

SAFETY DATA SHEET

Issuing Date 28-Jan-2014

Revision Date 28-Jan-2014

Revision Number 0

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

GHS product identifier

Product Name PILOCARPINE HYDROCHLORIDE 1%, 2%, 4%, 6%

Other means of identification

Product Code(s) 1631420315, 1631420415, 1631420615, 160900204RPG, 0065075212, 0065075612

Synonyms None

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

Emergency telephone number

Emergency Telephone Number CHEMTREC: +1-703-527-3887 (INTERNATIONAL)
1-800-424-9300 (NORTH AMERICA)

2. HAZARDS IDENTIFICATION

Classification

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

| | |
|---|------------|
| Acute Oral Toxicity | Category 4 |
| Acute Inhalation Toxicity - Dusts and Mists | Category 4 |
| Reproductive Toxicity | Category 2 |

GHS Label elements, including precautionary statements

Emergency Overview

| | |
|---|----------------|
| Signal Word | Warning |
| Hazard Statements | |
| <ul style="list-style-type: none">• Harmful if swallowed• Harmful if inhaled• Suspected of damaging fertility or the unborn child | |

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

- Avoid breathing dust/fume/gas/mist/vapors/spray
- Use only outdoors or in a well-ventilated area
- Wash face, hands and any exposed skin thoroughly after handling
- Do not eat, drink or smoke when using this product
- Obtain special instructions before use
- Do not handle until all safety precautions have been read and understood
- Use personal protective equipment as required.

General Advice

- If exposed or concerned: Get medical attention/advice

Inhalation

- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Ingestion

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

Storage

- Store locked up.

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 |
|---------------------------|------------|----------|--------------|
| Pilocarpine Hydrochloride | 54-71-7 | 6 | * |
| Boric acid | 10043-35-3 | <1 | * |

* 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****Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention if symptoms occur.

Skin Contact

Flush with cool water If skin irritation or rash occurs: Get medical advice/attention.

Inhalation Move to fresh air. If breathing is difficult, give oxygen. If symptoms persist, call a physician.

Ingestion Drink plenty of water. Do NOT induce vomiting. 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

| Chemical Name | ACGIH TLV | OSHA PEL | NIOSH IDLH |
|--------------------------|---|----------|------------|
| Boric acid 10043-35-3 | TWA: 2 mg/m ³ inhalable fraction STEL: 6 mg/m ³ inhalable fraction | - | - |

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

| | | | |
|-----------------------|--------------------------|-----------------------|--------------------------|
| Physical State | Liquid | Appearance | No information available |
| Odor | No information available | Odor Threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks/ - Method</u> |
|---|---------------------|--------------------------|
| pH | 6.5 - 7.5 | None known |
| Melting Point/Range | No data available | None known |
| Boiling Point/Boiling Range | Similar to water | None known |
| Flash Point | No data available | None known |
| Evaporation rate | No data available | None known |
| Flammability (solid, gas) | No data available | None known |
| Flammability Limits in Air | | |
| upper flammability limit | No data available | |
| lower flammability limit | No data available | |
| Vapor Pressure | No data available | None known |
| Vapor Density | No data available | None known |
| Relative Density | No data available | None known |
| Specific Gravity | Comparable to water | None known |
| Water Solubility | Completely soluble | None known |
| Solubility in other solvents | No data available | None known |
| Partition coefficient: n-octanol/water | No data available | None known |
| Autoignition Temperature | No data available | None known |
| Decomposition Temperature | No data available | None known |
| Viscosity | 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). Silica oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

| | |
|---------------------|--|
| Inhalation | Not an expected route of exposure Harmful by inhalation. |
| Eye Contact | May cause irritation. |
| Skin Contact | May cause mild skin irritation. |
| Ingestion | Not an expected route of exposure. Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. |

| Chemical Name | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|---------------------------|----------------------|------------------------|------------------------|
| Pilocarpine Hydrochloride | 203 mg/kg (mouse) | - | - |
| Boric acid | = 2660 mg/kg (Rat) | >2000 mg/kg (Rabbit) | >0.16 mg/L (Rat) 4 h |

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

Sensitization No information available.
Mutagenic Effects No information available.
Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity Suspected of damaging fertility or the unborn child.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

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

LD50 Oral 417 mg/kg; Acute toxicity estimate
Inhalation dust/mist 4.2 mg/L; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

| Chemical Name | Toxicity to Algae | Toxicity to Fish | Toxicity to Microorganisms | Daphnia Magna (Water Flea) |
|--------------------------|-------------------|--|----------------------------|--|
| Boric acid 10043-35-3 | | LC50 72 h: = 1020 mg/L flow-through (Carassius auratus) | | EC50 48 h: 115 - 153 mg/L (Daphnia magna) |

Persistence and Degradability No information available.

Bioaccumulation No information available.

| Chemical Name | Log Pow |
|---------------|---------|
| Boric acid | -0.757 |

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Do not re-use empty containers.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

| Chemical Name | California Hazardous Waste |
|---------------|----------------------------|
| Boric acid | Toxic |

14. TRANSPORT INFORMATION

DOT Not regulated

15. REGULATORY INFORMATION

International Inventories

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - 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

| | |
|--|-----|
| Acute Health Hazard | Yes |
| Chronic Health Hazard | Yes |
| Fire Hazard | No |
| Sudden Release of Pressure Hazard | No |
| Reactive Hazard | 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 | | | | |
|-----------------------|-------------------------|-----------------------|--------------------------|--|
| NFPA | Health Hazard 1 | Flammability 0 | Instability 0 | Physical and Chemical Hazards - |
| HMIS | Health Hazard 1* | Flammability 0 | Physical Hazard 0 | Personal Protection X |

*Indicates a chronic health hazard.

Prepared By Product Stewardship
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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