

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: BISOPROLOL FUMARATE
Chemical name	: 1-{4-[(2-Isopropoxyethoxy)methyl]phenoxy}-3-(isopropylamino)-2-propanol (2E)-2-butenedioate (2:1)
IUPAC name	: 1-{4-[(2-Isopropoxyethoxy)methyl]phenoxy}-3-(isopropylamino)-2-propanol (2E)-2-butenedioate (2:1)
CAS-No.	: 104344-23-2
Product code	: 71460
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C40H66N2O12
Synonyms	: Bisoprolol hemifumarate ; / 1-[4-[[2-(1-Methylethoxy)ethoxy]methyl]phenoxy]-3-[(1-methylethyl)amino]-2-propanol hemifumarate ; but-2-enedioic acid; 1-propan-2-ylamino-3-[4-(2-propan-2-yloxyethoxymethyl)phenoxy]-propan-2-ol
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: CANONICAL SMILES:CC(C)NCC(COC1=CC=C(C=C1)COCCOC(C)C)O.C(=CC(=O)O)C(=O)O

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API, Medicinal use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Laboratory activities Industrial For professional use only
Use of the substance/mixture	: Bisoprolol is a cardioselective β 1-adrenergic blocking agent used for secondary prevention of myocardial infarction (MI), heart failure, angina pectoris and mild to moderate hypertension. Antihypertensive
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

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

MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer

MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4 H302
Full text of H- and EUH-statements: see section 16

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Dust may form explosive mixture in air.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.

Precautionary statements (CLP) :

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

P280 - Wear eye protection, face protection.

2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
BISOPROLOL FUMARATE	CAS-No.: 104344-23-2	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Allow affected person to breathe fresh air. Allow the victim to rest. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Consult an ophthalmologist if irritation persists.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects	: Not expected to present a significant hazard under anticipated conditions of normal use. May cause drowsiness or dizziness.
Symptoms/effects after inhalation	: None under normal use. Anxious.
Symptoms/effects after skin contact	: Contact during a long period may cause light irritation.
Symptoms/effects after eye contact	: Direct contact with the eyes is likely to be irritating.

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Symptoms/effects after ingestion : Disorientation. Anxious. May cause drowsiness or dizziness. Cardiac arrhythmias.
Symptoms/effects upon intravenous administration : Cardiac arrhythmias.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Dust may form explosive mixture in air.
Explosion hazard : May form flammable/explosive vapour-air mixture.
Hazardous decomposition products in case of fire : Carbon dioxide. Carbon monoxide. Nitrogen oxides. Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire : Stop leak if safe to do so.
Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel. Do not get in eyes, on skin, or on clothing. Avoid breathing dust. Ventilate spillage area.
Measures in case of dust release : Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area. Stop leak if safe to do so. Shovel or sweep up and put in a closed container for disposal.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : In use, may form flammable vapour-air mixture. Keep away from Heat and ignition sources, Strong acids, strong bases and oxidation agents. No smoking.

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Ensure good ventilation of the work station. Eliminate all ignition sources if safe to do so. Mist formation: aerosol mask with filter type P3.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in original container. Keep container closed when not in use. Keep in fireproof place. Store in a well-ventilated place. Store at room temperature.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage area	: Store in a well-ventilated place.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use. Pharmaceuticals. Pharmaceutical Precursor Chemicals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment. Dust extraction (suction).

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Dust/aerosol mask with filter type P3. Protective clothing.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Hand protection:

Wear protective gloves.

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Hand protection		
Type	Material	Standard
Disposable gloves	Natural rubber, Polyvinylalcohol (PVA), Butyl rubber, Polyvinylchloride (PVC), Latex, Vinyl	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Dust.
Molecular mass	: 767 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 100 – 110 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Dust could form explosive mixtures with air
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 223 °C Bisoprolol F.P. estimated by ACDLABS
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 40 g/l Organic solvent: 8.8 g/100ml DMSO
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 2.2 Bisoprolol free base Estimated by ACDLABS
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	: 16 mJ
Additional information	: Layer Minimum flammability Temperature : Melt. Dust Cloud minimum Flammability Temperature : 400°C. Explosion Class : ST1. Explosivity Pmax : 7.2 bar-g. Explosion Severity Factor Kmax (bar.m/s) : 134. Minimum Explosive Concentration : 10 g/m3

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under use and storage conditions as recommended in section 7.

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

On exposure to high temperature, may decompose, releasing toxic gases. fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

BISOPROLOL FUMARATE (104344-23-2)	
LD50 oral rat	940 [mg/kg/24h]
LD50, oral	678 mg/kg
LD50, oral, Dog	40 mg/kg
LD50, intravenous, rat	39 mg/kg
LD50, intravenous, mouse	111 mg/kg

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if swallowed.
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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

BISOPROLOL FUMARATE (104344-23-2)

LC50 - Fish [1]	> 100 mg/l [Oncorhynchus mykiss]
EC50 - Crustacea [1]	> 100 mg/l

12.2. Persistence and degradability

BISOPROLOL FUMARATE (104344-23-2)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

BISOPROLOL FUMARATE (104344-23-2)

Partition coefficient n-octanol/water (Log Pow)	2.2 Bisoprolol free base Estimated by ACDLABS
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.5. Results of PBT and vPvB assessment

BISOPROLOL FUMARATE (104344-23-2)

vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV; ID No. 3195).
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed
SZW-lijst van mutagene stoffen : The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

Data sources : 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

Safety Data Sheet (SDS), EU

BISOPROLOL FUMARATE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.