# Material Safety Data Sheet

## 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th><strong>Product Name</strong></th>
<th>Zebeta</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Common Name</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Chemical Name</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Synonyms</strong></td>
<td>Bisoprolol Fumarate</td>
</tr>
<tr>
<td><strong>Product Use</strong></td>
<td>Pharmaceutical product</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Cardiovascular Beta-adrenergic Blocking Agent</td>
</tr>
</tbody>
</table>
| **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.

<table>
<thead>
<tr>
<th><strong>Appearance</strong></th>
<th>Pharmaceutical tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical State</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

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

**Potential Health Effects**

<table>
<thead>
<tr>
<th><strong>Eyes</strong></th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>
| **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.

**Potential Environmental Effects**  
Not listed by OSHA, NTP or IARC.

See Section 12.
### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisoprolol Fumarate</td>
<td>104344-23-2</td>
<td>5-10 mg/tablet</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Remainder</td>
</tr>
</tbody>
</table>

### 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/m³

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

pH
Not available

Specific Gravity
Not applicable

Solubility
Not applicable

Partition Coefficient (n-octanol/water)
Not available

Boiling Point
Not available

Flash Point
Not available

Melting Point
Not available

Flammability Limits in Air
Upper Not applicable

Explosion Limits
Upper Not applicable

Water Solubility
Not available

Evaporation Rate
Not applicable

Vapor Pressure
Not applicable

Autoignition Temperature Method
Not available

Not applicable

None

Not applicable

Not applicable

Not applicable

Not applicable

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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 Oral</td>
<td>940 mg/kg rats</td>
</tr>
<tr>
<td>Acute Dermal Irritation</td>
<td>Not irritating to rabbit skin.</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Not irritating to rabbit eyes.</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

Multiple Dose Toxicity

Bisoprolol Fumarate

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Toxicologic Effect</td>
<td>See Carcinogenicity</td>
</tr>
</tbody>
</table>

Maximum Tolerated Dose (MTD), Oral

Bisoprolol Fumarate

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity</td>
<td>Long-term studies in rats and mice revealed no evidence of carcinogenicity.</td>
</tr>
<tr>
<td>Genetic Toxicity</td>
<td>No evidence of mutagenicity was observed in a battery of <em>in vitro</em> and <em>in vivo</em> assays.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>Studies in rats were found to have no effect on fertility.</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>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.</td>
</tr>
</tbody>
</table>

Bisoprolol Fumarate

<table>
<thead>
<tr>
<th>Target Organ(s) of Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organ(s) of Toxicity</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

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