

# SAFETY DATA SHEET

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

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### Contact information

#### General



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Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

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<b>Product identifier</b>	Ephedrine Sulfate Injection, USP
<b>Synonyms</b>	1-Phenyl-2-methylamine-propanol-1-sulfate; (-)-erythro-1-Hydroxy-2-(methylamino)-1-phenylpropane sulfate
<b>Trade names</b>	CORPHEDRA™ (ephedrine sulfate injection, USP), 50 mg/mL, for intravenous injection
<b>Chemical family</b>	Phenethylamine derivative
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Active pharmaceutical ingredient
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the active pharmaceutical ingredient.

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## SECTION 2 - HAZARDS IDENTIFICATION

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### Classification of the substance or mixture

<b>Globally Harmonized System [GHS]</b>	Specific Target Organ Toxicity (repeated exposure) - Category 2. Reproductive Toxicity - Category 2. Acute Toxicity (Oral) Category 4.
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### Label elements

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**GHS hazard pictogram**



**GHS signal word**

Warning

**GHS hazard statements**

H302 - Harmful if swallowed. H361d - Suspected of damaging the unborn child. H373 - May cause damage to cardiovascular and central nervous systems through prolonged or repeated exposure.

**GHS precautionary statements**

P308 + P313 - IF exposed or concerned: get medical advice/attention. P330 - Rinse mouth. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves/eye protection/face protection.

**Other hazards**

Ephedrine sulfate is a sympathetic nervous system activator. The recommended IV dose is 5-10 mg, up to 50 mg. The maximum recommended dose for a healthy adult is 100 mg in a 24-hour period for not more than 12 weeks. The most common adverse effects were observed in the cardiovascular system (high blood pressure, palpitations, increased heart rate, heart attacks, cardiac arrhythmia), the central nervous system (seizure, stroke, agitation, restlessness, anxiety, insomnia), and the gastrointestinal (GI) system (nausea, vomiting). Limited data suggests ephedrine may cause fetal heart defects when administered to pregnant women. Placental transfer is high (~70% of maternal blood levels), and it is also secreted in breast milk; single use has been linked to reduced breast milk production. Ephedrine has the potential to induce addiction following prolonged exposure; withdrawal symptoms may occur upon abrupt cessation.

**Note**

This substance meets criteria for classification 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).

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Ephedrine Sulfate	134-72-5	205-154-4	~100%	RT-2: H361d; STOT-R2: H373; ATO4: H302

**Note**

The substance listed above is considered dangerous/hazardous. See Section 16 for full text of GHS classifications.

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## SECTION 4 - FIRST AID MEASURES

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### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes. If exposed or concerned: Get medical advice/attention.
<b>Eye Contact</b>	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.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	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.
<b>Ingestion</b>	If swallowed, call a physician immediately. 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.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: none identified. Treat symptomatically and supportively.

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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit carbon monoxide, carbon dioxide, and oxides of sulfur and nitrogen.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

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<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	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 into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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**SECTION 7 - HANDLING AND STORAGE**

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<b>Precautions for safe handling</b>	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Protect from moisture.
<b>Specific end use(s)</b>	Pharmaceutical.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Ephedrine Sulfate	--	--	--

<b>Exposure/Engineering controls</b>	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.
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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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<b>Respiratory protection</b>	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.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.
<b>Skin protection</b>	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.
<b>Eye/face protection</b>	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.
<b>Environmental Exposure Controls</b>	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.
<b>Other protective measures</b>	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). Decontaminate all protective equipment following use.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Powder
<b>Color</b>	White
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	4.5 to 7 in aqueous solution
<b>Melting point/ freezing point</b>	Melting Point: 38.1 °C

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Initial boiling point and boiling range</b>	Boiling Point: 260 °C (ephedrine)
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	56,900 mg/L at 25 °C (ephedrine sulfate)
<b>Solvent solubility</b>	Soluble in oils, ethanol, ether, benzene, and chloroform.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	1.13 (ephedrine)
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	428.6
<b>Molecular formula</b>	C <sub>10</sub> H <sub>15</sub> NO ° H <sub>2</sub> SO <sub>4</sub>

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Stable under recommended handling and storage conditions.
<b>Possibility of hazardous reactions</b>	No information identified.
<b>Conditions to avoid</b>	Avoid extreme temperatures.

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**SECTION 10 - STABILITY AND REACTIVITY ...continued**

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**Incompatible materials** No information identified.  
**Hazardous decomposition products** No information identified.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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**Information on toxicological effects**

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

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Ephedrine Sulfate	LD <sub>50</sub>	Oral	Rat	600 mg/kg
	LD <sub>50</sub>	IV	Rat	102 mg/kg
	LD <sub>50</sub>	IV	Mouse	74 mg/kg

**Irritation/Corrosion** No studies were identified.

**Sensitization** No studies were identified.

**STOT-single exposure** IV doses of 7 times the maximum human dose of 50 mg ephedrine sulfate (~350 mg) in rats and rabbits resulted in convulsions, paralysis, and increased respirations, followed by mortality due to cardiac failure and reductions in cardiac contractions.

**STOT-repeated exposure/Repeat-dose toxicity** Decreased body weight and food consumption were observed in rats and mice following feed administration  $\geq 125$  ppm (~6.25 mg/kg) ephedrine for up to 2 years. No adverse effects were observed in mice and rats at doses up to 29 and 11 mg/kg, respectively. In 13 week studies, dietary doses of  $\geq 1000$  ppm (~50 mg/kg) caused hyperactivity and excitability in rats.

**Reproductive toxicity** No studies were identified.

**Developmental toxicity** Malformation frequency was increased in rabbits treated with 17-33 times the daily human dose of ephedrine (in combination with theophylline and phenobarbital). Ventricular septal defects were observed in the pups following maternal dosing of 0.1-50 mg/kg ephedrine.

**Genotoxicity** Ephedrine sulfate was negative *in vitro* in a bacterial reverse mutation assay, a mouse lymphoma assay, a sister chromatic exchange, and a chromosomal aberration assay. *In vivo* tests were not identified.

**Carcinogenicity** No carcinogenicity was observed a two year study in rats and mice administered up to 10 and 27 mg/kg/day, respectively.

**Aspiration hazard** No data available.

**Human health data** See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**

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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Ephedrine Sulfate	--	--	--

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**Persistence and Degradability**

Ephedrine is readily biodegradable.

**Bioaccumulative potential**

A BCF of 1.4 suggests ephedrine's potential for bioaccumulation is low.

**Mobility in soil**

High Mobility

**Results of PBT and vPvB assessment**

No data identified.

**Other adverse effects**

No data available.

**Note**

Releases to the environment should be avoided.

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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**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**

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**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**

Avoid release to the environment.

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**SECTION 14 - TRANSPORT INFORMATION ...continued**

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**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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**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.

**WHMIS classification** Not classified.

**TSCA status** Drugs are exempt from TSCA.

**SARA section 313** Not listed.

**California proposition 65** Not listed.

**Additional information** No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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**Full text of H phrases and GHS classifications** ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. H361d - Suspected of damaging the unborn child. RT2 - Reproductive toxicity Category 2. H373 - May cause damage to the cardiovascular system and central nervous system through prolonged or repeated exposure. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2.

**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

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Abbreviations  
...continued**

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**

20 September 2016

**Revisions**

Updated pH in solution in Section 9

**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.