


Section 1: Identification

Common Name/Trade Name	THEOPHYLLINE ANHYDROUS	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	N/A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 3)	
Signal Word	Danger	
Hazard Statement(s)	H301 Toxic if swallowed	
Pictogram(s)		
Precautionary Statement(s)	P264 Wash hands thoroughly after handling. P301+P310 IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. P330 Rinse mouth. P405 Store locked up. P501 Dispose of contents/container to an approved waste disposal plant.	
Hazards Not Otherwise Classified	None	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	1-H-Purine-2,6-dione, 3,7-dihydro-1,3-dimethyl-
Common Name	Theophylline Anhydrous
CAS Number	58-55-9
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
If Inhaled	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most Important Symptoms and Effects	Treatment of overdose should be symptomatic and supportive and may include the following: DO NOT induce vomiting. Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in the Trendelenburg and left lateral decubitus position or by endotracheal intubation. In severely poisoned patients, consider multi-dose activated charcoal. Carhartics are NOT recommended. Persistent vomiting may interfere with activated charcoal administration. Treat with ranitidine, ondansetron, or metoclopramide. In patients with high risk for seizures, perform seizure prophylaxis with phenobarbital. For seizures, administer intravenous diazepam or lorazepam. Monitor for hypotension, respiratory depression, and need for endotracheal intubation. For hypotension, administer saline and place in Trendelenburg position. For severe tachycardia with hemodynamic compromise or ischemia, treat with beta blocking agents until hemodialysis or hemoperfusion can be performed. A short-acting cardioselective agent, such as esmolol, is preferred. Use CAUTION in patients with asthma or COPD. Begin intravenous hydration and replace electrolytes as needed. Obtain serial theophylline levels, follow serum electrolytes, Obtain an ECG, and institute continuous cardiac monitoring. For life threatening toxicity (significant dysrhythmias, hypotension, seizures), treat with hemoperfusion or hemodialysis. [Meditext]

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2. Unsuitable extinguishing media None known.
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling	As a general rule, when handling chemicals, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for Safe Storage	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No biological exposure limits noted for the ingredient(s). No exposure standards allocated.
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures. Handle in accordance with good industrial hygiene and safety practice.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
PPE - Body Protection	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Section 9: Physical and Chemical Properties

Appearance	White crystalline powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless
Vapor Pressure	< 0.0000001 kPa at 25 Å°C
Odor Threshold	Not available.
Vapor Density	Not available.
pH	4 - 6 (2% aqueous solution)
Relative Density	Not available
Melting Point/Freezing Point	Melting point/freezing point 518 - 525.2 Å°F (270 - 274 Å°C)
Solubility	Solubility in water Slightly soluble. Solubility (other) Freely soluble in solutions of alkali hydroxides and in ammonia; sparingly soluble in alcohol, in chloroform, and in ether.
Initial Boiling Point and Boiling Range	Not available.
Flash Point	Not available.
Evaporation Rate	Not available.
Flammability (Solid, Gas)	Not applicable.
Partition Coefficient	Partition coefficient (n-octanol/water) -0.02 also reported as -0.0076
Auto-Ignition Temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.

Section 10: Stability and Reactivity

Reactivity	Not available.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known.
Incompatible Materials	Alkaline metals. Peroxides.
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Mouse 332 mg/kg
Acute Toxicity - Inhalation	Due to lack of data the classification is not possible.
Acute Toxicity - Dermal	Due to lack of data the classification is not possible.
Acute Toxicity - Eye	Based on available data, the classification criteria are not met.
Skin Corrosion/Irritation	Based on available data, the classification criteria are not met.
Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
Carcinogenicity IARC	Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity ACGIH	Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity NTP	Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity OSHA	Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive Toxicity	Based on available data, the classification criteria are not met. Several large studies of infants born to women treated with theophylline during pregnancy showed no increase in birth defects. 15 mg/kg/day Reproductive study Result: Dose-related increase in birth defects (cleft palate, skeletal anomalies) in offspring. Species: Rabbit 259 mg/kg/day Reproductive study Result: No significant increase in birth defects. Species: Rat 396 mg/kg/day Reproductive study Result: No significant increase in birth defects. Species: Mouse Reproductive study (6 to 25 times the human dose) Result: Dose-related increase in birth defects (cleft palate, skeletal anomalies) observed in offspring treated at high doses. Species: Rat
Specific Target Organ Toxicity - Single Exposure	Due to lack of data the classification is not possible
Specific Target Organ Toxicity - Repeated Exposure	Due to lack of data the classification is not possible
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Toxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	Not available.
Mobility in Soil	Not available.
Other Adverse Effects	Not available.

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Waste Treatment Methods Packaging	Not available. Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	UN2811
UN Proper Shipping Name	Toxic solid, organic, n.o.s. (Theophylline)
Transport Hazard Class(es)	6.1
Packaging Group	III
Environmental Hazards	No data available.

Section 15: Regulatory Information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous chemical Yes SARA 313 (TRI reporting) Not regulated. Other federal regulations Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. US. California Proposition 65 Not Listed. International Inventories Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) Yes Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) Yes Europe European Inventory of Existing Commercial Chemical Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) Yes Korea Existing Chemicals List (ECL) Yes New Zealand New Zealand Inventory Yes Country(s) or region Inventory name On inventory (yes/no)* Philippines Philippine Inventory of Chemicals and Chemical Substances Yes (PICCS) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
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