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## MATERIAL SAFETY DATA SHEET

MANUFACTURER: AMERICAN CYANAMID COMPANY MSDS NO.: 03144-01  
LEDERLE LABORATORIES  
MIDDLETOWN ROAD DATE: SUPERSEDES: (NEW)  
PEARL RIVER, NY 10965 08/31/93

EMERGENCY TELEPHONE: (914) 732-5000

## I. PRODUCT IDENTIFICATION

PRODUCT NAME: AMOXICILLIN CAPSULES, USP, 250 MG:  
(PRODUCT CODE: 03144)  
AMOXICILLIN CAPSULES, USP, 500 MG:  
(PRODUCT CODE: 03145)

WARNING! MAY CAUSE ALLERGIC REACTIONS (SENSITIZATION) UPON PROLONGED OR REPEATED CONTACT.

CHEMICAL/THERAPEUTIC FAMILY: SEMISYNTHETIC PENICILLIN; AMPICILLIN ANALOG; ANTIBACTERIAL.

## II. HAZARDOUS INGREDIENTS AND EXPOSURE LIMITS

CHEMICAL AND COMMON NAMES OSHA TLV (1992-93) ACCO-TWA	CAS NO.	%	RECOMMENDED AIRBORNE LEVELS
AMOXICILLIN USP, TRIHYDRATE EST. (2S,5R,6R)-6-[(R)-(-)-2-AMINO-2-(P-HYDROXYPHENYL)ACETAMIDO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTANE-2-CARBOXYLIC ACID TRIHYDRATE; CL 143,258; CL 181,096	[61336-70-7]	H96	NOT EST. NOT EST. NO
SILICON DIOXIDE NF 10 MG/M3# SILICA GEL; SIO2 DUST)	[112926-00-8] 5 MG/M3#	H1	6 MG/M3# (TOTAL

#THE TLV ESTABLISHED IS FOR THE TOTAL DUST CONTAINING NO ASBESTOS AND &lt; 1% CRYSTALLINE SILICA.

## III. PHYSICAL PROPERTIES

MOLECULAR WEIGHT: 419.45( EMPIRICAL FORMULA: C16H19N3O5S.3H2O(

APPEARANCE AND ODOR: LIGHT GRAY/WHITE (250 MG) OR LIGHT GRAY (500 MG) CAPSULES; ODORLESS.

250 MG: LIGHT GRAY/WHITE CAPSULES PRINTED SCRIPT "LEDERLE" OVER "A33" ON CAP AND BODY.  
500 MG: LIGHT GRAY CAPSULES PRINTED SCRIPT "LEDERLE" OVER "A34" ON CAP AND BODY.

BOILING POINT: NOT AVAILABLE MELTING POINT: 194 C (DECOMPOSES) (

(PROPERTY OF AMOXICILLIN USP, TRIHYDRATE.

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### III. PHYSICAL PROPERTIES

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VAPOR PRESSURE: NOT AVAILABLE      SPECIFIC GRAVITY: NOT AVAILABLE

VAPOR DENSITY: NOT AVAILABLE      PERCENT VOLATILE: NOT AVAILABLE

SOLUBILITY, ORGANIC SOLVENTS: AMOXICILLIN TRIHYDRATE IS SLIGHTLY SOLUBLE IN ALCOHOL AND METHYL ALCOHOL; PRACTICALLY INSOLUBLE IN CHLOROFORM, ETHER, AND FIXED OILS.

SOLUBILITY, AQUEOUS (WATER): AMOXICILLIN TRIHYDRATE IS SLIGHTLY SOLUBLE IN WATER; DISSOLVES IN DILUTE SOLUTIONS OF ACIDS AND OF ALKALI HYDROXIDES.

PH: 3.5 - 6.0 (0.2% AQUEOUS SOLUTION) (

SATURATION IN AIR (BY VOLUME): NOT AVAILABLE

EVAPORATION RATE: NOT AVAILABLE

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(PROPERTY OF AMOXICILLIN USP, TRIHYDRATE.

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### IV. FIRE AND EXPLOSION HAZARD DATA

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FLASH POINT: NOT AVAILABLE      FLAMMABLE LIMITS: NOT AVAILABLE  
(METHOD: NOT APPLICABLE (N/A))      LOWER: N/A      UPPER: N/A

AUTOIGNITION TEMP.: NOT AVAILABLE

HAZARDOUS COMBUSTION PRODUCTS: NOT DETERMINED; COMBUSTION PRODUCTS WILL VARY WITH : CONDITIONS AND OXYGEN SUPPLY TO THE FLAME. AS WITH OTHER ORGANIC MATERIALS, COMBUSTION MAY PRODUCE CARBON MONOXIDE, CARBON DIOXIDE, NITROGEN OXIDES, IRRITATING ALDEHYDES, KETONES AND ORGANIC ACIDS AND, POSSIBLY, HYDROGEN CYANIDE. FUMES OF SULFUR OXIDES AND SILICON OXIDES AND OTHER SULFUR- AND SILICON-CONTAINING COMPOUNDS MAY ALSO BE GENERATED.

EXPLOSION HAZARDS: NOT AVAILABLE

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### V. REACTIVITY DATA

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STABILITY: STABLE      CONDITIONS TO AVOID: N/A

POLYMERIZATION: WILL NOT OCCUR      CONDITIONS TO AVOID: N/A

INCOMPATIBLE MATERIALS: NONE KNOWN

DECOMPOSITION TEMPERATURE: AMOXICILLIN TRIHYDRATE DECOMPOSES UPON MELTING AT 194 °C

HAZARDOUS DECOMPOSITION PRODUCTS: NONE KNOWN

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VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

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SIGNS AND SYMPTOMS OF OVEREXPOSURE IN THE WORKPLACE:

EYES: MAY CAUSE EYE IRRITATION AND/OR HYPERSENSITIVITY REACTIONS IN SENSITIVE INDIVIDUALS.

SKIN: MAY CAUSE HYPERSENSITIVITY REACTIONS UPON REPEATED SKIN CONTACT.

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INHALATION: INHALATION OF DUSTS MAY CAUSE RESPIRATORY TRACT IRRITATION AND/OR HYPERSENSITIVITY REACTIONS IN SENSITIVE INDIVIDUALS.

INGESTION: NONE KNOWN OR EXPECTED.

MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE: AS WITH OTHER PENICILLINS, AMOXICILLIN MAY CAUSE ALLERGIC REACTIONS IN INDIVIDUALS WHO HAVE PREVIOUSLY DEMONSTRATED HYPERSENSITIVITY TO PENICILLINS AND IN THOSE WITH A HISTORY OF ALLERGY, ASTHMA, HAY FEVER OR URTICARIA. GASTROINTESTINAL EFFECTS (NAUSEA, VOMITING, DIARRHEA), HYPERSENSITIVITY REACTIONS (REDNESS, RASHES, URTICARIA), REVERSIBLE EFFECTS ON THE BLOOD SYSTEM AND CENTRAL NERVOUS SYSTEM (HYPERACTIVITY, AGITATION, ANXIETY, INSOMNIA), AND EFFECTS ON THE LIVER HAVE ALSO BEEN REPORTED AS ASSOCIATED WITH THE USE OF PENICILLINS.

CLINICAL USE OF AMOXICILLIN IS CONTRAINDICATED IN INDIVIDUALS WITH A HISTORY OF ALLERGIC REACTIONS TO ANY OF THE PENICILLINS.

PRIMARY ROUTE(S) OF EXPOSURE/ENTRY:

INHALATION OF DUSTS; EYE OR SKIN CONTACT. THE POTENTIAL FOR ABSORPTION THROUGH INTACT OR BROKEN SKIN HAS NOT BEEN EVALUATED.

CANCER INFORMATION:

NONE OF THE COMPONENTS OF THIS FORMULATION ARE LISTED BY THE NATIONAL TOXICOLOGY PROGRAM (NTP) AS CARCINOGENS. NONE HAVE BEEN EVALUATED FOR CARCINOGENIC POTENTIAL BY THE INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC). NONE ARE REGULATED AS CARCINOGENS BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA).

LONG-TERM TOXICITY STUDIES FOR AMOXICILLIN HAVE NOT BEEN CONDUCTED IN LABORATORY ANIMALS.

REPORTED HUMAN EFFECTS:

PHARMACOLOGIC (DRUG-RELATED) EFFECTS NOTED DURING CLINICAL USE OF AMOXICILLIN ARE DISCUSSED ABOVE UNDER "MEDICAL CONDITIONS ...".

SILICON DIOXIDE, MAY CAUSE NON-SPECIFIC IRRITATION AND DRYING OF THE SKIN AND MUCOUS MEMBRANES, BUT IS CHEMICALLY AND BIOLOGICALLY INERT WHEN INGESTED. ALTHOUGH THIS FORM OF SILICA DOES NOT APPEAR TO BE ASSOCIATED WITH SILICOSIS, CHRONIC INHALATION OF CERTAIN TYPES OF AMORPHOUS SILICA MAY CAUSE SILICOSIS, A PROGRESSIVE LUNG DISEASE. THE HAZARDS OF INHALING VARIOUS FORMS OF AMORPHOUS SILICA ARE DIRECTLY RELATED TO THE LEVELS OF CONTAMINATING CRYSTALLINE SILICA. THESE CRYSTALLINE FORMS MAY BE CARCINOGENIC AND MAY CAUSE FIBROGENIC CHANGES

(SCAR TISSUE FORMATION) IN THE LUNG TISSUE ALONG WITH AN OBSTRUCTIVE EMPHYSEMA. THESE CHANGES COULD

CONTINUED...

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VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

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REPORTED HUMAN EFFECTS (CONTINUED...):  
EVENTUALLY LEAD TO

RESPIRATORY FAILURE AND FATAL CARDIO-RESPIRATORY FAILURE. IN ADDITION, EPIDEMIOLOGICAL EVIDENCE SUGGESTS THAT LUNG CANCER MAY BE MORE COMMON AMONG THOSE WITH SILICOSIS AS COMPARED TO THE GENERAL POPULATION.

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REPORTED ANIMAL EFFECTS:

ORAL LD50S FOR AMOXICILLIN ARE REPORTED TO BE > 25 G/KG IN MICE, > 15 G/KG IN RATS, AND > 12.5 G/KG IN RABBITS (DETAILS NOT REPORTED). INTRAPERITONEAL LD50S FOR AMOXICILLIN IN MICE AND RATS WERE 3590 MG/KG AND 2870 MG/KG, RESPECTIVELY. SIGNS OF TOXICITY INCLUDED ALTERED SLEEP TIME AND DROWSINESS. THE SUBCUTANEOUS LD50 OF AMOXICILLIN ARE REPORTED TO BE > 20 G/KG IN MICE AND > 8 G/KG IN RATS (DETAILS NOT REPORTED).

NO ADVERSE

EFFECTS ON FERTILITY OR REPRODUCTION WERE SEEN IN RATS TREATED WITH AMOXICILLIN AT DOSES OF 400 AND 1200 MG/DAY ON DAYS 6-15 AND 15-21, RESPECTIVELY. AMOXICILLIN WAS NOT TERATOGENIC TO PIGS WHEN ADMINISTERED BY GAVAGE AT DOSES OF 600 MG/KG ON DAYS 12-42.

THE ORAL LD50S

OF SILICON DIOXIDE WAS > 8000 MG/KG IN MICE, AND > 4500 MG/KG IN RATS; 6-MONTH FEED. IN RATS AT UP TO 10% IN DIET PRODUCED NO EFFECTS.

OTHER:

NOT APPLICABLE

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VII. EMERGENCY AND FIRST AID PROCEDURES

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EYES: IMMEDIATELY FLUSH EYES WITH PLENTY OF COOL, LOW-PRESSURE WATER FOR AT LEAST 20 MINUTES. CONTACT A PHYSICIAN IF IRRITATION OCCURS.

SKIN: PROMPTLY WASH WITH SOAP AND COOL RUNNING WATER. REMOVE CONTAMINATED CLOTHING. CONTAMINATED CLOTHING SHOULD BE WASHED BEFORE REUSE. CONTACT A PHYSICIAN IF IRRITATION OCCURS.

INHALATION: REMOVE TO FRESH AIR. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. CALL A PHYSICIAN.

INGESTION: DO NOT INDUCE VOMITING EXCEPT AS DIRECTED BY MEDICAL PERSONNEL. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. NEVER INDUCE VOMITING IN AN UNCONSCIOUS PERSON. CALL A PHYSICIAN.

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VIII. EXPOSURE CONTROL METHODS

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## ENGINEERING CONTROLS:

USE CLOSED-SYSTEM HANDLING, LABORATORY BENCH HOOD OR LOCAL EXHAUST VENTILATION TO CONTROL DUST OR MIST.

## WORK PRACTICE CONTROLS:

MINIMIZE EXCESS HANDLING. KEEP CONTAINER CLOSED WHEN NOT IN USE. WASH HANDS, FACE AND EXPOSED BODY PARTS AT LUNCH AND BREAKS, AND AT END OF SHIFT.

## PERSONAL PROTECTION EQUIPMENT:

WHEN ENGINEERING CONTROLS ARE NOT ADEQUATE TO CONTAIN DUST/MIST, WEAR AN APPROVED AIR-PURIFYING RESPIRATOR WITH HIGH-EFFICIENCY CARTRIDGES OR A SUPPLIED-AIR RESPIRATOR.

RUBBER GLOVES SHOULD BE WORN TO PREVENT CONTACT WITH THE SKIN. EYE PROTECTION SHOULD BE WORN.

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IX. SPILL OR LEAK PROCEDURES

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STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

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WEARING RUBBER GLOVES CONTAIN AND COLLECT SPILLED MATERIALS.

## WASTE DISPOSAL:

DISPOSE OF IN ACCORDANCE WITH ALL FEDERAL, STATE, AND LOCAL REGULATIONS. INCINERATION IS RECOMMENDED. THIS IS NOT A RCRA-REGULATED HAZARDOUS WASTE.

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X. STORAGE AND HANDLING

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MAINTAIN GOOD HOUSEKEEPING AND PERSONAL HYGIENE PROCEDURES.

STORE AT CONTROLLED ROOM TEMPERATURE, 15 - 30 C (59 - 86 F).

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XI. SARA SECTION 313 INFORMATION

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NOT APPLICABLE.

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XII. APPENDIX

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THE INFORMATION AND STATEMENTS HEREIN ARE BELIEVED TO BE RELIABLE BUT ARE NOT TO BE CONSTRUED AS A WARRANTY OR REPRESENTATION FOR WHICH WE ASSUME LEGAL RESPONSIBILITY. USER SHOULD UNDERTAKE SUFFICIENT VERIFICATION AND TESTING TO DETERMINE THE SUITABILITY FOR HIS OWN PARTICULAR PURPOSE OF ANY INFORMATION OR PRODUCTS REFERRED TO HEREIN. A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE IS MADE.

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