

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 1 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 1. Identification

GHS product identifier : Alprostadil Injection, USP
Other means of identification : Alprostadil Injection, USP
Product type : Liquid.

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

Product use : Pharmaceuticals. (For intended use only.)
Observe technical data sheet/instructions for use.
Specific Treatments: Palliative therapy to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ducts for survival.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

Telephone: 224-443-4617
www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : H225 FLAMMABLE LIQUIDS - Category 2
H319 EYE IRRITATION - Category 2A
H336 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3

GHS label elements

Hazard pictograms :



Signal word : Danger

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 2 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 2. Hazards identification

Hazard statements	: H225 - Highly flammable liquid and vapor. H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness.
Precautionary statements	
Prevention	: P280 - Wear protective gloves, protective clothing, eye protection, face protection, or hearing protection. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P271 - Use only outdoors or in a well-ventilated area. P261 - Avoid breathing vapor. P264 - Wash thoroughly after handling.
Response	: P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.
Storage	: P405 - Store locked up. P403 + P233 - Store in a well-ventilated place. Keep container tightly closed.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Avoid contact with skin and clothing. Wash thoroughly after handling.
Hazards not otherwise classified	: Prolonged or repeated contact may dry skin and cause irritation.
Hazards identified when used	: No known significant effects or critical hazards.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Alprostadil Injection, USP

Ingredient name	Synonyms	%	Identifiers
Ethanol alprostadil	Ethyl alcohol -	≥80 ≤0.1	CAS: 64-17-5 CAS: 745-65-3

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 3 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Wash skin thoroughly with soap and water or use recognized skin cleanser. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.
- Skin contact** : Defatting to the skin. May cause skin dryness and irritation.
- Ingestion** : Can cause central nervous system (CNS) depression.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 4 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 4. First aid measures

- Skin contact** : Adverse symptoms may include the following:
irritation
dryness
cracking
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : Do not use water jet.

- Specific hazards arising from the chemical** : Highly flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 5 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 6 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Ethanol	ACGIH TLV (United States, 1/2025) A3. STEL 15 minutes: 1000 ppm. NIOSH REL (United States, 10/2020) TWA 10 hours: 1000 ppm. TWA 10 hours: 1900 mg/m ³ . OSHA PEL (United States, 5/2018) TWA 8 hours: 1000 ppm. TWA 8 hours: 1900 mg/m ³ . CAL OSHA PEL (United States, 1/2025) TWA 8 hours: 1900 mg/m ³ . TWA 8 hours: 1000 ppm.
alprostadil	None.

Biological exposure indices

None known.

Appropriate engineering controls : Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures



SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 7 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 8. Exposure controls/personal protection

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Clear.]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** :

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 8 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 9. Physical and chemical properties

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Ethanol	9.7	49.5	Abel-Pensky	17.7	63.9	

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Ethanol	42.94865	5.7				

Relative vapor density : Not available.

Relative density : 0.788

Density : 0.788 g/cm³ [25°C (77°F)]

Media	Result
water	Easily soluble

Miscible with water : Yes.

Partition coefficient: n-octanol/water : Not applicable.

Ingredient name	°C	°F	Method
Ethanol	455	851	DIN 51794

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Dynamic (room temperature): Not applicable.
Kinematic (room temperature): Not applicable.
Kinematic (40°C (104°F)): Not applicable.

Particle characteristics

Median particle size : Not applicable.

Other information

Physical/chemical properties comments : No additional information.

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 9 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.
- Conditions to avoid** : Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
- Incompatible materials** : Reactive or incompatible with the following materials:
oxidizing materials
Reactive or incompatible with the following materials: oxidizing materials.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name

Ethanol

Result

Rat - Oral - LD50

7 g/kg

Rat - Inhalation - LC50 Vapor

124700 mg/m³ [4 hours]

alprostadil

Rat - Oral - LD50

228 mg/kg

Conclusion/Summary [Product] : Not available.

Skin corrosion/irritation

Conclusion/Summary [Product] : Not available.

Serious eye damage/eye irritation

Product/ingredient name

Result



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 10 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 11. Toxicological information

Ethanol

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

Rabbit - Eyes - Moderate irritant

Duration of treatment/exposure:

0.06666667 minutes

Amount/concentration applied: 100 mg

Rabbit - Eyes - Moderate irritant

Amount/concentration applied: 100 uL

Rabbit - Eyes - Severe irritant

Amount/concentration applied: 500 mg

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 1 hours

Amount/concentration applied: 50 pph

Conclusion/Summary [Product]

: Not available.

Respiratory corrosion/irritation

Conclusion/Summary [Product]

: Not available.

Respiratory or skin sensitization

Skin

Conclusion/Summary [Product]

: Not available.

Respiratory

Conclusion/Summary [Product]

: Not available.

Germ cell mutagenicity

Conclusion/Summary [Product]

: Not available.

Carcinogenicity

Conclusion/Summary [Product]

: Not available.

Reproductive toxicity

Conclusion/Summary [Product]

: Not available.

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 11 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 11. Toxicological information

Specific target organ toxicity (single exposure)

Product/ingredient name

Ethanol

Result

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
(Narcotic effects) - Category 3

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure

Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact

: Causes serious eye irritation.

Inhalation

: Can cause central nervous system (CNS) depression. May cause drowsiness or dizziness.

Skin contact

: Defatting to the skin. May cause skin dryness and irritation.

Ingestion

: Can cause central nervous system (CNS) depression.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact

: Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation

: Adverse symptoms may include the following:
nausea or vomiting
headache
drowsiness/fatigue
dizziness/vertigo
unconsciousness

Skin contact

: Adverse symptoms may include the following:
irritation
dryness
cracking

Ingestion

: No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 12 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 11. Toxicological information

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary [Product] : Not available.

General : Prolonged or repeated contact can defat the skin and lead to irritation, cracking and/or dermatitis.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Ethanol	7000	N/A	N/A	124.7	N/A
alprostadil	228	N/A	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name

Ethanol

Result

Acute - LC50 - Fresh water

Fish - Rainbow trout, donaldson trout -
Oncorhynchus mykiss
42 mg/l [4 days]

Effect: Mortality

Acute - EC50 - Marine water

Algae - Green algae - *Ulva pertusa*
17.921 mg/l [96 hours]

Effect: Reproduction

Chronic - NOEC - Marine water

Algae - Green algae - *Ulva pertusa*
4.995 mg/l [96 hours]

Effect: Reproduction

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 13 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 12. Ecological information

Chronic - NOEC - Fresh water

Effect: Mortality

Daphnia - Water flea - *Daphnia magna* - Neonate

Age: <24 hours

100 µl/l [21 days]

Chronic - NOEC - Fresh water

Effect: Morphology

Fish - Eastern mosquitofish - *Gambusia holbrooki* - Larvae

Age: 3 days

0.375 µl/l [12 weeks]

Acute - EC50 - Fresh water

Effect: Intoxication

Daphnia - Water flea - *Daphnia magna*
2 mg/l [48 hours]

Conclusion/Summary [Product] : Not available.

Persistence and degradability

Conclusion/Summary [Product] : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
Ethanol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethanol	-0.35	-	Low
alprostadil	3.2	-	Low

Mobility in soil

Soil/Water partition coefficient : Not available.

Other adverse effects

No known significant effects or critical hazards.

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 14 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	UN1170	UN1170	UN1170
UN proper shipping name	Ethanol solutions	ETHANOL SOLUTION	Ethanol solution
Transport hazard class(es)	3 	3 	3 
Packing group	II	II	II
Environmental hazards	No.	No.	No.

Additional information

DOT Classification

: **Limited quantity** Yes.
Packaging instruction Exceptions: 4b, 150. Non-bulk: 202. Bulk: 242.
Quantity limitation Passenger aircraft/rail: 5 L. Cargo aircraft: 60 L.
Special provisions 24, IB2, T4, TP1

IMDG

: **Emergency schedules** F-E, S-D
Special provisions 144

IATA

: **Quantity limitation** Passenger and Cargo Aircraft: 5 L. Packaging instructions: 353. Cargo Aircraft Only: 60 L. Packaging instructions: 364. Limited Quantities - Passenger Aircraft: 1 L. Packaging instructions: Y341.
Special provisions A3, A58, A180



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 15 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 14. Transport information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): All components are active or exempted.

TSCA 12(b) - Chemical export notification

Not applicable.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 2
EYE IRRITATION - Category 2A
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
HNOC - Defatting irritant

Composition/information on ingredients

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 16 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 15. Regulatory information

Name	%	Classification
Ethanol	≥80	FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3
alprostadil	≤0.1	HNOC - Defatting irritant ACUTE TOXICITY (oral) - Category 3 TOXIC TO REPRODUCTION - Category 2

SARA 313

Not applicable.

State regulations

- Massachusetts** : The following components are listed: ETHYL ALCOHOL
- New York** : None of the components are listed.
- New Jersey** : The following components are listed: ETHYL ALCOHOL
- Pennsylvania** : The following components are listed: ETHANOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	2
Flammability		3
Physical hazards		0

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 17 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 16. Other information

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



Procedure used to derive the classification

Classification	Justification
FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3	Expert judgment Calculation method Calculation method

History

Date of issue/Date of revision	: 04/03/2026
Date of previous issue	: 04/19/2024
Version	: 2.0
Prepared by	: Sphera Solutions
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods IMO = International Maritime Organization LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available SGG = Segregation Group TDG = Transportation of Dangerous Goods UN = United Nations
References	: HCS (U.S.A.)- Hazard Communication Standard International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Alprostadil Injection, USP Safety Data Sheet	SDS Number: SDS-000092	Page Number: Page 18 of 18
Function: Regulatory Affairs	Effective Date: April 03, 2026	Version number: 2.0

Section 16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Effective