Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1101163
Product name: Brevibloc
Synonyms: Brevibloc Double Strength Premixed Injection; Brevibloc Premixed Injection; Brevibloc Injection; Brevibloc Double Strength Injection; NOVAPLUS Brevibloc; Esmolol; Esmolol Hydrochloride Injection
Chemical Family: beta-adrenergic blocking agent
Product Type: Regulated Prescription Drug
Container Information: Brevibloc Double Strength Premixed Injection, Ready-to-use IntraVia Bags, 100 mL; Brevibloc Premixed Injection, Ready-to-use IntraVia Bags, 250 ml; Brevibloc Injection, Ready-to-use Vials, 10 ml; Brevibloc Double Strength Injection, Ready-to-use Vials, 5 ml; Esmolol Hydrochloride Injection, Ready-to-use Vials, 10 ml.
Product Use: Cardiovascular Drug

Supplier
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number
PROSAR: USA (888) 990-0996 OUTSIDE USA (651)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>UN Number:</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>&lt;1</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>1-2</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>&lt;0.1</td>
<td>UN2790 (solution)</td>
<td>R10 C; R35</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>&lt;1</td>
<td>None</td>
<td>Xi; R38</td>
</tr>
<tr>
<td>Water</td>
<td>&gt;97</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency overview: No specific hazards other than therapeutic effects.
Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.
Inhalation: Inhalation not likely under normal use conditions.
3. HAZARDS IDENTIFICATION

Ingestion: Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). No specific hazards other than therapeutic effects.

Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish.

Special protective equipment for firefighters: Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Specific methods: No information available.

Flash point: Not available.

Autoignition temperature: Not available.

Flammable limits in air-lower (%): Not available.

Flammable limits in air-upper (%): Not available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use suitable protective equipment. Follow all fire fighting procedures.

Environmental precautions: Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Methods for cleaning up: For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling: Technical measures/precautions: Wash thoroughly after handling.

Storage: 

Product id: 1101163  Product name: Brevibloc
7. HANDLING AND STORAGE


Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA- Time Weighted Average:</th>
<th>OSHA- Short Term Exposure Limit:</th>
<th>OSHA- Ceiling Limits</th>
<th>ACGIH- Time Weighted Average:</th>
<th>ACGIH- Short Term Exposure Limit:</th>
<th>ACGIH- Ceiling Limit Value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>10 ppm</td>
<td>None</td>
<td>10 ppm</td>
<td>15 ppm</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Water</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Not available.
Appearance: Not available.
Color: Clear, colorless to light yellow.
Odor: No information available.
pH: 4.5 to 5.5
Molecular weight: Not applicable.
Boiling point/range: 100°C (212°F)
Melting point/range: May start to solidify at 0°C (32°F) based on data for: Water.
Density: The only known value is 1 g/cm3 (Water).
Vapor pressure: No data available
Evaporation rate: <1
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): No data available.
Viscosity: No data available
% Volatile by Volume: No data available

Product id: 1101163  Product name: Brevibloc
10. STABILITY AND REACTIVITY

Stability: This product is stable.

Polymerization: No data available

Hazardous decomposition products: No data available.

Materials to avoid: No data available.

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
<th>LD50 Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>10 g/kg (rabbit)</td>
<td>30 g/m³ (rat)</td>
<td>.? (rat)</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>1060 mg/kg (rabbit)</td>
<td>11.4 mg/L (rat)</td>
<td>3310 mg/kg (rat)</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>10 g/kg (rabbit)</td>
<td>42 g/m³ (rat)</td>
<td>3 g/kg (rat)</td>
</tr>
<tr>
<td>Water</td>
<td>-</td>
<td>-</td>
<td>90 mL/kg (rat)</td>
</tr>
</tbody>
</table>

Acute toxicity: Signs and Symptoms of Overexposure: nausea/vomiting, dizziness/vertigo, low blood pressure, and slow heart rate.

Chronic toxicity: May cause damage to the following organs: cardiovascular system.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Long-term animal carcinogenicity studies have not been performed.

Mutagenic effects: No mutagenicity studies have been conducted.

Reproductive toxicity: Reproductive studies have not been conducted on the product itself. Teratogenic at maternally toxic doses.

FDA Pregnancy Catagory: C

12. ECOLOGICAL INFORMATION

Environmental properties:

<table>
<thead>
<tr>
<th>Component</th>
<th>Ecotoxicity - Water Flea Data</th>
<th>Fish Species Ecotoxicity</th>
<th>Ecotoxicity - Freshwater Algae Data</th>
<th>Ecotoxicity - Microtox Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
<td>7200mg/LEC50Pseudomonas pulida18h</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
</tbody>
</table>

Product id: 1101163 Product name: Brevibloc
### 12. ECOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 24 h</th>
<th>LC50 96 h</th>
<th>Description</th>
<th>EC50 48 h</th>
<th>LC50 96 h</th>
<th>Description</th>
<th>EC50 48 h</th>
<th>LC50 96 h</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic Acid 64-19-7</td>
<td>47 mg/L</td>
<td>75 mg/L</td>
<td>Lepomis macrochirus 96 h</td>
<td>65 mg/L</td>
<td>79 mg/L</td>
<td>Lepomis macrochirus 96 h</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td>48 h</td>
<td>LC50</td>
<td>Pimephales promelas 96 h</td>
<td></td>
<td></td>
<td>Photobacterium phosphoreum 15 min</td>
<td>8.8 mg/L</td>
<td></td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24 h</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride 7647-14-5</td>
<td>340.7 - 469.2 mg/L</td>
<td>4747-7824 mg/L</td>
<td>Oncorhynchus mykiss 96 h</td>
<td>1000 mg/L</td>
<td>5560-6080 mg/L</td>
<td>Lepomis macrochirus 96 h</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
<tr>
<td></td>
<td>EC50 48 h</td>
<td>LC50 96 h</td>
<td>Pimephales promelas 96 h</td>
<td></td>
<td></td>
<td>Pimephales promelas 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>48 h</td>
<td></td>
<td></td>
<td>15 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ecotoxicity effects:** No data available

**Bioaccumulation:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Classification:** Not regulated.

**Waste from residues / unused products:** In accordance with local and national regulations.

### 14. TRANSPORT INFORMATION

**DOT:**
- **DOT shipping name:** None
- **UN Number:** None
- **DOT Packing Group:** None
- **DOT Hazard class:** None

**TDG (Canada):**
- **TDG Proper shipping name:** None
- **TDG UN/NA Number:** None
- **TDG Packing Group:** None
- **TDG Hazard class:** None

**ADR/RID:**
- **ADR Official Transport Name:** None
- **ADR Proper shipping name:** None
- **ADR UN/NA number:** None
- **ADR Hazard Class:** None
## 14. TRANSPORT INFORMATION

**ICAO / IATA:**
- **IATA Proper shipping name:** None
- **IATA UN Number:** None
- **IATA Primary Hazard:** None
- **IATA Packing group:** None
- **ICAO ERG Code:** None

**IMO / IMDG:**
- **IMDG Proper Shipping Name:** None
- **IMDG Hazard Class and Division:** None
- **IMDG Packing Group:** None
- **IMDG Subsidiary Risks:** None

## 15. REGULATORY INFORMATION

**U.S. Regulations:**
- **TSCA Inventory List -** The product is exempt from TSCA, it is FDA Regulated
- **OTHER REGULATIONS:**
  - **Japanese Inventory (ENCS)** This product does not comply with JPENCS

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight %</th>
<th>RCRA Status</th>
<th>CERCLA Reportable Quantity</th>
<th>CERCLA/SARA - 302 Ext. haz. substances</th>
<th>Listed as Sara 313</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>&lt;1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>1-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>&lt;0.1</td>
<td>Not Listed</td>
<td>5000 lb</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>&lt;1</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>&gt;97</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**STATE REGULATIONS:**

<table>
<thead>
<tr>
<th>Component</th>
<th>California Prop. 65</th>
<th>Minnesota Right-To-Know</th>
<th>Florida Right-To-Know Reporting List</th>
<th>Rhode Island Right-To-Know List</th>
<th>Massachusetts Right-To-Know List</th>
<th>Pennsylvania Right-To-Know:</th>
<th>New Jersey Right-to-Know:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Acetate Trihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Esmolol Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Acetic Acid</td>
<td>Not Listed</td>
<td>Present</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**CANADIAN REGULATIONS:**

- **Canada DSL Inventory List -** This product does not comply with DSL

- **EU EINECS List -** This product does not comply with EINECS

**Risk Phrases:**
- NONE
16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
New MSDS format. New MSDS number. Additional product codes.

Additional information:
Not Available.

Prepared by: Technology Resources, Baxter Healthcare Corporation

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet: