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

Product Identifier

Material Name: Alprostadil Concentrate for Solution for Infusion
Trade Name: Prostin VR Pediatric Sterile Solution; Prostivas; Prolisina
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

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.

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Flammable liquids- Category 2

EU Classification:
EU Indication of danger: F - Highly flammable

EU Risk Phrases:
R11 - Highly flammable.

Label Elements

Signal Word: Danger
Hazard Statements: H225 - Highly flammable liquid and vapor
Precautionary Statements:
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P240 - Ground/Bond container and receiving equipment
- P241 - Use explosion-proof electrical/ventilating/lighting/equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- P370 + P378 - In case of fire: Use Extinguish fires with CO2, extinguishing powder, foam, or water for extinction
- P403 + P235 - Store in a well-ventilated place. Keep cool
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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 Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS 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>Flam. Liq. 2 (H225)</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>Acute Tox. 3 (H301)</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 and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of 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.
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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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Carbon dioxide, carbon monoxide
Fire / Explosion Hazards: Flammable liquid and vapor. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
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.

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

Methods and Material for Containment and Cleaning Up
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.
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

Precautions for Safe Handling
Keep away from heat, sparks, flame and all other sources of ignition. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Use with adequate ventilation. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
### Specific end use(s):
Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Ethanol

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Control Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Australia TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Austria OEL - MAKs</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Belgium OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Bulgaria OEL - TWA</td>
<td>1000.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Czech Republic OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Denmark OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Estonia OEL - TWA</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Finland OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>France OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Latvia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
</tr>
<tr>
<td></td>
<td>OSHA - Final PELS - TWAs:</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Russia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Slovakia OEL - TWA</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Slovenia OEL - TWA</td>
<td>1000 ppm</td>
</tr>
<tr>
<td></td>
<td>Sweden OEL - TWAs</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Switzerland OEL - TWAs</td>
<td>500 ppm</td>
</tr>
<tr>
<td></td>
<td>Vietnam OEL - TWAs</td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Control Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>0.5 µg/m³</td>
</tr>
</tbody>
</table>

---

**Revision date:** 07-Jul-2015

**Version:** 4.0

---
SAFETY DATA SHEET

Material Name: Alprostadil Concentrate for Solution for Infusion
Revision date: 07-Jul-2015
Version: 4.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION


Exposure Controls

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.

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 Formula: Mixture

Solvent Solubility: Soluble: Alcohols
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): 78.3 (ethanol)

Partition Coefficient: (Method, pH, Endpoint, Value)
Alprostadil Predicted 7.4 Log D -0.35
Ethanol No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
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

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions Oxidizing Properties: No data available
10. STABILITY AND REACTIVITY

| Conditions to Avoid: | Fine particles (such as dusts, mists and vapors) may fuel fires/explosions. Keep away from heat, spark, flames and all other sources of ignition. |
| Incompatible Materials: | As a precautionary measure, keep away from strong oxidizers |
| Hazardous Decomposition Products: | No data available |

11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

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

**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.

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alprostadil</strong></td>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>228 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Para-periosteal</td>
<td>LD 50</td>
<td>19.2mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>24.9mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>186mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Intravenous</td>
<td>LD 50</td>
<td>21mg/kg</td>
</tr>
<tr>
<td><strong>Ethanol</strong></td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>3,450 g/m³</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>7,060mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>Inhalation</td>
<td>LC50 4h</td>
<td>39g/m³</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>Inhalation</td>
<td>LC50 10h</td>
<td>20,000ppm</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethanol</strong></td>
<td>Eye Irritation</td>
<td>Rabbit</td>
<td>Severe</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alprostadil</strong></td>
<td>Not specified</td>
<td>Rat</td>
<td>Oral</td>
<td>1 mg/kg/day</td>
<td>Maternal toxicity, Reproductive toxicity</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alprostadil</strong></td>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Unscheduled DNA Synthesis</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mammalian Cell Mutagenicity</td>
<td>HGPRT</td>
<td>Negative</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. None of the other components of this mixture are listed as a carcinogen by IARC, NTP or OSHA.

Ethanol IARC: Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fingerling Trout</td>
<td>NPDES</td>
<td>LC50</td>
<td>24 Hours</td>
<td>11,200 mg/L</td>
</tr>
<tr>
<td>Oncorhynchus mykiss (Rainbow Trout)</td>
<td>NPDES</td>
<td>LC50</td>
<td>96 Hours</td>
<td>12,900 mg/L</td>
</tr>
<tr>
<td>Pimephales promelas (Fathead Minnow)</td>
<td>NPDES</td>
<td>LC50</td>
<td>96 Hours</td>
<td>14,200 mg/L</td>
</tr>
</tbody>
</table>

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

<table>
<thead>
<tr>
<th>Method</th>
<th>pH</th>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predicted</td>
<td>7.4</td>
<td>Log D</td>
<td>-0.35</td>
</tr>
</tbody>
</table>

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

UN number: UN 1170
SAFETY DATA SHEET

Material Name: Alprostadil Concentrate for Solution for Infusion
Revision date: 07-Jul-2015

UN proper shipping name: Ethanol solution
Transport hazard class(es): 3
Packing group: II

Flash Point (°C): 12 C (54 F)

Exceptions: For small quantities packed in combination packaging, exceptions may apply. Please refer to the applicable dangerous goods regulations for additional information.

Flash Point (°C): 12 C (54 F)

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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

Ethanol
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 in alcoholic beverages
Inventory - United States TSCA - Sect. 8(b):
Present
Australia (AICS):
Present
EU EINECS/ELINCS List
200-578-6

Alprostadil
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
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 and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor