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Section 1 - Identification


- (a) **Product Identifier:** Metoprolol Tartrate Injection, USP
- (b) **Product Code:** 70860-300
- Common/Trade Name:** Lopressor[®], Beloc[®], Betaloc[®]
- Chemical Name:** (±)-1-(Isopropylamino)-3-[p-(2-methoxyethyl)phenoxy]-2-propanol L- (+)-tartrate (2:1) salt
- Chemical Family:** Adrenoceptor Blocking Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **Classification:** **US OSHA Classification:** Target Organ Toxin, Possible Irritant
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 1 |
| Fire Hazard | 1 |
| Reactivity Hazard | 0 |

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	- WARNING
<u>Hazard Statements</u>	
- Causes irritation of the eyes, skin, gastrointestinal and respiratory tracts	
<u>GHS Precautionary Statements</u>	
- P260: Do not breathe dust/fume/gas/mist/vapors/spray	
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling	
- Get medical attention if you feel unwell	

- (d) **Unknown Acute Toxicity:** N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(±)-1-(Isopropylamino)-3-[p-(2-methoxyethyl)phenoxy]-2-propanol L- (+)-tartrate (2:1) salt	Metoprolol Tartrate, USP	5 mg*/unit	56392-17-7	N/A
Sodium Chloride	Sodium Chloride, USP	45 mg/unit	7647-14-5	N/A
Water	Water for Injection, USP	q.s. to 5 mL	7732-18-5	N/A

*Assay correction is to be made on an as is basis.

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

- (a) **Extinguishing Media** Use water or an ABC multi-purpose extinguisher.
- (b) **Hazardous Combustion Products:** When heated, Metoprolol Tartrate solution thermally decomposes to form toxic vapors (ie Carbon Monoxide, Carbon Dioxide, and Nitrogen Oxides)
- (c) **Special Protective Equipment / Precautions:** 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.

Section 6 - Accidental Release Measures

- Spill:** Absorb Metoprolol Tartrate Injection with absorbent materials and dispose according to local, state, and federal guidelines.

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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.

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

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Metoprolol Tartrate, USP	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	1.0 mg/m ³
Sodium Chloride, USP	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Water for Injection, USP	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

(b) Engineering Controls

Ventilation: Handle product in a well-ventilated area.

(c) Individual Protection Measures

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
Skin Protection:	Latex or nitrile gloves, lab coat
Other Protective Equipment:	Not applicable

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Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.
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Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless solution
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	5.0 – 8.0
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Approx. 100°C
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Nonflammable, noncombustible
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Specific Gravity: Approx 1.0
(n)	Solubility(ies)	Soluble in water. Freely soluble in methylene chloride, in chloroform, and alcohol. Slightly soluble in acetone, and insoluble in ether
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Do not store near water-reactive materials.
(e)	Incompatible Materials	Water reactive materials
(f)	Hazardous Decomposition Products	Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon and nitrogen.

Section 11 - Toxicological Information

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(a) Likely Routes of Exposure	Contact with skin/eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Metoprolol Tartrate Injection presents little hazard.
(b) Symptoms related to the physical, chemical and toxicological characteristics	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.
(c) Delayed and immediate effects and also chronic effects from short and long term exposure	Possible irritation to skin, eyes, and respiratory tract. Irregular heartbeat, disturbance of sleep patterns, dizziness, headache, diarrhea, change in breathing rate and convulsions.

(d) 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
Metoprolol Tartrate	LD ₅₀	Oral	Mouse	1500 mg/kg
Metoprolol Tartrate	LD ₅₀	Intravenous	Mouse	84 mg/kg
Metoprolol Tartrate	LD ₅₀	Intraperitoneal	Mouse	202 mg/kg
Metoprolol Tartrate	LD ₅₀	Subcutaneous	Mouse	510 mg/kg
Metoprolol Tartrate	LD ₅₀	Oral	Dog	1090 mg/kg
Metoprolol Tartrate	LD ₅₀	Intravenous	Rabbit	28.7 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).

(e) Hazardous Chemical Listings


NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a) Ecotoxicity	Product is known to be toxic to fish; 96 hour LC ₅₀ (Rainbow Trout): 130 mg/kg
(b) Persistence and degradability	Not available
(c) Bioaccumulative potential	Not available
(d) Mobility in soil	Not available
(e) Other Adverse Effects	Not available

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Section 13 - Disposal Considerations

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

Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II MARPOL 73/78 and IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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

SARA 302 – Not on this list

RCRA – Not on this list


California Proposition 65: Not Listed

Section 16 - Other Information

As of the date of effectiveness, 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 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:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS004

Revision: 02

Title: Metoprolol Tartrate Injection, USP

All dates and times are in Eastern Standard Time.

SDS revision

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	QA Document Specialist	26 Nov 2019, 07:24:32 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	10 Dec 2019, 12:07:18 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	10 Dec 2019, 03:21:54 PM	Approved