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|  | Sagent Pharmaceuticals, Inc. | | | |
| | Orphenadrine Citrate Injection, USP | | Material Safety Data Sheet (MSDS) | |
| | Issue Date: Jun 03, 2010 | MSDS No.: MSDS 036 | Version No.: 1.0 | Form Number: R-SOP-009-F001 |

Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Orphenadrine Citrate Injection, USP (30 mg/mL)
Product Code: 25021-651
Common/Trade Name: Mephenamine citrate; Norflex®; Benhexal®; Orfenadrina®
Chemical Name: 2-dimethylaminoethyl 2- methylbenzhydryl ether citrate
Chemical Family: Analgesic / Anti-cholinergic
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials

Section 2 - Composition / Information on Ingredients


| Ingredient | Qty mg/mL | CAS No. |
|----------------------|--------------|-----------|
| Orphenadrine Citrate | 30.0 | 4724-58-7 |
| Sodium Metabisulfite | 1.0 | 7681-57-4 |
| Sodium Chloride | 2.9 | 7647-14-5 |
| Sodium Hydroxide | q.s. | 1310-73-2 |
| Water for Injection | q.s. to 1 mL | 7732-18-5 |

Section 3 - Hazards Identification

Primary Physical and Health Hazard: Short-term contact may cause skin, eye, gastrointestinal tract, and respiratory irritation. Orphenadrine Citrate contains a sodium metabisulfite that can cause allergic reactions in some individuals.

Routes of Entry: Inhaled, eye/skin contact, ingestion

Signs & Symptoms of Exposure: Possible irritation or allergic reaction to material if inhaled, ingested or in contact with skin. May also cause dryness or mouth, heart arrhythmia, blurred vision, nausea, vomiting, headache, dizziness, blurred vision, eye difficulties, and confusion.

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Chemical Listed as Carcinogen: NTP: No IARC: No OSHA: No

Medical Conditions Generally Aggravated by Exposure: Glaucoma, ulcers, urinary tract problems, cardio-spasm and myasthenia gravis.

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes

Skin Exposure: Wash skin with cool, soapy water for 15 minutes.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

Injection: Not available

Inhalation: Remove from exposure. If difficulty breathing, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

Flash Point: Not established


Auto-ignition Temperature: Not established

Flammable Limits in Air: Lower %: Not established
Upper %: Not established

Flammable Limits: Not established

Extinguishing Media: Use water or an ABC multi-purpose extinguisher for surrounding materials.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Product is aqueous-based and is not expected to present a fire hazard concern.

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Unusual Fire/Explosion Hazards: None known

Section 6 - Accidental Release Measures

Spill: Absorb with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: Wash hands following use. No eating, drinking, or smoking while handling this product.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.] Protect from light.

Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.


Eye Protection: Safety glasses

Ventilation: Handle product in a well-ventilated area.

Skin Protection: Lab coat

Other Protective Equipment: Latex or nitril gloves.

Additional Exposure Precautions: None established

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Exposure Limits


| <u>Compound</u> | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
|----------------------|---------------|-------------|------------|
| Orphenadrine Citrate | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ---- | STEL | NE |
| Sodium Metabisulfite | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ---- | STEL | NE |
| Sodium Chloride | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ---- | STEL | NE |
| Sodium Hydroxide | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ---- | STEL | NE |
| Water for Injection | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ---- | STEL | NE |

Section 9 - Physical and Chemical Properties

| | | | |
|-----------------------------|---------------|-----------------------------|-----------------|
| Physical State: | Liquid | Specific Gravity: | Approx to Water |
| Appearance and Odor: | Colorless | Evaporation Rate: | Approx to Water |
| Boiling Point: | Approx. 100°C | Melting Point: | Not applicable |
| Vapor Pressure: | Not available | Solubility in Water: | Soluble |
| Vapor Density: | Not available | pH: | 5.5 |
| | | Molecular Weight: | 461.50 |

Section 10 - Stability and Reactivity

| | |
|--|--|
| Stability: | Stable |
| Incompatibility (Materials to avoid): | Water-reactive materials |
| Hazardous Decomposition: | Decomposition products of this compound may include potentially hazardous byproducts, acrid and toxic fumes. |

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Hazardous Polymerization: Will not occur

Conditions to Avoid: Storage near water reactive materials.

Section 11 - Toxicological Information

Signs & Symptoms of Exposure: Possible irritation or allergic reaction to material if inhaled, ingested or in contact with skin. May also cause dryness or mouth, heart arrhythmia, blurred vision, nausea, vomiting, headache, dizziness, blurred vision, eye difficulties, and confusion.

Acute Toxicity

| Component | Type | Route | Species | Dosage |
|----------------------|------------------|---------------|---------|-----------|
| Orphenadrine Citrate | LD ₅₀ | Oral | Rat | 150 mg/kg |
| Orphenadrine Citrate | LD ₅₀ | Intravenous | Rat | 26 mg/kg |
| Orphenadrine Citrate | LD ₅₀ | Intramuscular | Rat | 208 mg/kg |
| Orphenadrine Citrate | LD ₅₀ | Intravenous | Mouse | 37 mg/kg |


Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) registry of Toxic Effects of Chemical Substances (RTECS) Number KR6125000.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

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Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *No*

CERCLA - *Not on this list*

SARA 313 - *Not on this list*

OSHA Substance Specific - *No*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


For additional information contact:

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

| | |
|------------|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AIHA | American Industrial Hygiene Association |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| EPA | Environmental Protection Agency |
| HEPA | High Efficiency Particulate Air (Filter) |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport Association |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NIOSH | National Institute for Occupational Safety and Health |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |