

SAFETY DATA SHEET

Section 1: Identification	
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Product	Cyclobenzaprine Hydrochloride Tablets USP 10mg
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-872-10 (bottles of 100's)
Section 2: Hazard(s) Identification	
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This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).	
Acute oral toxicity	Category 3
Label Elements	
Signal Word	Danger
Hazard Statements	Toxic if swallowed
	
Precautionary Statements	
Prevention	Wash face, hands and exposed skin thoroughly after handling. Do not Eat, drink or smoke when using this product.
Ingestion	IF SWALLOWED: Immediately call a POISON CONTROL CENTER or doctor/ Physician. Rinse mouth.
Storage	Store locked up.
Disposal	Dispose of contents/container to an approved waste disposal plant.

Hazards not otherwise classified (HNOC)		
None identified		
Section 3: Composition/Information on Ingredients		
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Component	CAS Number	Weight %
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl)ammonium chloride	6202-23-9	<=100
Section 4: First-Aid Measures		
Section 4, First-Aid Measures		
General Advice Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.		
Eye Contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.		
Skin Contact Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.		
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. Immediate medical attention is required.		
Ingestion Do NOT induce vomiting. Call a physician or poison control center immediately.		
Most important symptoms and effects None reasonably foreseeable.		
Notes to Physician Treat symptomatically		
Section 5: Fire-Fighting Measures		
Section 5, Fire-Fighting Measures		
Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO 2, water spray or alcohol-resistant foam.		
Unsuitable Extinguishing Media No information available		
Flash Point	No information available	
Method -	No information available	
Autoignition Temperature	No information available	
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

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

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. Thermal decomposition can lead to release of irritating gases and vapors.

NFPA

Health
2

Flammability
1

Instability
0

Physical hazards
N/A

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

Environmental Precautions

Should not be released into the environment.

Methods for Containment and Clean Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

Section 7: Handling and Storage

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Handling

Wear personal protective equipment/face protection. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.

Storage

Keep container tightly closed. To maintain product quality: Keep refrigerated. Incompatible Materials. Oxidizing agent.

Section 8: Exposure Controls / Personal Protection

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Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Measures

Ensure adequate ventilation, especially in confined areas.

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

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Section 9: Physical and Chemical Properties

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Physical State	Crystalline Solid
Appearance	White
Odor	No information available
Odor Threshold	No information available
pH	No information available
Melting Point/Range	216 - 218 °C / 420.8 - 424.4 °F
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	Not applicable
Flammability (solid,gas)	No information available
Flammability or explosive limits	
Upper	No data available
Lower	No data available
Vapor Pressure	No information available
Vapor Density	Not applicable
Specific Gravity	No information available
Solubility	Soluble in water
Partition coefficient; n-octanol/water	No data available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	Not applicable
Molecular Formula	C ₂₀ H ₂₂ Cl N
Molecular Weight	311.85

Section 10: Stability and Reactivity

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Reactive Hazard

None known, based on information available

Stability

Stable under recommended storage conditions

Conditions to Avoid

Heat

Incompatible Materials

Oxidizing agent

Hazardous Decomposition Products

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

Hazardous Polymerization

Hazardous polymerization does not occur

Hazardous Reactions

None under normal processing

Section 11: Toxicological Information

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Acute Toxicity

Product Information

Caution – substance not yet tested completely

Component information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl)ammonium chloride	250 mg/kg (mouse)	Not listed	Not listed

Toxicologically Synergistic Products

No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation

No information available

Sensitization

No information available

Carcinogenicity

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

Component	CAS Number	IARC	NTP	ACGIH	OSHA	Mexico
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl)ammonium chloride	6202-23-9	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects

No information available

Reproductive Effects

No information available.

Developmental Effects

No information available.

Teratogenicity

No information available.

STOT - single exposure

None known

STOT - repeated exposure

None known

Aspiration hazard

No information available

Symptoms / effects, both acute and delayed

No information available

Endocrine Disruptor Information

No information available

Other Adverse Effects

The toxicological properties have not been fully investigated.

Section 12: Ecological Information
Section 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.

Section 13: Disposal Considerations
Section 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.

Section 14: Transport Information
Section 14, Transport Information
DOT

UN-No	UN2811
Proper Shipping Name	TOXIC SOLIDS, ORGANIC, N.O.S.
Technical Name	3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl)ammonium chloride
Hazard Class	6.1
Packing Group	III

TDG

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard Class	6.1
Packing Group	III

IATA

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard Class	6.1

Packing Group	III
IMDG/IMO	
UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard Class	6.1
Packing Group	III

Section 15: Regulatory Information

Section 15, Regulatory Information

United States of America Inventory

Component	CAS Number	TSCA	TSCA Inventory Notification – Active-Inactive	TSCA – EPA Regulatory Flags
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl)ammonium chloride	6202-23-9	---	---	---

Legend:
TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)
X - Listed
'-' - Not Listed

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
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl) ammonium chloride	6202-23-9	X	---	228-264-4	---	---	---	---	---	---

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)
U.S. Federal Regulations
SARA 313 Not applicable
SARA 311/312 Hazard Categories See section 2 for more information
CWA (Clean Water Act) Not applicable
Clean Air Act Not applicable
OSHA - Occupational Safety and Health Administration
Not applicable
CERCLA Not applicable
California Proposition 65 This product does not contain any Proposition 65 chemicals.
U.S. State Right-to-Know Regulations
Not applicable

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

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)
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl) ammonium chloride	6202-23-9	Not applicable	Not applicable	Not applicable	Not applicable

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)
3-(5H-Dibenzo[a,d]cyclohepten-5-ylidene)propyl(dimethyl) ammonium chloride	6202-23-9	Not applicable	Not applicable	Not applicable	Not applicable

Section 16: Other Information

Section 16, Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.