



SDS: Promethazine Hydrochloride and Dextromethorphan Hydrobromide Oral Solution

SAFETY DATA SHEET

1. Identification

Product Identifier: Promethazine Hydrochloride and
Dextromethorphan Hydrobromide Oral Solution

Synonyms: Proazamine chloride; D-Methorphan hydrobromide
monohydrate

National Drug Code (NDC): 50383-803-16

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

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

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

Hazards Not Otherwise Classified: Not classifiable.

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Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Promethazine Hydrochloride	58-33-3	Proazamine chloride	C ₁₇ H ₂₀ N ₂ S•HCl	320.88	0.125%
Dextromethorphan Hydrobromide	6700-34-1	D-Methorphan hydrobromide monohydrate	C ₁₈ H ₂₅ NO•HBr•H ₂ O	370.32	0.3%
Alcohol	64-17-5	Ethyl alcohol	C ₂ H ₅ OH	46.07	7%

*The formula also contains Citric Acid, D&C Yellow #10, FD&C Yellow #6, Glycerin, Invert Sugar Syrup, Natural and Artificial Raspberry Flavor, Purified Water, Saccharin Sodium, Sodium Benzoate, Sodium Citrate, and Sodium Propionate.

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).

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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.
Medical Conditions Aggravated by Exposure:	None.
Notes to Physician:	Treat supportively and symptomatically.
Other Health Warnings:	Dextromethorphan: Drowsiness, dizziness and GI disturbance. Overdosage Promethazine: Signs and symptoms of overdosage with promethazine range from mild depression of the central nervous system and cardiovascular system to profound hypotension, respiratory, depression, and unconsciousness. Stimulation may be evident, especially in children and geriatric patients. Convulsions may rarely occur.

5. Firefighting Measures

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary. With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

Unsuitable Extinguishing Media: Not determined.

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.

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.



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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:** Keep container tightly closed. Store between 59°F – 77°F. 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
Promethazine Hydrochloride	0.025 mg/m ³ TWA
Dextromethorphan Hydrobromide	10 mg/m ³ TWA

- Engineering Controls:** 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:** Not required for the normal use of this product. 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:** Not required for the normal use of this product. Chemically compatible gloves. 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:** Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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9. Physical and Chemical Properties

Physical State/Color:	Yellow syrup.
Odor:	Raspberry odor.
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:	>140°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):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.30000.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions. Avoid source 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.

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**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:

No data available.

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.



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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): 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: 2
Reactivity: 0

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