

# SAFETY DATA SHEET

Issue Date: 01/09/2024

Revision Date: N/A

Revision Number: 02

## 1. IDENTIFICATION

**Product identifier:** Guaifenesin and Codeine Phosphate Oral Solution

**Product Codes:** 0121-1775-40, 0121-1550-40

**Supplier Name and Address:** Pharmaceutical Associates, Inc.  
201 Delaware Street

Greenville, SC 29605

**Telephone number:** (864) 277-7282

**Emergency phone number:** CHEMTREC 800-424-9300

**Recommended use:** Human drug – treatment of cough

**Restrictions on use:** Prescription use only.

## 2. HAZARD(S) IDENTIFICATION

**Classification:**

Physical	Health
Not hazardous	Skin Sensitization Category 1 Reproductive Toxicity Category 1B Effects on or via Lactation

**Label Elements:**  
Danger!



**Hazard statement(s)**

May cause an allergic skin reaction.  
May damage fertility or the unborn child.  
May cause harm to breast-fed children.

**Precautionary statement(s)**

Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Avoid contact while nursing.

**Precautionary statement(s)**

Avoid breathing vapors or mists.  
Wash thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
Wear protective clothing and gloves.  
IF on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.  
IF exposed or concerned: Get medical attention.  
Store locked up.  
Dispose in accordance with local and national regulations.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Codeine Phosphate	52-28-8	0.2%
Guaifenesin	93-14-1	2%
Glycerin	56-81-5	Proprietary

Propylene Glycol	57-55-6	Proprietary
Sodium Saccharin	6155-57-3	Proprietary
Sorbitol	50-70-4	Proprietary
FD&C Red #40	25956-17-6	Proprietary
FD&C Yellow #6	2783-94-0	Proprietary
FD&C Blue #1	3844-45-9	Proprietary
Cherry Flavor	Mixture	Proprietary
Menthol	1490-04-6	Proprietary
Edetate Disodium	139-33-3	Proprietary
Citric Acid	77-92-9	Proprietary
Sodium Citrate	68-04-2	Proprietary
Sodium Benzoate	532-32-1	Proprietary
Water	7732-18-5	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** Remove contaminated clothing. Wash skin with soap and water. If irritation or symptoms of exposure develop, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** In the case of unintentional ingestion or overdose, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

**Most important symptoms/effects, acute and delayed:** May cause mild eye and skin irritation. Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, sweating, and constipation. Severe overdose may result in respiratory depression and, to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest. Codeine phosphate can cause physical and psychological dependence. Overdose of guaifenesin may cause nausea and drowsiness.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is recommended for unintended ingestion or overdose.

#### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

**Specific hazards arising from the chemical:** Product is not classified as flammable but will burn in a fire after the water has evaporated.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

**7. HANDLING AND STORAGE**

**Precautions for safe handling:** Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging in a secure location.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****Exposure guidelines:**

Codeine Phosphate	None Established
Acetaminophen	None Established
Glycerin	5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
Propylene Glycol	10 mg/m <sup>3</sup> TWA AIHA WEEL
Sodium Saccharin	None Established
Sorbitol	10 mg/m <sup>3</sup> TWA ACGIH TLV 5 mg/m <sup>3</sup> (respirable particulate) TWA OSHA PEL 15 mg/m <sup>3</sup> (total particulate) TWA OSHA PEL
FD&C Red #40	None Established
FD&C Yellow #6	None Established
FD&C Blue #1	None Established
Cherry Flavor	None Established
Menthol	1 ppm TWA, 3 ppm STEL OARS & AIHA WEEL
Edetate Disodium	None Established
Citric Acid	None Established
Sodium Citrate	None Established
Sodium Benzoate	None Established

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

**Individual protection measures:**

**Respiratory protection:** None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the

contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** None required for normal use. Impervious gloves recommended for manufacturing operations.

**Eye protection:** None required for normal use. Chemical safety goggles recommended for manufacturing operations.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Clear, red-orange liquid

**Odor:** Cherry

<b>Odor threshold:</b> Not applicable	<b>pH:</b> 5.0-5.5
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> Not applicable	<b>Evaporation rate:</b> Not determined
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Vapor density:</b> Not determined
<b>Relative density:</b> 1.12-1.13	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> Not determined

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** None known.

**Conditions to avoid:** None known.

**Incompatible materials:** Avoid oxidizing agents.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Acute effects of exposure:

**Inhalation:** Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

**Ingestion:** Swallowing large amounts causes central nervous system depression with drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, sweating, and constipation. Severe overdosage may result in respiratory depression and, to a lesser degree, circulatory depression, respiratory arrest, shock, and cardiac arrest. Codeine phosphate can cause physical and psychological dependence. Overdosage of guaifenesin may cause nausea and drowsiness.

**Skin contact:** May cause mild irritation. Absorption through the skin is possible with effects similar to ingestion.

**Eye contact:** May cause mild irritation with redness and tearing.

**Chronic Effects:** Prolonged use of codeine phosphate may lead to dependence and withdrawal symptoms when use stops.

**Sensitization:** Codeine phosphate may cause skin sensitization.

**Germ Cell Mutagenicity:** Codeine sulfate was not mutagenic in the *in vitro* bacterial reverse mutation assay or clastogenic in the *in vitro* Chinese hamster ovary cell chromosome aberration assay.

**Reproductive Toxicity:** Chronic use of opioids may cause reduced fertility in females and males of reproductive potential. It is not known whether these effects on fertility are reversible. A study in rats and rabbits reported no teratogenic effect of codeine administered during the period of organogenesis in doses ranging from 5 to 120 mg/kg. In the rat, doses at the 120 mg/kg level, in the toxic range for the adult animal, were associated with an increase in embryo resorption at the time of implantation. In another study a single 100 mg/kg subcutaneous dose of codeine administered to pregnant mice reportedly resulted in delayed ossification in the offspring. Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth. Codeine and its active metabolite, morphine, are present in human milk. There are published studies and cases that have reported excessive sedation, respiratory depression, and death in infants exposed to codeine via breast milk. Women who are ultra-rapid metabolizers of codeine achieve higher than expected serum levels of morphine, potentially leading to higher levels of morphine in breast milk that can be dangerous in their breastfed infants.

**Carcinogenicity:** None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA. Two-year carcinogenicity studies have been conducted with codeine sulfate in F344/N rats and B6C3F1 mice. There was no evidence of carcinogenicity in male and female rats, respectively, at dietary doses up to 70 and 80 mg/kg/day of codeine sulfate for two years. Similarly there was no evidence of carcinogenicity activity in male and female mice at dietary doses up to 400 mg/kg/day of codeine sulfate for two years.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: >5,000 mg/kg

Codeine Phosphate: Oral rat LD50 85 mg/kg

Acetaminophen: Oral rat LD50 1944 mg/kg

## 12. ECOLOGICAL INFORMATION

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

**Ecotoxicity values:** No data available.

**Persistence and degradability:** No data available.

**Bioaccumulative potential:** No data available.

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

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

## 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

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**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Refer to Section 2 for the OSHA Hazard Classification

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**California Proposition 65:** This product is not known to contain regulated chemicals.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

## 16. OTHER INFORMATION

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**Revision Number:** 01

**Revision Date:** New SDS

**SDS Revision History:** New SDS

**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.