

Theophylline

(CAS number- 58-55-9)

TAJMTF-YCWPHN7722

Taj Active Pharmaceuticals Ingredients

www.tajapi.com

Active Pharmaceutical Ingredients
TAJ PHARMACEUTICALS LIMITED INDIA

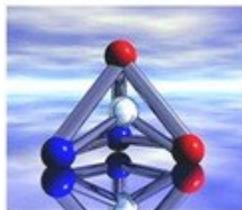
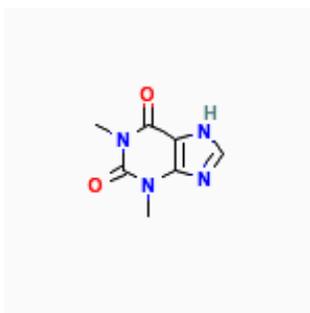


Raw Material / Chemicals Index

Taj Pharmaceuticals Ltd.

Theophylline

CAS. Number 58-55-9



Product Name: Theophylline

CAS#: 58-55-9

RTECS: XH3850000

TSCA: TSCA 8(b) inventory: Theophylline

Synonym: Acet-theocin; Armophylline; Asmax, Austyn, Duraphy, Elixicon, Elixophyllin, Elixophylline, Euphyllong, Lanophyllin, Liquophylline, Nuelin, Optiphyllin; Parkophyllin, Pseudotheophylline, Slo-Phyllin, Solosin, Teofyllamin, Theo-Dur, Teocin, Theofol, Theograd, Theolair, Theolix, Theophyllin; 1,3-Dimethyl-2,6-dihydroxypurine; 1,3-Dimethylxanthine; 1H-Purine-2,6-dione, 3,7-dihydro-1,3-dimethyl-

Chemical Name: Theophylline

Chemical Formula: C₇H₈N₄O₂

Toxicological Data on Ingredients: Theophylline: ORAL (LD50): Acute: 225 mg/kg [Rat]. 235 mg/kg [Mouse]. 350 mg/kg [Rabbit].

Hazards Identification

Potential Acute Health Effects:

Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.

Potential Chronic Health Effects:

Carcinogenic Effects: Classified 3 (Equivocal evidence.) by NTP. 3 (Not classifiable for human.) by IARC.

Mutagenic Effects: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast.
TERATOGENIC

The substance may be toxic to kidneys, the nervous system, heart, Smooth Muscle. Repeated or prolonged exposure to the substance can produce target organs damage.

Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Products of Combustion: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂...).

Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards:

Material in powder form, capable of creating a dust explosion. As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Accidental Release Measures

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Handling and Storage

Precautions:

Keep away from heat. Keep away from sources of ignition. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Exposure Controls/Personal Protection

Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Gloves.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline solid. Crystalline powder.)

Odor: Odorless.

Taste: Bitter.

Molecular Weight: 180.17 g/mole

Color: White.

Melting Point: 274.5°C (526.1°F)

Water/Oil Dist. Coeff.: The product is equally soluble in oil and water; $\log(\text{oil/water}) = -0.02$

Dispersion Properties: See solubility in water.

Solubility: Partially soluble in cold water. Very slightly soluble in diethyl ether. Soluble in dilute mineral acids. Water solubility: 7,400 mg/l @ 25 deg. C.

Stability and Reactivity Data

Stability: The product is stable.

Conditions of Instability: Excess heat, dust generation

Incompatibility with various substances: Not available.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Will not occur.

**Toxicological Information:**

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 225 mg/kg [Rat].

Chronic Effects on Humans:

CARCINOGENIC EFFECTS: Classified 3 (Equivocal evidence.) by NTP. 3 (Not classifiable for human.) by IARC.

MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. May cause damage to the following organs: kidneys, the nervous system, heart, Smooth Muscle.

Other Toxic Effects on Humans:

Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation.

Special Remarks on Toxicity to Animals:

Lowest Published Lethal Dose: LDL [Woman] - Route: Oral; Dose: 130 mg/kg

Special Remarks on Chronic Effects on Humans:

Human: passes through the placenta, excreted in maternal milk. May cause adverse reproductive effects and birth defects (teratogenic) May affect genetic material (mutagenic). May cause cancer based on animal test data.

Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: May cause eye irritation. Inhalation: May cause respiratory tract irritation. Ingestion: Harmful if swallowed. Can cause gastrointestinal tract irritation with nausea, vomiting, headache, vague abdominal discomfort, diarrhea, caffeine-like side effects insomnia, light-headedness, or a feeling of being "spaced-out." Other symptoms may include excitement, incoordination, tremor, hyperglycemia, metabolic acidosis, cardiac (ventricular)arrhythmias, hypotension, tachycardia, circulatory failure, respiratory stimulation, seizures/clonic and tonic convulsions, and death. Chronic Potential Health Effects: Ingestion: Prolonged or repeated ingestion may affect metabolism (weight loss), liver, urinary system (kidneys), blood (changes in white blood cell count, pigmented or nucleated red blood cells), brain, behavior/central nervous system (somnolence)

Ecological Information

Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are as toxic as the original product.

Disposal Considerations

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Transport Information

DOT Classification: Not a DOT controlled material (United States).

Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Theophylline

Other Regulations:

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS D-1B: Material causing immediate and serious toxic effects (TOXIC).

DSCL (EEC): R22- Harmful if swallowed. S36- Wear suitable protective clothing.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator

when ventilation is inadequate. Safety glasses.

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