spectrum®



SAFETY DATA SHEET

Preparation Date: 12/28/2018

1.1

Revision Number: E1

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifiers Product name	:	Bisoprolol Fumarate, USP
Product Number Brand	:	B2497 Spectrum Chemical
CAS-No.	:	104344-23-2

1.2 Details of the supplier of the safety data sheet

Company	:	Spectrum Chemical 14422 South San Pedro St.
		Gardena, CA 90248
Telephone Fax	:	+1 310-516-8000 +1 310-516-9843

1.3 **Emergency telephone number**

Emergency Phone # +1-800-424-9300 (CHEMTREC) 2

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 Acute toxicity, Oral (Category 4), H302

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

H302

Labelling according Regulation (EC) No 1272/2008 Pictogram

Signal word Warning Hazard statement(s)

Harmful if swallowed.

none

Precautionary statement(s) IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

Supplemental Hazard Statements

P301 + P312 + P330

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula	: C18H31NO4 · .5C4H4O4
Molecular weight	: 383.5 g/mol
CAS-No.	: 104344-23-2

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component		Classification	Concentration
Bisoprolol hemifuma	arate		
CAS-No.	104344-23-2	Acute Tox. 4; H302	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

- **4.2** Most important symptoms and effects, both acute and delayed The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
- **4.3 Indication of any immediate medical attention and special treatment needed** No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

- 5.2 Special hazards arising from the substance or mixture Carbon oxides, Nitrogen oxides (NOx)
- **5.3** Advice for firefighters Wear self-contained breathing apparatus for firefighting if necessary.
- 5.4 Further information No data available

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust. For personal protection see section 8.
- 6.2 Environmental precautions Do not let product enter drains.
- 6.3 Methods and materials for containment and cleaning up Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
- 6.4 Reference to other sections For disposal see section 13.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.
- 7.2 Conditions for safe storage, including any incompatibilities Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Storage class (TRGS 510): Non Combustible Solids
- **7.3** Specific end use(s) Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle r (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

9.1	Information on basic physical and chemical pro			
	a)	Appearance	Form: solid	
	b)	Odor	No data available	
	c)	Odor Threshold	No data available	
	d)	рН	No data available	
	e)	Melting point/freezing point	No data available	
	f)	Initial boiling point and boiling range	No data available	
	g)	Flash point	No data available	
h) Evaporation		Evaporation rate	No data available	
i) Flammability (solid, gas) No data avai		No data available		
	j)	Upper/lower flammability or explosive limits	No data available	
	k)	Vapor pressure	No data available	
	I)	Vapor density	No data available	
	m)	Relative density	No data available	
	n)	Water solubility	No data available	
	o)	Partition coefficient: n- octanol/water	No data available	
	p)	Auto-ignition temperature	No data available	
	q)	Decomposition temperature	No data available	
	r)	Viscosity	No data available	
	s)	Explosive properties	No data available	
	t)	Oxidizing properties	No data available	
9.2	Othe	er safety information		

No data available

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 No data available
- **10.4 Conditions to avoid** No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx)

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - Rat - 940 mg/kg(Bisoprolol hemifumarate) Remarks: Behavioral: Somnolence (general depressed activity). Behavioral: Tremor. Behavioral: Convulsions or effect on seizure threshold.

Skin corrosion/irritation

No data available(Bisoprolol hemifumarate)

Serious eye damage/eye irritation No data available(Bisoprolol hemifumarate)

Respiratory or skin sensitization No data available(Bisoprolol hemifumarate)

Germ cell mutagenicity

No data available(Bisoprolol hemifumarate)

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Specific target organ toxicity - single exposure No data available(Bisoprolol hemifumarate)

Specific target organ toxicity - repeated exposure No data available

Aspiration hazard

No data available(Bisoprolol hemifumarate)

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. (Bisoprolol hemifumarate)

SECTION 12: Ecological information

- 12.1 Toxicity No data available
- 12.2 Persistence and degradability No data available
- **12.3 Bioaccumulative potential** No data available
- 12.4 Mobility in soil No data available(Bisoprolol hemifumarate)
- 12.5 Results of PBT and vPvB assessment This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
- 12.6 Other adverse effects

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging

Dispose of as unused product.

SECT	SECTION 14: Transport information					
14.1	UN number ADR/RID: -	IMDG: -	IATA: -			
14.2	UN proper shipping nameADR/RID:Not dangerous goodsIMDG:Not dangerous goodsIATA:Not dangerous goods					
14.3	Transport hazard class(es) ADR/RID: -	IMDG: -	IATA: -			
14.4	Packaging group ADR/RID: -	IMDG: -	IATA: -			
14.5	Environmental hazards ADR/RID: no	IMDG Marine pollutant: no	IATA: no			
14.6	Special precautions for user No data available					

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H302 Harmful if swallowed.

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet