



SDS: Paremyd® (hydroxyamphetamine hydrobromide/
tropicamide ophthalmic solution) 1%/0.25%

SAFETY DATA SHEET

1. Identification

Product Identifier: Paremyd® (hydroxyamphetamine hydrobromide/
tropicamide ophthalmic solution) 1%/0.25%

Synonyms: Hydroxyamphetamine Hydrobromide; Tropicamide

National Drug Code (NDC): 17478-704-12

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: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: None.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Hydroxyamphetamine Hydrobromide	306-21-8	Hydroxyamphetamine Hydrobromide; Tropicamide	C ₉ H ₁₃ NO•HBr	Not available.	1.0%
Tropicamide	1508-75-4	Benzeneacetamide, N-ethyl-alpha-(hydroxymethyl)-N-(4-pyridinylmethyl)-, (+/-)-	C ₁₇ H ₂₀ N ₂ O ₂	284.36	0.25%

* The formula also contains Benzalkonium Chloride, 0.005% as a preservative; Edetate Disodium, 0.015%; Sodium Chloride, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH between (4.2 – 5.8 during its shelf life) and Water for Injection.

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).
Signs and Symptoms:	Not determined. Please see package insert for more information.
Medical Conditions Aggravated by Exposure:	Not determined.
Notes to Physician:	Patients should be advised not to touch the dropper tip to any surface since this may contaminate the solution. Patients should be advised to use caution when driving or engaging in other hazardous activities while pupils are dilated. Patients may experience photophobia and/or blurred vision and should protect their eyes in bright illumination when pupils are dilated. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration.

5. **Firefighting Measures**

Suitable Extinguishing Media: Water spray, foam, CO₂, or dry chemical, as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: Toxic fumes of Co, CO₂, NO, and NO₂.

Explosion: Presumed to be combustible when heated to decomposition.

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: Wear appropriate protective gear. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Place spillage in appropriately labeled container for disposal. Wash spill site.

Environmental Precautions: No data available.

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

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:** Store according to label and/or product insert information. Store product upright in original containers with cap tightly closed at a controlled room temperature 20°C – 25°C (68°F – 77°F).

Specific End Use: Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Hydroxyamphetamine Hydrobromide	Not established.
Tropicamide, USP	Not established.

Engineering Controls: Provide exhaust ventilation or other engineering controls to keep the air born concentrations of vapors below their threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

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.

Contaminated Equipment: Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to federal, state and local regulation.

9. **Physical and Chemical Properties**

Physical State/Color: Clear, colorless liquid solution.
Odor: Odorless.
Odor Threshold: No data available.
pH: 4.2 – 5.8.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: No data available.

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Evaporation Rate:	No data available.
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:	No data available.
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:	1.00 – 1.04.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Exposures to heat and light.
Incompatible Materials:	Oxidizing agents, strong acid and alkaline solutions, and alkali metals.
Hazardous Decomposition Products:	At burning condition produces toxic fumes, oxides of carbon.
Hazardous Polymerization:	Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May cause irritation, allergic reaction.
Ingestion:	May cause irritation, allergic reaction. Material is readily absorbed from the gastrointestinal tract.
Skin Contact:	Prolonged skin exposure may cause irritation and allergic reaction.
Eye Contact:	Product is irritating to the eyes and may cause prolonged pupil dilation.
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.

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Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Tropicamide	Rat	Oral	LD ₅₀	865 mg/kg
Tropicamide	Mouse	Oral	LD ₅₀	565 mg/kg
Tropicamide	Rat	Intraperitoneal	LD ₅₀	1,210 mg/kg

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: Based on available data, the classification criteria are not met.

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.
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.
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16. Other Information

Not made with natural rubber latex.

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