



MATERIAL SAFETY DATA SHEET

Revision date: 25-Jul-2013

Version: 3.0

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

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Material Name: Alprostadil Concentrate for Solution for Infusion

Trade Name:	Prostin VR Pediatric Sterile Solution; Prostinvas; Prolisina
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.

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.
Hazardous Substance. Dangerous Goods.

Australian Hazard Classification (NOHSC):

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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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Ethanol	64-17-5	200-578-6	F; R11	99.95
Alprostadil	745-65-3	212-017-2	Xn;R22	0.05

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.

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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: 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.

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 (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³
France OEL - TWA	1000 ppm
	1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m ³
Germany (DFG) - MAK	500 ppm
	960 mg/m ³
Greece OEL - TWA	1000 ppm
	1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm
	1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Spain OEL - TWA	1000 ppm 1910 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³

Alprostadil
Pfizer OEL TWA-8 Hr: 0.5 µg/m³

Analytical Method: Analytical method available for Alprostadil. Contact Pfizer Inc for further information.
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	Color:	Clear
Odor:	Alcohol like	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

Solvent Solubility: Soluble: Alcohols
Boiling Point (°C): 78.3 (ethanol)

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

Chemical Stability: Stable under normal conditions of use.

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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

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 Para-periosteal LD 50 19.2 mg/kg
Rat Intraperitoneal LD 50 24.9 mg/kg
Mouse Oral LD 50 186 mg/kg
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:

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)
OSHA: Listed

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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
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC50	96 Hours	12,900 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	96 Hours	14,200 mg/L

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
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)
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15. REGULATORY INFORMATION

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

EU Risk Phrases:	R11 - Highly flammable.
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EU Safety Phrases:	S 9 - Keep container in a well-ventilated place. S16 - Keep away from sources of ignition - No smoking.
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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 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

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 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 7 - Handling and Storage. Updated Section 14 - Transport Information.

Prepared by:

Product Stewardship 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