

Promethazine Syrup Plain 6.25mg/5mL (Promethazine HCl Syrup)

Safety Data Sheet

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

1.1. Product identifier

Product name : Promethazine Syrup Plain 6.25mg/5mL (Promethazine HCl Syrup)

1.2. Other means of identification

Synonyms : Promethazine HCl Oral Solution

1.3. Recommended Use

Promethazine is useful for: Perennial and seasonal allergic rhinitis. Vasomotor rhinitis. Allergic conjunctivitis due to inhalant allergens and foods. Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

1.4. Uses Advised Against

Contraindicated in pediatric patients under two years of age. Contraindicated in comatose patients or those known hypersensitive to promethazine or phenothiazines. Contraindicated in treatment of lower respiratory tract symptoms including asthma.

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 : Reproductive toxicity Category 1 B

Physical Hazards : Not classified

2.2. 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 the Safety Data Sheet (SDS).

2.3. Label elements

Warning

Emergency Overview

Hazard statements: Promethazine should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

Postmarketing cases of respiratory depression, including fatalities, have been reported with use of Promethazine in pediatric patients less than 2 years of age. A wide range of weight-based doses of Promethazine have resulted in respiratory depression in these patients.

Caution should be exercised when administering Promethazine to pediatric patients 2 years of age and older. It is recommended that the lowest effective dose of Promethazine be used in pediatric patient 2 years of age and older and concomitant administration of other drugs with respiratory depressant effects be avoided.

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.

Physical State: liquid

Odor: practically odorless

Appearance: white to faint yellow

2.4. Hazards Not Otherwise Classified

Hazards Not Otherwise Classified (HNOC) : No data available

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SECTION 3: Composition/information on ingredients

3.1. Mixture

Chemical Name	CAS No.	Weight-%
Promethazine Hydrochloride, USP	58-33-3	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 Blue No. 1	3844-45-9	Proprietary
FD&C Red No. 40	25956-17-6	Proprietary
D&C Yellow No. 10	8004-92-0	Proprietary
Flavors	Not applicable	Proprietary

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 at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Continue rinsing. Seek medical attention if irritation persists.
Skin Contact	: Immediately flush skin with copious amounts of water for at least 15 minutes. Remove contaminated clothing. Seek medical attention if symptoms persist.
Inhalation	: Inhalation is not anticipated route for liquid handling. For intended use, see product label.
Ingestion	: Rinse mouth. Do NOT induce vomiting. Get immediate medical attention.
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.

4.2. Most Important Symptoms and effects

Symptoms	: Drowsiness, Sedation, somnolence, blurred vision, dizziness, confusion, disorientation, nausea, dry mouth, vomiting, jaundice.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to Physicians	: Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Suitable Extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment available.

Unsuitable extinguishing media None known.

5.2. Special hazards

Not available.

5.3. Advice for firefighters

Protective Equipment and precautions : 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

Dispose of in accordance with local, state, and national 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.

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

None known based on information supplied.

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SECTION 8: Exposure controls/personal protection

8.1. Exposure Limits

Chemical Name	Employee Exposure Limits
Promethazine Hydrochloride	TWA 0.025 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 : 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.

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

Stable at normal conditions.

10.2. Chemical stability

Stable at ambient temperatures and atmospheric pressures under recommended storage and handling conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Not available.

10.5. Incompatible materials

Not known based on information supplied.

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.

Common side effects associated with use of this product include the following: mild constipation, nausea; dizziness, drowsiness; feeling restless; blurred vision, ringing in ears; flushing (warmth, redness or tingly feeling); sleep problems (insomnia); dry mouth; itching, mild rash, increased sweating.

Carcinogenicity, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to assess the carcinogenic potential of promethazine nor are there other animal or human data concerning carcinogenicity, mutagenicity, or impairment of fertility with this drug. Promethazine was nonmutagenic in the Salmonella test system of Ames.

Reproductive Toxicity : Not available

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 available.

12.3. Mobility

Not available

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, regulations.

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.