

MSDS|Amoxycylav 50, 200, 250 and 500 Broadspectrum Antibiotic Tablets

Apex Laboratories Pty. Ltd. | ACN 000 397 240 | www.apexlabs.com.au | Phone: 02 4372 1661 | Fax: 02 4372 1668 (International +61) | Email: info@apexlabs.com.au

Material Safety Data Sheet

Amoxycylav 50, 200, 250 and 500 Broadspectrum Antibiotic Tablets

Classified as hazardous according to the criteria of NOHSC

SECTION I Identification of the Material and Supplier

Product Name	Amoxycylav 50, 200, 250 and 500 Broadspectrum Antibiotic Tablets
Recommended Use	Treatment of bacterial infections sensitive to amoxicillin and clavulanic acid.
Supplier Details	Apex Laboratories Pty. Ltd.
ACN Number	000 397 240
Street	61 Chivers Road
Suburb	Somersby
State	NSW
Country	Australia
Post Code	2250
Phone	+61 2 4372 1661 (Business hours – 8.30am – 5.00pm)
Fax	+61 2 4372 1668 (fax)
Website	http://www.apexlabs.com.au
Emergency contact	As above or Poisons Information Centre 131126 (Australia)

SECTION II Hazard Identification

Classification	Classified as hazardous according to the criteria of NOHSC
Risk Phrases	R42/43 May cause sensitisation by inhalation and skin contact
Safety Phrases	None allocated
ADG Class	None allocated
Hazchem Code	None allocated
Poisons Schedule	S4

SECTION III Composition

Ingredients	CAS No	Proportion	TWA mg/m3	STEL mg/m3
Amoxicillin	61336-70-7	30-60%	not set	not set
Clavulanic Acid	61177-45-5	<10%	not set	not set
Other non hazardous ingredients	NA	to 100%	NA	NA

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week over an entire working lifetime. The TWA exposure standard set by Worksafe Australia for dusts not otherwise specified is 10mg/m3. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL.

SECTION IV First Aid Measures

Ingestion	Generally not required. If concerned rinse mouth with water, give water to drink and seek medical advice.
Eye	Immediately flush eye(s) with lukewarm water for 20 minutes holding eyelids open. Seek medical advice.
Skin	Generally not required. If concerned wash well with soap and water and seek medical advice.
Inhalation	Generally not required. If concerned move to fresh air and seek medical advice.

SECTION V Fire Fighting Measures

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Extinguishing Media	Foam, dry chemical powder, carbon dioxide, water spray (large fires). As appropriate for surrounding materials.
Combustion Hazards	Toxic fumes may be emitted under fire conditions.
Precautions for Firefighters	Wear breathing apparatus.
Hazchem Code	None allocated

SECTION VI Accidental Release Measures

Emergency Procedures	Spillage of formulated product from marketed packaging is unlikely to ever be serious, however, in the event of a major spill, protect drains and water courses from contamination.
Materials and Methods	Wear protective clothing (overalls, goggles, gloves and boots) and prevent further spillage. Shovel spillage into labelled containers and dispose after consulting appropriate authorities.

SECTION VII Handling and Storage

Precautions	Always use good occupational work practices and observe recommendations on the label. Keep exposure to this product to a minimum. Prohibit eating, drinking and smoking in storage and handling areas. Wash hands after handling and remove contaminated clothing and any protective equipment before entering eating areas.
Conditions	Store product in original containers as per label instruction (below 25oC, air conditioning).

SECTION VIII Exposure Controls and Personal Protection

National Exposure Standards	No exposure standard has been allocated for this mixture or any significant ingredient within this mixture.
Biological Limit Values	No biological limit has been allocated for this mixture.
Engineering Controls	No specific engineering controls are required for this mixture.

Personal Protective Equipment

Eye	Eye protection is not normally necessary. If concerned wear protective goggles or glasses.
Skin	Skin protection is not normally necessary, however it is good practice to avoid contact with chemicals by wearing suitable gloves when handling.
Respiratory	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to build up then use of a suitable dust mask would be appropriate.

SECTION IX Physical and Chemical Properties

Appearance	Round beige quarter scored tablets.
Odour	Typical penicillin odour.
pH	No data available.
Vapour pressure	No data available.
Boiling point/range	No data available.
Freezing/Melting point	No data available.
Solubility	No data available.
Specific gravity/density	No data available.
Flash Points	No data available.
Flammable limits (in air)	No data available.
Ignition temperature	No data available.

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SECTION IX Physical and Chemical Properties

Chemical stability	This mixture is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
Conditions to avoid	Avoid excessive humidity and keep under 25oC.
Incompatible materials	Oxidising agents.
Decomposition products	Amoxycillin trihydrate (active ingredient) can emit toxic fumes under fire conditions.
Hazardous reactions	Hazardous polymerisation will not occur with amoxycillin.

SECTION XI Toxicological Information

Handling of the formulated product is not expected to cause any adverse affects. The following data pertains particularly to the active and any hazardous ingredients in the formulation, rather than this specific formulation.

Acute Health Effects

Ingestion

Eye Eye contact is not a great risk as this product is a tablet. The data available suggests that this product may cause a transient irritation that is unlikely to be anything more than mildly uncomfortable. This effect should disappear when the product is removed.

Skin Skin contact is not a great risk as this product is a tablet. The data available suggests that this product is not harmful. Allergic skin reactions may develop in sensitive individuals.

Inhalation Inhalation is not a great risk as this product is a tablet. The data available suggests that this product will not harm the respiratory system if inhaled. Allergic reactions can result in sensitive individuals following inhalation.

Chronic Health Effects

Ingestion Repeated ingestion of penicillin products may cause vomiting and or nausea, diarrhoea, sore and dry throat, sore and black hairy tongue. Some bacterial may develop resistance to this antibiotic with chronic exposure and there is risk of superinfection due to overgrowth of non-susceptible organisms.

Eye There is no data available on the long term effects of eye contamination with this product.

Skin The data available suggests that chronic skin contact may lead to sensitisation.

Inhalation The data available suggests that chronic inhalation may lead to sensitisation.

Advice to Doctor Treatment for any adverse effects should be symptomatic. Amoxycillin is widely distributed in body fluids and tissues including pleural, pericardial, peritoneal and synovial fluid. It also crosses the placenta. The blood brain barrier is only significantly crossed in the presence of inflammation. Skin reactions usually spontaneously resolve within a few days of withdrawal of amoxycillin. Antihistamines with or without corticosteroids may alleviate symptoms. If serious anaphylactoid reactions occur, treatment including adrenalin, oxygen, intravenous corticosteroids and endotracheal intubation may be required.

Carcinogenicity No ingredient in this formulation is known to be carcinogenic.

Compounding effects Amoxycillin is secreted in breast milk.

SECTION XII Ecological Information

Ecotoxicity No data available.

Persistence and Degradability No data available.

Mobility No data available.

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Source: <http://www.apexlabs.com.au/veterinary/MSDS/4/Amoxyclav+50%2C+200%2C+250+and+500+Broadpectrum+Antibiotic>

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SECTION XIII Disposal Considerations

Disposal Methods	Empty containers may be recycled or sent to a commercial waste disposal site. Unused product should be suitable for landfill however contact the relevant local Waste Disposal Authority.
Special Precautions	Do not dispose into sewers or waterways.

SECTION XIV Transport Information

UN Number	None allocated.
UN Shipping Name	None allocated.
ADG Class	None allocated
Packing Group	None allocated.
Special Precautions	None allocated.
Hazchem Code	None allocated

SECTION XV Regulatory Information

Poisons Schedule	S4
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SECTION XVI Other Information

Date	This MSDS has been reviewed and updated as required in May 2009.
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Key to Abbreviations

NOHSC: National Occupational Health and Safety Commission
ADG Class: Australian Dangerous Goods Class
CAS Number: Chemical Abstracts Service Number
TWA: Time Weighted Average
STEL: Short Term Exposure Limit
UN: United Nations

Disclaimer

This Material Safety Data Sheet has been developed according to WORKSAFE Australia, NOHSC Guidelines.

Hazard Classifications have been determined in consultation with the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. However, to the best of our knowledge, the finished product is unlikely to cause harm to humans handling, administering and dispensing as per label instructions.

The data, information and recommendations herein are represented in good faith and are believed to be correct as of the date hereof.

The purpose of this Material Safety Data Sheet is to describe products in terms of their safety requirements.

Apex Laboratories Pty Ltd make no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product").

The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability prior to use of the product.

The physical data shown herein are typical values based on material tested. These values should not be construed as guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots hereof.

Due care should be taken to make sure that the use or disposal of this product and/or its packaging is in compliance with relevant Federal, State and Local Government Regulations.