

Promethazine with Dextromethorphan Cough Syrup

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Promethazine DM Oral Solution

1.2. Other means of identification

Synonyms : Refer to Medical Insert Sheet

1.3. Recommended Use

Temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold.

1.4. Uses Advised Against

Not available.

1.5. Details of the supplier of the safety data sheet

Xttrium Laboratories, Inc.
1200 East Business Center Drive
Mt. Prospect, IL 60056

1.6. Emergency telephone number

Emergency Telephone number : 773-268-5800

SECTION 2: Hazards identification

2.1. Classification

Health Hazards : Not classified

Physical Hazards : Not classified

2.2. Label elements

Warning

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 consistent with the labeled directions.

Physical State: liquid

Odor: Fruit scent

Appearance: clear yellow liquid

2.3. Hazards Not Otherwise Classified

Hazards Not Otherwise Classified (HNOC) : Not available.

SECTION 3: Composition/information on ingredients

3.1. Mixture

Chemical Name	CAS No.	Weight-%
Promethazine Hydrochloride, USP	58-33-3	Proprietary
Dextromethorphan Hydrobromide, USP	125-69-9	Proprietary
Purified Water	7732-18-5	Proprietary
Sucrose	57-50-1	Proprietary
Glycerin	56-81-5	Proprietary
Sodium Citrate Dihydrate	6132-04-3	Proprietary
Edatate Disodium	139-33-3	Proprietary
Sodium Benzoate	532-32-1	Proprietary
Saccharin Sodium	128-44-9	Proprietary
Sodium Propionate	137-40-6	Proprietary
Ascorbic Acid	50-81-7	Proprietary
Citric Acid Anhydrous	77-92-9	Proprietary
Dehydrated Alcohol	64-17-5	Proprietary
Methylparaben	99-76-3	Proprietary
FD&C Yellow No. 6	2783-94-0	Proprietary
D&C Yellow No. 10	8004-92-0	Proprietary
Flavors	Not applicable	Proprietary

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SECTION 4: First aid measures

4.1. General Advise

Consult a physician. Show this SDS to the attending doctor.

Eye Contact	: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation develops.
Skin Contact	: Wash off with soap and water. Remove contaminated clothing. Seek medical attention if symptoms persist.
Inhalation	: Move to fresh air. If symptoms persist, call a physician.
Ingestion	: Rinse mouth. Do NOT induce vomiting. Get immediate medical attention.

4.2. Most Important Symptoms and effects

Symptoms : Drowsiness, dizziness, nausea, dry mouth, stomach upset.

4.3. Indication of any immediate medical attention and special treatment needed

Note to Physicians : Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Suitable Extinguishing media

Use extinguishing media suitable for surrounding fire.

Unsuitable extinguishing media None known.

5.2. Special hazards

Specific Hazards: None under normal use conditions. .

5.3. Protective Equipment

Wear self-contained breathing apparatus and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with skin, eyes, and clothing.

6.2. Environmental Precautions

Prevent further leakage or spillage if safe to do so. Do not let products enter drains.

6.3. Methods for Cleanup

Absorb with inert material and dispose of in accordance with local regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes, or clothing.

7.2. Storage Conditions

Storage conditions : Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Keep tightly closed. Protect from light.

7.3. Incompatible Materials

Strong oxidizing agents.

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SECTION 8: Exposure controls/personal protection

8.1. Exposure Limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose	TWA 10 mg/m ³	TWA 15 mg/m ³	TWA 10 mg/m ³

8.2. Engineering controls and Personal Protective Equipment

Ensure adequate ventilation. Maintain levels below exposure limits.

Eye Protection : Safety glasses with side shields are recommended.

Skin Protection : Protective gloves and clothing.

Respiratory Protection : Not required under normal use. Use appropriate respirator if exposure limits are exceeded.

Hygiene Measures : Wash hands after handling. Do not eat, drink, or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	: clear to yellow liquid
Odor	: Fruit Scent
Physical state	: Liquid
pH	: 4.7 - 5.2
Boiling point	: No data available
Melting point	: No data available
Flash point	: No data available
Solubility	: No data available
Specific gravity	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal conditions.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Extreme temperatures.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

None under normal use conditions.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Likely Routes of Exposure : Eye contact, skin contact, ingestion. inhalation.

Symptoms : Drowsiness, dizziness, nausea, vomiting, dry mouth.

11.2. Acute toxicity

No known significant effects or critical hazards under normal use.

11.3. Carcinogenicity

Long-term animal studies have not been performed to assess the carcinogenic potential of promethazine or dextromethorphan. There are no animal or human data concerning the carcinogenicity, mutagenicity, or impairment of fertility with these drugs.

Reproductive Toxicity : Not established

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Ecotoxicity

Not expected to be harmful to the environment in small quantities.

12.2. Persistence and Degradability

Not established.

12.3. Mobility

Not determined.

12.4. Other adverse effects

None known.

SECTION 13: Disposal considerations

13.1. Waste Disposable

Waste disposal recommendations : Dispose of in accordance with local, state, and federal regulations. Contaminated Packaging: Disposal should be in accordance with applicable regional, national as unused product.

SECTION 14: Transport information

DOT / IMDG / IATA not regulated

SECTION 15: Regulatory information

15.1. State Regulations

California Proposition 65 : Not listed.

SECTION 16: Other information

Disclaimer: This Safety Data Sheet (SDS) is offered for your consideration and guidance when exposed to this product. Xttrium Laboratories makes no warranties and assumes no liability in connection with any use of this information.