

**SAFETY DATA SHEET****SECTION 1 – IDENTIFICATION OF THE PRODUCT & THE COMPANY**

- a) **Product Name** : Metoprolol Tartrate Injection (1mg/mL)
- b) **Common/Trade Name** : Metoprolol Tartrate Injection (1mg/mL)  
**Chemical Names** : (±)-1-(isopropylamino)-3-[p-(2-methoxyethyl)phenoxy]-2-propanol (2:1) dextro-tartrate salt  
**Chemical Family** : Adrenoceptor Blocking Agent
- c) **Product Use** : Pharmaceutical product used as beta-adrenergic receptor blocking agent.  
**Product Type** : Regulated Prescription Drug  
**Container Information** : Vial (5mL vial)
- d) **Manufacturers Name & Address** : **Gland Pharma Limited**  
: Survey No.: 143–148, 150&151  
: Near Gandimaisamma Cross Roads,  
: D.P.Pally, Quthubullapur Mandal  
: Ranga Reddy District  
: Hyderabad- 500043  
: Telangana, India
- e) **Telephone Number for Info** : +91-40-30510999

**SECTION 2 – HAZARDS IDENTIFICATION**a) **Classification****NFPA Rating**

Health Hazard : Not available

Fire Hazard : Not available

Reactivity Hazard : Not available

b) <b>Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):</b>	c) <b>Description of Hazards:</b>
<b>Signal Word:</b> Warning	-Not Available
Suspected of causing genetic defects	



## SAFETY DATA SHEET

### SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

a) Chemical Name	b) Common Name/Synonym	%Composition or other measure	c) CAS Number	d) Impurities / Stabilizing Additives
(±)-1-(isopropylamino)-3-[p-(2-methoxyethyl)phenoxy]-2-propanol (2:1) dextro-tartrate salt	Metoprolol Tartrate	1 mg/mL	56392-17-7	N/A
Sodium chloride	Sodium chloride	9 mg/mL	7647-14-5	N/A
Water	Water for Injection	q.s.to 1 mL	7732-18-5	N/A

### SECTION 4 – FIRST AID MEASURES

- Eye Exposure** : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Exposure** : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion** : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation** : Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician** : See patient package insert in shipping carton for complete information

### SECTION 5 – FIRE FIGHTING MEASURES

- a) Extinguishing Media** : Use carbon dioxide, dry chemical, or water spray..
- b) Hazardous Combustion Products** : Formation of toxic gases is possible during heating or fire. May emit toxic fumes of oxides of carbon and nitrogen.
- c) Special Protective Equipment / Precautions** : During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.



## SAFETY DATA SHEET

### SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Spill** : Absorb Metoprolol Tartrate injection with absorbent materials and dispose according to local, State, and federal guidelines.
- Release to Environment** : If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

### SECTION 7 – HANDLING AND STORAGE

- General Handling** : Gloves, masks and goggles are recommended during handling.
- Storage Conditions** : Store at 25°C (77°F). Excursions to 15°C-30°C (59°F-86°). See USP Controlled Room Temperature. Protect from light.

### SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

#### (a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Metoprolol Tartrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	1.0 mg/m <sup>3</sup>
Sodium Chloride, NF	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

#### b) Engineering Controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels within the OEB range.



## SAFETY DATA SHEET

### (c) Individual Protection Measures

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Respiratory Protection :	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)
Eye Protection :	Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin Protection :	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

### SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

a)	<b>Appearance/Description</b>	:	A clear colorless solution.
b)	<b>Odor</b>	:	NA
c)	<b>Odor Threshold</b>	:	NA
d)	<b>p<sup>H</sup></b>	:	Between 5.0 and 8.0
e)	<b>Melting Point</b>	:	NA
f)	<b>Initial Boiling Point</b>	:	NA
g)	<b>Flash Point</b>	:	NA
h)	<b>Evaporation Rate</b>	:	NA
i)	<b>Flammability</b>	:	NA
j)	<b>Upper Lower Flammability or Explosion Limits</b>	:	NA
k)	<b>Vapor Pressure:</b>	:	NA
l)	<b>Vapor Density</b>	:	NA
m)	<b>Relative Density</b>	:	NA
n)	<b>Solubility(ies)</b>	:	Soluble in water
o)	<b>Partition Coefficient: n-octanol/water</b>	:	NA
p)	<b>Auto-ignition Temperature</b>	:	NA
q)	<b>Decomposition Temperature</b>	:	NA
r)	<b>Viscosity</b>	:	NA



## SAFETY DATA SHEET

### SECTION 10 – STABILITY AND REACTIVITY

a)	<b>Reactivity</b>	Not determined.
b)	<b>Chemical Stability</b>	Stable under normal use and storage conditions.
c)	<b>Possibility of Hazardous Reactions</b>	Not determined
d)	<b>Conditions to Avoid</b>	Strong oxidizers
e)	<b>Incompatible Materials</b>	Not determined
f)	<b>Hazardous Decomposition Products</b>	Not determined

### SECTION 11 – TOXICOLOGICAL INFORMATION

a)	<b>Likely Routes of Exposure</b>	Inhalation, eye/skin contact, or ingestion
b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Hypertension and angina, tiredness and dizziness
c)	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	Bradycardia, hypotension, bronchospasm, and cardiac failure.

#### d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Metoprolol Tartrate	LD50	Intravenous	Rat	90 mg/kg
	LD50	Intraperitoneal	Rat	219 mg/kg
	LD50	Oral	Rat	5500 mg/kg

#### e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

### SECTION 12 – ECOLOGICAL INFORMATION

a)	<b>Ecotoxicity</b>	Avoid release into the environment.
b)	<b>Persistence and degradability</b>	Not established
c)	<b>Bioaccumulative potential</b>	Not established
d)	<b>Mobility in soil</b>	Not established
e)	<b>Other Adverse Effects</b>	Not established

### SECTION 13 – DISPOSAL CONSIDERATIONS

**Waste Disposal:** All waste materials must be properly characterized. Further, disposal should be Performed in accordance with the federal, state or local regulatory requirements.



## SAFETY DATA SHEET

### SECTION 14 – TRANSPORTATION 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 of MARPOL 73/78 and the IBC Code)	Not available
g)	Special Precautions	Not available

**DOT:** Not regulated

**ICAO/IATA:** Not regulated

**IMDG:** Not regulated

### SECTION 15 – REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible 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

SARA 302 - Not on this list

SARA 313 - Not on this list

Prop 65 (Calif.) – 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 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.



## SAFETY DATA SHEET

**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
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
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)