

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Aminophylline Injection, USP

Product Code: 0517-3810-01; 0517-3810-25; 0517-3820-01; 0517-3820-25

1.2. Intended Use of the Product

Use of the Substance/Mixture: For professional use only. Aminophylline Injection is indicated as an adjunct to inhaled beta-2 selective agonists and systemically administered corticosteroids for the treatment of acute exacerbations of the symptoms and reversible airflow obstruction associated with asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis.

1.3. Name, Address, and Telephone of the Responsible Party

Company

American Regent, Inc.

5 Ramsey Road

PO Box 9001

Shirley, NY 11967

1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Resp. Sens. 1 H334

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Danger

Hazard Statements (GHS-US) :

H317 - May cause an allergic skin reaction.

H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US) :

P261 - Avoid breathing mist, spray, vapors.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, and eye protection.

P284 - [In case of inadequate ventilation] wear respiratory protection.

P302+P352 - If on skin: Wash with plenty of water.

P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

P321 - Specific treatment (see section 4 on this SDS).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA / water	(CAS-No.) 7732-18-5	97.6	Not classified
Theophylline	3,7-Dihydro-1,3-dimethyl-1H-purine-2,6-dione / 1,3-Dimethylxanthine / NSC 2066 / 1H-Purine-2,6-dione, 3,7-dihydro-1,3-dimethyl- / Theophylline, anhydrous / Xanthine, 1,3-dimethyl- / 1H-Purine-2,6-dione, 3,9-dihydro-1,3-dimethyl- / THEOPHYLLINE / Theophylline anhydrous / 1,3-Dimethyl-1H-purine-2,6(3H,9H)-dione / theophylline anhydrous	(CAS-No.) 58-55-9	2	Acute Tox. 3 (Oral), H301 Aquatic Acute 3, H402
Ethylenediamine	1,2-Diaminoethane / Ethane, 1,2-diamino- / 1,2-Ethanediamine / 1,2-Ethylenediamine / Diaminoethane / Ethane-1,2-diamine / ETHYLENEDIAMINE	(CAS-No.) 107-15-3	0.4	Flam. Liq. 3, H226 Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Acute Tox. 4 (Inhalation:vapour), H332 Skin Corr. 1B, H314 Eye Dam. 1, H318 Resp. Sens. 1, H334 Skin Sens. 1, H317 Aquatic Acute 3, H402 Aquatic Chronic 3, H412

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None known.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Thermal decomposition generates: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Refer to product insert for usage instructions and product information. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Use appropriate personal protective equipment (PPE).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash contaminated clothing before reuse.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20° to 25 °C (68° to 77 °F); excursions permitted to 15° to 30 °C (59° to 86 °F) (See USP Controlled Room Temperature).

7.3. Specific End Use(s)

For professional use only. Aminophylline Injection is indicated as an adjunct to inhaled beta-2 selective agonists and systemically administered corticosteroids for the treatment of acute exacerbations of the symptoms and reversible airflow obstruction associated with asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Ethylenediamine (107-15-3)		
USA ACGIH	ACGIH OEL TWA [ppm]	10 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen, Skin - potential significant contribution to overall exposure by the cutaneous route
USA NIOSH	NIOSH REL (TWA)	25 mg/m ³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA IDLH	IDLH [ppm]	1000 ppm
USA OSHA	OSHA PEL (TWA) [1]	25 mg/m ³
USA OSHA	OSHA PEL (TWA) [2]	10 ppm

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Environmental Exposure Controls

: Avoid release to the environment.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless to slightly yellow liquid
Odor	: No data available
Odor Threshold	: No data available
pH	: 8.6 – 9.0
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: $\approx 32^{\circ}\text{F}$ (0°C)
Boiling Point	: $\approx 214^{\circ}\text{F}$ (101.11°C)
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: ≈ 1 (Water=1)
Solubility	: Water: Freely soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition may produce: Carbon oxides (CO , CO_2). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Acute Toxicity (Inhalation): Not classified

Theophylline (58-55-9)	
LD50 Oral Rat	225 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 6.7 mg/l/4h
Ethylenediamine (107-15-3)	
LD50 Oral Rat	637 mg/kg
LD50 Dermal Rabbit	560 mg/kg
LC50 Inhalation Rat	14.7 mg/l/4h
LC50 Inhalation Rat	11.06 mg/l/4h
ATE (Dust/Mist)	14.70 mg/l/4h

Skin Corrosion/Irritation: Not classified

pH: 8.6 – 9.0

Serious Eye Damage/Irritation: Not classified

pH: 8.6 – 9.0

Respiratory or Skin Sensitization: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Theophylline (58-55-9)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects.

Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Theophylline (58-55-9)	
LC50 Fish 1	100 mg/l
NOEC Chronic Algae	12.5 mg/l
Ethylenediamine (107-15-3)	
LC50 Fish 1	98.6 – 131.6 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	17 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	191 – 254 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
NOEC Chronic Crustacea	0.16 mg/l

12.2. Persistence and Degradability

Aminophylline Injection, USP	
Persistence and Degradability	Readily biodegradable.

12.3. Bioaccumulative Potential

Aminophylline Injection, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.
Ethylenediamine (107-15-3)	
Partition coefficient n-octanol/water (Log Pow)	-1.221

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Aminophylline Injection, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization
Ethylenediamine (107-15-3)	
Listed on the United States SARA Section 302	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	10000 lb

15.2. US State Regulations

Ethylenediamine (107-15-3)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 08/02/2022

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:vapour)	Acute toxicity (inhalation:vapor) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Sens. 1	Skin sensitization, Category 1
H226	Flammable liquid and vapor
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction

Aminophylline Injection, USP

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

H318	Causes serious eye damage
H332	Harmful if inhaled
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)