

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CYCLOPENTOLATE HYDROCHLORIDE, USP
PRODUCT CODE	0848
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Anticholinergic (Mydriatic)

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5)		
PICTOGRAM	Not Applicable		
SIGNAL WORD	Warning		
HAZARD STATEMENT(S)	May be harmful if swallowed Suspected skin sensitiser May cause long lasting harmful effects to aquatic life and the environment		
AUSTRALIA-ONLY HAZARDS	Repeated exposure may cause skin dryness or cracking.		
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable	
	Response	Not applicable	
	Storage	Not applicable	
	Disposal	Not applicable	
HMIS CLASSIFICATION	Health Hazard	1	Flammability 0
	Reactivity	0	Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Benzene acetic acid, α -(1-hydroxycyclopentyl)-, 2-(dimethylamino)ethyl ester, hydrochloride, (\pm)-.
BOTANICAL NAME	Not applicable
SYNONYM	Not applicable
CHEMICAL FORMULA	C ₁₇ H ₂₅ NO ₃ •HCl
CAS NUMBER	5870-29-1

ALTERNATE CAS NUMBER

Not applicable

MOLECULAR WEIGHT

327.849

COMPOSITION

CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
CYCLOPENTOLATE HCl	5870-29-1	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

Chemical family: O-Acyl-ethanolamine derivative; tertiary amine.

SECTION 4: FIRST-AID MEASURES**IN CASE OF EYE CONTACT**

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SYMPTOMS AND EFFECTS

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CYCLOPENTOLATE HYDROCHLORIDE CAS #: 5870-29-1

	TWA	Ceiling	STEL	REL	IDLH	Remarks
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
OSHA PEL	N/L	N/L	-	-	-	-
HSE	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or 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.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

White, crystalline powder, which upon standing develops a characteristic odor.

SOLUBILITY

Very soluble in water; freely soluble in alcohol; insoluble in ether.

ODOR

Characteristic odor

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD

Not available

pH

4.5 - 5.5 (1%)

MELTING POINT

(135 - 141)°C,
(275-285.8)°F

BOILING POINT

Not available

FREEZING POINT

(135 - 141)°C,
(275-285.8)°F

FLASH POINT

Not available

SPECIFIC GRAVITY

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	3.124 (20°C)
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

NOTES

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	Strong oxidants, acids, bases.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): >4000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY OR SKIN SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Based on available data, the classification criteria are not met. Suspected skin sensitizer: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	OSHA CYCLOPENTOLATE HCl is not listed. NTP CYCLOPENTOLATE HCl is not listed. IARC CYCLOPENTOLATE HCl is not evaluated. California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	Due to lack of data the classification is not possible.
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY -
REPEATED EXPOSURE**

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF
EXPOSURE**

Symptoms related to the physical, chemical, and toxicological characteristics

Anticholinergics: Dry mouth, throat, nose, skin, or eyes. Flushing. Decreased sweating. Fever. Decreased urination. Fast heartbeat. Headache. Dizziness. Drowsiness. Unsteadiness. Weakness. Restlessness. Confusion. Memory problems. Hallucinations. Insomnia. Seizures. Slurred speech. Blurred vision. Dilated pupils. Decreased sexual interest and ability. Nausea. Indigestion. Constipation. Diarrhea. Difficulty swallowing.

Delayed and immediate effects of exposure

Anticholinergics: Dependence. High blood pressure. Hyperthermia. Tachycardia. Respiratory depression. Central nervous system excitation. Dehydration. Coma. Death.

Medical conditions aggravated by exposure

Anticholinergics: Heart disease. Tachycardia. Hyperthyroidism. High blood pressure. Myasthenia gravis. Gastrointestinal reflux or obstruction. Ulcerative colitis. Paralytic ileus. Urinary retention or obstruction. Glaucoma. Kidney or liver impairment. Bleeding disorders. Prostate enlargement. Epilepsy. Porphyria.

POTENTIAL HEALTH EFFECTS**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.**Ingestion** May be harmful if swallowed.**Skin** May be harmful if absorbed through skin. May cause skin irritation. Suspected skin sensitiser.**Eyes** May cause eye irritation.**SECTION 12: ECOLOGICAL INFORMATION****TOXICITY**

CYCLOPENTOLATE:

EC50: 48 Hr: Crustacea: (Daphnia) (mg/L): 3.45*

LC50: 96 Hr: Fish: (Fathead Minnow) (mg/L): 22.05**

IC50: 72 Hr: Algae: (Green algae) (mg/L): 2.56*

PERSISTENCE AND DEGRADABILITY

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

Moderate: LogPow: 3.124 (20°C)

MOBILITY IN SOIL

Very soluble in water

OTHER ADVERSE EFFECTS

Suspected hazardous to the aquatic environment

This product is not intended to be released into the environment

NOTES

-The Danish QSAR database

**Fathead Minnow toxicity model (EPA) in VEGA (Q)SAR platform prediction (moderate reliability)

SECTION 13: DISPOSAL CONSIDERATIONS**WASTE DISPOSAL**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UNITED STATES & CANADA****UN PROPER SHIPPING NAME**

Not dangerous good

UN NUMBER

Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME Not dangerous good

UN NUMBER Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

HAZCHEM Not Applicable

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
CYCLOPENTOLATE HCl, 5870-29-1	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
CYCLOPENTOLATE HCl, 5870-29-1	N/L	Listed as Schedule 4	N/L

NOTES

*Listed as the base

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

02/2018

SUPERSEDES

08/2017



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SAFETY DATA SHEET

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.