

# SAFETY DATA SHEET

Issuing Date 28-Jan-2014

Revision Date 15-May-2015

Revision Number 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

### GHS product identifier

Product Name CYCLOMYDRIL

Synonyms Cyclopentolate Hydrochloride and Phenylephrine Hydrochloride Ophthalmic Solution

### Recommended use of the chemical and restrictions on use

Recommended Use Topical ophthalmic solution

Uses advised against No information available

### Supplier's details

#### Supplier Address

Alcon Laboratories, Inc.  
6201 South Freeway  
Ft. Worth, TX 76134-2099  
TEL: 817-551-4444

### For further information, please contact:

E-mail Address [safety.datasheets@alcon.com](mailto:safety.datasheets@alcon.com)

### Emergency telephone number

Emergency Telephone Number

CHEM TEL: 1-888-255-3924 (NORTH AMERICA); +1-813- 248-0573 (INTERNATIONAL)

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200)

Skin Sensitization	Category 1
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### GHS Label elements, including precautionary statements

#### Emergency Overview

Signal Word	Warning
Hazard Statements	
• May cause an allergic skin reaction	

**Appearance** No information available**Physical State** Liquid.**Odor** No information available**Precautionary Statements****Prevention**

- Avoid breathing dust/fume/gas/mist/vapors/spray
- Contaminated work clothing should not be allowed out of the workplace
- Wear protective gloves.

**General Advice**

- Specific treatment (see supplemental first aid instructions on this label)

**Skin**

- IF ON SKIN: Wash with plenty of soap and water
- If skin irritation or rash occurs: Get medical advice/attention
- Wash contaminated clothing before reuse.

**Storage**

- None

**Disposal**

- Dispose of contents/container to an approved waste disposal plant.

**Hazard Not Otherwise Classified (HNOC)**

Not applicable

**Other information****3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS-No	Weight %	Trade secret
2-(2-(1-Hydroxycyclopentyl)-2-phenylacetoxy)ethyl dimethylammonium chloride	5870-29-1	<0.5	*

\* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

**4. FIRST AID MEASURES****Description of necessary first-aid measures**

<b>Eye Contact</b>	Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.
<b>Skin Contact</b>	Rinse with plenty of water In the case of skin irritation or allergic reactions see a physician.
<b>Inhalation</b>	Move to fresh air. If breathing is difficult, give oxygen. If symptoms persist, call a physician.
<b>Ingestion</b>	Do NOT induce vomiting. Drink plenty of water. Consult a physician if necessary

**Most important symptoms/effects, acute and delayed****Most Important Symptoms/Effects** No information available.

**Indication of immediate medical attention and special treatment needed, if necessary**

**Notes to Physician** Treat symptomatically.

**5. FIRE-FIGHTING MEASURES****Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** CAUTION: Use of water spray when fighting fire may be inefficient.

**Specific Hazards Arising from the Chemical**

No information available.

**Explosion Data**

**Sensitivity to Mechanical Impact** None.

**Sensitivity to Static Discharge** None.

**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.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

**Personal Precautions** Ensure adequate ventilation. In case of insufficient ventilation wear suitable respiratory equipment. Avoid contact with skin, eyes and clothing. Use personal protective equipment.

**Environmental Precautions**

**Environmental Precautions** Dispose of contents/container to an approved waste disposal plant. See Section 12 for additional Ecological Information

**Methods and materials for containment and cleaning up**

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for Cleaning Up** Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Dispose of promptly. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE****Precautions for safe handling**

**Handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Storage** Keep container tightly closed.

**Incompatible Products** None known.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION****Control parameters**

**Exposure Guidelines**

**Appropriate engineering controls**

**Engineering Measures**                      Showers  
    Eyewash stations  
    Ventilation systems

**Individual protection measures, such as personal protective equipment**

**Eye/Face Protection**                      Safety glasses with side-shields.  
**Skin and Body Protection**              Lightweight protective clothing. Rubber gloves.  
**Respiratory Protection**                  If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn.

**Hygiene Measures**                        Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES****Information on basic physical and chemical properties**

<b>Physical State</b>	Liquid	<b>Appearance</b>	No information available
<b>Odor</b>	No information available	<b>Odor Threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
<b>pH</b>	4.0-4.8	None known
<b>Melting Point/Range</b>	No data available	None known
<b>Boiling Point/Boiling Range</b>	Similar to water	None known
<b>Flash Point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limits in Air</b>		
upper flammability limit	No data available	
lower flammability limit	No data available	
<b>Vapor Pressure</b>	No data available	None known
<b>Vapor Density</b>	No data available	None known
<b>Relative Density</b>	No data available	None known
<b>Specific Gravity</b>	Comparable to water	None known
<b>Water Solubility</b>	Completely soluble	None known
<b>Solubility in other solvents</b>	No data available	None known
<b>Partition coefficient: n-octanol/water</b>	No data available	None known
<b>Autoignition Temperature</b>	No data available	None known
<b>Decomposition Temperature</b>	No data available	None known
<b>Viscosity</b>	No data available	None known

**Flammable Properties**                      Not flammable

**Explosive Properties**                        No data available

**Oxidizing Properties**                        No data available

**Other information**

**VOC Content (%)**                              No data available

**10. STABILITY AND REACTIVITY****Reactivity**

No data available.

**Chemical stability**

Stable under recommended storage conditions.

### Possibility of hazardous reactions

None under normal processing.

### Conditions to avoid

None known based on information supplied.

### Incompatible materials

None known.

### Hazardous decomposition products

Combustion may release toxic fumes of: Nitrogen oxides (NOx). Sulfur oxides.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Health injuries are not known or expected under normal use
<b>Eye Contact</b>	Contact with eyes may cause irritation.
<b>Skin Contact</b>	May cause irritation.
<b>Ingestion</b>	Not expected to be toxic following ingestion.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
2-(2-(1-Hydroxycyclopentyl)-2-phenylacetoxylethyl)dimethylammonium chloride	4 g/kg ( Rat )	-	-

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

### Delayed and immediate effects and also chronic effects from short and long term exposure

<b>Sensitization</b>	No information available.
<b>Mutagenic Effects</b>	No information available.
<b>Carcinogenicity</b>	Contains no ingredients above reportable quantities listed as a carcinogen.
<b>Reproductive Toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration Hazard</b>	No information available.

### Numerical measures of toxicity - Product

*The following values are calculated based on chapter 3.1 of the GHS document:*

**LD50 Oral** 35000 mg/kg; Acute toxicity estimate

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

The environmental impact of this product has not been fully investigated.

**Persistence and Degradability** No information available.

**Bioaccumulation** No information available.

**Other Adverse Effects**

No information available.

**13. DISPOSAL CONSIDERATIONS****Waste Disposal Methods** Dispose of in accordance with federal, state, and local regulations**Contaminated Packaging** Do not re-use empty containers.**14. TRANSPORT INFORMATION****DOT** Not regulated**15. REGULATORY INFORMATION****International Inventories****Legend****TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List**U.S. Federal Regulations**

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**

<b>Acute Health Hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	No

**Clean Water Act**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**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.

**U.S. State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated by state right-to-know regulations.

### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION				
<u>NFPA</u>	Health Hazard 0	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 0	Flammability 0	Physical Hazard 0	Personal Protection X

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Issuing Date 28-Jan-2014  
Revision Date 15-May-2014  
Revision Note Second Release.

### General Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

**End of Safety Data Sheet**