



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 11

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

Product identifier

Chemical Name Pilocarpine Hydrochloride

Other means of identification

Product Code 54-71-7

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Pharmaceutical

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

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

Acute toxicity - Oral	Category 2
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Reproductive toxicity	Category 1B
Effects on or via lactation	Yes

Label elements

Emergency Overview

Danger

Hazard statements

H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children

**Appearance** powder**Physical state** Solid**Odor** Odorless**Chemical Name**
Pilocarpine Hydrochloride**Symptoms**

The most frequent adverse experiences associated with this medication are the consequence of expected pharmacologic effects of the medication. This includes: sweating, nausea, rhinitis, diarrhea, chills, flushing, urinary frequency, dizziness, asthenia. In addition the following adverse events (less than or equal to 3% incidence) were reported at dosages at 15-30 mg/day in the controlled clinical trials: headache, dyspepsia, lacrimation, edema, abdominal pain, amblyopia, vomiting, pharyngitis, hypertension.

Chemical Name
Pilocarpine Hydrochloride**Medical Conditions Aggravated by Exposure**

This medication is contraindicated in patients with uncomfortable asthma, known hypersensitivity to pilocarpine, and when miosis is undesirable, e.g., in acute iritis and in narrow-angle (angle closure) glaucoma.

Precautionary statements

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P321 - Specific treatment (see supplemental first aid instructions on this label)

P330 - Rinse mouth

P271 - Use only outdoors or in a well-ventilated area

P284 - Wear respiratory protection

P310 - Immediately call a POISON CENTER or doctor/physician

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P320 - Specific treatment is urgent (see .? on this label)

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P405 - Store locked up

P501 - Dispose of contents/ container to an approved waste disposal plant

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P201 - Obtain special instructions before use

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P263 - Avoid contact during pregnancy/while nursing

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Information

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Pilocarpine Hydrochloride	54-71-7	200-212-5	100

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice	Immediate medical attention is required.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

Chemical Name
Pilocarpine Hydrochloride

Note to physicians

Patients with significant cardiovascular disease may be unable to compensate for transient changes in hemodynamics of rhythm induced by this medication. Pulmonary edema has been reported as a complication of pilocarpine toxicity from high ocular doses given for acute angle-closure glaucoma. This medication should be administered with caution in and under close medical supervision of patients with significant cardiovascular disease. This medication has been reported to cause visual blurring which may result in decreased visual acuity, especially at night and in patients with central lens changes, and to cause impairment of depth perception. Caution should be advised while driving at night or performing hazardous activities in reduced lighting. This medication has been reported to increase airway resistance, bronchial smooth muscle tone and bronchial secretions. This medication should be administered with caution to and under close medical supervision in patients with controlled asthma, chronic bronchitis, or chronic obstructive pulmonary disease requiring pharmacotherapy. This medication should be administered with caution to patients with known or suspected cholelithiasis or biliary tract disease. Contractions of the gallbladder of biliary smooth muscle could precipitate complications including cholecystitis, cholangitis, and biliary obstruction. This medication may increase ureteral smooth muscle tone and could theoretically precipitate renal colic (or "ureteral reflux"), particularly in patients with nephrolithiasis. Cholinergic agonists may have dose-related central nervous system effects. This should be considered when treating patients with underlying cognitive or psychiatric disturbances.

5. FIRE-FIGHTING MEASURES**Suitable extinguishing media**

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

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Some are oxidizers and may ignite combustibles (wood, paper, oil, clothing, etc.).

Explosion data

Sensitivity to Mechanical Impact
Sensitivity to Static Discharge

Not impact sensitive.

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition

source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective suit.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Use personal protective equipment as required. Keep people away from and upwind of spill/leak.
Other Information	Do not get water inside containers or in contact with substance.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.
Methods for containment	Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
Methods for cleaning up	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.
Storage Conditions	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.
Incompatible materials	None known based on information supplied.

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

Exposure Guidelines	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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Appropriate engineering controls

Engineering Controls	The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.
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Individual protection measures, such as personal protective equipment

PPE	The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply
Eye/face protection	Tight sealing safety goggles.
Skin and body protection	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Respiratory protection	Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	Appearance	powder
Color	white	Odor	Odorless
Odor threshold	No information available		

Property

pH	No information available
Melting point/freezing point	202 °C / 396 °F
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Values**Other Information**

Molecular weight	244.75
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY**Reactivity**

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Pilocarpine Hydrochloride	200 mg/kg (mouse)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Pilocarpine Hydrochloride	No information available.	Animal studies in mice didn't show carcinogenicity at any dose and studies in rats showed tumorigenicity only at doses significantly higher than the equivalent human therapeutic dose.	Animal studies in mice, rats and dogs have shown fertility impairment which was likely due to decrease in spermatogenesis. Animal studies in rats have shown an increase of skeletal variations, body weight decrease, increased still born birth at doses significantly higher than the equivalent human therapeutic dose.	It is not known whether this drug is excreted in human milk. Because of the potential for tumorigenicity shown for albuterol in some animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Chronic toxicity
Target Organ Effects Prolonged or repeated exposure increases the risk. Possible risk of irreversible effects.
Central nervous system, Gastrointestinal tract (GI), heart, Respiratory system.

Numerical measures of toxicity - Product Information

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

ATEmix (oral) 5 mg/kg
ATEmix (inhalation-dust/mist) 0 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION**International Inventories**

TSCA	Listed
DSL/NDSL	Listed
EINECS/ELINCS	Listed

Legend:

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

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US 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

Acute health hazard	Yes
Chronic Health Hazard	Yes
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (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

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations**16. OTHER INFORMATION**

Revision Date	02-Oct-2018
Revision Note	No information available

Disclaimer

The information provided in this Material 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.

End of Safety Data Sheet