

Safety Data Sheet**Metipranolol**

according to Regulation (EU) nr. 1907/2006

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

Product name Metipranolol

Product code 04 7517 3

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

Use

- pharmaceutical active substance (hypotensive)
- for the treatment of the glaucoma (eye drops)

1.3. Details of the supplier of the safety data sheet

Company information

Enquiries:
F. Hoffmann-La Roche AG
Postfach
CH-4070 Basel
Switzerland

Local representation:

Phone +41-61/688 54 80
Fax +41-61/681 72 76
E-Mail info.sds@roche.com

1.4. Emergency telephone number

Emergency telephone number Phone +41-61/688 54 80

Metipranolol

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification

Health Hazards:

- 3.1 Acute toxicity (Category 4)
H302 Harmful if swallowed.

Environmental Hazards:

- 4.1 Hazardous to the aquatic environment (Category 2)
H411 Toxic to aquatic life with long lasting effects.

Signalword: Warning

Label:



Precautionary statements:

- P273 Avoid release to the environment.
- P312 Call a POISON CENTER or doctor/physician if you feel unwell.

2.3. Other hazards

Note

- may form explosible dust-air mixture if dispersed

SECTION 3: Composition/information on ingredients

Characterization

pharmaceutical active substance in the class of β -blocker

Chemical name

- 4-{2-Hydroxy-3-[(1-methylethyl)amino]propoxy}-2,3,6-trimethyl-1-acetyl-phenol

Synonyms

- BM 01.004
- 1-(4-Acetoxy-2,3,5-trimethylphenoxy)-3-isopropylamino-propanol
- Trimepranol
- Betanol

CAS number

22664-55-7

UN number

3077

Roche number

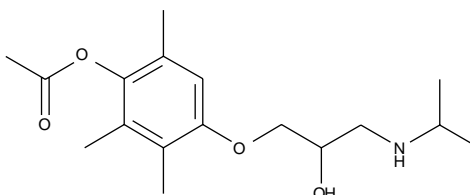
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Empirical formula

$C_{17}H_{27}NO_4$

Molecular mass

309.41 g/mol



SECTION 4: First aid measures

4.1. Description of first aid measures

- | | |
|--------------|---|
| Eye contact | - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents |
| Inhalation | - remove the casualty to fresh air and keep him/her calm
- get medical treatment |

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

- | | |
|------|----------------------------|
| Note | - no information available |
|------|----------------------------|

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

- | | |
|-------------------|-------------------------|
| Note to physician | - treat symptomatically |
|-------------------|-------------------------|

SECTION 5: Firefighting measures

5.1. Extinguishing media

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|------------------------------|---|
| Suitable extinguishing media | - water spray jet, dry powder, foam, carbon dioxide |
|------------------------------|---|

5.2. Special hazards arising from the substance or mixture

- | | |
|------------------|---|
| Specific hazards | - formation of toxic and corrosive combustion gases (nitrogen oxides (NO _x)) possible
- consider dust explosion hazard |
|------------------|---|

5.3. Advice for firefighters

- | | |
|-----------------------------|--|
| Protection of fire-fighters | - precipitate gases/vapours/mists with water spray |
|-----------------------------|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- | | |
|----------------------|------------------|
| Personal precautions | - avoid exposure |
|----------------------|------------------|

6.2. Environmental precautions

- | | |
|--------------------------|---|
| Environmental protection | - do not allow to enter drains or waterways |
|--------------------------|---|

Metipranolol

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	- collect solids (avoid dust formation) and hand over to waste removal
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures	<ul style="list-style-type: none">- processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)- local exhaust ventilation necessary- take precautionary measures against electrostatic charging- avoid dust formation; high dust explosion hazard
Suitable materials	- aluminium, glass, polypropylene, stainless steel, enamel

7.2. Conditions for safe storage, including any incompatibilities

Packaging materials	- tightly closing; material: aluminium, stainless steel, polypropylene
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Note	- no information available
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8.2. Exposure controls

General protective and hygiene measures	- instruction of employees recommended
Respiratory protection	- in case of open handling or accidental release: particle mask or respirator with independent air supply
Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour	white
Form	solid
Odour	odourless

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Solubility	130 mg/l, water (~ 22 °C, pH 10.1, HPLC, 24 h) ≥ 265 mg/l, aquatic ecotoxicity media (~ 22 °C, pH 6.4, HPLC, 24 h) soluble, methanol
Partition coefficient	log P _{ow} 2.66 (n-octanol/water) (citation from literature)
pH value	9 to 10 (25 g/l saturated aqueous solution)
Melting temperature	105 to 129 °C

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- LD ₅₀	1'545	mg/kg	(oral, rat)
	- LD ₅₀	239	mg/kg	(i.p., rat)
Chronic toxicity	- NOAEL	22 mg/kg/d	(oral, rat; 104 weeks)	
	- NOAEL	~ 15 mg/kg/d	(oral, dog; 6 months)	

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Local effects	- no information available
Sensitization	- no information available
Mutagenicity	- no information available
Carcinogenicity	- no indication for carcinogenicity (oral, rat)
Reproductive toxicity	- no information available
STOT-single exposure	- no information available
STOT-repeated exposure	- no information available
Aspiration hazard	- no information available
Note	<ul style="list-style-type: none">- β-receptor blocker- metabolism and elimination via liver and faeces- oral bioavailability 50 %- elimination half-life: 3 h- therapeutic dose: 20 to 80 mg/d- prolonged exposition or high dosing may cause: bradycardia, cardiac arrhythmias, tiredness, hypotension, convulsions, loss of consciousness- the following symptoms may occur: asthma

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	<ul style="list-style-type: none">- strongly toxic for algae (<i>Scenedesmus</i> (=Desmodesmus) subspicatus) ErC₅₀ (72 h) 4.44 mg/l EbC₅₀ (72 h) 2.56 mg/l NOEC (72 h) 1.25 mg/l (OECD No. 201)- moderately toxic for planktonic crustaceans (<i>Daphnia magna</i>) EC₅₀ (48 h) 37.5 mg/l (average measured concentration) NOEC (48 h) < 5.8 mg/l (average measured concentration) (OECD No. 202)- acute fish toxicity in a limit test is lower than daphnid or algal toxicity, hence not relevant for classification (guppy) LC₅₀ (96 h) > 10 mg/l (highest concentration tested) LC₀ (96 h) 8.44 mg/l (average measured concentration) (OECD No. 203)- no adverse influence on substrate biodegradation (activated sludge) concentration (14 d) 100 mg/l (Manometric Respirometry Test, OECD No. 301 F)
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12.2. Persistence and degradability

Ready biodegradability - not readily biodegradable
31 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F)

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Air pollution - observe local/national regulations

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

IATA	Class	UN/ID	PG		PI	Label	Mark	
	9	3077	III		956/956	9	EHS	
IMDG	Class	UN	PG	EmS	PI	Label	Mark	
	9	3077	III	F-A S-F	P002/IBC08	9	marine pollutant	
RID/ADR	Class	UN	PG	Haz.no	PI	Label	Mark	Classif. code
	9	3077	III	90	P002/IBC08	9	EHS	M7

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Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Technical name Metipranolol

SECTION 15: Regulatory information

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

Water hazard class (Germany) 2: hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Safety-lab number - BS-7927

Edition documentation - changes from previous version in sections 2, 6, 8

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.