

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

Contact information

General



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Product identifier	Phenylephrine
Synonyms	3-[(1R)-1-hydroxy-2-(methylamino)ethyl]phenol
Trade names	Not applicable
Chemical family	Phenethylamine derivative
Relevant identified uses of the substance or mixture and uses advised against	Active pharmaceutical ingredient, used in treatment of hypotension, primarily for vasodilation in the setting of anesthesia.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the substance.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS]

Acute Toxicity (Oral) Category 4. Specific Target Organ Toxicity (repeated exposure) - Category 2. Skin sensitizer - Category 1. Effects via lactation.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard pictogram



GHS signal word

Warning

GHS hazard statements

H302 - Harmful if swallowed. H317 - May cause allergic skin reaction. H362 - May cause harm to breast-fed children. H373 - May cause damage to the liver through prolonged or repeated exposure. H361d - Suspected of damaging the unborn child.

GHS precautionary statements

P201 - Obtain special instructions before use. P301+P312: IF SWALLOWED: Call a Poison Center or doctor/physician if you feel unwell. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P308 + P313 - IF exposed or concerned: get medical advice/attention. P330 - Rinse mouth. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P362 + P364 - Take off contaminate clothing and wash it before reuse. P260 - Do not breathe dust. P263 - Avoid contact during pregnancy/while nursing. P264 - Wash hands thoroughly after handling. P314 - Get medical advice/attention if you feel unwell. P270 - Do not eat, drink or smoke when using this product. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P405 - Store locked up. P501 - Dispose of contents/ container to location in accordance with local/regional/national/international regulations.

Other hazards

Phenylephrine is a sympathetic nervous system stimulate that induces vasoconstriction. Oral doses of 10 mg every 4 hours or 12 mg every 6 hours (up to a maximum dose of 60 mg) has been used. Parenteral doses range from 1-10 mg. Common adverse effects reported with use include nausea, vomiting, and headache. Cardiovascular effects, including reduced heart rate, high blood pressure, and irregularities, have also occurred.

Phenylephrine hydrochloride in eye drops has rarely caused skin sensitivity in humans following topical exposure. Phenylephrine has been associated with reduced milk production in lactating women.

Note

This substance is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Phenylephrine	59-42-7	200-424-8	~100%	ATO4: H302; STOT-R2: H373; SSI: H317; LACT: H362

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

Note The substance listed above is considered dangerous/hazardous or is the active ingredient. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes. If exposed or concerned: Get medical advice/attention.
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11.
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and other nitrogen-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

SECTION 5 - FIREFIGHTING MEASURES...continued

Advice for firefighters Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust.

Environmental precautions Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust.

Conditions for safe storage including any incompatibilities Store at room temperature (~15°C to 30°C) away from incompatible materials. Avoid extreme temperatures. Keep in tightly sealed containers in a well-ventilated area. Protect from light.

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control Parameters/
Occupational Exposure
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Phenylephrine	--	--	--

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued

Exposure/Engineering controls	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
Respiratory protection	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Skin protection	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Solid - powder
Color	White
Odor	Odorless
Odor threshold	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

pH	Not applicable.
Melting point/ freezing point	169-174°C
Initial boiling point and boiling range	341.1 °C
Flash point	163.4 °C
Evaporation rate	Not applicable.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	4.77e ⁻⁰⁷ mmHg
Vapor density	No information identified.
Relative density	1.2 g/cm ³
Water solubility	Soluble.
Solvent solubility	Soluble in hot methanol
Partition coefficient (<i>n</i>-octanol/water)	0.07
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	Not applicable.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular formula	C ₉ H ₁₃ NO ₂
Molecular weight	167.21

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	No information identified.
Possibility of hazardous reactions	Not expected to occur.

SECTION 10 - STABILITY AND REACTIVITY ...continued

Conditions to avoid	Avoid extreme temperatures.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact, eye contact, and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Phenylephrine	LD ₅₀	Oral	Rat	350 mg/kg
	LD ₅₀	Oral	Mouse	120 mg/kg
	LD ₅₀	Intravenous	Mouse	38 mg/kg

Irritation/Corrosion No information identified.

Sensitization No information identified.

STOT-single exposure No information identified.

STOT-repeated exposure/Repeat-dose toxicity In a 2-year dietary study in rats, phenylephrine hydrochloride induced chronic inflammation of the liver (females and males) and prostate (males) at oral doses ≥ 24 mg/kg/day.

Reproductive toxicity No information identified.

Developmental toxicity Fetal growth restriction, reduced fetal weight, and premature delivery were reported in rabbits administered 1 mg phenylephrine subcutaneously during gestation (equivalent to doses lower than human therapeutic levels). Reduced uterine blood flow was reported in sheep after intravenous (IV) infusion (possibly secondary to vasoconstrictive mechanism).

Genotoxicity Phenylephrine was not genotoxic in the Ames bacterial mutagenicity assay. It produced equivocal results in *in vitro* mouse lymphoma assays, and induced sister chromatid exchanges in Chinese hamster ovary cells (without metabolic activation). It was negative *in vitro* in a chromosomal aberration assay in Chinese hamster ovary cells, and *in vivo* in a rat micronucleus assay. Overall, the genotoxic potential of phenylephrine is low.

Carcinogenicity Phenylephrine was not carcinogenic in rats and mice treated orally with 50 and 270 mg/kg/day, respectively, for 2 years.

Aspiration hazard No information identified.

Human health data See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity	Type	Species	Concentration
<u>Compound</u> Phenylephrine	--	--	--
Persistence and Degradability	No data available.		
Bioaccumulative potential	Based on low Log Kow (0.07), bioaccumulation potential for phenylephrine is low.		
Mobility in soil	No data available.		
Results of PBT and vPvB assessment	Not performed.		
Other adverse effects	No data available.		
Note	The environmental characteristics of this substance have not been fully investigated. Releases to the environment should be avoided.		

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this substance is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Due to lack of data, avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. H373 - May cause damage to the liver through prolonged or repeated exposure. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. H317 - May cause an allergic skin reaction. SS1 - Skin sensitizer Category 1. H362 - May cause harm to breast-fed children. Effects via lactation
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date	2 August 2017
Revisions	This is the first version of this SDS.

SECTION 16 - OTHER INFORMATION ...continued

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product.

The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.