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|  | Sagent Pharmaceuticals, Inc. | | | |
| | Metoprolol Tartrate Injection, USP | | Material Safety Data Sheet (MSDS) | |
| | Issue Date: Oct 05, 2009 | MSDS No.: MSDS 021 | 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: Metoprolol Tartrate Injection, USP (1 mg/mL- 5 mL)
Product Code: NDC 25021-303-05
Common/Trade Name: Lopressor[®], Beloc[®], Betaloc[®]
Chemical Name: (±)-1-(Isopropylamino)-3-[p-(β-methoxyethyl) phenoxy]-2-propanol L-(+)-tartrate (2:1) salt
Chemical Family: Adrenoceptor Blocking Agent
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vial

Section 2 - Composition / Information on Ingredients


| Ingredient | Weight % | CAS No. |
|--------------------------|----------|------------|
| Metoprolol Tartrate, USP | 0.1 | 56392-17-7 |
| Sodium Chloride, NF | 0.9 | 7647-14-5 |
| Water for Injection | 99 | 7732-18-5 |

Section 3 - Hazards Identification

Primary Physical and Health Hazards: Metoprolol Tartrate Injection is generally used as a beta-blocking cardiac drug that affects the circulatory, central nervous and digestive systems. Minimal adverse health effect should occur from routine use with this product. Chronic effects may be toxic to a developing fetus.

Routes of Entry: Contact with skin/eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Metoprolol Tartrate Injection presents little hazard.

Signs & Symptoms of Exposure: Possible irritation to skin, eyes, and respiratory tract. Irregular heartbeat, disturbance of sleep patterns, dizziness, headache, diarrhea, change in breathing rate and convulsions.

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Chemical Listed as Carcinogen: NTP: No IARC: None OSHA: No


Medical Conditions Generally Aggravated by Exposure: Persons allergic to Metoprolol, beta-blocking cardiac drugs or those with cardiac disease.

Section 4 - First Aid Measures

- Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes. Seek medical attention if irritation or signs of exposure are noted.
- Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Seek medical attention if irritation or signs of exposure are noted.
- Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- Injection:** In cases of accidental injection, wash and disinfect area, seek medical attention.
- Inhalation:** If difficulty breathing, remove from exposure and 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
- Autoignition 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.

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Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard.

Unusual Fire/Explosion Hazards: Heat of the fire could cause vials or syringes to burst.

Section 6 - Accidental Release Measures

Spill: Absorb Metoprolol Tartrate Injection 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: Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

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

Storage Conditions: Protect from light and excessive heat. Store at controlled room temperature 20°-25°C (68°-77°F). Follow instructions provided in packaging.


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: Latex or nitrile gloves, lab coat

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Other Protective Equipment: Not applicable

Additional Exposure Precautions: Wash hands following use. No eating, drinking, or smoking while handling this product.

Exposure Limits


| <u>Compound</u> | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
|--------------------------|---------------|-------------|-----------------------|
| Metoprolol Tartrate, USP | OSHA | PEL | NE |
| | ACGIH | TLV | NE |
| | ----- | STEL | 1.0 mg/m ³ |
| Sodium Chloride, NF | 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: | Clear to Yellowish, odorless | Evaporation Rate: | Approx to water |
| Boiling Point: | Approx. 100°C | Solubility in Water: | Soluble |
| Vapor Pressure: | Not established | pH: | Not available |
| Vapor Density: | Not established | Molecular Weight: | 684.82 |

Section 10 - Stability and Reactivity

| | |
|--|--------------------------|
| Stability: | Stable |
| Incompatibility (Materials to avoid): | Water-reactive materials |

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Hazardous Decomposition: Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon and nitrogen.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Do not store near water-reactive materials.

Section 11 - Toxicological Information

Acute Toxicity

| Component | Type | Route | Species | Dosage |
|---------------------|------------------|-----------------|---------|--------------------------|
| Metoprolol Tartrate | TD _{LO} | Oral | Human | 150 mg/kg |
| Metoprolol Tartrate | LD ₅₀ | Oral | Rat | 5,500 mg/kg |
| Metoprolol Tartrate | LD ₅₀ | Intraperitoneal | Rat | 219 mg/kg |
| Metoprolol Tartrate | LD ₅₀ | Intravenous | Rat | 90 mg/kg |
| Metoprolol Tartrate | LD ₅₀ | Inhalation | Rat | >2,510 mg/kg/ 4 hours |
| Metoprolol Tartrate | LD ₅₀ | Dermal | Rabbit | >3,000 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).


Section 12 - Ecological Information

Information is currently not available on the environmental impact of Metoprolol Tartrate. Handle in a manner to prevent spills or releases to the environment.

Section 13 - Disposal Considerations

Dispose of by incineration at an approved/permitted incinerator. Review local, state, and federal regulations for your regulatory area.

Section 14 - Transport Information

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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 - *Yes*

CERCLA - *Not on this list*

SARA 313 - *Not on this list*


RCRA - *Not on this list*

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:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
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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) |