

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

Product form	: Substance
Trade name	: METOPROLOL SUCCINATE
Chemical name	: 1-Isopropylamino-3-(p-(2-methoxyethyl)phenoxy)-2-propanol (2:1) succinate salt
IUPAC name	: 1-Isopropylamino-3-(p-(2-methoxyethyl)phenoxy)-2-propanol (2:1) succinate salt
CAS-No.	: 098418-47-4
Product code	: 75220 // PF 439/1
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: 2(C ₁₅ H ₂₅ NO ₃). (C ₄ H ₆ O ₄)
Synonyms	: Metoprolol succinate : 1-(4-(-methoxyethyl)phenoxy)-3-(propan-2-ylamino)propan-2-ol (2:1) butanedioic acid
Other means of identification	: SMILE: COCCC1=CC=C(OCC(O)CNC(C)C)C=C1 (metoprolol base)

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

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

BENECHIM S.R.L.
rue René Magritte 163 (North Zoning)
B-7860 Lessines
Belgium
T + 32 68 33 49 13

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 // +32 (0)70 245 245 (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]**

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335

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Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. Causes eye irritation. May cause long lasting harmful effects to aquatic life.

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P273 - Avoid release to the environment.
P280 - Wear eye protection, protective gloves, respiratory protection, protective clothing.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

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

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
METOPROLOL SUCCINATE	CAS-No.: 098418-47-4	≈ 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). May cause harm to breast-fed children.

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

First-aid measures after skin contact

: Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation occurs: Gently wash with plenty of soap and water, Get medical advice/attention.

First-aid measures after eye contact

: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion

: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects	: If you feel unwell, seek medical advice. May cause drowsiness or dizziness.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: May cause drowsiness or dizziness.

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

Hazardous decomposition products in case of fire	: Thermal decomposition generates : Carbon dioxide. fume. Carbon monoxide. Toxic fumes may be released.
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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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No open flames. No smoking. Remove ignition sources. No flames, no sparks. Eliminate all sources of ignition.
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6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Avoid breathing dust, mist, spray. Evacuate unnecessary personnel.
Measures in case of dust release	: Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Shovel or sweep up and put in a closed container for disposal. Ventilate confined spaces before entering. Stop leak if safe to do so. Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: This material and its container must be disposed of in a safe way, and as per local legislation. 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.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Keep away from Strong acids, strong bases and strong oxidants, Heat and ignition sources. No smoking.
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. Avoid breathing dust, mist. Avoid contact with skin, eyes and clothing. Use only outdoors or in a well-ventilated area. Eliminate all ignition sources if safe to do so. Avoid dust formation. Avoid raising powdered material due to explosion hazard. Wear personal protective equipment.
Handling temperature	: Store at room temperature
Hygiene measures	: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Wash hands, forearms and face thoroughly after handling. Do not eat, drink or smoke when using this product. Separate working clothes from town clothes. Launder separately.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a well-ventilated place. Store at room temperature.
Incompatible products	: Oxidizing agent. Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage area	: Store in a well-ventilated place. Store away from heat.

7.3. Specific end use(s)

Pharmaceuticals.

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: 2 (0.1 - 1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure. Safety glasses. Gloves. Dust/aerosol mask with filter type P3.

Personal protective equipment symbol(s):



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8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Latex, Polyvinylchloride (PVC), Natural rubber, Butyl rubber, Polyvinylalcohol (PVA), Nitrile rubber (NBR)	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	Protection for Solid particles, Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Consumer exposure controls:

Avoid contact during pregnancy/while nursing.

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	: Local powder.
Molecular mass	: 652.8 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 137 – 140 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: See 9.2 Dust could form explosive mixtures with air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 6 – 8 (2% aq. sol)

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pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 1.6 Metoprolol base
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 320 kg/m ³
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
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	: 8-10 mJ
Additional information	: Layer Minimum flammability Temperature >400 °C. Dust Cloud minimum Flammability Temperature : 420 ° C. Explosivity Pmax 8.5 bar. Explosion Severity Factor Kmax (bar.m/s) 313 bar.m.s-1. Explosion Class St3

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. Stable under use and storage conditions as recommended in section 7.

10.2. Chemical stability

The product is stable at normal handling and storage conditions. Not established.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

10.4. Conditions to avoid

Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition. Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Oxidizing agent. Strong acids. Strong bases.

10.6. Hazardous decomposition products

Nitrogen oxides. fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified

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Acute toxicity (inhalation) : Not classified
Additional information : Based on available data, the classification criteria are not met

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LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Causes skin irritation. pH: 6 – 8 (2% aq. sol)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 6 – 8 (2% aq. sol)
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 (Based on available data, the classification criteria are not met)
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
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

11.2.2. Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met
Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

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LC50 - Fish [1]	130 mg/l rainbow trout
EC50 - Crustacea [1]	> 120 mg/l
EC50 72h - Algae [1]	47 mg/l

12.2. Persistence and degradability

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Persistence and degradability	May cause long-term adverse effects in the environment.
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12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Pow)	1.6 Metoprolol base
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Avoid release to the environment. Discharging into rivers and drains is forbidden. Dispose in a safe manner in accordance with local/national regulations.
Additional information : Clean up even minor leaks or spills if possible without unnecessary risk. Industrial waste.
Ecology - waste materials : Avoid release to the environment.
European List of Waste (LoW) code : 16 05 08* - discarded organic chemicals consisting of or containing dangerous substances

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

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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
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

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

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)

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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)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
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

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

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:

LD50	Median lethal dose
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
SDS	Safety Data Sheet
STP	Sewage treatment plant
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
EC50	Median effective concentration
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road

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:

Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2

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Full text of H- and EUH-statements:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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.