

This safety data sheet complies with the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date: 05/15/2015

Revision Date: 05/23/2016

## **Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

### **1.1. Product Identifier**

**SDS Number:** 1101163  
**Product Name:** Brevibloc  
**Product Code(s):** NDC 10019-075-87; NDC 10019-055-61; NDC 10019-015-01, NDC 10019-115-01, NDC 10019-126-01, NDC 0641-2965-45, NDC 10019-085-01, NDC 0641-2966-45, NDC 0641-2966-41, NDC 0641-2965-41, NDC 10019-085-84, NDC 10019-115-39, NDC 10019-126-39, NDC 10019-120-01, NDC 10019-120-39  
**Synonyms:** Brevibloc Double Strength Premixed Injection; Brevibloc Premixed Injection; Brevibloc Injection; Brevibloc Double Strength Injection; NOVAPLUS Brevibloc; Esmolol; Esmolol Hydrochloride Injection

### **1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Product Use:** Cardiovascular Drug  
**Product Type:** Regulated Prescription Drug  
**Uses advised against** No information available

### **1.3. Details of the supplier of the safety data sheet**

BAXTER HEALTHCARE CORPORATION  
DEERFIELD, ILLINOIS 60015  
0044 1635 206345

### **E-mail address**

medinfo\_emea@baxter.com

### **1.4. Emergency telephone number**

Carechem24 International  
+44 (0) 1235 239 670

## **Section 2: HAZARDS IDENTIFICATION**

### **2.1. Classification of the substance or mixture**

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

### **2.2. Label elements**

#### **Product Identifier**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

### **2.3. Other hazards**

No information available

## **Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### **3.1 Substances**

Component	EU EINECS List	CAS-No	Weight-%	EU - GHS Substance Classification	REACH Reg. No
Esmolol Hydrochloride 81161-17-3	-	81161-17-3	1-2	No data available	No data available
Sodium Acetate Trihydrate 6131-90-4	-	6131-90-4	<1	No data available	No data available
Acetic Acid 64-19-7	200-580-7	64-19-7	<0.1	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	01-2119475328-30
Sodium Chloride 7647-14-5	231-598-3	7647-14-5	<1	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	01-2119485491-33
Water 7732-18-5	231-791-2	7732-18-5	>97	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>General Advice</b>	Treat symptomatically and supportively.
<b>Eye contact:</b>	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Skin contact:</b>	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention.
<b>Ingestion:</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

No information available.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

## Section 5: FIRE FIGHTING MEASURES

### 5.1. Extinguishing media

#### Suitable extinguishing media

Use foam or all purpose dry chemicals to extinguish.

#### Extinguishing media which must not be used for safety reasons

No information available

### 5.2. Special hazards arising from the substance or mixture

No information available

### 5.3. Advice for firefighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Follow all fire fighting procedures (Section 5). Use suitable protective equipment (Section 8).

### 6.2. Environmental precautions

Do not allow material to contaminate ground water system.

### **6.3. Methods and material for containment and cleaning up**

#### **Methods for Containment:**

If emergency personnel are unavailable, contain spilled material.

#### **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.

### **6.4. Reference to other sections**

See Section 12 for more information

## **Section 7: HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

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

### **7.2. Conditions for safe storage, including any incompatibilities**

**Technical measures and storage conditions** Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature 25 °C (77 °F). Protect from freezing. Avoid excessive heat.

**Incompatible materials** No special restrictions on storage with other products.

### **7.3. Specific end use(s)**

**Other Guidelines** None.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1. Control parameters**

#### **Exposure Limits:**

<b>Component</b>	<b>European Union</b>	<b>Uk oes/mel:</b>	<b>France</b>	<b>Spain</b>	<b>Germany</b>
Esmolol Hydrochloride 81161-17-3	None	None	None	None	None
Sodium Acetate Trihydrate 6131-90-4	None	None	None	None	None
Acetic Acid 64-19-7	None	None	10 ppm STEL [VLCT]; 25 mg/m <sup>3</sup> STEL [VLCT]	15 ppm STEL 37 mg/m <sup>3</sup> STEL 10 ppm TWA 25 mg/m <sup>3</sup> TWA	10 ppm TWA 25 mg/m <sup>3</sup> TWA 20 ppm Peak 50 mg/m <sup>3</sup> Peak
Sodium Chloride 7647-14-5	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
<b>Component</b>	<b>Italy</b>	<b>Portugal</b>	<b>Netherlands</b>	<b>Finland</b>	<b>Denmark</b>
Esmolol Hydrochloride 81161-17-3	None	None	None	None	None
Sodium Acetate Trihydrate 6131-90-4	None	None	None	None	None
Acetic Acid 64-19-7	None	10 ppm TWA 25 mg/m <sup>3</sup> TWA 15 ppm STEL	25 mg/m <sup>3</sup> TWA	5 ppm TWA 13 mg/m <sup>3</sup> TWA 10 ppm STEL 25 mg/m <sup>3</sup> STEL	10 ppm TWA 25 mg/m <sup>3</sup> TWA
Sodium Chloride 7647-14-5	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
<b>Component</b>	<b>Austria</b>	<b>Switzerland</b>	<b>Poland</b>	<b>Norway</b>	<b>Ireland</b>
Esmolol Hydrochloride 81161-17-3	None	None	None	None	None
Sodium Acetate Trihydrate 6131-90-4	None	None	None	None	None

Acetic Acid 64-19-7	10 ppm TWA 25 mg/m <sup>3</sup> TWA 20 ppm STEL 50 mg/m <sup>3</sup> STEL	None	25 mg/m <sup>3</sup> TWA 50 mg/m <sup>3</sup> STEL	10 ppm TWA 25 mg/m <sup>3</sup> TWA 10 ppm STEL 25 mg/m <sup>3</sup> STEL	15 ppm STEL 37 mg/m <sup>3</sup> STEL 10 ppm TWA 25 mg/m <sup>3</sup> TWA
Sodium Chloride 7647-14-5	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None
<b>Component</b>	<b>Sweden</b>				
Esmolol Hydrochloride 81161-17-3	None				
Sodium Acetate Trihydrate 6131-90-4	None				
Acetic Acid 64-19-7	5 ppm TLV 13 mg/m <sup>3</sup> TLV 10 ppm STV; 25 mg/m <sup>3</sup> STV				
Sodium Chloride 7647-14-5	None				
Water 7732-18-5	None				

## 8.2. Exposure controls

### Engineering Measures

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

### Personal protective equipment

#### Eye protection

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

#### 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.

### Environmental exposure controls

Do not allow material to contaminate ground water system.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state:</b>	Liquid
<b>Appearance:</b>	Aqueous solution
<b>Color:</b>	Clear, colorless to light yellow.
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	4.5 to 5.5
<b>Melting point / melting range:</b>	May start to solidify at 0°C (32°F) based on data for: Water.
<b>Boiling point / boiling range:</b>	100°C (212°F)
<b>Flash point:</b>	No information available
<b>Flammability (solid, gas):</b>	No information available
<b>Evaporation rate:</b>	<1
<b>Flammable limits</b>	No information available
<b>in air-upper (%):</b>	
<b>Flammable limits</b>	No information available
<b>in air-lower (%):</b>	
<b>Vapor pressure:</b>	No information available
<b>Vapor Density:</b>	No information available
<b>Density:</b>	The only known value is 1 g/cm <sup>3</sup> (Water).
<b>Solubility:</b>	Soluble in water.
<b>Partition coefficient</b>	No information available
<b>(n-octanol/water):</b>	
<b>Autoignition temperature:</b>	No information available
<b>Decomposition Temperature:</b>	No information available

**Viscosity:** No information available  
**Explosive Properties:** No information available  
**Oxidizing Properties:** No information available

## 9.2. Other information

# Section 10: STABILITY AND REACTIVITY

## 10.1. Reactivity

No data available.

## 10.2. Chemical stability

Stable under recommended storage conditions

## 10.3. Possibility of hazardous reactions

**Polymerization** Not applicable  
**Hazardous Reactions** None under normal processing

## 10.4. Conditions to avoid

Do not freeze.

## 10.5. Incompatible materials

None known

## 10.6. Hazardous decomposition products

No data available

# Section 11: TOXICOLOGICAL INFORMATION

Component	Inhalation LC50	Dermal LD50	Oral LD50
Esmolol Hydrochloride 81161-17-3	-	-	-
Sodium Acetate Trihydrate 6131-90-4	-	-	-
Acetic Acid 64-19-7	11.4 mg/L	= 1060 mg/kg ( Rabbit )	= 3310 mg/kg ( Rat )
Sodium Chloride 7647-14-5	42 g/m <sup>3</sup>	> 10 g/kg ( Rabbit )	= 3 g/kg ( Rat )
Water 7732-18-5	-	-	> 90 mL/kg ( Rat )

## 11.1. Information on toxicological effects

### Acute Toxicity

**Inhalation:** Inhalation not likely under normal use conditions.

**Eye contact:** May cause eye irritation.

**Skin contact:** May cause skin irritation.

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

### Unknown Acute Toxicity

**Unknown Acute Toxicity** 2.74 % of the mixture consists of ingredient(s) of unknown toxicity.

### Acute Oral Toxicity

2.28 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

### Acute dermal toxicity

2.28 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

### Acute inhalation toxicity - gas

2.74 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

### Acute inhalation toxicity - Vapor

2.69 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

### Acute inhalation toxicity - dust/mist

2.74 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

**Irritation:** Not classified  
**Corrosivity:** Not classified  
**Sensitization:** Not classified.  
**Mutagenic effects:** No mutagenicity studies have been conducted.  
**Carcinogenic effects:** Long-term animal carcinogenicity studies have not been performed.

Component	ACGIH	IARC	NTP	OSHA	EU Annex I Carcinogen Information	UK
Esmolol Hydrochloride 81161-17-3	-	-	-	-	-	-
Sodium Acetate Trihydrate 6131-90-4	-	-	-	-	-	-
Acetic Acid 64-19-7	-	-	-	-	-	-
Sodium Chloride 7647-14-5	-	-	-	-	-	-
Water 7732-18-5	-	-	-	-	-	-

**Reproductive toxicity:** Teratogenic at maternally toxic doses. See patient package insert for additional information.  
**STOT - single exposure:** Not classified.  
**STOT - repeated exposure:** Not classified.  
**Aspiration Hazard:** Not classified

## Section 12: ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Esmolol Hydrochloride 81161-17-3	None.	None.	None.	None.
Sodium Acetate Trihydrate 6131-90-4	None.	None.	None.	7200mg/LEC50Pseudomonas putida18h
Acetic Acid 64-19-7	47 mg/L EC50 24 h 65 mg/L EC50 48 h	79 mg/L LC50 Pimephales promelas 96 h 75 mg/L LC50 Lepomis macrochirus 96 h	None.	8.8mg/LEC50Photobacterium phosphoreum15min 8.8mg/LEC50Photobacterium phosphoreum25min 8.8mg/LEC50Photobacterium phosphoreum5min

Sodium Chloride 7647-14-5	1000 mg/L EC50 48 h 340.7 - 469.2 mg/L EC50 48 h	4747 - 7824 mg/L LC50 Oncorhynchus mykiss 96 h 12946 mg/L LC50 Lepomis macrochirus 96 h 6020 - 7070 mg/L LC50 Pimephales promelas 96 h 6420 - 6700 mg/L LC50 Pimephales promelas 96 h 5560 - 6080 mg/L LC50 Lepomis macrochirus 96 h 7050 mg/L LC50 Pimephales promelas 96 h	None.	None.
Water 7732-18-5	None.	None.	None.	None.

#### **12.1. Toxicity**

No information available

#### **12.2. Persistence and degradability**

No information available.

#### **12.3. Bioaccumulative potential**

No information available

#### **12.4. Mobility in soil**

No information available

#### **12.5. Results of PBT and vPvB assessment**

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

#### **12.6. Other adverse effects**

This product does not contain any known or suspected endocrine disruptors.

### **Section 13: DISPOSAL CONSIDERATIONS**

#### **13.1. Waste treatment methods**

##### **Waste from residues/unused products**

In accordance with local and national regulations

##### **Contaminated Packaging**

In accordance with local and national regulations.

### **Section 14: TRANSPORT INFORMATION**

#### **IMDG/IMO**

<b>14.1 UN-No:</b>	Not regulated.
<b>14.2 Proper Shipping Name</b>	Not regulated.
<b>14.3 Hazard Class</b>	Not regulated.
<b>14.4 Packing Group</b>	Not regulated.
<b>14.5 Marine Pollutant</b>	Not applicable

<b>14.6 Special Provisions</b>	None
<b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	No information available

**RID**

14.1	UN-No	Not regulated
14.2	Proper Shipping Name	Not regulated
14.3	Hazard Class	Not regulated
14.4	Packing Group	Not regulated
14.5	Environmental hazard	Not applicable
14.6	Special Provisions	None

## ADR Road Transport

14.1 UN-No	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing Group:	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

**IATA UN Numbers:**

<b>14.1 UN-No</b>	Not regulated
<b>14.2 Proper Shipping Name</b>	Not regulated
<b>14.3 Hazard Class</b>	Not regulated
<b>14.4 Packing Group</b>	Not regulated
<b>14.5 Environmental hazard</b>	Not applicable
<b>14.6 Special Provisions</b>	None

## Section 15: REGULATORY INFORMATION

### **15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

## International Inventories

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

### Legend

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

## 15.2. Chemical safety assessment

No information available

## Section 16: OTHER INFORMATION

### Full text of H-Statements referred to under section 3

H314 - Causes severe skin burns and eye damage  
H226 - Flammable liquid and vapor  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

**Additional information:**

Not Available.

### Key literature references and sources for data

[www.ChemADVISOR.com/](http://www.ChemADVISOR.com/)

**Prepared by** Baxter Research & Development  
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**This data sheet contains changes from the previous version in section(s):**

New GHS format. Changes to Section 1.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

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**