

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
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-yl 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 For professional use only Industrial
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

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)
------------------	--------------------------------------

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
Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412
Full text of H 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.

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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, face protection
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
P501 - Dispose of contents/container to an approved waste disposal plant

2.3. Other hazards

Other hazards not contributing to the 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

Full text of R- and H-statements: see section 16

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).

First-aid measures after inhalation

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

First-aid measures after skin contact

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

First-aid measures after eye contact

: Rinse cautiously with water for several minutes. If eye irritation persists: Rinse cautiously with water for several minutes, If eye irritation persists: Get medical advice/attention. Get medical advice/attention.

First-aid measures after ingestion

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

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. 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.

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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.

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.

6.1.1. For non-emergency personnel

Protective equipment : Breathing equipment.

Emergency procedures : Evacuate unnecessary personnel. Avoid breathing dust, mist, spray.

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.

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 : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials. This material and its container must be disposed of in a safe way, and as per local legislation.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

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. Use only outdoors or in a well-ventilated area. Eliminate all ignition sources if safe to do so. Avoid contact with skin, eyes and clothing. 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 and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. 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. Keep container closed when not in use. Store in a well-ventilated place. Store at room temperature.

Incompatible products : Strong bases. Strong acids. Oxidizing agent.

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.

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional information : MOEHS occupational exposure band : 2 (0.1 - 1 mg/m3)

8.2. Exposure controls

Appropriate engineering controls:

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

Personal protective equipment:

Avoid all unnecessary exposure. Mist formation: aerosol mask with filter type P3. Safety glasses. Gloves. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Hand protection:

Wear protective gloves

Type	Material	Standard
Disposable gloves	Latex, Polyvinylchloride (PVC) , Natural rubber, Butyl rubber, Polyvinylalcohol (PVA), Nitrile rubber (NBR)	EN 374

Eye protection:

Chemical goggles or safety glasses. Face shield

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear appropriate mask

Device	Filter type	Condition	Standard
Dust mask	Type P3	Protection for Solid particles, Dust protection	EN 143



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
Appearance	: Local powder.
Molecular mass	: 652.8 g/mol
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 6 - 8 (2% aq. sol)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 137 - 140 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: See 9.2 Dust could form explosive mixtures with air
Vapour pressure	: No data available

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 320 kg/m ³
Solubility	: Soluble in water.
Log Pow	: 1.6 Metoprolol base
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

Minimum ignition energy	: 8 - 10 mJ
Additional information	: Layer Minimum flammability Temperature 420 °C. Dust Cloud minimum Flammability Temperature > 400 ° 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.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid dust formation. No flames, no sparks. Eliminate all sources of ignition. Direct sunlight.

10.5. Incompatible materials

Strong acids. Strong bases. Oxidizing agent.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

METOPROLOL SUCCINATE (098418-47-4)

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
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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
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.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Harmful to aquatic life with long lasting effects.

METOPROLOL SUCCINATE (098418-47-4)	
LC50 fish 1	130 mg/l rainbow trout
EC50 Daphnia 1	> 120 mg/l
EC50 72h algae (1)	47 mg/l

12.2. Persistence and degradability

METOPROLOL SUCCINATE (098418-47-4)	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

METOPROLOL SUCCINATE (098418-47-4)	
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. 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	: Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment. Discharging into rivers and drains is forbidden.
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

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

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

14.6. Special precautions for user

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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

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

No REACH Annex XVII restrictions

METOPROLOL SUCCINATE is not on the REACH Candidate List

METOPROLOL SUCCINATE is not on the REACH Annex XIV List

15.1.2. National regulations

Germany

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

Denmark

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

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 R-, 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
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H412	Harmful to aquatic life with long lasting effects
R36/37/38	Irritating to eyes, respiratory system and skin
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Xi	Irritant

METOPROLOL SUCCINATE

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SDS EU (REACH Annex II)

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