



Issue Date 16-Apr-2021

Revision Date Not Applicable

Version 1

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**

**Product identifier**

**Product Name** Theophylline Anhydrous Extended Release Tablets

**Other means of identification**

**Synonyms** Theo-24, Uniphyll, Theo-Dur, Theo-Time, TheoCap, Theochron, and Quibron-T(2)

**Recommended use of the chemical and restrictions on use**

**Recommended Use** For treatment of asthma, bronchospasm, and COPD.

**Uses advised against** Do not use without a prescription.

**Details of the supplier of the safety data sheet**

**Supplier Address**

Rhodes Technologies  
498 Washington Street  
Coventry, RI 02816

**Emergency telephone number**

**Company Phone Number** Phone: 401-262-9400  
Fax: 401-262-9401

**24 Hour Emergency Phone Number** CHEMTREC Day or Night  
USA and Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

**2. HAZARDS IDENTIFICATION**

**Classification**

**Health Hazards**

Not classified.

**Physical Hazards**

Not classified.

**OSHA Regulatory Status**

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200, Revision 3. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Label elements**Emergency Overview**

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

**Appearance** Tablet**Physical state** Solid**Odor** Not known**Hazards not otherwise classified (HNOC)**

Not applicable.

**Other information**

Not available.

**Unknown Acute Toxicity**

46.5% of the mixture consists of ingredient(s) of unknown toxicity.

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Synonyms**

Theo-24, Uniphyl, Theo-Dur, Theo-Time, TheoCap, Theochron, Elixophyllin, and Quibron-T(2)

Chemical name	CAS No	Weight-%
Theophylline Anhydrous, USP	58-55-9	30-50
Hypromellose, USP	9004-65-3	30-50
Povidone, USP	9003-39-8	1-10
Colloidal silicon dioxide, NF	112945-52-5	<1
Lactose Monohydrate, NF	10039-26-6	1-10
Magnesium stearate, NF	557-04-0	<1

**4. FIRST AID MEASURES****Description of first aid measures****Eye Contact**

In case of eye contact of broken tablets, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

**Skin Contact**

In case of contact broken tablets, remove contaminated clothing. Immediately wash exposed area with soap and water. Obtain medical attention if skin reaction occurs or irritation / symptoms persist.

**Inhalation**

Immediately move exposed subject to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

**Ingestion**

In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Self-Protection of the First Aider**

Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give 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, both acute and delayed****Symptoms**

Not available.

**Indication of any immediate medical attention and special treatment needed**

**Note to Physicians** Treat symptomatically.

**5. FIRE-FIGHTING MEASURES****Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** No information available.

**Specific hazards arising from the chemical**

Toxic gas formation is possible during heating or fire.

**Explosion data**

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

**Protective equipment and precautions for firefighters**

Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

**Personal Precautions** Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

**Environmental precautions**

**Environmental Precautions** See Section 12 for additional ecological information.

**Methods and material for containment and cleaning up**

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for Cleaning Up** Pick up and transfer to properly labeled containers. Avoid creating dust.

**7. HANDLING AND STORAGE****Precautions for safe handling**

**Advice on Safe Handling** Do not break or crush tablets. If tablets are crushed and/or broken, avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Dispense in a well-closed, container with child resistant closure. Store at 20°-25°C (68°-77°F).

**Incompatible materials** Not available.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Control parameters**

**Exposure Guidelines** This product, as supplied, contains the following hazardous material(s) with occupational exposure limits established by the region-specific regulatory bodies.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Magnesium stearate, NF 557-04-0	TWA: 10 mg/m <sup>3</sup> inhalable particulate matter TWA: 3 mg/m <sup>3</sup> respirable particulate matter TWA: 10 mg/m <sup>3</sup> inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m <sup>3</sup> respirable particulate matter except stearates of toxic metals	-	-

**Appropriate engineering controls****Engineering Controls**

None required for consumer use. In laboratories or industrial settings, handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

**Individual protection measures, such as personal protective equipment****Eye/Face Protection**

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and Body Protection**

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory Protection**

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**General Hygiene Considerations**

Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<b>Physical state</b>	Solid	<b>Odor</b>	Not known
<b>Appearance</b>	Tablet	<b>Odor Threshold</b>	Not available
<b>Color</b>	Not known		

**Property****Values****Remarks**

<b>pH</b>	Not available.
<b>Melting Point/Freezing Point</b>	Not available.
<b>Boiling Point/Boiling Range</b>	Not available.
<b>Flash Point</b>	Not available.
<b>Evaporation Rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Flammability Limit in Air</b>	
<b>Upper Flammability Limit:</b>	Not available.

<b>Lower Flammability Limit:</b>	Not available.
<b>Vapor Pressure</b>	Not available.
<b>Vapor Density</b>	Not available.
<b>Specific Gravity</b>	Not available.
<b>Water Solubility</b>	Not available.
<b>Solubility in Other Solvents</b>	Not available.
<b>Partition Coefficient</b>	Not available.
<b>Autoignition Temperature</b>	Not available.
<b>Hyphen</b>	Not available.
<b>Kinematic Viscosity</b>	Not available.
<b>Dynamic Viscosity</b>	Not available.
<b>Explosive Properties</b>	Not available.
<b>Oxidizing Properties</b>	Not available.

**Other information**

<b>Softening Point</b>	Not available.
<b>Molecular Weight</b>	Not available.
<b>VOC Content (%)</b>	Not available.
<b>Density</b>	Not available.
<b>Bulk Density</b>	Not available.

## 10. STABILITY AND REACTIVITY

**Reactivity**

Stable at normal conditions. Not available.

**Chemical stability**

Stable under recommended handling and storage conditions.

**Possibility of hazardous reactions**

Not available.

**Hazardous Polymerization** Not available.

**Conditions to avoid**

Not available.

**Incompatible materials**

Not available.

**Hazardous decomposition products**

Not available.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Theophylline Anhydrous, USP 58-55-9	= 225-250 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 6.7 mg/L (Rat) 4 h	-
Povidone, USP 9003-39-8	= 100 g/kg (Rat)	-	-	-
Colloidal silicon dioxide, USP 112945-52-5	= 3160 mg/kg (Rat)	-	-	-

**Symptoms related to the physical, chemical and toxicological characteristics****Symptoms**

Anorexia, nausea and occasional vomiting, diarrhea, insomnia, irritability, restlessness, and headache commonly occur. Other symptoms of toxicity may include agitated maniacal behavior, frequent vomiting, extreme thirst, slight fever, tinnitus, palpitation, and arrhythmias, delirium, muscle twitching, severe dehydration, albuminuria, emesis of a

"coffee ground" material, hyperthermia, and profuse diaphoresis (Theophylline).

**Delayed and immediate effects as well as chronic effects from short- and long-term exposure**

<b>Skin Corrosion/Irritation</b>	Theophylline can cause skin irritation.
<b>Serious Eye Damage/Eye Irritation</b>	Theophylline can cause eye irritation.
<b>Irritation</b>	Theophylline can produce GI irritation.
<b>Sensitization</b>	No information available
<b>Germ Cell Mutagenicity</b>	Theophylline has been studied in Ames Salmonella test, in vivo and in vitro cytogenetics, micronucleus and Chinese hamster ovary test systems and has not been shown to be genotoxic.
<b>Carcinogenicity</b>	The product contains the following chemicals listed by IARC that are not classifiable as to its carcinogenicity to humans (Group 3).

Chemical name	ACGIH	IARC	NTP	OSHA
Theophylline Anhydrous, USP 58-55-9	-	Group 3	-	-
Povidone, USP 9003-39-8	-	Group 3	-	-
Colloidal silicon dioxide, NF 112945-52-5	-	Group 3	-	-

**Reproductive Toxicity** Theophylline has been used in the treatment of asthma and chronic obstructive pulmonary disease in pregnant patients. There has been no observable increase in congenital defects. Some reports have suggested that theophylline might increase the risk of premature birth. Specific investigations on human developmental effects of theophylline did not uncover an association with malformations or stillbirth. In animal studies, theophylline was shown to decrease the number of live pups per litter and a significant decrease in live pup weight in mice. Feeding theophylline to immature rats produced severe testicular atrophy, oligo-spermatogenesis and aspermatogenesis.

**STOT - Single Exposure** Not available.

**STOT - Repeated Exposure** Decreased bodyweight, increased mean cell volume of red blood cells, time-dependent bone loss, and a significant decrease in liver tissue hydroxyproline content together with reduction in portal hypertension were found in theophylline treated animals in subchronic or prechronic exposure studies in rat and mice.

**Aspiration Hazard** Due to the physical form of the product, it is not an aspiration hazard.

**Unknown Acute Toxicity** 46.5% of the mixture consists of ingredient(s) of unknown toxicity

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

0% of the mixture consists of components(s) of unknown hazards to the aquatic environment

**Persistence and degradability**

Not available.

**Bioaccumulation**

Not available.

**Mobility**

Theophylline is expected to have very high mobility in soil.

**Other adverse effects**

Not available.

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

<b>Disposal of Wastes</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations.
<b>Contaminated Packaging</b>	Do not reuse container.

### 14. TRANSPORT INFORMATION

<b><u>DOT</u></b>	Not regulated
<b><u>IATA</u></b>	Not regulated.

### 15. REGULATORY INFORMATION

#### International Inventories

<b>TSCA</b>	Does not comply
<b>DSL/NDL</b>	Does not comply
<b>EINECS/ELINCS</b>	Does not comply
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply

#### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

#### US Federal Regulations

##### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

##### SARA 311/312 Hazard Categories

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

##### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

##### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level

---

pertaining to releases of this material.

### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated by state right-to-know regulations.

#### **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable.

## **16. OTHER INFORMATION**

<b>Prepared By</b>	IES Engineers
<b>Issue Date</b>	16-Apr-2021
<b>Revision Date</b>	Not Applicable.
<b>Revision Note</b>	New SDS.

#### **Disclaimer**

The information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

**End of Safety Data Sheet**