



# **SAFETY DATA SHEET**

	Section 1: Identification						
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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						
	<u>www.solameds.us</u>						
	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)**



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#### 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



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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-



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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			



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Phenylephrine Hydrochloride	61-76-7	None	None	None	None	
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#### 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	61-76-7	None	None
Hydrochloride	01 70 7	None.	1,0116

#### **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.

# <u>Individual protection measures, such as personal protective equipment</u> 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:Appearance:Color:SolidPowderWhite

Odor: Taste: Formula:

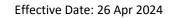
Odorless Bitter C9H13NO2•HCl

Molecular/Formula weight (g/mole): Flammability Flashpoint (°C/°F):

203.67 No information available No information available

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%):

Not available No information available No information available





Upper Explosion Limit (%): Melting point/range (°C/°F): Decomposition temperature (°C/°F):

No information available 140°-145°C/284°-293°F No information available

Boiling point/range (°C/°F): Bulk density: Density (g/cm3):

No information available No information available No information available

Specific gravity: pH: Vapor pressure @ 20°C (kPa):

Evaporation rate: Vapor density: VOC content (g/L):

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

No information available

Miscibility: Solubility:

No information available 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

recommendedstorage 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 (NOx).

**Other Information** 

Corrosivity: No information available

**Special Remarks on Corrosivity:**No information available

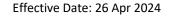
# **Section 11: Toxicological Information**

# **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

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50information = 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 - 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



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(confusion). May affect behavior/central nervous system (convulsions/seizures). May cause

difficulty breathing. May affect behavior/central nervous system (somnolence).

**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- Caracinogens	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 availableDevelopmental Effects:No information availableTeratogenic 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.

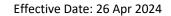
Persistence and degradability:No information availableBioaccumulative potential:No information available.Mobility:No information available.

## **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):

Special Provisions:

No Information available

No information available

No information available

No information available

# TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name:
Hazard Class:
Subsidiary Risk:
Packing Group:
Marine Pollutant:
Description:
No information available
No information available
No Information available
No information available

#### **ADR**

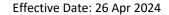
UN-No: Not Regulated

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

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

# **U.S. Regulations**

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

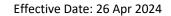
## Chemicals Known to the State of California to Cause Cancer:

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

## **WHIMIS 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	61-76-7	Present	Not listed
Hydrochloride			

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	<b>Concentration Limits</b>	Safety Phases
Phenylephrine	61-76-7		No information	
Hydrochloride	01-70-7		No illiorination	

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

# Indication of danger:

Xn - Harmful.

Xi - Irritant.





# **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.