



Zebeta

Preparation Date 04-Dec-2006

Revision Date 31-Mar-2008

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Zebeta
Common Name Not available
Chemical Name Not applicable
Synonyms Bisoprolol Fumarate
Product Use Pharmaceutical product
Classification Cardiovascular Beta-adrenergic Blocking Agent

Supplier Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical tablet **Physical State** Solid **Odor** Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes Not available
Skin Not available
Inhalation Not available
Ingestion The most common effects may include dryness of mouth, increased thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, gastrointestinal disturbances such as nausea and vomiting, lowered blood pressure, bradycardia, dizziness, headache, acidosis, unconsciousness, ataxia, or impaired motor coordination.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Cardiovascular system.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Bisoprolol Fumarate	104344-23-2	5-10 mg/tablet
Inactive Ingredients	Not applicable	Remainder

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Presumed to be a combustible particulate solid.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Bisoprolol Fumarate	Exposure Guideline 25 mcg/m ³
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment..
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical tablet	Physical State	Solid
Color	Various	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not available	Method	None
Melting Point	Not available		
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Bisoprolol Fumarate

LD50 Oral	940 mg/kg rats
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	Not irritating to rabbit eyes.
Sensitization	Not applicable

Multiple Dose Toxicity

Bisoprolol Fumarate

No Toxicologic Effect Dose/Species/Study Length:	See Carcinogenicity
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Maximum Tolerated Dose (MTD), Oral

Bisoprolol Fumarate

Carcinogenicity	Long-term studies in rats and mice revealed no evidence of carcinogenicity.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility.
Developmental Toxicity	No teratogenic effects were observed in rats and rabbits at doses up to 150 and 12.5 mg/kg/day respectively. In the rat, fetotoxicity was observed at 50 mg/kg/day and was maternotoxic at the highest dose. In the rabbit, fetal mortality was increased at the highest dose.

Bisoprolol Fumarate

Target Organ(s) of Toxicity	No data available
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12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Bisoprolol Fumarate

Mobility	Not available
Biodegradability	Not readily biodegradable.
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity

Bisoprolol Fumarate

Microorganisms	EC50/> 1000 mg/l (3hr)h/bacteria = mg/l
Algae	Not available
Daphnia	EC50/48h > 100 mg/l
Fish	LC50/96h/Danio Rerio > 100 mg/l

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	Product Profiles
Revision Summary	Changes to Section 8

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