



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 03/04/2023 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Substance
Substance name	: Metoprolol
Product code	: 201600587
Synonyms	: Metoprolol, salts, hydrates, isomers and impurities where applicable
1.2. Relevant identified uses of the substan	ce or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category	: The product is intended for research, analysis and scientific education.
Use of the substance/mixture	: For professional use only
Function or use category	: Laboratory chemicals
1.2.2. Uses advised against	
Restrictions on use	: Do not use : Ingestion, Inhalation, Dermal

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare EDQM, Council of Europe 7, Allée Kastner, CS30026 F- 67081 Strasbourg France T +33(0)388412035 - F +33(0)388412771 <u>sds@edqm.eu</u> - <u>www.edqm.eu</u>

1.4. Emergency telephone number

Emergency number

: +33(0)390215608

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
Acute toxicity (dermal), Category 4	H312
Specific target organ toxicity – Repeated exposure, Category 2	H373
Full text of H- and EUH-statements: see section 16	

Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

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Labelling according to Regulation (EC) N	o. 1272/2008 [CLP]
Hazard pictograms (CLP)	
	GHS07 GHS08
Signal word (CLP)	: Warning
Hazard statements (CLP)	: H302+H312 - Harmful if swallowed or in contact with skin.
	H373 - May cause damage to organs through prolonged or repeated exposure.
Precautionary statements (CLP)	: P260 - Do not breathe dust.
	P280 - Wear protective gloves.
	P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell.
	P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
Labelling according to: exemption for inner p	ackaging where the contents do not exceed 10ml

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

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Hazard pictograms (CLP)



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2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Metoprolol	-	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) STOT RE 2, H373

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

3.2. Mixtures

Not applicable

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures after skin contact First-aid measures after eye contact	Wipe off as much as possible (using a clean, soft, absorbent material).Rinse eyes with water as a precaution.
4.2. Most important symptoms and effe	ects, both acute and delayed
No additional information available	
4.3. Indication of any immediate medic	al attention and special treatment needed
No additional information available	
SECTION 5: Firefighting measures	
SECTION 5: Firefighting measures 5.1. Extinguishing media	
	: Extinguishing blanket.
5.1. Extinguishing media	: Extinguishing blanket.
5.1. Extinguishing media Suitable extinguishing media	: Extinguishing blanket.
 5.1. Extinguishing media Suitable extinguishing media 5.2. Special hazards arising from the subscription 	: Extinguishing blanket. ubstance or mixture

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SECTION 6: Accidental release measure	res
6.1. Personal precautions, protective equip	ment and emergency procedures
6.1.1. For non-emergency personnel Emergency procedures	: Avoid all unnecessary exposure.
6.1.2. For emergency responders No additional information available	
6.2. Environmental precautions	
No additional information available	
6.3. Methods and material for containment	and cleaning up
No additional information available	
6.4. Reference to other sections	
No additional information available	
SECTION 7: Handling and storage	
7.1. Precautions for safe handling	

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

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

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

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8.2.2.2. Skin protection

Skin and body protection: Lab coat

Hand protection: Protective gloves

8.2.2.3. Respiratory protection

No additional information available

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state		Solid
Colour		Not available
Appearance	÷	Powder.
Odour	÷	Not available
Odour threshold		Not available
Melting point		Not available
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
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	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
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

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

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10.2. Chemical stability
lo additional information available
10.3. Possibility of hazardous reactions
lone known.
10.4. Conditions to avoid
lo additional information available
10.5. Incompatible materials
Ione under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

11.1. Information on hazard classes	as defined in Regulation (EC) No 1272/2008
Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Harmful in contact with skin.
Acute toxicity (inhalation)	: Not classified
Metoprolol	
LD50 oral rat	> 5500 mg/kg
Skin corrosion/irritation	Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Lack of data)
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Further details: Acute toxicity)
STOT-single exposure	: Not classified (Conclusive but not sufficient for classification)
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general Hazardous to the aquatic environment, short–term (acute) Hazardous to the aquatic environment, long–term (chronic)	Presents no specific risk for the environment.Not classifiedNot classified
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
12.4. Mobility in soil	
No additional information available	

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12.5. Results of PBT and vPvB assessment
No additional information available
12.6. Endocrine disrupting properties
No additional information available
12.7. Other adverse effects
No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

ADR	IMDG	ΙΑΤΑ
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
		Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
14.4. Packing group	·	
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards	·	
Not applicable	Not applicable	Not applicable
No supplementary information available		

14.6. Special precautions for user

Overland transport Not applicable

Transport by sea Not applicable

Air transport Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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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 applicable.

POP Regulation (Persistent Organic Pollutants) Not applicable.

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

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H373	May cause damage to organs through prolonged or repeated exposure.
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.