

# Safety Data Sheet

Issue Date 24FEB2021

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Version 00

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

### Product identifier

**Product Name** Promethazine VC with Codeine Oral Solution

### Other means of identification

**Product Code** 0121-0925-16  
**Synonyms** Promethazine HCl Oral Solution

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

**Recommended Use** Promethazine VC with Codeine Oral Solution is a combination of codeine, an opioid agonist; promethazine, a phenothiazine; and phenylephrine, an alpha-1 adrenergic receptor agonist, indicated for the temporary relief of cough and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold in patients 18 years of age and older. Promethazine is an antihistamine, Phenylephrine is a decongestant and Codeine is an opioid cough suppressant.

**Uses advised against** Not indicated for pediatric patients under 18 years of age.  
Promethazine is contraindicated in comatose states, and in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine or to other phenothiazines.  
Antihistamines are contraindicated for use in the treatment of lower respiratory tract symptoms, including asthma. Phenylephrine is contraindicated in patients with hypertension or with peripheral vascular insufficiency (ischemia may result with risk of gangrene or thrombosis of compromised vascular beds). Phenylephrine should not be used in patients known to be hypersensitive to the drug or in those receiving a monoamine oxidase inhibitor (MAOI).  
Not indicated for patients with narrow angle glaucoma, patients with difficulty urinating, patients with paralytic ileus (bowel obstruction).  
Not indicated for patients with allergic reactions to codeine or certain other opioid medications.  
Benzodiazepines or other medicines which can cause drowsiness or sleepiness should not be taken during treatment with Promethazine VC with Codeine.

### Details of the supplier of the safety data sheet

**Supplier Address**  
Pharmaceutical Associates, Inc.  
1700 Perimeter Road  
Greenville, SC 29605

### Emergency telephone number

**24 Hour Emergency Phone Number** Chemtrec  
1-800-424-9300  
**Emergency Telephone** 1-864-277-7282

## 2. HAZARDS IDENTIFICATION

### Classification

#### Health Hazards

Reproductive toxicity	Category 1B
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#### Physical hazards

Not classified.

#### OSHA Regulatory Status

This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

**Label elements**

**Emergency Overview**

**Danger**

**Hazard statements**

Reproductive Toxicity



This mixture is a drug product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the labeled directions.

**Appearance:** Clear and red solution

**Physical state:** Liquid

**Odor:** Strawberry menthol

**Precautionary Statements - Prevention**

Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Use personal protective equipment as required.

**Precautionary Statements - Response**

If exposed or concerned: Get medical advice/attention.

**Precautionary Statements - Storage**

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant.

**Hazards not otherwise classified (HNOC)**

Not available.

**Other Information**

Not available

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Synonyms Promethazine VC Oral Solution,

Chemical Name	CAS No.	Weight-%
Codeine phosphate	41444-62-6	0.1-1
Ethyl alcohol	64-17-5	7
Phenylephrine hydrochloride	61-76-7	0.01-0.1
Promethazine hydrochloride	58-33-3	0.1-1
Propylene glycol	57-55-6	Proprietary
Sucrose	57-50-1	Proprietary
Ascorbic acid	50-81-7	Proprietary
Citric acid Anhydrous	77-92-9	Proprietary
Water	7732-18-5	Proprietary
Saccharin sodium	6155-57-3	Proprietary
Propylparaben	94-13-3	Proprietary
Methylparaben	99-76-3	Proprietary
Sodium benzoate	532-32-1	Proprietary
Sodium citrate	6132-04-3	Proprietary
FD&C Yellow No. 6	2783-94-0	Proprietary
D&C Red no. 33		
Menthol	89-78-1	Proprietary
Strawberry flavor	Mixture	Proprietary

**4. FIRST AID MEASURES****First aid measures****General advice**

Consult a physician. Show this safety data sheet to the doctor in attendance.

**Eye contact**

In case of eye contact, 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, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

**Inhalation**

Inhalation is not an anticipated route for liquid handling. For the intended use, see product label.

**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**

Common side effects associated with use of this product include:

**Central Nervous System** – Drowsiness is the most prominent CNS effect of this drug. Sedation, somnolence, blurred vision, dizziness; confusion, disorientation, and extrapyramidal symptoms such as oculogyric crisis, torticollis, and tongue protrusion; lassitude, tinnitus, incoordination, fatigue, euphoria, nervousness, diplopia, insomnia, tremors, convulsive seizures, excitation, catatonic-like states, hysteria. Hallucinations have also been reported.

**Cardiovascular** – Hypertension and possible stroke

**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** None known.

**Specific hazards arising from the chemical**

Not available.

**Hazardous combustion products** Not available.

**Explosion data**

**Sensitivity to Mechanical Impact** None known.

**Sensitivity to Static Discharge** None known.

**Protective equipment and precautions for firefighters**

As in any fire, 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** Avoid excessive contact. Avoid contact with eyes.

**Environmental precautions**

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

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

**Methods for containment** Collect and place in a suitable container. Sorbents may be used.

**Methods for cleaning up** Dispose of in accordance with local, state, and national regulations.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store at 20°-25°C (68°-77°F). [see USP Controlled Temperature]. Other Precautions: Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP. Keep tightly closed. Protect from light.

**Incompatible materials** None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

**Exposure Guidelines** This product, as supplied, does not contain any other hazardous materials with Occupational Exposure Limits (OEL) established by the region-specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust
Ethyl alcohol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>

### Appropriate engineering controls

#### **Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

### 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**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

Physical state	Liquid	Odor	Strawberry Menthol
Appearance	Clear	Odor threshold	Not available.
Color	Red		

<u>Property</u>	<u>Values</u>	<u>Remarks • Not applicable</u>
pH	4.4-5.2	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Oxidizing properties	Not available.	

### Other Information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

## 10. STABILITY AND REACTIVITY

### Reactivity

Stable at normal conditions.

### Chemical stability

Stable at ambient temperatures and atmospheric pressures under recommended storage and handling conditions.

### Possibility of Hazardous Reactions

None under normal processing.

<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
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### Conditions to avoid

Not available.

### Incompatible materials

None known based on information supplied.

### Hazardous Decomposition Products

None under normal use conditions.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	No data available.
<b>Eye contact</b>	No data available.
<b>Skin Contact</b>	No data available.
<b>Ingestion</b>	No data available.

### Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Ethyl alcohol 64-17-5	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h	-
Codeine phosphate 41444-62-6	= 85- 266 mg/kg (Rat)	-	-	= 54 – 75 mg/kg (Rat) = 97.8 mg/kg (Dog)
Phenylephrine hydrochloride	= 350 mg/lg (Rat)			
Promethazine hydrochloride 57-55-6	= 326 mg/kg (Mouse )	= 225 mg/kg (Mouse) = 700 mg/kg (Rat)	-	= 40 mg/kg (Mouse) = 45 mg/kg (Rat)
Propylene glycol USP 57-55-6	= 20000 mg/kg (Rat)	= 20800 mg/kg (Rabbit)	-	-
Sucrose 57-50-1	= 29700 mg/kg (Rat)	-	-	-

### Information on toxicological effects

#### Symptoms

Common side effects associated with use of this product include the following: mild constipation, nausea; dizziness, drowsiness; feeling restless; blurred vision, ringing in ears; flushing (warmth, redness, or tingly feeling); sleep problems (insomnia); dry mouth; itching, mild rash, increased sweating.

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

#### Skin corrosion/irritation

Not available.

#### Serious eye damage/eye irritation

Not available.

#### Irritation

Not available.

#### Corrosivity

Not available.

#### Sensitization

Codeine phosphate: No data found. Allergic responses have been reported. Anaphylactic reactions are rare.

#### Germ cell mutagenicity

Codeine phosphate was negative in the Ames test, chromosome aberration (CHO cells) assay, micronucleus test (mouse bone marrow), and the sex-linked recessive Lethal test (drosophila).

#### Carcinogenicity

**Codeine phosphate** was not carcinogenic when fed to rats (70 mg/kg) and mice (400 mg/kg) for 2 years. Not listed as a carcinogen by IARC, NTP or USOSHA.  
**Promethazine hydrochloride:** 103 Week mouse Study in Drinking Water was found to be negative.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethyl alcohol 64-17-5	A3	Group 1	-	X

#### Reproductive toxicity

Codeine phosphate: Diminished libido, erectile failure, and retarded ejaculation are common to chronic opiate abuse. Most research has been conducted with heroin and methadone but these effects are believed to be shared by all opiates including codeine. US FDA Pregnancy Category: C

#### Developmental Toxicity

Not available.

#### Teratogenicity

Teratogenicity studies in hamsters and mice have associated codeine administration with skeletal abnormalities. A more recent study did not find a significant increase in anomalies in the offspring of treated hamsters and mice; rather, developmental toxicity was manifest only in hamsters as a decrease in fetal body weight at a dose of 100 mg/kg/day. No increase in congenital anomalies was shown when codeine was administered to pregnant rats or rabbits.

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At the top dose in the rat study (120 mg/kg/d), maternal toxicity occurred and was associated with reduced fetal weight and increased resorptions. The top dose in the rabbit study (30 mg/kg/d) did not produce adverse effects on the pregnant animals or the offspring. Neonatal withdrawal, characterized by tremor, jitteriness, diarrhea, and poor feeding, has been seen in babies born both to addicted and non-addicted women when the women had been taking codeine-containing medications in the days prior to delivery. If present during labor, codeine can produce respiratory depression in the newborn, which can be alleviated by naloxone administration

<b>STOT - single exposure</b>	Not classified.
<b>STOT - repeated exposure</b>	Not classified.
<b>Chronic toxicity</b>	Not available.
<b>Subchronic toxicity</b>	Not available.
<b>Target Organ Effects</b>	Not available.
<b>Neurological effects</b>	Not available.
<b>Aspiration hazard</b>	Due to the physical form of the product it is not an aspiration hazard.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** Not available  
 The following values are calculated based on chapter 3.1 of the GHS document.

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

Known component ecotoxicity:

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethyl alcohol 64-17-5	-	12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static 100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through	-	9268 - 14221: 48 h Daphnia magna mg/L LC50 2: 48 h Daphnia magna mg/L EC50 Static 10800: 24 h Daphnia magna mg/L EC50
Propylene glycol USP 57-55-6	19000: 96 h Pseudokirchneriella subcapitata mg/L EC50	51600: 96 h Oncorhynchus mykiss mg/L LC50 static 41 - 47: 96 h Oncorhynchus mykiss mL/L LC50 static 51400: 96 h Pimephales promelas mg/L LC50 static 710: 96 h Pimephales promelas mg/L LC50	-	1000: 48 h Daphnia magna mg/L EC50 Static 10000: 24 h Daphnia magna mg/L EC50

**Persistence and degradability**

Not available.

**Bioaccumulation**

Not available.

**Mobility**

Chemical Name	Partition coefficient
Ethyl alcohol 64-17-5	-0.32

**Other adverse effects**

Not available.

**13. DISPOSAL CONSIDERATIONS****Waste treatment methods****Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations

**Contaminated packaging**

Disposal should be in accordance with applicable regional, national and local laws and regulations.



US EPA Waste Number Not available.

California Hazardous Waste Codes

Chemical Name	California Hazardous Waste Status
Ethyl alcohol 64-17-5	Toxic Ignitable

**14. TRANSPORT INFORMATION**

- DOT** Not regulated.
- TDG** Not regulated.
- MEX** Not regulated.
- ICAO (air)** Not regulated.
- IATA** Not regulated.
- IMDG** Not regulated.
- RID** Not regulated.
- ADR** Not regulated.
- ADN** Not regulated.

**15. REGULATORY INFORMATION**

**International Inventories**

- TSCA Does not comply
- DSL/NDSL Does not comply
- EINECS/ELINCS Does not comply
- ENCS Does not comply
- IECSC Does not comply
- KECL Does not comply
- PICCS Does not comply
- AICS Does not comply

**Legend:**

- TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL - 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**

Exempt from SARA Tier II and Section 313 of the Superfund Amendments and Reauthorization Act of 1986 reporting requirements - Any drug, cosmetic, or food regulated by the U.S. FDA or any substance used in a research laboratory, hospital or medical facility under the direct supervision of a technically qualified individual (i.e., those trainer in the research or medical fields, such as doctors and nurses).

**SARA 311/312 Hazard Categories**

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	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).

**US State Regulations****California Proposition 65**

This product contains the following Proposition 65 chemicals.

Chemical Name	California Proposition 65
Ethyl alcohol - 64-17-5	Carcinogen Developmental

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

This product may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sucrose 57-50-1	-	X	X
Ethyl alcohol 64-17-5	X	X	X
Propylene glycol USP 57-55-6	X	-	X

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not available.

**16. OTHER INFORMATION**

Issue Date	24FEB2021
Revision Date:	24FEB2021
Revision Note:	Rev 0: New SDS

**Disclaimer**

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

**End of Safety Data Sheet**