



## SAFETY DATA SHEET

### Bisoprolol hemifumarate - Bio-X

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

#### SECTION 1: Identification of the substance/mixture and of the company/undertaking

##### 1.1. Product identifier

Product name	Bisoprolol hemifumarate - Bio-X
Product number	BB164256
Synonyms; trade names	1-[4-[[2-(1-Methylethoxy)ethoxy]methyl]phenoxy]-3-[(1-methylethyl)amino]-2-propanol, concor, detensiel, emcor, euradial, isoten, monocor, soprol, zebeta,
CAS number	104344-23-2

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

Identified uses	Laboratory reagent. Manufacture of substances. Research and development.
-----------------	--

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

Supplier	Carbosynth Ltd 8&9 Old Station Business Park Compton Berkshire RG20 6NE UK +44 1635 578444 +44 1635 579444 info@carbosynth.com
----------	--

##### 1.4. Emergency telephone number

Emergency telephone	+44 7887 998634
---------------------	-----------------

#### SECTION 2: Hazards identification

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

###### Classification (EC 1272/2008)

Physical hazards	Not Classified
Health hazards	Acute Tox. 4 - H302
Environmental hazards	Not Classified

##### 2.2. Label elements

###### Pictogram



Signal word	Warning
Hazard statements	H302 Harmful if swallowed.

## Bisoprolol hemifumarate - Bio-X

<b>Precautionary statements</b>	P264 Wash contaminated skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301+P312 IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell. P330 Rinse mouth. P501 Dispose of contents/ container in accordance with national regulations.
---------------------------------	--

### 2.3. Other hazards

No data available.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

<b>Product name</b>	Bisoprolol hemifumarate - Bio-X
<b>CAS number</b>	104344-23-2
<b>Chemical formula</b>	$C_{18}H_{31}NO_4 \cdot \frac{1}{2}C_4H_4O_4$

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>General information</b>	Get medical advice/attention if you feel unwell.
<b>Inhalation</b>	Remove person to fresh air and keep comfortable for breathing. If breathing stops, provide artificial respiration. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention if symptoms are severe or persist.
<b>Ingestion</b>	Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if symptoms are severe or persist.
<b>Skin contact</b>	Remove contaminated clothing. Rinse with water. Continue to rinse for at least 15 minutes. Wash contaminated clothing before reuse. Get medical attention if symptoms are severe or persist.
<b>Eye contact</b>	Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if symptoms are severe or persist.

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

<b>General information</b>	See Section 11 for additional information on health hazards.
----------------------------	--

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

<b>Notes for the doctor</b>	Treat symptomatically.
-----------------------------	------------------------

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

<b>Suitable extinguishing media</b>	Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-extinguishing media suitable for the surrounding fire.
-------------------------------------	--

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

<b>Specific hazards</b>	None known.
<b>Hazardous combustion products</b>	Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Oxides of nitrogen.

### 5.3. Advice for firefighters

## Bisoprolol hemifumarate - Bio-X

**Special protective equipment for firefighters** Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents. Use protective equipment appropriate for surrounding materials.

### SECTION 6: Accidental release measures

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

**Personal precautions** Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material. Avoid inhalation of dust and vapours. Provide adequate ventilation. Keep unnecessary and unprotected personnel away from the spillage.

#### 6.2. Environmental precautions

**Environmental precautions** Avoid discharge into drains or watercourses or onto the ground.

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

**Methods for cleaning up** Wear protective clothing as described in Section 8 of this safety data sheet. Collect powder using special dust vacuum cleaner with particle filter or carefully sweep into suitable waste disposal containers and seal securely. Clear up spills immediately and dispose of waste safely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. For waste disposal, see Section 13.

#### 6.4. Reference to other sections

**Reference to other sections** For personal protection, see Section 8. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards. For waste disposal, see Section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Usage precautions** Wear protective clothing as described in Section 8 of this safety data sheet. Wash hands thoroughly after handling. Provide adequate ventilation. Avoid generation and spreading of dust. Avoid contact with skin and eyes. Avoid inhalation of dust and vapours. Do not eat, drink or smoke when using this product.

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

**Storage precautions** Keep container tightly closed. Store away from incompatible materials (see Section 10). Protect from light. Store at temperatures between 2°C and 8°C.

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

**Specific end use(s)** The identified uses for this product are detailed in Section 1.2.

### SECTION 8: Exposure Controls/personal protection

#### 8.1. Control parameters

##### Occupational exposure limits

No exposure limits known for ingredient(s).

#### 8.2. Exposure controls

**Appropriate engineering controls** Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

**Eye/face protection** Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye and face protection should comply with European Standard EN166.

## Bisoprolol hemifumarate - Bio-X

<b>Hand protection</b>	Wear protective gloves. To protect hands from chemicals, gloves should comply with European Standard EN374.
<b>Other skin and body protection</b>	Wear appropriate clothing to prevent repeated or prolonged skin contact.
<b>Respiratory protection</b>	Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked. Particulate filters should comply with European Standard EN143. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.
<b>Environmental exposure controls</b>	Keep container tightly sealed when not in use.

### SECTION 9: Physical and Chemical Properties

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

<b>Appearance</b>	Solid.
<b>Colour</b>	White/off-white.
<b>Odour</b>	No data available.
<b>Odour threshold</b>	No data available.
<b>pH</b>	No data available.
<b>Melting point</b>	99 to 102°C
<b>Initial boiling point and range</b>	No data available.
<b>Flash point</b>	No data available.
<b>Evaporation rate</b>	No data available.
<b>Flammability (solid, gas)</b>	No data available.
<b>Upper/lower flammability or explosive limits</b>	No data available.
<b>Vapour pressure</b>	No data available.
<b>Vapour density</b>	No data available.
<b>Relative density</b>	No data available.
<b>Solubility(ies)</b>	Soluble in the following materials: Chloroform. Ethanol. Methanol. Acetone. Insoluble in the following materials: Ether.
<b>Partition coefficient</b>	No data available.
<b>Auto-ignition temperature</b>	No data available.
<b>Decomposition Temperature</b>	No data available.
<b>Viscosity</b>	No data available.
<b>Explosive properties</b>	No data available.
<b>Oxidising properties</b>	No data available.

#### 9.2. Other information

<b>Molecular weight</b>	383.48
-------------------------	--------

## Bisoprolol hemifumarate - Bio-X

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

**Reactivity** No data available.

#### 10.2. Chemical stability

**Stability** Stable under the prescribed storage conditions.

#### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No data available.

#### 10.4. Conditions to avoid

**Conditions to avoid** No data available.

#### 10.5. Incompatible materials

**Materials to avoid** Strong oxidising agents.

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Oxides of carbon. Oxides of nitrogen.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute toxicity - oral

**Acute toxicity oral (LD<sub>50</sub> mg/kg)** 940.0

**Species** Rat

**Notes (oral LD<sub>50</sub>)** Acute Tox. 4 - H302 Harmful if swallowed.

**ATE oral (mg/kg)** 940.0

##### Acute toxicity - dermal

**Notes (dermal LD<sub>50</sub>)** Based on available data the classification criteria are not met.

##### Acute toxicity - inhalation

**Notes (inhalation LC<sub>50</sub>)** Based on available data the classification criteria are not met.

##### Skin corrosion/irritation

**Animal data** Based on available data the classification criteria are not met.

##### Serious eye damage/irritation

**Serious eye damage/irritation** Based on available data the classification criteria are not met.

##### Respiratory sensitisation

**Respiratory sensitisation** Based on available data the classification criteria are not met.

##### Skin sensitisation

**Skin sensitisation** Based on available data the classification criteria are not met.

##### Germ cell mutagenicity

**Genotoxicity - in vitro** Based on available data the classification criteria are not met.

##### Carcinogenicity

**Carcinogenicity** Based on available data the classification criteria are not met.

## Bisoprolol hemifumarate - Bio-X

<b>IARC carcinogenicity</b>	None of the ingredients are listed or exempt.
<b><u>Reproductive toxicity</u></b>	
<b>Reproductive toxicity - fertility</b>	Based on available data the classification criteria are not met.
<b>Reproductive toxicity - development</b>	Based on available data the classification criteria are not met.
<b><u>Specific target organ toxicity - single exposure</u></b>	
<b>STOT - single exposure</b>	Not classified as a specific target organ toxicant after a single exposure.
<b><u>Specific target organ toxicity - repeated exposure</u></b>	
<b>STOT - repeated exposure</b>	Not classified as a specific target organ toxicant after repeated exposure.
<b><u>Aspiration hazard</u></b>	
<b>Aspiration hazard</b>	Not relevant. Solid.
<b><u>General information</u></b>	
<b>General information</b>	Dust may irritate the eyes and the respiratory system. The severity of the symptoms described will vary dependent on the concentration and the length of exposure.
<b>Inhalation</b>	Dust may irritate the respiratory system. Frequent inhalation of dust over a long period of time increases the risk of developing lung diseases.
<b>Ingestion</b>	May cause discomfort if swallowed. Stomach pain. Nausea, vomiting.
<b>Skin contact</b>	Prolonged contact may cause dryness of the skin.
<b>Eye contact</b>	Dust may cause slight irritation.
<b>Route of exposure</b>	Ingestion Inhalation Skin and/or eye contact
<b>Target organs</b>	No specific target organs known.
<b>RTECS #</b>	UB8390000

### SECTION 12: Ecological Information

**Ecotoxicity** Not regarded as dangerous for the environment. However, large or frequent spills may have hazardous effects on the environment.

#### **12.1. Toxicity**

**Toxicity** Based on available data the classification criteria are not met.

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

**Persistence and degradability** The degradability of the product is not known.

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

**Bioaccumulative potential** No data available on bioaccumulation.

**Partition coefficient** No data available.

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

**Mobility** No data available.

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

**Results of PBT and vPvB assessment** No data available.

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

## Bisoprolol hemifumarate - Bio-X

**Other adverse effects**                      None known.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

**General information**                      Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered.

**Disposal methods**                         Mix or dissolve the material in a combustible solvent and burn in chemical incinerator equipped with an afterburner and scrubber.

### SECTION 14: Transport information

**General**                                         The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

#### 14.1. UN number

Not applicable.

#### 14.2. UN proper shipping name

Not applicable.

#### 14.3. Transport hazard class(es)

No transport warning sign required.

#### 14.4. Packing group

Not applicable.

#### 14.5. Environmental hazards

##### **Environmentally hazardous substance/marine pollutant**

No.

#### 14.6. Special precautions for user

Not applicable.

#### 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

**Transport in bulk according to**    Not applicable.

**Annex II of MARPOL 73/78  
and the IBC Code**

### SECTION 15: Regulatory information

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

##### **National regulations**

Health and Safety at Work etc. Act 1974 (as amended).  
The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].  
EH40/2005 Workplace exposure limits.

##### **EU legislation**

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).  
Commission Regulation (EU) No 2015/830 of 28 May 2015.  
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).

## Bisoprolol hemifumarate - Bio-X

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

#### SECTION 16: Other information

<b>Abbreviations and acronyms used in the safety data sheet</b>	ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road. ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways. RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail. IATA: International Air Transport Association. ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air. IMDG: International Maritime Dangerous Goods. CAS: Chemical Abstracts Service. ATE: Acute Toxicity Estimate. LC <sub>50</sub> : Lethal Concentration to 50 % of a test population. LD <sub>50</sub> : Lethal Dose to 50% of a test population (Median Lethal Dose). EC <sub>50</sub> : 50% of maximal Effective Concentration. PBT: Persistent, Bioaccumulative and Toxic substance. vPvB: Very Persistent and Very Bioaccumulative.
<b>Training advice</b>	Only trained personnel should use this material.
<b>Revision date</b>	23/06/2017
<b>Revision</b>	1
<b>SDS number</b>	144926
<b>Hazard statements in full</b>	H302 Harmful if swallowed.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.