



# SDS: Hydrocodone Bitartrate and Homatropine Methylbromide Syrup CII

## SAFETY DATA SHEET

### 1. Identification

<b>Product Identifier:</b>	Hydrocodone Bitartrate and Homatropine Methylbromide Syrup CII
<b>Synonyms:</b>	Dihydrocodeione bitartrate hydrate; Homatropine methobromide
<b>National Drug Code (NDC):</b>	50383-043-16
<b>Recommended Use:</b>	Pharmaceutical.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. Hazard(s) Identification

<b>Physical Hazards:</b>	Combustible liquid	Category 4
<b>Health Hazards:</b>	Not classifiable.	
<b>Symbol(s):</b>	None.	
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H227 Combustible liquid.	
<b>Precautionary Statement(s):</b>	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.	
<b>Hazards Not Otherwise Classified:</b>	Not classifiable.	
<b>Supplementary Information:</b>	None.	

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### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Hydrocodone Bitartrate, USP	34195-34-1	Dihydrocodeione bitartrate hydrate	$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2\frac{1}{2}H_2O$	494.50	0.1%
Homatropine Methylbromide, USP	80-49-9	Homatropine methobromide	$C_{17}H_{24}BrNO_3$	370.29	0.03%

\*The formula also contains Caramel Color, Cherry Flavor, Citric Acid, FD&C Red #40, Methylparaben, Propylparaben, Purified Water, Sorbitol Solution and Sucrose Syrup. Citric Acid and/or Sodium Citrate may be added to adjust pH.

### 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:**

Use personal protective equipment (see section 8).

**WARNING:**

Hydrocodone Bitartrate and Homatropine Methylbromide Syrup may be habit forming (addictive).

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### Signs and Symptoms:

Solution is intended for human consumption under guidance of a physician. Solution is not considered hazardous under normal conditions.

Exposure to Hydrocodone Bitartrate and Homatropine Methylbromide Syrup may cause lightheadedness, sedation, dizziness, pinpoint pupils, nausea and vomiting. Other adverse effects include constipation, rash and itching. Feelings described as very comfortable progressing to extreme restlessness have been reported.

Exposure to Hydrocodone Bitartrate and Homatropine Methylbromide Syrup may cause hypersensitization. Hydrocodone, the active ingredient, is structurally related to other narcotics which are absorbed through the skin in toxic amounts and are potential skin and/or respiratory sensitizers. It is expected that hydrocodone will have similar properties.

Overexposure can lead to respiratory depression, extreme sleepiness, progressing to stupor or coma, relaxation of muscles, cold and clammy skin, slowed heart rate, lowered blood pressure and death.

Hydrocodone, the base of one of the active ingredients in the product, is structurally-related to other opiates which have been reported to cause hormonal effects which may alter reproductive function. The weight of evidence indicates no association exists between malformation or congenital defects in babies born to women who had taken hydrocodone during the first trimester or pregnancy. As with most opiates, repeated exposure is believed to result in physical dependence and subsequent withdrawal symptoms in the fetus or neonate. Hydrocone is expected to pass into breast milk.

### Medical Conditions Aggravated by Exposure:

None.

### Notes to Physician:

Treat supportively and symptomatically.

### Other Health Warnings:

The narcotic antagonist naloxone hydrochloride (NARCAN) is a specific antidote for overexposure to narcotics including Hydrocodone Bitartrate and Homatropine Methylbromide Syrup. In the presence of hypoventilation or apnea, oxygen should be administered and respiration should be assisted or controlled as indicated.

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### 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:** None, however, observe usual precautions for hand care of flammable liquid.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/  
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### 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:** Not available.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:** Hydrocodone Bitartrate and Homatropine Methylbromide Syrup is a Schedule II narcotic and therefore subject to the Federal Controlled Substance Act; handle accordingly. 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:** Keep container tightly closed and store between 68°F – 77°F. Store according to label and/or product insert information.

**Specific End Use:** Pharmaceuticals.

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### 8. Exposure Controls/Personal Protection

#### Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Hydrocodone Bitartrate	STEL: 100 mg/m <sup>3</sup> 33 mg/m <sup>3</sup> TWA
Homatropine Methylbromide	Not established.

**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.

**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:** Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Red viscous liquid.
<b>Odor:</b>	Cherry odor.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	140°F.
<b>Evaporation Rate:</b>	Same as water.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	>1.

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<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. Stability and Reactivity

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

### 11. Toxicological Information

#### Information on the Likely Routes of Exposure:

<b>Inhalation:</b>	Harmful if inhaled.
<b>Ingestion:</b>	Harmful if swallowed.
<b>Skin Contact:</b>	Harmful if absorbed through skin.
<b>Eye Contact:</b>	No data available.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	No data available.
<b>Acute Toxicity – Oral:</b>	No data available.
<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	May cause sensitization by inhalation or skin contact.
<b>Toxicokinetics/Metabolism:</b>	No data available.

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<b>Target Organ Effects:</b>	May cause central nervous system, cardiovascular, respiratory gastrointestinal or hormonal effects.
<b>Reproductive Effects:</b>	May cause effects to the unborn child or breastfed babies.
<b>Carcinogenicity:</b>	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.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.

### 12. Ecological Information

#### Ecotoxicity

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

### 13. Disposal Considerations

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

### 14. Transport Information

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

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### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Not listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

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

#### State Regulations

**California Proposition 65:** Not listed.

### 16. Other Information

#### **NFPA Rating:**

Health: 0  
Flammability: 1  
Reactivity: 0

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