

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200)

1. Identification

Product Name	Propranolol Extended Release capsule USP, 60mg, 80mg, 120mg, 160mg
Cat No. :	AC207320000; AC207320050; AC207320250; AC207321000
CAS No	318-98-9
Synonyms	DL-1-(Isopropylamino)-3-(1-naphthoxy)-2-propanol hydrochloride
Recommended Use	Laboratory chemicals.
Uses advised against	Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company	Creekwood Pharmaceuticals LLC 11130, Route 46 W, Suite 21 Parsippany, New Jersey 07045
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2. Hazard(s) identification

Classification

This chemical is considered hazardous according to [US] OSHA (29 CFR 1910.1200, 2024)

Acute oral toxicity	Category 4
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Label Elements

Signal Word
Warning

Hazard Statements
Harmful if swallowed


Precautionary Statements
Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

None identified

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available

3. Composition/information on Ingredients

Component	CAS No	Weight %
[2-Hydroxy-3-(naphthylloxy)propyl]isopropylammonium chloride	318-98-9	>95

4. First-aid measures

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately.
Most important symptoms and effects	No information available.
Notes to Physician	Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media	Water spray. Carbon dioxide (CO ₂). Dry chemical. Chemical foam.
Unsuitable Extinguishing Media	No information available
Flash Point	No information available
Method -	No information available

Autoignition Temperature	Not applicable
Explosion Limits	
Upper	No data available
Lower	No data available
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition.

Hazardous Combustion Products

Nitrogen oxides (NO_x). Carbon monoxide (CO). Carbon dioxide (CO₂). Hydrogen chloride gas.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

NFPA

Health
1

Flammability
1

Instability
0

Physical hazards
N/A

6. Accidental release measures

Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required.
Environmental Precautions	See Section 12 for additional Ecological Information.

Methods for Containment and Clean Up	Sweep up and shovel into suitable containers for disposal. Do not let this chemical enter the environment. Avoid dust formation.
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7. Handling and Storage

Handling	Ensure adequate ventilation. Avoid contact with skin and eyes. Do not breathe dust. Do not ingest. If swallowed then seek immediate medical assistance. Minimize dust generation and accumulation. Wash hands before breaks and immediately after handling the product.
Storage.	Keep in a dry, cool and well-ventilated place. Keep container tightly closed. Incompatible Materials. Strong oxidizing agents. Strong acids.

8. Exposure controls / personal protection

Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Engineering Measures	Ensure adequate ventilation, especially in confined areas.
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Personal Protective Equipment

Eye/face Protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin and body protection	Wear appropriate protective gloves and clothing to prevent skin exposure.
Respiratory Protection	No protective equipment is needed under normal use conditions.
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

<u>Appearance</u>			
Physical State	Powder Solid		
Color	Off-white		
Odor	Odorless		
Odor Threshold	No information available		
<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>• Method</u>
Melting Point/Range	163 - 166 °C / 325.4 - 330.8 °F		
Softening Point	No data available		
Boiling Point/Range	No information available		
Flash Point	No information available	Method - No information available	
Flammability (liquid)	Not applicable		
Flammability (solid,gas)	No information available		
Explosion Limits	No data available		
Autoignition Temperature	Not applicable		
Decomposition Temperature	No data available		
pH	No information available		
Viscosity	Not applicable	Solid	
Water Solubility	Soluble		
Solubility in other solvents	No information available		
Partition Coefficient (n-octanol/water)			
Vapor Pressure	No data available		
Density / Specific Gravity	No data available		
Bulk Density	No data available		
Vapor Density	Not applicable	Solid	
Particle characteristics	No data available		
<u>Other Information</u>			
Molecular Formula	C16 H21 N O2 . H Cl		
Molecular Weight	295.8		
Evaporation Rate	Not applicable - Solid		

10. Stability and reactivity

Reactive Hazard	None known, based on information available
Stability	Stable under recommended storage conditions.
Conditions to Avoid	Incompatible products. Avoid dust formation.
Incompatible Materials	Strong oxidizing agents, Strong acids
Hazardous Decomposition Products	Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO ₂), Hydrogen chloride gas
Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.

11. Toxicological information

Information on expected route of exposure

Inhalation	Avoid breathing dust or spray mist. May be harmful if inhaled.
Ingestion	May be harmful if swallowed.
Eyes	Avoid contact with eyes.
Skin	Avoid contact with skin

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
[2-Hydroxy-3-(naphthoxy)propyl]isopropyl ammonium chloride	LD50 = 466 mg/kg (Rat)	-	-

Toxicologically Synergistic Products No information available

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;
 Respiratory No data available
 Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity;

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
[2-Hydroxy-3-(naphthyl oxy)propyl]isopropyl ammonium chloride	318-98-9	Not listed	Not listed	Not listed	Not listed	Not listed

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; Not applicable
 Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and delayed No information available.

Other Adverse Effects The toxicological properties have not been fully investigated.

Endocrine Disrupting Properties This product does not contain any known or suspected endocrine disruptors.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Mobility Will likely be mobile in the environment due to its water solubility.

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

14. Transport information

DOT Not regulated
TDG Not regulated
IATA Not regulated
IMDG/IMO Not regulated

15. Regulatory Information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
[2-Hydroxy-3-(naphthoxy)propyl]i sopropylammonium chloride	318-98-9	-	-	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT) Not applicable

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
[2-Hydroxy-3-(naphthoxy)propyl]i sopropylammonium chloride	318-98-9	X	-	206-268-7	-	-		X	-	KE-23956

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Health Administration Not applicabl

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65 This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations Not applicabl

U.S. Department of Transportation

Reportable Quantity (RQ): N
 DOT Marine Pollutant N
 DOT Severe Marine Pollutant N

U.S. Department of Homeland Security This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH Not applicable

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
[2-Hydroxy-3-(naphthoxy)propyl]isopropylammonium chloride	318-98-9	-	-	-

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

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
[2-Hydroxy-3-(naphthoxy)propyl]isopropylammonium chloride	318-98-9	Not applicable	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
2-Hydroxy-3-(naphthoxy)propyl]isopropylammonium chloride	318-98-9	Not applicable	Not applicable	Not applicable	Not applicable

16. Other Information

Prepared By
(Regulatory affairs)

Creekwood Pharmaceuticals LLC

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text