

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Ephedrine Sulfate Injection, USP

1.2. Intended Use of the Product

Indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Endo Ventures Limited
Minerva House
Simmons Court Road
Dublin 4
+35312682073

EVLLogisticsteam@endo.com

www.endo.com

Manufacturer

OSO BioPharmaceuticals Manufacturing LLC
4272 Balloon Park Rd. NE
Albuquerque, NM 87109
+1.505.923.1500

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC – TOLL FREE 24 HOUR EMERGENCY TELEPHONE NUMBER

Within USA and Canada: 1-800-424-9300; Outside USA and Canada: +1 703-741-5970 (collect calls accepted)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :



GHS07

Signal Word (GHS-US/CA) :

Warning

Hazard Statements (GHS-US/CA) :

H317 - May cause an allergic skin reaction.

Precautionary Statements (GHS-US/CA) :

P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P321 - Specific treatment (see section 4 on this SDS).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

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3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	98.6079	Not classified
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT / sodium chloride	(CAS-No.) 7647-14-5	0.8949	Not classified
Ephedrine sulfate	Benzenemethanol, .alpha.-[(1S)-1-(methylamino)ethyl]-, (.alpha.R)-, sulfate (2:1) (salt) / Benzenemethanol, .alpha.-[1-(methylamino)ethyl]-, [R-(R,)]-, sulfate (2:1) (salt) / Benzenemethanol, .alpha.-[1-(methylamino)ethyl]-, [R-(R*,S*)]-, sulfate (2:1) (salt) / Bis[[R-(R*,S*)]-.beta.-hydroxy-.alpha.-methylphenethyl)methylammonium] sulphate / l-Ephedrine sulfate / Ephedrine sulfate (2:1) (salt), (-) / 1-Phenyl-2-methylamine-propanol-1-sulfate / Benzenemethanol, .alpha.-[(1S)-1-(methylamino)ethyl]-, (.alpha.R)-, sulfate (2:1) (salt) / Benzenemethanol, .alpha.-[(1S)-1-(methylamino)ethyl]-, (.alpha.R)-, sulfate (2:1) / (1R,2S)-1-Phenyl-2-methylaminopropanol-1-sulfate / Benzenemethanol, .alpha.-[1-(methylamino)ethyl]-, [R-(R*,S*)]-, sulfate (2:1)	(CAS-No.) 134-72-5	0.4972	Acute Tox. 3 (Oral), H301 Skin Sens. 1, H317
Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / ACETIC ACID / Acetic acid solution / Acetic acid ...% / acetic acid	(CAS-No.) 64-19-7	Used to adjust pH	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 3, H402 Aquatic Chronic 3, H412

Full text of H-phrases: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

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Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Skin sensitization.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Overexposure can cause paranoid psychosis, delusions and hallucinations. Mydriasis may occur.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Will not support combustion unless the water has evaporated.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Trace oxides of sulfur and nitrogen.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Use only as directed by the information identified in the package insert.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

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Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Acetic acid (64-19-7)		
USA ACGIH	ACGIH TWA (ppm)	10 ppm
USA ACGIH	ACGIH STEL (ppm)	15 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	10 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	25 mg/m ³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	37 mg/m ³
USA NIOSH	NIOSH REL STEL [ppm]	15 ppm
USA IDLH	US IDLH (ppm)	50 ppm
Alberta	OEL STEL (mg/m ³)	37 mg/m ³
Alberta	OEL STEL (ppm)	15 ppm
Alberta	OEL TWA (mg/m ³)	25 mg/m ³
Alberta	OEL TWA (ppm)	10 ppm
British Columbia	OEL STEL (ppm)	15 ppm
British Columbia	OEL TWA (ppm)	10 ppm
Manitoba	OEL STEL (ppm)	15 ppm
Manitoba	OEL TWA (ppm)	10 ppm
New Brunswick	OEL STEL (mg/m ³)	37 mg/m ³
New Brunswick	OEL STEL (ppm)	15 ppm
New Brunswick	OEL TWA (mg/m ³)	25 mg/m ³
New Brunswick	OEL TWA (ppm)	10 ppm
Newfoundland & Labrador	OEL STEL (ppm)	15 ppm
Newfoundland & Labrador	OEL TWA (ppm)	10 ppm
Nova Scotia	OEL STEL (ppm)	15 ppm
Nova Scotia	OEL TWA (ppm)	10 ppm
Nunavut	OEL STEL (ppm)	15 ppm
Nunavut	OEL TWA (ppm)	10 ppm
Northwest Territories	OEL STEL (ppm)	15 ppm
Northwest Territories	OEL TWA (ppm)	10 ppm
Ontario	OEL STEL (ppm)	15 ppm
Ontario	OEL TWA (ppm)	10 ppm
Prince Edward Island	OEL STEL (ppm)	15 ppm
Prince Edward Island	OEL TWA (ppm)	10 ppm
Québec	VECD (mg/m ³)	37 mg/m ³
Québec	VECD (ppm)	15 ppm
Québec	VEMP (mg/m ³)	25 mg/m ³
Québec	VEMP (ppm)	10 ppm

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Saskatchewan	OEL STEL (ppm)	15 ppm
Saskatchewan	OEL TWA (ppm)	10 ppm
Yukon	OEL STEL (mg/m ³)	43 mg/m ³
Yukon	OEL STEL (ppm)	25 ppm
Yukon	OEL TWA (mg/m ³)	25 mg/m ³
Yukon	OEL TWA (ppm)	10 ppm

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
Alberta	OEL Ceiling (mg/m ³)	2 mg/m ³
British Columbia	OEL Ceiling (mg/m ³)	2 mg/m ³
Manitoba	OEL Ceiling (mg/m ³)	2 mg/m ³
New Brunswick	OEL Ceiling (mg/m ³)	2 mg/m ³
Newfoundland & Labrador	OEL Ceiling (mg/m ³)	2 mg/m ³
Nova Scotia	OEL Ceiling (mg/m ³)	2 mg/m ³
Nunavut	OEL Ceiling (mg/m ³)	2 mg/m ³
Northwest Territories	OEL Ceiling (mg/m ³)	2 mg/m ³
Ontario	OEL Ceiling (mg/m ³)	2 mg/m ³
Prince Edward Island	OEL Ceiling (mg/m ³)	2 mg/m ³
Québec	PLAFOND (mg/m ³)	2 mg/m ³
Saskatchewan	OEL Ceiling (mg/m ³)	2 mg/m ³
Yukon	OEL Ceiling (mg/m ³)	2 mg/m ³

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless solution essentially free of visible particles.
Odor	: Not available
Odor Threshold	: Not available
pH	: 4.5 – 7
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available

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Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapor Pressure	: Not available
Relative Vapor Density at 20°C	: Not available
Relative Density	: Not available
Specific Gravity	: 1.0056 g/ml
Solubility	: Not available
Partition Coefficient: N-Octanol/Water	: Not available
Viscosity	: Not available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition may produce : Trace oxides of sulfur and nitrogen.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Not classified

pH: 4.5 – 7

Eye Damage/Irritation: Not classified

pH: 4.5 – 7

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Overexposure can cause paranoid psychoses, delusions and hallucinations. Mydriasis may occur.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
Ephedrine sulfate (134-72-5)	

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LD50 Oral Rat	189 mg/kg
Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

12.2. Persistence and Degradability

Ephedrine Sulfate Injection, USP	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Ephedrine Sulfate Injection, USP	
Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
BCF Fish 1	(no bioaccumulation)
Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)

12.4. Mobility in Soil Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

- 14.1. In Accordance with DOT Not regulated for transport
- 14.2. In Accordance with IMDG Not regulated for transport
- 14.3. In Accordance with IATA Not regulated for transport
- 14.4. In Accordance with TDG Not regulated for transport

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SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Ephedrine Sulfate Injection, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Ephedrine sulfate (134-72-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb

15.2. US State Regulations

Acetic acid (64-19-7)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
Sodium hydroxide (1310-73-2)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)
Sodium chloride (7647-14-5)
Listed on the Canadian DSL (Domestic Substances List)
Ephedrine sulfate (134-72-5)
Listed on the Canadian DSL (Domestic Substances List)
Acetic acid (64-19-7)
Listed on the Canadian DSL (Domestic Substances List)
Sodium hydroxide (1310-73-2)
Listed on the Canadian DSL (Domestic Substances List)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 12/10/2020

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1

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Flam. Liq. 3	Flammable liquids Category 3
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Sens. 1	Skin sensitization, Category 1
H226	Flammable liquid and vapor
H301	Toxic if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H402	Harmful to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)