



A Pfizer Company

SAFETY DATA SHEET

Revision date: 06-Jan-2017

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Metoprolol Tartrate Injection (Hospira, Inc.)

Trade Name: Not applicable

Chemical Family: Cardioselective Beta-Blocker

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use: anti-arrhythmic Anti-anginal; anti-hypertensive

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

Label Elements

Signal Word: Warning

Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Metoprolol Tartrate	56392-17-7	260-148-9	Repr. 2 (H361d) Acute 2 (H401) Chronic 2 (H411)	0.1
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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Medical Conditions None known
Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize generating airborne mists and vapors. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Metoprolol Tartrate

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Sodium chloride

Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls

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 below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:

Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:

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.)

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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Liquid

Color:

Clear, Colorless

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

6.0-7.0

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Metoprolol Tartrate

Measured Log P 2.15

Sodium chloride

No data available

Water for Injection

No data available

Decomposition Temperature (°C):

No data available.

Evaporation Rate (Gram/s):

No data available

Vapor Pressure (kPa):

No data available

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Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Antihypertensive drug; has blood pressure-lowering properties
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.
Known Clinical Effects: Adverse effects most commonly reported in clinical use include irregular heartbeat (cardiac arrhythmia) symptoms of asthma decreased blood sugar (hypoglycemia) troubled breathing swelling nausea stomach discomfort and lack of appetite Due to intended use, dangerous lowering of blood pressure can occur.

Acute Toxicity: (Species, Route, End Point, Dose)

Metoprolol Tartrate

Rat Oral LD50 5500 mg/kg
Rat Para-periosteal LD50 71.9mg/kg
Mouse Oral LD50 1500mg/kg
Mouse Intravenous LD50 62mg/kg
Mouse Intraperitoneal LD50 > 200mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

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11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Metoprolol Tartrate

Reproductive & Fertility	Rat	Oral	430 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Rat	Oral	430 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	430 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	64 mg/kg/day	LOAEL	Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Metoprolol Tartrate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative with activation
Chromosome Aberration	Human Lymphocytes	Negative
Dominant Lethal Assay	Mouse	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Metoprolol Tartrate

2 Year(s)	Rat	Oral	800 mg/kg/day	NOAEL	Not carcinogenic
21 Month(s)	Mouse	Oral	750 mg/kg/day	NOAEL	Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Metoprolol Tartrate

<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	63.9 - 438 mg/L
<i>Ceriodaphnia dubia</i> (Daphnids)	EC50	48 Hours	8.8 - 45.3 mg/L
<i>Hyallela azteca</i> (Freshwater Amphipod)	LC50	96 Hours	> 100 mg/L
<i>Desmodesmus subcapitata</i> (Green Alga)	OECD EC50	72 Hours	7.3 mg/L

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Metoprolol Tartrate	Ready	0-10% After	28 Day(s)	Not Ready
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Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Metoprolol Tartrate

Measured	Log P	2.15
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Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Metoprolol Tartrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	260-148-9

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet