

MATERIAL SAFETY DATA SHEET

SECTION 1-IDENTITY

COMMON NAME.	AMOXICILLIN TRIHYDATE
SYNONYMS.	AMINOBENZYL PENCILLIN
CAS NUMBER.	61336-70-7
CHEMICAL NAME.	(6R) - 6 - (a-D - 4 - HYDROXYPHENYLGLYCYL AMINO) PENICILLANIC ACID, TRIHYDATE.
CHEMICAL FAMILY.	AN AMINOPENICILLANIC ACID DERIVATIVE
THERAPEUTICAL CATEGORY.	ANTIBACTERIAL
MANUFACTURER / SUPPLIER	M/S.AUROBINDO PHARMA LIMITED PLOT NO.2, MAITRI VIHAR, AMEERPET, HYDERABAD-500038. A.P. INDIA. 3741083/3741084

SECTION 2-INGREDIANT INFORMATION

PRINCIPALCOMPONENTS	PERCENT
AMOXICILLIN TRIHYDATE.	100%

SECTION 3-HEALTH HAZARD INFORMATION

USUAL ADULT DOSE	THE USUAL DOSE OF AMOXICILLIN IS 250 TO 500 MG EVERY SIX HOURS. NOT TO EXCEED A MAXIMUM OF 6 GRAMS DAILY.
ADVERSE EFFECTS	ADVERSE REACTIONS ARE GENERALLY MILD AND CONSISTS OF SKIN RASHES OR DIARRHOEA. OTHER ADVERSE EFFECTS INCLUDE NAUSEA OR VOMITING SOUR MOUTH OR TONGUE AND RARELY LABORED BREATHING. JOINT PAIN SORE THROAT. FEVER HYPERTENSION, STOMACH CRAMP, AND SEVERE DIARRHOEA POSSIBLE ALLERGIC REACTION TO MATERIAL IF INHALED.INGESTED OR IN CONTACT WITH SKIN.
OVER DOSE EFFECT	n/f
ACTE	POSSIBLE EYE SKIN GASTROINTESTINAL AND/OR RESPIRATORY TRACT IRRITATION.

CHRONIC	POSSIBLE HYPER SENSITIZATION SUPER INFECTIONS.
INHALATION	MAY CAUSE IRRITATION. AVOID INHALATION REMOVE TO FRESH AIR.
EYE	MAY CAUSE IRRITATION FLUSH WITH COPIOUS QUANTITIES OF WATER.
SKIN	MAY CAUSE IRRITATION FLUSH WITH COPIOUS QUANTITIES OF WATER.
INGESTION	MAY CAUSE IRRITATION. FLUSH MOUTH WITH WATER THIS MATERIAL WILL BE WELL ABSORBED FROM EMPTY STOMACH.
MEDICAL CONDITIONS AGGREGATED BY EXPOSURE.	HYPERSENSITIVITY TO MATERIAL. HISTORY OF ALLERGIES. BLEEDING DISORDERS OR GASTROINTESTINAL DISEASE, INFECTIOUS MONONUCLEOSIS AND IMPAIRED KIDNEY FUNCTION.
GROSS SENSITIVITY	PERSONS WITH PREVIOUS HISTORY OF SIGNIFICANT ALLERGY OR ASTHMA SHOULD AVOID POTENTIAL EXPOSURE TO THIS MATERIAL. INDIVIDUALS ALLERGIC TO ONE OF THE PENICILLINS OR TO CEPHALOSPORINS, CEPHAMYCINS, GRISEOFULVIN, OR PENICILLAMINE MAY ALSO ALLERGIC TO AMOXICILLINS. PREGNANCY COMMENTS THERE ARE NO ADEQUATE AND WELL CONTROLLED PREGNANCY STUDIES IN HUMAN. HOWEVER STUDIES IN ANIMALS HAVE REVEALED NO EVIDENCE OF ADVERSE EFFECTS ON FOETUS DUE TO PENICILLINS.
PREGNANCY CATEGORY	B IN CASE OF CONTACT, IMMEDIATELY WASH SKIN WITH SOAP AND COPIOUS AMOUNTS OF WATER. IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.

IF SWALLOWED , WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS. CALL A PHYSICIAN.

SECTION 4 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA WATER SPARY	CARBON DIOXIDE , DRY CHEMICAL POWDER OR APPROPRIATE FOAM.
SPECIAL FIRE FIGHTING PROCEDURES	WEAR SELF -CONTAINED BREATHING APPA- RATUS AND PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.
UNUSUAL FIRE AND SIONS HAZARDS	EMITS TOXIC FUMES UNDER FIRE EXPLO CONDITIONS.

SECTION 5 - ACCIDENTAL RELEASE MEASURES

	WEAR RESPIRATOR, CHEMICAL SAFETY GOGGLES, RUBBER BOOTS AND HEAVY RUBBER GLOVES.
	SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.
AVOID RAISING DUST	VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

SECTION 6 - HANDLING AND STORAGE

HANDLING	AS A GENERAL RULE WHEN HANDLING AVOID ALL CONTACT AND INHALTION OF DUST . MISTS . AND / OR VAPOURS ASSOCI- ATED WITH THE MATERIAL . WASH THOR- OUGHLY AFTER HANDLING.
STORAGE	STORE IN TIGHT CONTAINER AS DEFINED IN THE LABEL . THE MATERIAL SHOULD BE HANDLED AND STORED AS PER LABLE INSTRUCTIONS TO ENSURE PRODUCT INTEGRITY.

SECTION 7 - EXPOSURE CONTROLS/ PERSONAL PROTECTION

WEAR APPROPRIATE NIOSH/MSHA-APPROVED
RESPIRATOR, CHEMICAL-RESISTANT GLOVES,
SAFETY GOGGLES, OTHER PROTECTIVE
CLOTHING.

SPILL RESPONSE

WEAR APPROVED RESPIRATOR, CHEMICALLY COMPATIBLE GLOVES AND PROTECTIVE CLOTHING. WIPE UP SPILLAGE OR COLLECT SPILLAGE USING A HIGH EFFICIENCY VACUUM CLEANER. AVOID BREATHING PLACE SPILLAGE IN APPROPRIATELY LABELLED CONTAINER FOR DISPOSAL. WASH SPILL SITE.

DISPOSAL

DISPOSE OF WASTE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE AND LOCAL LAWS.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION

WHEN WORKING WITH SMALL QUANTITIES IN A WELL VENTILATED AREA. RESPIRATORY PROTECTION MAY NOT BE REQUIRED. THE USE OF AN APPROVED DUST MASK IS RECOMMENDED.

VENTILATION

NO SPECIAL VENTILATION REQUIREMENTS.

GLOVES

RUBBER

EYE PROTECTION

SAFETY GLASSES

PROTECTIVE CLOTHING

PROTECT EXPOSED SKIN.

SECTION 9 - PHYSICAL CHEMICAL PROPERTIES

APPEARANCE AND ODOUR

A WHITE OR ALMOST WHITE CRYSTALLINE POWDER. PRACTICALLY ODOURLESS.

MELTING POINT

216°C to 218 °C (DECOMPOSES)

SPECIFIC GRAVITY

n/f

REACTIVITY IN WATER

n/f

% VOLATILE BY VOLUME

n/f

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

<u>Trade name:</u>	Potassium Clavulanate
<u>Use:</u>	Active Pharmaceutical Ingredient
<u>Directions for use:</u>	Raw material for medical products manufacture
<u>Company identification:</u>	Fermic S.A. de C.V. 873 Reforma Iztapalapa 09850 D.F. Mexico City Mexico Emergency telephone number: 52 55 5037 0000 Telephone number for information: 52 55 5037 0000

2. HAZARDS IDENTIFICATION

<u>Risk Phrases:</u>	Possible allergic reaction to material if inhaled, ingested or in contact with skin.
<u>Adverse human health effects:</u>	Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation Chronic: Possible hypersensitization Inhalation: May cause irritation of respiratory tract. Eyes: May cause irritation. Skin: May cause irritation. Ingestion: May cause irritation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Components:</u>						
<i>Substance name:</i>	<i>Contents:</i>	<i>CAS No.</i>	<i>EC No.</i>	<i>Annez No.</i>	<i>Classification:</i>	
Potassium Clavulanate	100%	61177-45-5			R42/43, R52	

4. FIRST AID MEASURES

<u>First aid measures</u>	
<u>Inhalation:</u>	Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.
<u>Skin contact:</u>	Remove affected clothing and wash all exposed skin area with mild soap and water.
<u>Eye contact:</u>	Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persist.
<u>Ingestion:</u>	Rinse mouth. If swallowed, seek medical advice immediately and show this Safety Data Sheet or label.
<u>Overdose treatment:</u>	Administering epinephrine, adrenocorticoids, and antihistamines for allergic reactions.

5. FIRE-FIGHTING MEASURES

Extinguishing media

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Water spray, dry chemical, carbon dioxide or foams as appropriate for surrounding fire and materials.

Unsuitable extinguishing media:

Do not use a heavy water stream.

Surrounding fires:

Use water spray or fog for cooling exposed containers.

Protection against fires:

Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous combustion products:

Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases (NO_x).

6. ACCIDENTAL RELEASE MEASURES

General precautions:

Remove ignition sources. Evacuate area.

Personal precautions:

Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

Clean up methods:

To clean the floor and all objects contaminated by this material, use: Water./Detergent. Avoid dust production. Ensure adequate ventilation. Wash contaminated clothing before reuse.

7. HANDLING AND STORAGE

Personal protection:

Avoid all unnecessary exposure.

Use the appropriate personal protective equipment (see 8)

Technical protective measures:

Material should be handled with adequate dust control.(e.g. in a laboratory hood).

Handling:

Handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin or clothing. Avoid breathing dust. Use with adequate dust control. Wash thoroughly handling wear clothing daily. Wash contaminated clothing before reuse. Ventilate area.

Storage:

Store in dry cool place between 2 and 8°C (36 and 46°F) in air tight containers packed under inert atmosphere. This material should be handled and stored per label and other instructions to ensure product integrity.

Storage - away from:

All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal protection

Respiratory protection:

Wear approved mask.

In case of insufficient ventilation, wear suitable respiratory equipment.

Hand protection:

Wear suitable gloves resistant to a chemical penetration.

Skin protection:

Wear suitable protective clothing.

Eye protection:

Chemical goggles or safety glasses.

Industrial hygiene:

Provide local exhaust or general room ventilation.

9. PHYSICAL AND CHEMICAL PROPERTIES

<u>Chemical formula:</u>	C ₈ H ₈ KNO ₅
<u>Molecular weight:</u>	237.25 g/mol
<u>Physical state at 20 °C:</u>	Crystalline powder
<u>Colour:</u>	White
<u>pH value:</u>	5,5 - 8,0 (solution)
<u>Melting point [°C]:</u>	No data available
<u>Boiling point [°C]:</u>	No data available
<u>Solubility in water:</u>	Potassium Clavulanate is very soluble in water with decomposition
<u>Flash point [°C]:</u>	No data available
<u>Log P octanol / water at 20 °C:</u>	No data available

10. STABILITY AND REACTIVITY

<u>Stability and reactivity:</u>	Stable under storage conditions.
<u>Materials to avoid:</u>	Strong oxidizers.
<u>Conditions to avoid:</u>	Light. Heat. Moisture.
<u>Hazardous decomposition products:</u>	Carbon monoxide. Carbon dioxide. Nitrogen oxides. When heated to decomposition, emits dangerous fumes.
<u>Hazardous reactions:</u>	None under normal conditions.
<u>Hazardous polymerization:</u>	Will not occur.

11. TOXICOLOGICAL INFORMATION

<u>RTECS nr:</u>	No data available.
<u>Rat oral LD50 [mg/kg]:</u>	> 10.000
<u>Rabbit dermal LD50 [mg/kg]:</u>	No data available.
<u>Rat inhalation LD50 [mg/L/4h]:</u>	No data available.
<u>Acute toxicity:</u>	No data available.
<u>Chronic toxicity:</u>	No data available.
<u>Sensitization:</u>	No data available.
<u>NTP:</u>	No data available.
<u>IARC:</u>	No data available.
<u>Target Organ (s):</u>	Gastrointestinal system, kidney
<u>OSHA:</u>	No data available.

12. ECOLOGICAL INFORMATION

<u>Ecological effects information</u>	
<u>LC50 - 96 Hour - fish [mg/L]:</u>	No data available.
<u>EC50 - 48 Hour - Daphnia magna [mg/L]:</u>	No data available.
<u>IC50 - 72 Hour - Algae [mg/L]:</u>	No data available.
<u>Biodegradation [%]:</u>	No data available.
<u>Persistence - degradability:</u>	Biodegradable.
<u>Log P octanol / water at 20 °C:</u>	No data available.
<u>Bioaccumulative potential:</u>	No data available.

13. DISPOSAL CONSIDERATIONS

<u>General:</u>	Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local and federal regulation.
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14. TRANSPORT INFORMATIONGeneral information:

Not regulated for transport under USDOT, EUADR, IATA or IMDF regulations.
Transport under conditions indicated in section 7

15. REGULATORY INFORMATIONSymbol (s):

Xn: Harmful.

R Phrase (s):

R42/43: May cause sensitization by inhalation and skin contact.

R52: Harmful to aquatic organisms.

S Phrase (s):

S22: Do not breathe the dust.

S24: Avoid contact with skin.

S36/37: Wear suitable protective clothing and gloves.

S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label when possible).

S61: Avoid release to the environment.

16. OTHER INFORMATIONFurther information:

Revision 1.0

List of relevant R phrases:

R42: May cause sensitization by inhalation.

R43: May cause sensitization by skin contact.

R52: Harmful to aquatic organisms.

NOTICE

This information contained herein is applicable solely to this chemical substance when used as intermediate for production of drug finished form. Its use is intended by personnel having technical skill and at their own discretion and risk. The information is considered reliable but has not been independently verified. Therefore, Fermic cannot guarantee the accuracy of the information of these sources nor should the statements contained herein be considered as official expression.