

# Safety Data Sheet

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## 1. Identification of the substance/preparation and the company/undertaking

### GHS product identifier

Product name: Theophylline Oral Solution USP

### Other means of identification

Product code(s): 0121-0820-04, 0121-0820-16, 0121-4820-15, 0121-4820-40

UN-Number: NA

Synonyms: NA

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

Recommended use: Pharmaceutical product indicated for the treatment of symptoms and reversible airflow obstruction associated with chronic asthma and other chronic lung diseases.

Uses advised against: Do not use except as recommended.

### Supplier address/information

Pharmaceutical Associates, Inc.  
201 Delaware Street  
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

## 2. Hazards Identification

**Classification** This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

**Chemical family:** Mixture

**Statement of Hazard:** This is a prescription pharmaceutical product, and is generally nonhazardous when taken as recommended.

### Additional Hazard Information:

**Short term:**

Adverse reactions are generally mild when peak serum concentrations are in the recommended range, and mainly consist of transient caffeine-like adverse effects such as nausea, vomiting, headache, and insomnia.

**Long term:**

No data available.

### Known Clinical Effects:

Theophylline interacts with a wide variety of drugs. Patients should contact medical personnel before adding or discontinuing another prescription or OTC drug or dietary supplement.

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EU Indication of danger:

Not classified.

## Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

## Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

## 3. Composition/Information on ingredients

Chemical name	CAS-No	mg/15 mL	Trade Secret
Theophylline	58-55-9	80 mg/ 15 mL	
Citric Acid Anhydrous	77-92-9		X
Sodium Saccharin	82385-42-0		X
Ethanol	64-17-5		X
FD&C Red No. 40	25956-17-6		X
FD&C Yellow No. 6	2783-94-0		X
PFC F-8580 Cherri Beri	Mixture		X
Sodium Citrate	6132-04-3		X

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## 4. First aid measures

### Description of necessary first-aid measures

#### Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

#### Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

#### Inhalation:

Remove to fresh air and contact medical personnel.

#### Ingestion:

Overdose or accidental ingestion – The patient or caregiver should seek medical attention whenever nausea, vomiting, persistent headache, insomnia or rapid heartbeat occurs during treatment with Theophylline, even if another cause is suspected. These could be symptoms of an overdose.

### Most important symptoms/effects, acute and delayed

Not Available

### Indication of immediate medical attention and special treatment needed, if necessary

Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

## 5. Fire-fighting measures

### Suitable extinguishing media:

Use carbon dioxide, dry chemical or water spray.

### Specific hazards arising from the chemical

Not applicable

### Explosion data:

Not applicable

### Protective equipment and precautions for firefighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

### Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and materials for containment and cleaning up

- Methods for containment: Isolate area around spill as specified by site procedures.
- Methods for cleaning up: Absorb the liquid with suitable material. Dispose of spill material

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in accordance with applicable federal, state or local regulations.

## 7. Handling and storage

### Precautions for safe handling

Handling:

No special handling required for hazard control under conditions of normal product use.

### Conditions for safe storage, including any incompatibilities

Storage:

No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products:

As a precautionary measure, keep away from strong oxidizers.

## 8. Exposure controls/personal protection

### Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Theophylline	Not Available	Not Available	Not Available
Citric Acid Anhydrous	10 mg/m <sup>3</sup> TWA	15 mg/m <sup>3</sup> TWA	Not Available
Sodium Saccharin	Not Available	Not Available	Not Available
Ethanol	Not Available	1900 mg/m <sup>3</sup> TWA (200 Proof)	1000 ppm TWA
FD&C Red No. 40	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available
PFC F-8580 Cherri Beri	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available

### Appropriate engineering controls

Engineering measures:

Engineering controls should be used to limit exposure.

### Individual protection measures, such as personal protective equipment

Eye/face protection:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection:

Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures:

Wash hands thoroughly after use.

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## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state: Solution  
 Odor: Fruity  
 Appearance: Clear red solution  
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	4.0 – 4.3	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	0.90 – 1.10	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%)

Alcohol 20% v/v

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## 10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

## 11. Toxicological information

### Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Ethanol may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
- Ingestion: Prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Theophylline	272 mg/kg Rat	>2000 mg/kg rat	>6.7 mg/L 4 hr Rat
Citric Acid Anhydrous	5400 mg/kg Rat	>2000 mg/kg Rat	Not Available
Sodium Saccharin	14200 mg/kg Rat	Not Available	Not Available
Ethanol	3632 mg/kg Mouse	17100 mg/kg Rabbit	64000 ppm / 4hr. Rat
FD&C Red No. 40	>10000mg/kg Rat	>10000 mg/kg Rabbit	Not Available
FD&C Yellow No. 6	5000 mg/kg Mouse	Not Available	Not Available
PFC F-8580 Cherri Beri	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available

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**Symptoms related to the physical, chemical and toxicological characteristic:**

No data available

**Delayed and immediate effects and also chronic effects from short and long term exposure**

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

**Numerical measures of toxicity – product**

- No data available

## 12. Ecological information

**Ecotoxicity:**

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

**Persistence and Degradability:**

No data available

**Bioaccumulation:**

No data available

**Other adverse effects:**

No data available

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Theophylline	>100 mg/L 72 hr Desmodesmus subspicatus	100 mg/L 96 hr Leuciscus idus	Not Available	178 mg/L 48 hr
Citric Acid Anhydrous	Not Available	440 mg/L 48 hr Leuciscus idus melanotus	Not Available	1535 mg/L 24 hr.
Sodium Saccharin	Not Available	Not Available	Not Available	Not Available
Ethanol	Not Available	Not Available	Not Available	Not Available
FD&C Red No. 40	Not Available	Not Available	Not Available	Not Available
FD&C Yellow No. 6	Not Available	Not Available	Not Available	Not Available
PFC F-8580 Cherri Beri	Not Available	Not Available	Not Available	Not Available
Sodium Citrate	Not Available	Not Available	Not Available	Not Available

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### 13. Disposal considerations

**Waste disposal methods**

Dispose of waste in accordance with all federal, state and local regulations.

**Contaminated packaging**

Dispose of waste in accordance with all federal, state and local regulations.

### 14. Transport information

**Notes:**

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

### 15. Regulatory information

**TSCA:**

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The following components are included on the inventory: Theophylline, Citric Acid, Sodium Saccharin, Ethanol, Citric Acid, FD&C Red No. 40 and FD&C Yellow No. 6.

**International inventories****EINECS:**

Theophylline, Citric Acid, Sodium Saccharin, Ethanol, FD&C Red No., 40 FD&C Yellow No. 6. and Sodium Citrate are listed on the EINECS inventory.

**U.S. Federal regulations****OSHA Label:**

Not applicable

**SARA 311/312 Hazard categories:**

Not Applicable

**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:**

No components are listed under CERCLA.

**California Proposition 65:**

This product contains Sodium Saccharin which the state of California has found to cause cancer and requires a warning under California Proposition 65.

This product contains Ethanol which is listed as Proposition 65 chemicals as developmental toxicity.



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## U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Theophylline	X		X		
Citric Acid Anhydrous	X		X		
Sodium Saccharin	X	X	X	X	X
Ethanol	X	X	X	X	X
FD&C Red No. 40					
FD&C Yellow No. 6					
PFC F-8580 Cherri Beri					
Sodium Citrate	X		X		

## U.S. EPA label information:

Not applicable

## 16. Other information

Prepared by: Pharmaceutical Associates Regulatory Affairs Department  
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### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**