Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Ephedrine Sulfate Injection, USP

Other means of identification : 50 mg/mL, 1 mL single-dose vial in package of 25; NDC 55150-373-25

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC

279 Princeton Hightstown Road East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Ephedrine sulfate	(CAS-No.) 134-72-5	5	Acute Tox. 4 (Oral), H302
Sodium hydroxide	(CAS-No.) 1310-73-2	≤1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Acetic acid	(CAS-No.) 64-19-7	≤ 1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed

by warm water rinse.

First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water.

First-aid measures after ingestion : Go into open air and ventilate suspected area.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation.

Symptoms/effects after eye contact : May cause eye irritation.

Symptoms/effects after ingestion : May be harmful if swallowed.

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4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Recycle product or dispose safely.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 20 to 25 °C (68 to 77 °F)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m³
OSHA	OSHA PEL TWA	2 mg/m³
IDLH	IDLH	10 mg/m³
NIOSH	NIOSH REL (Ceiling)	2 mg/m³
Acetic acid (64-19-7)		
ACGIH	ACGIH OEL TWA	10 ppm
ACGIH	ACGIH OEL STEL	15 ppm
OSHA	OSHA PEL TWA	25 mg/m³
OSHA	OSHA PEL TWA	10 ppm
IDLH	IDLH	50 ppm
NIOSH	NIOSH REL (TWA)	25 mg/m³
NIOSH	NIOSH REL (TWA)	10 ppm
NIOSH	NIOSH REL (STEL)	37 mg/m³

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Acetic acid (64-19-7)		
NIOSH	NIOSH REL (STEL)	15 ppm

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use neoprene or rubber gloves.

Eye protection : Wear protective goggles.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Color : Colorless
Odor : Odorless

Odor threshold : No data available

pH : 4.5 – 7

Melting point No data available Freezing point No data available **Boiling point** : No data available Flash point : No data available : No data available Relative evaporation rate (butyl acetate=1) Flammability : No data available : No data available Vapor pressure Relative vapor density at 20°C : No data available Relative density : No data available Solubility : No data available Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available No data available **Explosion limits** Explosive properties No data available : No data available Oxidizing properties

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ephedrine sulfate (134-72-5)		
ATE US (oral)	500 mg/kg body weight	
Sodium hydroxide (1310-73-2)		
LD50 oral rat	140 – 340 mg/kg	
LD50 dermal rabbit	1350 mg/kg	
ATE US (dermal)	1350 mg/kg	
Acetic acid (64-19-7)		
LD50 oral rat	3310 mg/kg	
LD50 dermal rabbit	1060 mg/kg	
LC50 Inhalation - Rat	11.4 mg/l/4h	
ATE US (oral)	3310 mg/kg	
ATE US (dermal)	1060 mg/kg	
Skin corrosion/irritation	: Not classified	
Serious eye damage/irritation	: Not classified	
Respiratory or skin sensitization	: Not classified	
Germ cell mutagenicity	: Not classified	
Carcinogenicity	: Not classified	
Reproductive toxicity	: Not classified	
STOT-single exposure	: Not classified	
STOT-repeated exposure	: Not classified	
Aspiration hazard	: Not classified	

SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)		
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])	
Acetic acid (64-19-7)		
LC50 - Fish [1]	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])	
EC50 - Crustacea [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])	

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

International Air Transport Association (IATA)

In accordance with IATA

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Acetic acid (64-19-7)	
Acetic acid (04-19-1)	
Listed on the United States TSCA (Toxic Substan	ices Control Act) inventory

15.2. US State regulations

Sodium hydroxide (1310-73-2)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

Acetic acid (64-19-7)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 3	Flammable liquids Category 3
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H226	Flammable liquid and vapor
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

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.

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