



SDS: Acetaminophen and Codeine Phosphate Oral Solution,
USP CV

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Acetaminophen and Codeine Phosphate Oral Solution, USP CV

Synonyms: Paracetamol, Methymorphine Phosphate

National Drug Code (NDC): 50383-079-16

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Combustible liquid Category 4

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: Warning.

Hazard Statement(s): H227 Combustible liquid.

Precautionary Statement(s): P210 Keep away from flames and hot surfaces. No smoking.

P280 Wear protective gloves/eye protection/ face protection.

P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.

P403 + P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Acetaminophen	103-90-2	Paracetamol	C ₈ H ₉ NO ₂	151.16	2.4%
Codeine Phosphate	52-28-8	Methylmorphine Phosphate	C ₁₈ H ₂₁ NO ₃ ·H ₃ OP ₄ ·½H ₂ O	406.37	0.24%

*The formula also contains Alcohol, 7%; Artificial Cherry Flavor, Citric Acid, FD&C Yellow No. 6, Propylene Glycol, Purified Water, Saccharin Sodium, Sodium Benzoate, and Sucrose.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Signs and Symptoms:

Use personal protective equipment (see section 8). Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.

Medical Conditions Aggravated by Exposure:

Product is pharmaceutical, overdose to be handled as per instruction form a physician.

SDS: Acetaminophen and Codeine Phosphate Oral Solution, USP CV

Other Health Warnings:

Toxicity from codeine poisoning includes the opioid triad of: pinpoint pupils, depression of respiration, and loss of consciousness. Convulsions may occur.

In acetaminophen overdose: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adult hepatic toxicity has rarely been reported with acute overdose of less than 10 grams, or fatalities with less than 15 grams.

Notes to Physician:

Advise patients that some people have a genetic variation that results in codeine changing into morphine more rapidly and completely than other people. Most people are unaware of whether they are an ultra-rapid codeine metabolizer or not. These higher-than-normal levels of morphine in the blood may lead to life-threatening or fatal respiratory depression or signs of overdose such as extreme sleepiness, confusion, or shallow breathing. Children with this genetic variation who were prescribed codeine after tonsillectomy and/or adenoidectomy for obstructive sleep apnea may be at greatest risk based on reports of several deaths in this population due to respiratory depression. Codeine-containing products are contraindicated in all children who undergo tonsillectomy and/or adenoidectomy. Advise caregivers of children receiving codeine-containing products for other reasons to monitor for signs of respiratory depression.

5. Firefighting Measures

Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media:

With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

Not determined.

Other Specific Hazards:

Not determined.

Special Protective Equipment/ Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

SDS: Acetaminophen and Codeine Phosphate Oral Solution, USP CV

6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Pick up in the most efficient manner. Soak up with sawdust, sand oil dry or other absorbent material.
Environmental Precautions:	No data available.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
Conditions for Safe Storage, Including Any Incompatibilities:	Store according to label and/or product insert information. Store away from oxidizing agents and acids.
Specific End Use:	Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Acetaminophen	5 mg/m ³ TWA
Codeine Phosphate	200 mg/m ³ TWA
Alcohol	OSHA PEL: 100 ppm NIOSH PEL: 1900 mg/m ³ NIOSH IDLH: 3300 ppm ACGIH REL: 1900 mg/m ³ ; 1000 ppm ACGIH TLV: 1000 ppm TWA STEL: 1000 ppm

Engineering Controls: Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

SDS: Acetaminophen and Codeine Phosphate Oral Solution, USP CV

Hand Protection:	Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color:	Yellow to Amber thick clear syrup.
Odor:	Cherry aroma.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	>150°F.
Evaporation Rate:	Same as water.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	>1.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions. Avoid sources of ignition.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Strong oxidizer.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.
Hazardous Polymerization:	Will not occur.

11. **Toxicological Information**

Information on the Likely Routes of Exposure:

Inhalation:	No data available.
Ingestion:	No data available.
Skin Contact:	No data available.
Eye Contact:	No data available.

**Symptoms Related to the Physical,
Chemical and Toxicological
Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of
Exposure:**

No data available.

Acute Toxicity – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on
Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health
Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: Based on available data, the classification criteria are not met.

12. **Ecological Information**

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Acetaminophen is listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Codeine Phosphate is listed.

16. Other Information

NFPA Rating:
Health: 1
Fire: 2
Reactivity: 0

Revision Date: 04/30/2015

Revision Number: 1

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.