

Issue Date: 27-May-2025

Version 01

**1. PRODUCT AND COMPANY IDENTIFICATION****Product identifier**

**Product Name:** Promethazine DM Oral Solution  
**Product Codes:** 0121-1070-16

**Other means of identification**

**Synonyms** Refer to Medical Insert Sheet

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

**Recommended Use** Temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold.  
**Uses advised against** Not available.

**Details of the supplier of the safety data sheet****Supplier Address**

PAI Pharma  
201 Delaware Street  
Greenville, SC 29605  
(864) 277-7282

**Emergency telephone number**

**Emergency Telephone** CHEMTREC 1-800-424-9300

**2. HAZARDS IDENTIFICATION****Classification****Health Hazards**

Not classified.

**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**

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 yellow solution

**Physical state** Liquid

**Odor** Pineapple menthol

**Hazards not otherwise classified (HNOC)**

Not available.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Synonyms** Refer to Medical Insert Sheet

Chemical Name	CAS No.	Weight-%
Dextromethorphan hydrobromide USP	125-71-3	0.1-1
Ethyl alcohol	64-17-5	Proprietary
Promethazine hydrochloride	58-33-3	0.1-1
Propylene glycol USP	57-55-6	Proprietary
Sucrose	57-50-1	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 the use of this product include the following: dizziness; drowsiness; dry mouth; nausea; stomach upset.

**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: 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		
Appearance	Clear yellow	Odor	Pineapple menthol
Color	solution Yellow	Odor threshold	Not available.

<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.

**Hazardous polymerization**

Hazardous polymerization does not occur.

**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
Dextromethorphan hydrobromide USP 125-71-3	= 116 mg/kg ( Rat )	-	-	-
Ethyl alcohol 64-17-5	= 7060 mg/kg ( Rat )	-	= 124.7 mg/L ( Rat ) 4 h	-
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 the use of this product include the following: dizziness; drowsiness; dry mouth; nausea; stomach upset.

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

<b>Skin corrosion/irritation</b>	Not available.
<b>Serious eye damage/eye irritation</b>	Not available.
<b>Irritation</b>	Not available.
<b>Corrosivity</b>	Not available.
<b>Sensitization</b>	Not available.
<b>Germ cell mutagenicity</b>	Not available.
<b>Carcinogenicity</b>	Long-term animal studies have not been performed to assess the carcinogenic potential of promethazine or dextromethorphan. 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**

Specific studies to test the action of the Promethazine DM Oral Solution on parturition, lactation, and development of the animal neonate were not done, but a general preliminary study in rats indicated no effect on these parameters. Although antihistamines have been found to

**Developmental Toxicity  
Teratogenicity**

produce fetal mortality in rodents, the pharmacological effects of histamine in the rodent do not parallel those in man. There are no adequate and well-controlled studies of promethazine in pregnant women. Promethazine and dextromethorphan should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

Not available.

*Pregnancy Category C:* Teratogenic effects have not been demonstrated in rat-feeding studies at doses of 6.25 and 12.5 mg/kg of promethazine HCl. These doses are from approximately 2.1 to 4.2 times the maximum recommended total daily dose of promethazine for a 50-kg subject, depending upon the indication for which the drug is prescribed. Daily doses of 25 mg/kg intraperitoneally have been found to produce fetal mortality in rats.

**STOT - single exposure**  
**STOT - repeated exposure**  
**Chronic toxicity**  
**Subchronic toxicity**  
**Target Organ Effects**  
**Neurological effects**  
**Aspiration hazard**

Not classified.

Not classified.

Not available.

Not available.

Not available.

Not available.

Due to the physical form of the product it is not an aspiration hazard.

**Numerical measures of toxicity - Product Information**
**12. ECOLOGICAL INFORMATION**
**Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
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
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

**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

<b>TSCA</b>	Does not comply
<b>DSL/NDL</b>	Does not comply
<b>EINECS/ELINCS</b>	Does not comply
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply

##### Legend:

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

**DSL/NDL** - 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 trained 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
Propylene glycol USP 57-55-6	X	-	X
Ethyl alcohol 64-17-5	X	X	X

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not available.

**16. OTHER INFORMATION**

Issue Date 27-May-2025

Revision Date

Revision Note

Not available.

**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