



Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

**MATERIAL SAFETY DATA SHEET****Section 1: PRODUCT AND COMPANY INFORMATION**

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**PRODUCT NAME:** Metoprolol Tartrate Injection, USP

**PRODUCT CODE (NDC):** 1 mg/mL: 0517-1355-25

**Section 2: HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

Appearance / Odor

Clear, colorless solution.

**WARNING!**

Skin, eye, respiratory and  
gastrointestinal irritant

Causes irritation of the eyes, skin, gastrointestinal and  
respiratory tracts.

Toxicity to fish/aquatic organisms

Product is known to be toxic to fish; 96 hour LC50: 130 mg/kg -  
Rainbow Trout

*Potential Health Effects: See  
Section 11 for more information*

Likely Routes of Exposure

Eye contact, skin contact, inhalation and ingestion.

Eye

Causes irritation of the eye.

Skin

Causes slight irritation of the skin.

Inhalation

May cause irritation of the upper and lower respiratory tract.

Ingestion

May cause irritation of the gastrointestinal tract.

Skin Absorption

Not absorbed through the skin.

Medical Conditions Aggravated by  
Exposure

Personnel with hypersensitivity to this product and  
cardiovascular system disorders should avoid exposure to this  
product.

Target Organs

Cardiovascular system.

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**Section 2: HAZARDS IDENTIFICATION (continued)**

<i>Potential Environmental Effects: See Section 12 for more information</i>	This product is known to be toxic to fish; 96 hour LC <sub>50</sub> : 130 mg/kg - Rainbow Trout
This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	

**Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS**

Component	CAS Number	Percentage (%) by Weight
Metoprolol Tartrate	56392-17-7	0.1 percent
Sodium Chloride	7647-14-5	0.9 percent
Water for Injection	7732-18-5	99.0 percent

**Section 4: FIRST AID MEASURES**

Eye Contact	Causes eye irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	May cause skin irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause irritation of the gastrointestinal tract. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Adverse reactions to the product may result in headaches, dizziness, tiredness, hypotension, shortness of breath, rash, nausea, vomiting and diarrhea. See prescribing information.

**Section 5: FIRE FIGHTING MEASURES**

Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ). <b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Metoprolol Tartrate solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides).
<u>Protection for firefighters:</u> Metoprolol Tartrate solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.	

**Section 6: ACCIDENTAL RELEASE MEASURES**

Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is known to be a water pollutant. Do not let spilled or leaking material enter waterways.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous based solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material needs to be reported to the National Response Center. 800-424-8802

**Section 7: HANDLING AND STORAGE**Handling:

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is discarded or destroyed.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Metoprolol Tartrate	Not Listed	Not Listed	
Sodium Chloride	Not Listed	Not Listed	
Water for Injection	Not Listed	Not Listed	
Personal Protective Equipment		Description	
Ventilation		Local exhaust or general ventilation is recommended.	
Respiratory Protection		Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / organic vapor cartridges.	
Eye Protection		Wear ANSI approved chemical splash goggles or safety glasses.	
Skin Protection		When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.	

Section 9: PHYSICAL AND CHEMICAL PROPERTIES	
Color	Clear, colorless solution
Odor / Odor Threshold	Odorless
Physical State	Liquid
pH	5.0 to 8.0
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Approximately 212 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.0
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

**Section 10: STABILITY AND REACTIVITY**

Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with strong alkalis and strong oxidizers.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide and Nitrogen Oxides may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

**Section 11: TOXICOLOGY INFORMATION**

<b>Acute Effects</b>	
Oral (LD <sub>50</sub> )	LD <sub>50</sub> : 1500 mg/kg oral - mouse LD <sub>50</sub> : 5500 mg/kg oral - rat
Intravenous (LD <sub>50</sub> )	LD <sub>50</sub> : 84 mg/kg intravenous - mouse LD <sub>50</sub> : 90 mg/kg intravenous - rat
Intraperitoneal (LD <sub>50</sub> )	LD <sub>50</sub> : 202 mg/kg intraperitoneal - mouse LD <sub>50</sub> : 219 mg/kg intraperitoneal - rat
Subcutaneous (LD <sub>50</sub> )	LD <sub>50</sub> : 510 mg/kg subcutaneous - mouse LD <sub>50</sub> : 1150 mg/kg subcutaneous - rat
Dermal (LD <sub>50</sub> )	No data available
Inhalation	Respiratory irritation is possible.
Eye Irritation	Eye irritation is possible.
Skin Irritation	Skin irritation is possible.
Sensitization	Hypersensitive reactions may result in skin rash, weakness and fever.
<b>Chronic Effects</b>	
Organ Systems	May be toxic to central nervous system and cardiovascular system. Chronic exposures result in changes to blood cell count and hyperglycemia.
Carcinogenicity	Metoprolol Tartrate is not considered a carcinogen.
Mutagenicity	Metoprolol Tartrate is not considered a mutagen. Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast.

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<b>Section 11: TOXICOLOGY INFORMATION (continued)</b>	
Reproductive Effects	Exposure to Metoprolol Tartrate can cause adverse reproductive effects.
Developmental Effects	Not considered a teratogen. No adequate and well controlled studies in humans. Classified as Pregnancy Category C.
<b>Section 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	96 hour LC <sub>50</sub> : 130 mg/kg - Rainbow Trout
Persistence / Degradability	Short term products of biodegradation are possible. Long term degradation of the products is possible.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air. Freely mobile in the aquatic environment.
<b>Section 13: DISPOSAL CONDITIONS</b>	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.
<b>Section 14: TRANSPORTATION INFORMATION</b>	
Regulatory Agency	Shipping Description
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.
<b>Section 15: REGULATORY INFORMATION</b>	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	UB7450100
TSCA	8b Inventory - No
NFPA Rating	Health - 1, Fire - 1, Reactivity - 0
WHMIS (Canada)	Not Controlled

**Section 16: OTHER INFORMATION**

Metoprolol Tartrate Injection, USP is indicated in the treatment of hemodynamically stable patients with definite or suspected acute myocardial infarction to reduce cardiovascular mortality. Treatment with intravenous Metoprolol Tartrate can be initiated as soon as the patient's clinical condition allows. Alternatively, treatment can begin within 3 to 10 days of the acute event.

Refer to Luitpold / American Regent's prescribing information for further information at [http://www.americanregent.com/product\\_index.asp](http://www.americanregent.com/product_index.asp)

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