

## SAFETY DATA SHEET

1. Identification

**Product Identifier:** Orphenadrine Citrate Injection, USP

**Synonyms:** Mephenamine citrate

**National Drug Code (NDC):** 17478-538-02

**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:** May be harmful if swallowed Category 5

**Symbol(s):** None.

**Signal Word:** Warning.

**Hazard Statement(s):** H303 May be harmful if swallowed.

**Precautionary Statement(s):** P312 Call a POISON CENTER/doctor if you feel unwell.

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Orphenadrine Citrate	4682-36-4	Mephenamine citrate	$H_{18}H_{23}NO \cdot C_6H_8O_7$	461.50	6%

\*The formula also contains Sodium Chloride, 5.8 mg; Sodium Metabisulfite, 2.0 mg; Sodium Hydroxide to adjust pH between 5.0 – 6.0 and Water for Injection.

**4. First Aid Measures**

<b>Ingestion:</b>	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.
<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Possible irritation or allergic reaction to material if inhaled, ingested or applied onto skin. May also cause dryness of mouth, heart arrhythmia, blurred vision, nausea, vomiting, headache, and confusion.
<b>Medical Conditions Aggravated by Exposure:</b>	Not determined.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

**5. Firefighting Measures**

<b>Explosion:</b>	Not determined.
<b>Suitable Extinguishing Media:</b>	Water spray, dry chemical, fog, foam, or carbon dioxide.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

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### 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:** Ventilate area of large spill. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. Absorb with inorganic material. Carefully sweep up material into an approved container, seal and save for disposal.

**Environmental Precautions:** The products of degradation are less toxic than orphenadrine itself.

**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 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
Orphenadrine Citrate	Not established.
Sodium Chloride USP	Not established.
Sodium Metabisulfite	NIOSH REL: 5 mg/m <sup>3</sup> ACGIH TLV: 5 mg/m <sup>3</sup> TWA

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

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<b>Respiratory Protection:</b>	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).
<b>Eyes Protection:</b>	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.
<b>Hand Protection:</b>	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.
<b>Skin Protection:</b>	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Colorless clear liquid solution.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	~100°C
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	~Aqueous.
<b>Volatile:</b>	None.

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):** Storage near to reactive materials.

**Incompatible Materials:** Avoid excessive heat, water-reactive materials, and oxidizing agents.

**Hazardous Decomposition Products:** Burning may produce carbon monoxide, carbon dioxide, and nitrogen oxides.

**Hazardous Polymerization:** Will not occur.

11. **Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Route of Entry:** Orphenadrine may be absorbed into skin, inhaled or accidentally ingested.

**Inhalation:** Unlikely to occur.

**Ingestion:** Moderate Toxic.

**Skin Contact:** Irritation by absorption.

**Eye Contact:** Acute irritation.

**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:**

Compound	Species	Route	Type	Dose
Orphenadrine Citrate	Rat	Oral	LD <sub>50</sub>	150 mg/kg
Orphenadrine Citrate	Rat	Intravenous	LD <sub>50</sub>	26 mg/kg
Orphenadrine Citrate	Mouse	Intravenous	LD <sub>50</sub>	37 mg/kg
Orphenadrine Citrate	Rat	Intramuscular	LD <sub>50</sub>	208 mg/kg

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	No data available.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	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.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	No data available.

**12. Ecological Information****Ecotoxicity**

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

**13. Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

**14. Transport Information**

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	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**

Not made with natural rubber latex.

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