 M.I.D.C. Tarapur
Boisar, - 401506
State: Maharashtra
Country: - India

Tel. No: 7410055574 / 75

Timing: 10.30 am to 5.00pm
(Indian Standard Time)

1.4. Emergency Telephone number: Tel. No: (91-22-) 66227575



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MATERIAL SAFETY DATA SHEET AZITHROMYCIN IP/BP/EP/USP Section 2 : Hazards Identification:

2.1 Classification of the substance or mixture CLP Classification-Regulation (EC) No. 1272/2008[EU-GHS/CLP]

Respiratory Sensitization, (Category 1), H334

Skin Sensitization, (Category 1), H317

2.2 Label elements Labeling according to Regulation (EC) No.1272/2008

Pictogram:



Signal word : Danger

Hazard Statement(s)

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

Precautionary Statement(s)

P261 : Avoid breathing dust / fume / gas /mist/vapors/spray.
P280 : Wear protective gloves
P342 +P311 : If experiencing respiratory symptoms ; Call a POISON CENTER / Doctor.

Supplemental Hazard Statement (S) : None

2.3 Other Hazards: None



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Section 3: Composition / Information On Ingredients:

3.1 Substances

CAS-No : 83905-01-5
Molecular Formula : $C_{38}H_{72}N_2O_{12}$

3.2 Nomenclature:

1-Oxa-6-azacyclopentadecan-15-one, 13-((2'-6-dideoxy-3-c-methyl-3-O-methyl-alpha-L-ribo-hexopyranosyl)oxy)-2-ethyl-3,4,10-trihydroxy-

Section 4: First Aid Measures

4.1 Description of First Aid Measures:

In case of Eyes Contact: Immediately flush eyes with plenty of water for at least 15 minutes occasionally lifting the upper and lower lids. Get medical aid..

In case of Skin Contact: Flush skin with plenty of soap and water Immediately flush eyes with plenty of water. Get medical aid.

In case of Ingestion: Flush mouth with water and get medical attention.

In case of Inhalation: Remove from exposure to fresh air immediately. If not breathing gives artificial respiration. Get medical aid immediately.

4.2 Most Important symptoms and effects, both acute and delayed

The known symptoms and effects are described in section 2.2.

4.3 Indication of immediate medical attention and special treatment needed

No data Available



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5.1 Extinguishing media

Suitable Extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: No data available

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides(Nox).

5.3 Special Protective Equipment and precautions for fire fighting.

Wear self contained breathing apparatus for fire fighting if necessary

Section 6: Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency procedures:

Use personnel protective equipment. Avoid dust formation. Avoid breathing vapors, Mist or gas. Ensure adequate ventilation. Evacuate personnel to safe area. Avoid breathing dust. For personnel protection see section 8.

6.2 Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and material for containment and cleaning up:

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections:

For disposal see section 13.

Section 7: Handling And Storage

7.1 Precautions to be taken in Handling:

Avoid formation of dust. Avoid exposure-obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2



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7.2 Precautions to be taken in Storing:

Store in an air tight container, protected from light at a temperature not exceeding 30°C.

7.3 Specific end uses

No data available

Section 8: Exposure Controls, Personal Protection

8.1 Control Parameters:

Components with work place control parameters.

8.2 Exposure Controls:

Appropriate Engineering Controls: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personnel Protective Equipment's:

Eye / Face protection: Tightly fitting safety goggle ; face shield (8 inch minimum).Use equipment for eye protection tested and approved under appropriate government standard such as NIOSH (US).

Skin Protection: Handle with gloves .Gloves must be inspected prior to use .Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product .Dispose contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands .The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection: Complete suit protecting against chemicals. The type of protective equipment's must be selected according to the concentration and amount of the dangerous substance at the specific work place.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is



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the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Environment exposure controls: Do not empty into drains.

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance	A white or almost crystalline powder.
Odor	No data available
Threshold	No data available
pH (0.5% W/V in water)	10.1
Melting/freezing point	No Data Available
Initial boiling point and boiling range	No data available
Flash point	No data available
Flammability (Solid, gas)	No data available
Vapor pressure	No data available
Relative density	No data available
Water Solubility	Practically insoluble in water, freely soluble in Ethanol and Methylene chloride.
Partition coefficient: n-octanol/water	No data available
Auto ignition Temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available



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Vapor density

No data available

Thermal decomposition

No data available

9.2 Other safety information

Soluble in other solvents

No data available

Section 10: Stability And Reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable Under recommended Storage Conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strongly Oxidizing agents.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions - Carbon Oxides,
Nitrogen Oxides (NO_x).

Other decomposition products – No data Available

In the Event of Fire : See Section 5



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11.1 Information on toxicological effects

Acute toxicity : LD50 Oral – Mouse - >2,000 mg/ kg

Skin corrosion / irritation: No data available

Serious eye damage: No data Available

Respiratory or skin sensitization : No data Available

Germ cell mutagenicity : No Data Available

Carcinogenicity : IARC : No component of this product present at levels greater than or equal to 0.1 % is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity : No data available

Specific target organ toxicity- single exposure: No data available

Specific target organ toxicity - Repeated exposure: No data available

Aspiration hazard : No data available

Numerical measures of toxicity : No Data Available.

Section 12: Ecological Information

12.1 Eco toxicity: No data available

12.2 Persistence and degradability: No data available

12.3 Bioaccumulative potential : No data available

12.4 Mobility in soil : No data available



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12.5 PBT and vPvB assessment result : PBT / vPvB assessment not available as chemical safety assessment not required / not conducted.

12.6 Other adverse effects: No data available

Section 13: Disposal Considerations

13.1 Waste treatments methods

Product

Offer surplus and non – recyclable solutions to licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material, Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

13.2 Contaminated packaging

Dispose of as unused product.

Section 14: Transport Information

14.1 UN-No

ADR/ RID :-

IMDG :-

IATA :-

14.2 UN proper shipping name

ADR / RID : Not dangerous goods

IMDG : Not dangerous goods

IATA : Not dangerous goods

14.3 Transport hazard class(es)

ADR/ RID :-

IMDG :-

IATA :-

14.4 Packaging group

ADR/ RID :-

IMDG :-

IATA :-

14.5 Environmental hazards

ADR/ RID :- no

IMDG Marine pollutant :- no

IATA :-no

14.6 Special precautions for user : No data available



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Section 15: Regulatory Information

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

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

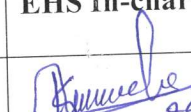
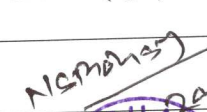
For this product a chemical safety assessment was not carried out.

Section 16 : Additional Information

For full text of H-Statements refer to section 2.

MSDS Prepared on : 29/07/2020

The above information is believed to be accurate and represents the best information currently available with us. However, we make no warranty or merchantability or any other warranty, express or implied, with respect to such information and we assume no liability resulting from its use. User should make their own investigations to determine the suitability of the information for their particular purpose. In no way shall the company be liable for any claims, losses or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if the company has been advised of the possibility of such damages.

	Prepared By	Checked By
Name	Mr. K.D. Dhanawade	Mr. Nilesh Mohare
Designation	EHS In-charge	AGM (QA)
Sign & Date	 29/07/2020	 29/07/2020

