

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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METOPROLOLI TARTRAS

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Metoprolol tartrate
Metoprololi tartras
Metoprololtartraat
Métoprolol (tartrate de)
Metoprololtartrat

N° CAS: 56392-17-7

N° EC: 260-148-9

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute toxicity (category 4)	H302
Skin irritation (category 2)	H315
Eye irritation (category 2)	H319
Reproductive toxicity (category 2)	H361
Aquatic chronic (category 3)	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H361	Suspected of damaging fertility or the unborn child.
H412	Harmful to aquatic life with long lasting effects.
Precautionary statements:	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Not applicable.
P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see ... on this label).
P330	Rinse mouth.
P332 + P313	If skin irritation occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with federal, state and local environmental control regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Metoprolol tartrate
IUPAC name:	(2R,3R)-2,3-dihydroxybutanedioic acid;1-[4-(2-methoxyethyl)phenoxy]-3-(propan-2-ylamino)propan-2-ol
Synonyms:	Bis[(2RS)-1-[4-(2-methoxyethyl)phenoxy]-3-[(1-methylethyl)amino]propan-2-ol](2R,3R)-2,3-dihydroxybutanedioate 2-Propanol, 1-(isopropylamino)-3-(p-(2-ethoxyethyl)phenoxy)-, (+)-, tartrate (2:1)
N° CAS:	56392-17-7
N° EC:	260-148-9
Molecular Formula:	C ₃₄ H ₅₆ N ₂ O ₁₂

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Content: 99.0 % to 101.0 % (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Not applicable.

After inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

After skin contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

After eye contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

After ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Self-protection of the first aider: Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Small fire: Use DRY chemical powder.
Large fire: Use water spray, fog or foam. Do not use water jet.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Flammability of the product: May be combustible at high temperature.

Fire hazards in presence of various substances: Slightly flammable to flammable in presence of heat.

Remarks on fire hazards: As with most organic solids, fire is possible at elevated temperatures.

Explosion hazards in presence of various substances: Slightly explosive in presence of open flames and sparks.

Special remarks on explosion hazards: Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Not available.

Hazardous combustion products: These products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂ ...).

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Not available.

For emergency responders

Not available.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large spill: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Keep away from heat. Keep away from sources of ignition. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

Personal protection:

Not available.

Technical protective measures:

Ground all equipment containing material.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light. Store in light-resistant containers.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

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Appropriate engineering control

Local exhaust ventilation, or other engineering controls to keep airborne levels below.

Large spill: If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures

Eye/face protection: Safety glasses.

Large spill: Splash goggles.

Skin protection: Lab coat.

Large spill: Full suit, boots, suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Hand protection: Gloves.

Large spill: Gloves.

Respiratory protection: Dust respirator. Be sure to use an approved/certified respirator or equivalent.

Large spill: Dust respirator. A self-contained breathing apparatus should be used to avoid inhalation of the product.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not applicable.

pH: (2 % soln/water): 6.5

Melting/freezing point: 120 °C (248 °F) – 122 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): May be combustible at high temperature.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not applicable.

Vapour density: Not applicable.

Relative density: Not available.

Solubility: Very soluble in water, freely soluble in ethanol (96 %). It shows polymorphism.

Solubility in water: Easily soluble in cold water.

Partition coefficient (n-octanol/water): Not available.

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Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 684.81

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

The product is stable.

10.3 Possibility of hazardous reactions

Polymerisation will not occur.

10.4 Conditions to avoid

Excess heat, incompatible materials, sensitive to light.

10.5 Incompatible materials

Reactive with oxidizing agents.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀): 1090 mg/kg (dog)

Skin corrosion/irritation: Slightly hazardous in case of skin contact (irritant).

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: May cause adverse reproductive effects and birth defects (teratogenic) based on animal test data.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Slightly hazardous in case of ingestion, of inhalation.

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11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	May cause skin irritation.
Inhalation:	May cause respiratory tract irritation. Symptoms may include wheezing, nasal congestion, difficulty breathing, shortness of breath.
Ingestion:	May cause nausea, vomiting, diarrhoea, constipation, stomach discomfort. May affect behaviour/central nervous system (dizziness, drowsiness, unusual tiredness or weakness, ataxia, convulsions, somnolence trouble sleeping, fainting, anxiety or nervousness, mental depression), respiration (difficulty breathing, shortness of breath). Other symptoms may include irregular heartbeat, blue discoloration of the fingernails or palms (cyanosis). Prolonged or repeated ingestion may cause hyperglycaemia. It may also affect the blood (changes in cell count), respiration (symptoms similar to that of acute ingestion), behaviour (symptoms similar to that of acute ingestion).
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

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ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
14.2 UN proper shipping name	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
14.3 Transport hazard class(es)	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
14.4 Packing group	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
14.5 Environmental hazards	
ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not classified.
14.6 Special precautions for user	
Not available.	
14.7 Transport in bulk according to annex II of Marpol and the IBC Code	
Not available.	
14.8 Additional transport information	
Not a DOT controlled material (United States).	
SECTION 15: REGULATORY INFORMATION	
15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture	
Hazard symbol:	Not applicable.
Risk phrases:	Not applicable.
Safety phrases:	Not applicable.
15.2 Chemical safety assessment	
Not available.	
SECTION 16: OTHER INFORMATION	
16.1 Changes since the previous version	
Not applicable.	
16.2 Abbreviations and acronyms used	
ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods

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IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be