


SAFETY DATA SHEET

Section 1: Identification	
Section 1, Identification	
Product	Phenylephrine Hydrochloride Ophthalmic Solution USP
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-865-02 (2.5% 2mL) 70512-865-15 (2.5% 15mL) 70512-866-05 (10% 5mL)
Section 2: Hazard(s) Identification	
Section 2, Hazard(s) Identification	
Classification	
This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)	
Acute Toxicity – Oral	Category 4
Skin corrosion / irritation	Category 2
Serious eye damage / eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3
Label elements	
WARNING	
Hazard statements	
Harmful if swallowed	
Causes skin irritation	
Causes serious eye irritation	
May cause respiratory irritation	
	
Hazards not otherwise classified (HNOC)	

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 Avoid breathing dust/fume/gas/mist/vapors/spray
 Use only outdoors or in a well-ventilated area
 Wear protective gloves

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water
 If skin irritation occurs: Get medical advice/attention
 Take off contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed
 Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Section 3: Composition/Information on Ingredients

Section 3, Composition/Information on Ingredients

Components	CAS-No.	Weight %
Phenylephrine Hydrochloride	61-76-7	100

Section 4: First-Aid Measures

Section 4, First-Aid Measures

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms

- Causes serious eye irritation
- Eye contact may result in redness or pain
- Causes skin irritation
- Skin contact may result in redness, pain, inflammation, itching, scaling
- Irritating to respiratory system
- Ingestion may cause nausea, vomiting, and diarrhea
- May cause loss of appetite
- Upset stomach
- May affect the cardiovascular system
- Weak, rapid pulse or rapid heart rate (Tachycardia)
- Cardiac arrhythmias
- Hypertension
- May cause central nervous system effects
- Dizziness
- Lightheadedness
- Anxiety
- Headache
- Tremors
- Excitement
- Somnolence
- May cause nervousness, agitation, restlessness, insomnia
- May cause seizures
- May cause warmth, tingling, or redness under the skin

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
 Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides.
 Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal precautions

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

Section 7: Handling and Storage

Section 7, Handling and Storage

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Do not store above 25°C/77°F. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

- Acids
- Oxidizing agents

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure Controls / Personal Protection

Control parameters

National occupational exposure limits

United States

Components	CAS No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Phenylephrine Hydrochloride	61-76-7	None	None	None	None

Canada

Components	CAS No.	Canada – Alberta	Canada – British Columbia	Canada – Ontario	Canada - Quebec
Phenylephrine Hydrochloride	61-76-7	None	None	None	None

Australia and Mexico

Components	CAS No.	Australia	Mexico
Phenylephrine Hydrochloride	61-76-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment
Personal Protective Equipment

Eye protection:	Safety glasses with side-shields or Goggles
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
Respiratory protection:	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

Section 9: Physical and Chemical Properties
Section 9, Physical and Chemical Properties

Physical state: Liquid	Appearance: Liquid/Solution	Color: White
Odor: Odorless	Taste: Bitter	Formula: C9H13NO2•HCl
Molecular/Formula weight (g/mole): 203.67	Flammability No information available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range (°C/°F): 140°-145°C/284°-293°F	Decomposition temperature (°C/°F): No information available

Boiling point/range (°C/°F): No information available	Bulk density: No information available	Density (g/cm³): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Easily soluble in cold water Easily soluble in hot water	

Section 10: Stability and Reactivity

Section 10, Stability and Reactivity

Reactivity

Reactive with acids
Reactive with oxidizing agents

Chemical stability

Stability: Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Exposure to light. Incompatible materials.

Incompatible Materials: Acids
Oxidizing agents

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NO_x).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

Section 11: Toxicological Information

Section 11, Toxicological Information

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Phenylephrine Hydrochloride	
CAS No.	61-76-7

LD50/oral/rat =	350 mg/kg Oral LD50 Rat
LD50/oral/mouse =	120 mg/kg Oral LD50 Mouse
LD50/dermal/rabbit =	No information available
LD50/dermal/rat =	No information available
LC50/inhalation/rat =	No information available
LC50/inhalation/mouse =	No information available
Other LD50 or LC50 information =	No information available

Product Information

LD50/oral/rat =	
VALUE- Acute Tox Oral =	350 mg/kg

LD50/oral/mouse =	
Value - Acute Tox Oral =	120 mg/kg

LD50/dermal/rabbit	
VALUE-Acute Tox Dermal =	No information available

LD50/dermal/rat	
VALUE -Acute Tox Dermal =	No information available

LC50/inhalation/rat	
VALUE-Vapor =	No information available
VALUE-Gas =	No information available
VALUE-Dust/Mist =	No information available

LC50/Inhalation/mouse	
VALUE-Vapor =	No information available
VALUE - Gas =	No information available
VALUE - Dust/Mist =	No information available

Symptoms

Skin Contact:	Causes skin irritation.
Eye Contact:	Causes serious eye irritation.
Inhalation:	Irritating to respiratory system.
Ingestion:	Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May cause upset stomach. May cause loss of appetite. May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (hypertension, increase in pulse rate, arrhythmias). May cause headache. May also cause anxiety and stress. May affect behavior/central nervous system (headache, weakness, dizziness, nervousness, lightheadedness, trembling). May affect behavior/central nervous system

(confusion). May affect behavior/central nervous system (convulsions/seizures). May cause difficulty breathing. May affect behavior/central nervous system (somnia).
Aspiration hazard No information available.

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

Chronic Toxicity No information available.
Sensitization: No information available.
Mutagenic Effects: May affect genetic material based on animal test data. Animal experiments showed mutagenic effects. Mutagenic effects in mammalian somatic cells.
 Sister Chromatid Exchange: Hamster ovary (RTECS)
Carcinogenic effects: Not considered carcinogenic.

Components	CAS No	IARC	ACGIH-Carcinogens	NTP	OSHA HCS-Carcinogens	Australia-Notifiable Carcinogenic Substances	Australia-Prohibited Carcinogenic Substances
Phenylephrine Hydrochloride	61-76-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)
 IARC (International Agency for Research on Cancer)
 NTP (National Toxicology Program)
 OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure: Respiratory system.
STOT - repeated exposure: No information available.
Target Organs: No information available.

Section 12: Ecological Information

Section 12, Ecological Information

Ecotoxicity

Ecotoxicity effects: No data available.
Persistence and degradability: No information available
Bioaccumulative potential: No information available.
Mobility: No information available.

Section 13: Disposal Considerations

Section 13, Disposal Considerations

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS No.	RCRA – F Series Wastes	RCRA – K Series Wastes	RCRA – P Series Wastes	RCRA – U Series Wastes
Phenylephrine Hydrochloride	61-76-7	None	None	None	None

Section 14: Transport Information

Section 14, Transport Information

DOT

UN-No: Not Regulated
 Proper Shipping Name: No information available
 Hazard Class: No information available
 Subsidiary Class: No information available
 Packing group: No information available
 Emergency Response
 Guide Number: No information available
 Marine Pollutant: No data available
 DOT RQ (lbs): No information available
 Special Provisions: No Information available
 Symbol(s): No information available
 Description: No information available

TDG (Canada)

UN-No: Not Regulated
 Proper Shipping Name: No information available
 Hazard Class: No information available
 Subsidiary Risk: No information available
 Packing Group: No information available
 Marine Pollutant: No Information available
 Description: No information available

ADR

UN-No: Not Regulated
 Proper Shipping Name: No information available
 Hazard Class: No information available
 Packing Group: No information available
 Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
 Proper Shipping Name: No information available
 Hazard Class: No information available

Subsidiary Risk:	No information available
Packing Group:	No information available
Marine Pollutant:	No information available
RID	
UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
ICAO	
UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
IATA	
UN-No:	Not Regulated
Proper Shipping Name:	No information available
Hazard Class:	No information available
Subsidiary Risk:	No information available
Packing Group:	No information available
ERG Code:	No information available
Special Provisions:	No information available

Section 15: Regulatory Information

Section 15, Regulatory Information

International Inventories

Components	CAS No.	US TSCA	Korea KECL	Philippines (PICCCS)	Japan ENCS	China	Australia (AICS)	EINECS-No.
Phenylephrine Hydrochloride	61-76-7	Present Active	Present KE-20631	Present	Not present	Not present	Present	Present 200-517-3

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity
Phenylephrine Hydrochloride	61-76-7	Not listed	Not listed	Not listed	Not listed

CERCLA/SARA

Components	CAS No.	CERCLA-Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 – Chemical Category	Section 313 – Reporting de minimis
Phenylephrine Hydrochloride	61-76-7	None	None	None	None	None

U.S. TSCA

Components	CAS No.	TSCA Section 5(a)2 – Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) – Health and Safety Reporting
Phenylephrine Hydrochloride	61-76-7	Not applicable	Not applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or Reviewed yet.

Canada Hazardous Products Regulation

This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR.

WHMIS 1988 Hazard Class

D1B Toxic materials
D2B Toxic materials

Canada Controlled Products Regulation

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS No.	Canada (DSL)	Canada (NDSL)
Phenylephrine Hydrochloride	61-76-7	Present	Not listed

Components	CAS No.	CEPA Schedule I – Toxic Substances
Phenylephrine Hydrochloride	61-76-7	Not listed
Components	CAS No.	CEPA – 2010 Greenhouse Gases Subject to Mandatory Reporting
Phenylephrine Hydrochloride	61-76-7	Not listed

EU Classification
EU GHS – SV – CLP 1272/2008

Components	CAS No.	EU GHS – SV – CLP (1272/2008)
Phenylephrine Hydrochloride	61-76-7	No information

R-phrase(s)

R22 - Harmful if swallowed.
R36/37/38 - Irritating to eyes, respiratory system and skin.

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37 - Wear suitable protective clothing and gloves.

Components	CAS No.	Classification	Concentration Limits	Safety Phases
Phenylephrine Hydrochloride	61-76-7		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful.
Xi - Irritant.

Xn



Xi



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.