



PROPRANOLOL HYDROCHLORIDE Tablets USP 10mg, 20mg, 40mg, 60mg and 80mg

Ipca Laboratories Ltd.

Safety Data Sheet (Conforms to Regulations
(EU) No 2020/878)

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

1.1. Product Identifier

Product name	PROPRANOLOL HYDROCHLORIDE Tablets USP 10mg, 20mg, 40mg, 60mg and 80mg
Chemical Name	propranolol hydrochloride
Synonyms	1-Isopropylamino-3-(1-naphthoxy)propan-2-ol hydrochloride
Proper shipping name	Not Available
Chemical formula	C ₁₆ H ₂₂ NO ₂ Cl
Other means of identification	Not Available
CAS number	318-98-9
EC number	206-268-7
Index number	Not Available
REACH registration number	Not Available

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

Relevant identified uses	Pharmaceutical active: Beta-Adrenoceptor blocker management of hypertension, angina pectoris and dysrhythmias
Uses advised against	No data available

1.3. Details of the supplier of the safety data sheet

Registered company name	Ipca Laboratories Ltd.	Ipca Laboratories Ltd.
Address	P.O. Sejavta, Dist. Ratlam 457001 M.P. India	48, Kandivali Industrial Estate, Kandivali (West), 400067 Mumbai Maharashtra India
Telephone	(07412)278000	(022)6215000
Fax	-	(022)6215005
Website	-	-
Email	safety.ratlam@ipca.com	safety.ratlam@ipca.com

1.4. Emergency telephone number

Association / Organisation	-	-
Emergency telephone numbers	(07412)278099	-
Other emergency telephone numbers	-	-

SECTION 2 HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Physical State	10mg: Orange coloured, round, biconvex tablets, embossed with "P" and "10" on either side of the breakline on one side and plain on the other side. 20mg: Blue coloured, round, biconvex tablets, embossed with "P" and "20" on either side of the breakline on one side and plain on the other side. 40mg: Green coloured, round, biconvex tablets, embossed, with "P" and "40" on either side of the breakline on one side and plain on the other side. 60mg: Pink coloured, round, biconvex tablets, embossed with "P" and "60" on either side of the breakline on one side and plain on the other side. 80mg: Yellow coloured, round, biconvex tablets, embossed with "P" and "80" on either side of the breakline on one side and plain on the other side.
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Legend: Classification drawn from EC Directive 1272/2008 - Annex VI

2.2. Label elements

CLP label elements	Not Available
SIGNAL WORD	Warning

Hazard statement(s)

H302	Harmful if swallowed
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Supplementary statement(s)

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substances

1. CAS No	% [weight]					Name	Classification according to regulation (EC) No 1272/2008 [CLP]
	10mg	20mg	40mg	60mg	80mg		
318-98-9	< 10%	< 20%	< 20%	< 30%	< 30%	Propranolol Hydrochloride	Not Available
10039-26-6	< 46%	< 45%	< 45%	> 40%	> 40%	Lactose monohydrate	
9005-25-8	< 40%	< 35%	< 35%	< 30%	< 30%	Corn Starch	
9063-38-1	< 4%	< 4%	< 4%	< 4%	< 4%	Sodium starch glycolate	
9003-39-8	< 4%	< 4%	< 4%	< 4%	< 4%	Povidone (PVP K30)	
557-04-0	< 1%	< 1%	< 1%	< 1%	< 1%	Magnesium Stearate	
008004-92-0	< 0.1%	--	< 0.1%	--	< 0.1%	D & C Yellow No 10	
2783-94-0	< 0.1%	--	< 0.1%	--	< 0.1%	FD & C Yellow No 6	
3844-45-9	--	< 0.2%	< 0.1%	--	--	FD & C Blue No. 1	
2379-74-0	--	--	--	< 0.2%	--	D & C Red No. 30	

Legend: Classification drawn from EC Directive 1272/2008 - Annex VI

3.2. Mixtures

See 'Information on ingredients' in section 3.1

SECTION 4 FIRST AID MEASURES

4.1. Description of first aid measures

Eye Contact	Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Skin Contact	Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
Inhalation	Remove patient from exposure, keep warm and at rest. Obtain medical attention if ill effects occur.
Ingestion	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.

4.2 Most important symptoms and effects, both acute and delayed

	Refer to sections 2 and 11
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4.3. Indication of any immediate medical attention and special treatment needed

	Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.
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SECTION 5 FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable	▶ water spray ▶ foam ▶ dry powder ▶ CO2
Unsuitable	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

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5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	If involved in a fire, it may burn and emit noxious and toxic fumes.
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5.3. Advice for firefighters

Special protective actions for fire-fighters	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.
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SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

	Ensure suitable personal protection during removal of spillages. See Section 8. Avoid dispersal of dust in the air.
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6.2. Environmental precautions

	Prevent entry into drains, sewers or watercourses. Collect spillage.
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6.3. Methods and material for containment and cleaning up

Minor Spills	Moisten spillages with water. Transfer to a container for disposal or recovery. Wash the spillage area with water. Avoid release to the environment. See section 13.
Major Spills	Moisten spillages with water. Transfer to a container for disposal or recovery. Wash the spillage area with water. Avoid release to the environment. See section 13

6.4. Reference to other sections

	Not Available
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SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling	Do not breathe dust. Avoid contact with skin and eyes. See Section 8. Strong dust explosion indicated in test (ST2). Minimize dust generation and accumulation. The material may form explosible dust-air mixture if dispersed. Dust clouds are extremely sensitive to ignition by electrostatic discharge or other ignition sources. Ensure good earthing of equipment and personnel.
Fire and explosion protection	See section 5
Other information	Preserve in well closed containers Below 30°C

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	Preserve in well closed containers Below 30°C
Storage incompatibility	Preserve in well closed containers Below 30°C

PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

7.3. Specific end use(s)

Not applicable, refer to Section 1

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

DERIVED NO EFFECT LEVEL (DNEL)

Not Available

PREDICTED NO EFFECT LEVEL (PNEC)

Not Available

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OCCUPATIONAL EXPOSURE LIMIT (OEL)

PROPRANOLOL HYDROCHLORIDE	500 µg/m ³
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INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	TEEL-0	TEEL-1	TEEL-2	TEEL-3
PROPRANOLOL HYDROCHLORIDE	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
PROPRANOLOL HYDROCHLORIDE	Not Available	Not Available

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Not Available
8.2.2. Personal protection	
Eye and face protection	Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.
Hand protection	Not Available
Skin protection	Use impervious clothing to protect against direct contact with the substance if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the substance. If the substance is dissolved or wetted use a glove material that is resistant to the solvent/liquid.
Respiratory protection	Use an air fed hood if the risk assessment does not support the selection of other protection.
Other protection	Not Available
Thermal hazards	Not Available

8.2.3. Environmental exposure controls

See section 12

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Color	10mg: Orange coloured, round, biconvex tablets, embossed with "P" and "10" on either side of the breakline on one side and plain on the other side. 20mg: Blue coloured, round, biconvex tablets, embossed with "P" and "20" on either side of the breakline on one side and plain on the other side. 40mg: Green coloured, round, biconvex tablets, embossed, with "P" and "40" on either side of the breakline on one side and plain on the other side. 60mg: Pink coloured, round, biconvex tablets, embossed with "P" and "60" on either side of the breakline on one side and plain on the other side. 80mg: Yellow coloured, round, biconvex tablets, embossed with "P" and "80" on either side of the breakline on one side and plain on the other side.		
Physical state	Not Available	Relative density (Water = 1)	Not available
Odour	odourless or almost odourless	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not available
pH (as supplied)	Not Applicable	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not available	Volatile Component (%vol)	Negligible
Vapour pressure (kPa)	Not available	Gas group	Not Available

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Solubility in water (g/L)	soluble	pH as a solution(1%)	Not Applicable
Solubility in others (g/L)	soluble in:; ethanol slightly soluble in:; chloroform		
Minimum Ignition Temperature	Not Applicable	Minimum Ignition Energy	Not Applicable
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

9.2. Other information

Dissociation constant (pKa)	9.5	log Kow	0.722 (pH7)
Dust explosion constant (Kst)	242 bar m s-1	Dust explosion class (St)	2
Physical Hazard Class	Not Available		
Other Safety Characteristics	Not Available		

SECTION 10 STABILITY AND REACTIVITY

10.1. Reactivity	No known reactivity hazard under normal conditions.
10.2. Chemical stability	Stable under normal conditions.
10.3. Possibility of hazardous reactions	None known.
10.4. Conditions to avoid	No conditions producing hazardous situations known.
10.5. Incompatible materials	None known.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on Hazard classes as defined in regulation (EC) No 1272/2008

Inhaled	No information available on acute toxicity. May cause effects as described under single exposure (STOT)		
Mutagenicity	No evidence of genotoxicity based on in vitro tests.		
Ingestion	Harmful if swallowed. Oral Median Lethal Dose (rat) 1,000 - 1,500 mg/kg		
Skin Contact	May cause skin irritation after repeated exposure.		
Eye Contact	May cause eye irritation.		
Reproductive toxicity	No information available on Reproductive toxicity.		
Specific Target Organ Toxicity (STOT)	Single exposure Exposure routes: Oral, Inhalation Propranolol reduces heart rate and lowers blood pressure., Therapeutic doses may produce dizziness, fatigue, gastrointestinal disturbances, coldness of the fingers and toes, and difficulty in breathing. In rare cases, this product may present a risk of bronchospasm in individuals with asthma. Repeated exposure Propranolol reduces heart rate and lowers blood pressure.		
Sensitisation	Rare cases of skin sensitisation have been reported.		
Carcinogenicity	No evidence of carcinogenicity in animal studies		
propranolol hydrochloride	TOXICITY	IRRITATION	
	Oral (rat) LD50: 1,000 - 1,500 mg/kg		
Acute Toxicity		Carcinogenicity	
Skin Irritation/Corrosion		Reproductivity	
Serious Eye Damage/Irritation		STOT - Single Exposure	
Respiratory or Skin sensitisation		STOT - Repeated Exposure	
Germ Cell Mutagenicity		Aspiration Hazard	

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11.2. Information on Other Hazards

Endocrine Disrupting Properties	Not Available
Other Information	Not Available

CMR STATUS

Not Applicable

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

Toxic to aquatic life with long lasting effects.

Toxicity	EC50 Pseudokirchneriella subcapitata (green algae) 72 H growth rate 3.78 mg/l					
	EC50 Pseudokirchneriella subcapitata (green algae) 72 H biomass 0.78 mg/l					
Toxicity	NOEC Pseudokirchneriella subcapitata (green algae) 72 H biomass 0.156 mg/l					
	EC50 bacteria, aerobic 3 H 10 - 100 mg/l EC50 nitrifying bacteria 4H > 100 mg/l EC50 bacteria, anaerobic 15d > 100 mg/l EC50 Daphnia magna 48 H 1 - 10 mg/l					
Toxicity	EC50 Daphnia magna 24 H 3.08 mg/l (OECD 202)					
	NOEC Daphnia magna 9 d 0.055 mg/l (US EPA 1994) LC50 Rainbow trout 96 H (semi-static) 10 - 100 mg/l NOEC Rainbow trout 10 d growth rate 1 mg/l (OECD 215)					
Effect on Effluent Treatment	No information available.					
Ingredient	Endpoint	Test Duration	Effect	Value	Species	BCF
PROPRANOLOL HYDROCHLORIDE	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
propranolol hydrochloride	Rapidly degradable. (Modified OECD 302B, >60% mineralisation, passing 10 day window)	Not Available

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
propranolol hydrochloride	The substance has low potential for bioaccumulation.

12.4. Mobility in soil

Ingredient	Mobility
propranolol hydrochloride	Water solubility >= 1 mg/l.

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT and vPvB Criteria fulfilled	Not Available	Not Available	Not Available

12.6. Endocrine Disrupting Properties

Ingredient	
Not Available	Not Available

12.7. Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste treatment options	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal disposal is via incineration operated by an accredited disposal contractor.
Product / Packaging disposal	No Data Available
Contaminated Packaging	Empty container will retain product residue. Observe all hazard precautions.
Sewage disposal options	No relevant data

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SECTION 14 TRANSPORT INFORMATION
Land transport (ADR/ RID) : NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.4. Packing group	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.5. Environmental hazard	Not Applicable
14.3. Transport hazard class(es)	Class : Not Applicable
	Subrisk : Not Applicable
14.6. Special precautions for user	Hazard identification (Kemler) : Not Applicable
	Classification code : Not Applicable
	Hazard Label : Not Applicable
	Special provisions : Not Applicable
	Limited quantity : Not Applicable

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.4. Packing group	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.5. Environmental hazard	Not Applicable
14.3. Transport hazard class(es)	ICAO/IATA Class : Not Applicable
	ICAO / IATA Subrisk : Not Applicable
	ERG Code : Not Applicable
14.6. Special precautions for user	Special provisions : Not Applicable
	Cargo Only Packing Instructions : Not Applicable
	Cargo Only Maximum Qty / Pack : Not Applicable
	Passenger and Cargo Packing Instructions : Not Applicable
	Passenger and Cargo Maximum Qty / Pack : Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions : Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack : Not Applicable

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.4. Packing group	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.5. Environmental hazard	Not Applicable
14.3. Transport hazard class(es)	IMDG Class : Not Applicable
	IMDG Subrisk : Not Applicable
14.6. Special precautions for user	EMS Number : Not Applicable
	Special provisions : Not Applicable
	Limited Quantities : Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.4. Packing group	Not Applicable
14.2. UN proper shipping name	Not Applicable
14.5. Environmental hazard	Not Applicable
14.3. Transport hazard class(es)	Not Applicable
14.6. Special precautions for user	Classification code : Not Applicable
	Limited quantity : Not Applicable
	Equipment required : Not Applicable
	Fire cones number : Not Applicable

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14.7. Maritime transport in bulk according to IMO Instruments

Not Available

Transport in bulk according to Annex II of MARPOL 73 / 78 and the IBC code

Not Available

SECTION 15 REGULATORY INFORMATION

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

**propranolol hydrochloride
(206-268-7) is found on the
following regulatory lists**

This material and its container must be disposed of as hazardous waste.
In order to comply with legal duties it is necessary to consult local and national legislation.

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EU) No 2015/830, Regulation (EU) No 2020/878, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and their amendments as well as the following British legislation: - The Control of Substances Hazardous to Health Regulations (COSHH) 2002 - COSHH Essentials - The Management of Health and Safety at Work Regulations 1999

15.2. Chemical safety assessment

Not available.

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
propranolol hydrochloride	206-268-7	Not Available	Not Available
Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1&2	Acute toxicity Category 4	Not Available	H302

Harmonisation Code 1 = The most severe classification. Harmonisation Code = 2 The most prevalent classification

SECTION 16 OTHER INFORMATION

GLOSSARY

COM	In-house occupational exposure limit
LTEL	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	Threshold Limit Value (ACGIH)
TLV-C	Threshold Limit Value - Ceiling limit (ACGIH)
AGW	Arbeitsplatzgrenzwert (Germany TRGS 900)
HYG	An in-house analytical method for occupational exposure monitoring is available
Sk	Can be absorbed through skin, thus contributing to systemic effects
Sen	Capable of causing respiratory sensitisation