SAFETY DATA SHEETS

This SDS packet was issued with item:

078937291

N/A

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material **AMOXICILLIN/CLAVULANATE POTASSIUM BID TABLETS**

Synonyms AMOXICILLIN/CLAVULANATE POTASSIUM BID 500 MG TABLETS *
AMOXICILLIN/CLAVULANATE POTASSIUM BID 875 MG TABLETS

Company Name Penn Labs Inc
2200 Renaissance Blvd, Suite 105
King of Prussia, PA 19406 US
Transport Emergency (non EU) +1-703-527-3887
US number, available 24 hours
Multi-language response
Medical Emergency +1-612-221-3999, Ext 221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
AMOXICILLIN TRIHYDRATE	61336-70-7	56.4 to 68.7
POTASSIUM CLAVULANATE	61177-45-5	10.3 to 14.5
NON-HAZARDOUS INGREDIENTS	Unassigned	21.0 to 29.1

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health Exposure might occur via skin; eyes; ingestion.
May produce allergic skin reactions.
Respiratory allergen.
Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); nausea; vomiting; diarrhoea.
Health effects information is based on hazards of components.

Environment No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of penicillin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma. This material may cause or aggravate allergy to penicillin antibiotics.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Avoid breaking or crushing tablets.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Hygiene Air Monitoring Methods	Conduct monitoring in line with local chemical risk assessments to assess effectiveness of exposure controls.

ENGINEERING CONTROLS

Exposure Controls The active ingredient amoxicillin trihydrate has been assigned an occupational exposure limit of 100 mcg/m3 (15 min STEL)

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields if eye contact is possible.

Respirators If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.

Other Equipment or Procedures Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour White.

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity Adverse effects might occur following inhalation.

Skin Effects Irritation might occur following direct contact.

Eye Effects Minor irritation might occur following direct contact with eyes.

Target Organ Effects No specific target organ effects have been identified.

Sensitisation Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances.

Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by IARC, NTP or US OSHA.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions. No adverse effects have been reported following extensive use or exposure in humans.

Pharmacological Effects This material is a penicillin; an antibiotic.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary No information is available about the potential of this product to produce adverse environmental effects. This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Local regulations and procedures should be consulted prior to environmental release.

PERSISTENCE/DEGRADATION

Biodegradation The major component(s) of this mixture is not expected to persist in the environment.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

None.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

Date Approved/Revised 05-Dec-2003 **SDS Version Number** 1

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
IDENTIFICATION OF SUBSTANCE / PREPARATION AND	
PHYSICAL AND CHEMICAL PROPERTIES	

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.