

**AMERICAN REGENT, INC.  
MATERIAL SAFETY DATA SHEET**

**PRODUCT NAME:** AMINOPHYLLINE INJECTION, USP

**MANUFACTURER:** LUITPOLD PHARMACEUTICALS, INC.  
PO BOX 9001  
SHIRLEY, NY 11967

**EMERGENCY  
TELEPHONE  
NUMBER:** (800) 645-1706

**SECTION I: IDENTITY**

Common Name - Aminophylline  
Chemical Name - 3,7-Dihydro-1,3-dimethyl-1H-purine-2,6-dione compounded with 1,2-ethanediamine (2:1)  
Chemical Family - Antiasmatic  
Chemical Formula -  $C_9H_{16}N_6O_2$   
CAS No. - 317-34-0  
RTECS No. - XH5600000

**SECTION II: HAZARDOUS INGREDIENTS/ACTIVE INGREDIENTS**

<u>COMPONENT</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>
Theophylline	Not Established	Not Established
Ethylenediamine	10 ppm	10 ppm

**SECTION III: PHYSICAL & CHEMICAL CHARACTERISTICS**

**DESCRIPTION:** Aminophylline Injection, USP is a sterile, nonpyrogenic, clear, colorless solution with a pH of 8.6 - 9.0.

Appearance & Odor - Clear colorless solution; odorless  
Boiling Point - N/A  
Solubility in Water - Soluble  
Vapor Pressure - N/A  
Vapor Density - N/A

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#### **SECTION IV: FIRE & EXPLOSION DATA**

Flash Point - N/A

Extinguisher Media - Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire and materials.

Flammable Limits - (LEL) - N/A  
(UEL) - N/A

Unusual Fire and Explosion Hazards - Emits toxic fumes.

Hazardous Decomposition Products - Aminophylline emits toxic fumes when heated to decomposition.

Special Fire Fighting Procedures - Firefighters should use self-contained breathing apparatus and protective clothing.

#### **SECTION V: REACTIVITY DATA**

Stability - Stable

Conditions/Materials to Avoid - Exposure to light may cause decomposition. Do not mix with other drugs.

Hazardous Polymerization - Will not occur

#### **SECTION VI: HEALTH HAZARD DATA**

Primary Routes of Exposure - Inhalation, Ingestion, and Skin Absorption.

Chemical Listing as Carcinogen

National Toxicology Program - No

IARC Monographs - No

OSHA - No

#### Toxicity Data

LD <sub>50</sub> :	407 mg/Kg oral-rat;
LD <sub>50</sub> :	246 mg/Kg intraperitoneal-rat;
LD <sub>50</sub> :	184 mg/Kg intravenous-rat;
LD <sub>50</sub> :	167 mg/Kg intramuscular-rat;
LD <sub>50</sub> :	150 mg/Kg oral-mouse;
LD <sub>50</sub> :	217 mg/Kg intraperitoneal-mouse;
LD <sub>50</sub> :	186 mg/Kg subcutaneous-mouse;
LD <sub>50</sub> :	194 mg/Kg intravenous-mouse;
LD <sub>50</sub> :	200 mg/Kg oral-dog;
LD <sub>50</sub> :	150 mg/Kg intravenous-dog;
LD <sub>50</sub> :	200 mg/Kg rectal-dog;
LD <sub>50</sub> :	150 mg/Kg intravenous-rabbit;
LD <sub>50</sub> :	184 mg/Kg oral-guinea pig;
LD <sub>50</sub> :	252 mg/Kg intraperitoneal-guinea pig;
LD <sub>50</sub> :	143 mg/Kg intravenous-guinea pig

#### Signs and Symptoms of Overexposure

Nausea, vomiting, diarrhea, epigastric pain, hematemesis, headache, irritability, restlessness, insomnia, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions, palpitations, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, ventricular arrhythmias, tachypnea, albuminuria, increased excretion of renal tubular and red blood cells, potentiates diuresis, hyperglycemia, inappropriate ADH syndrome, and rash.

#### Emergency & First Aid Procedures

Inhalation: Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

Ingestion: Flush mouth out with water. Seek medical attention.

Skin Contact: Remove contaminated clothing. Flush area with water. Seek medical attention.

Eye Contact: Flush with water. Seek medical attention.

**FOR ADDITIONAL INFORMATION, REFER TO THE PRODUCT INSERT.**

## **SECTION VII: PROTECTIVE EQUIPMENT DATA**

Ventilation - Local exhaust recommended

Respiratory Protection- N/A, however, NIOSH-approved respirator should be available.

Eye Protection- Safety Goggles

Gloves - Disposable surgical latex gloves

Clothing - Disposable protective apparel (protect exposed skin).

## **SECTION VIII: STORAGE & HANDLING DATA**

Precautions - As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the product. Do not mix with other drugs.

## **SECTION IX: ACCIDENTAL SPILL PROCEDURES/WASTE DISPOSAL DATA**

Containment/Clean-up - Wear recommended personal protective equipment. Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with paper towels. Wipe working surfaces to dryness, then wash with soap and water.

Waste Disposal - Though not EPA regulated, waste should be disposed of in accordance with federal, state, and local regulations. Do not mix with other substances.

NOTICE: The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for his or her particular purpose. Luitpold Pharmaceuticals, Inc. assumes no additional liability or responsibility resulting from the use of, or reliance on, this information.

This Material Safety Data Sheet and the information it contains is offered to you in good faith as accurate. The information is believed to be correct but has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and

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use this product safely and to comply with all applicable laws and regulations. The user assumes all risks associated with the use of the product; Luitpold Pharmaceuticals, Inc., disclaims any liability arising from use of this information.

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