1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Material Name: Alprostadil Concentrate for Solution for Infusion
Trade Name: Prostin VR Pediatric Sterile Solution; Prostivas
Chemical Family: Mixture
Intended Use: Indicated to temporarily maintain the patency of the ductus arteriosus until surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ductus for survival.

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Alprostadil Concentrate for Solution for Infusion

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Signal Word: DANGER

Statement of Hazard: Highly flammable liquid and vapor.

Additional Hazard Information:
Short Term: May cause eye and skin irritation. May be harmful if absorbed through the skin. May be harmful if swallowed. Harmful if inhaled. Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system, the developing fetus. This product contains ethanol which can cause liver changes, central nervous system effects, and birth defects in the developing fetus

Known Clinical Effects: Clinical use of this drug has caused symptoms of asthma, vomiting, diarrhea, increased bleeding time, clotting abnormalities, flushing, decrease in blood pressure (hypotension), decreased heart rate (bradycardia). Stimulates smooth muscle contraction.

EU Indication of danger: F - Highly flammable

EU Hazard Symbols: F

EU Risk Phrases: R11 - Highly flammable.

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F;R11</td>
<td></td>
<td>99.95</td>
</tr>
<tr>
<td>Alprostadil</td>
<td>745-65-3</td>
<td>212-017-2</td>
<td>Xn;R22</td>
<td></td>
<td>0.05</td>
</tr>
</tbody>
</table>

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Flammable liquid and vapor. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Wash thoroughly after handling. Use with adequate ventilation. Keep away from heat, sparks, flame and all other sources of ignition.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Ethanol

- ACGIH Threshold Limit Value (TWA) 1000 ppm TWA
- ACGIH OELs - Notice of Intended Changes Listed
- Australia TWA 1000 ppm 1880 mg/m³
- Austria OEL - MAKs Listed
- Belgium OEL - TWA Listed
- Bulgaria OEL - TWA Listed
- Czech Republic OEL - TWA Listed
- Denmark OEL - TWA Listed
- Estonia OEL - TWA Listed
- Finland OEL - TWA Listed
- France OEL - TWA Listed
- Germany - TRGS 900 - TWAs 500 ppm 960 mg/m³
- Germany (DFG) - MAK 500 ppm MAK 960 mg/m³ MAK
- Greece OEL - TWA Listed
- Hungary OEL - TWA Listed
- Ireland OEL - TWAs Listed
- Latvia OEL - TWA Listed
- Lithuania OEL - TWA Listed
- OSHA - Final PELS - TWAs: 1000 ppm 1900 mg/m³
- Poland OEL - TWA Listed
- Portugal OEL - TWA Listed
- Romania OEL - TWA Listed
- Slovenia OEL - TWA Listed
- Spain OEL - TWA Listed
- Sweden OEL - TWAs Listed

Alprostadil

- Pfizer OEL TWA-8 Hr: 0.5 µg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

- Hands: Wear impervious gloves if skin contact is possible.
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Wear protective clothing when working with large quantities.
- Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: Alcohol like
Molecular Weight: Mixture

Solvent Solubility: Soluble: Alcohols

Flammability:
- Flash Point (Liquid) (°C): 12.8 (Closed cup (Ethanol))
- Upper Explosive Limits (Liquid) (% by Vol.): 19
- Lower Explosive Limits (Liquid) (% by Vol.): 3.3

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition.

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide and carbon dioxide

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

- **Alprostadil**
  - Rat Oral LD 50 228 mg/kg
  - Rat Intravenous LD 50 19.2 mg/kg
  - Rat Intraperitoneal LD 50 24.9 mg/kg
  - Mouse Oral LD 50 186 mg/kg

ALPROSTADIL INJECTION
11. TOXICOLOGICAL INFORMATION

Mouse Intravenous LD 50 21 mg/kg

Ethanol
Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060 mg/kg
Mouse Inhalation LC50 4h 39 g/m³
Rat Inhalation LC50 10h 20,000 ppm

Irritation / Sensitization: (Study Type, Species, Severity)

Ethanol
Eye Irritation Rabbit Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Alprostadil
Not specified Rat Oral 1 mg/kg/day Maternal toxicity, Reproductive toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Alprostadil
Bacterial Mutagenicity (Ames) Salmonella Negative
Unscheduled DNA Synthesis Negative
Mammalian Cell Mutagenicity HGPRT Negative

Carcinogen Status:
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Ethanol
IARC: Group 1
NTP: Listed
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview:
Environmental properties have not been investigated. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol
Fingerling Trout NPDES LC50 24 Hours 11,200 mg/L
Rainbow Trout NPDES LC50 96 Hours 12,900 mg/L
Fathead minnow NPDES LC50 96 Hours 14,200 mg/L
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

This material is regulated for transportation as a hazardous material/dangerous good.

**Proper shipping name:** Flammable Liquid, n.o.s. (ethyl alcohol)
**UN / ID No:** UN1993
**Hazard class:** 3
**Flash Point (°C):** 12 C (54 F)
**Packing group:** II

For small quantities, limited to inner packaging less than or equal to 1.0L (0.3 gal) and outer packaging less than or equal to 30 kg (66 lb.) gross weight, the following apply. Note: If your commodity meets the definition of a limited quantity and is packaged for retail sale, it may also be considered a Consumer Commodity and excepted from additional requirements as applicable.

**IATA / ICAO**
- **IATA Proper shipping name:** Consumer Commodity
- **IATA UN / ID No:** ID 8000
- **IATA Hazard Class:** 9
- **IATA Packing Group:** Not applicable

**IMDG**
- **IMDG Proper shipping name:** Flammable Liquid, n.o.s. (ethyl alcohol), Ltd Qty
- **IMDG UN / ID No:** UN 1993
- **IMDG Hazard Class:** 3
- **Flash Point (°C):** 12 C (54 F)
- **IMDG Packing Group:** II

**DOT**
- **DOT Proper shipping name:** Subject to Exemption DOT SP-9275, making it exempt from the 49 CFR regulations if: Inner packagings <=8.0 fl. Ounces; total inner packages <=192 fl.Oz.; total outer package <=66 lb. Current copy of exemption must be maintained and followed at shipping site.

15. REGULATORY INFORMATION

**EU Symbol:** F
**EU Indication of danger:** F - Highly flammable

**EU Risk Phrases:** R11 - Highly flammable.

**EU Safety Phrases:** S9 - Keep container in a well-ventilated place.
S16 - Keep away from sources of ignition - No smoking.
15. REGULATORY INFORMATION

OSHA Label:
DANGER
Highly flammable liquid and vapor.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class B, Division 2
Class D, Division 2, and Subdivision B.

Ethanol
California Proposition 65
carcinogen, initial date 7/1/88 (when associated with alcohol abuse)
developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)

Inventory - United States TSCA - Sect. 8(b)  Listed
Australia (AICS):                          Listed
EU EINECS/ELINCS List                    200-578-6

Alprostadil
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List                    212-017-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R11 - Highly flammable.
R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet