



MATERIAL SAFETY DATA SHEET

Revision date: 14-Jul-2011

Version: 1.0

Page 1 of 8

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

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Material Name: Dinoprost Tromethamine Sterile Solution

Trade Name:	PROSTIN F2 ALPHA
Chemical Family:	Prostaglandin
Intended Use:	Pharmaceutical active used for smooth muscle stimulation

2. HAZARDS IDENTIFICATION

Appearance:	Sterile Solution
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	May cause eye irritation. May cause irritation of respiratory tract. (based on components) . May be absorbed through the skin and cause systemic effects.
Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on testes and developing fetus.
Known Clinical Effects:	Common adverse effects include gastrointestinal disturbances, vomiting, nausea, diarrhea. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
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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.
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MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 2 of 8
Version: 1.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Dinoprost Tromethamine	38562-01-5	254-002-3	Repr.Cat.2;R61 Xn;R22 Xi;R36	5mg/mL
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	*

Additional Information:

** to adjust pH

* Proprietary

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:

May include oxides of Formation of toxic gases is possible during heating or fire. carbon and products of nitrogen

Fire Fighting Procedures:

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

Fire / Explosion Hazards:

Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 3 of 8
Version: 1.0

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: Minimize generating airborne mists and vapors. Avoid contact with skin and clothing. Avoid breathing mist or aerosols. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Dinoprost Tromethamine

Pfizer OEL TWA-8 Hr: 1 $\mu\text{g}/\text{m}^3$

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m^3
Australia PEAK 2 mg/m^3
Austria OEL - MAKs 2 mg/m^3
Bulgaria OEL - TWA 2.0 mg/m^3
Czech Republic OEL - TWA 1 mg/m^3
Estonia OEL - TWA 1 mg/m^3
France OEL - TWA 2 mg/m^3
Greece OEL - TWA 2 mg/m^3
Hungary OEL - TWA 2 mg/m^3
Japan - OELs - Ceilings 2 mg/m^3
Latvia OEL - TWA 0.5 mg/m^3
OSHA - Final PELs - TWAs: 2 mg/m^3
Poland OEL - TWA 0.5 mg/m^3
Slovakia OEL - TWA 2 mg/m^3
Slovenia OEL - TWA 2 mg/m^3
Sweden OEL - TWAs 1 mg/m^3

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m^3
Austria OEL - MAKs 5 ppm
8 mg/m^3
Belgium OEL - TWA 5 ppm
8 mg/m^3
Bulgaria OEL - TWA 8.0 mg/m^3

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 4 of 8
Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Cyprus OEL - TWA	5 ppm 8 mg/m ³
Czech Republic OEL - TWA	8 mg/m ³
Estonia OEL - TWA	5 ppm 8 mg/m ³
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m ³
Germany (DFG) - MAK	2 ppm 3.0 mg/m ³
Greece OEL - TWA	5 ppm 7 mg/m ³
Hungary OEL - TWA	8 mg/m ³
Ireland OEL - TWAs	5 ppm 8 mg/m ³
Italy OEL - TWA	5 ppm 8 mg/m ³
Japan - OELs - Ceilings	5 ppm 7.5 mg/m ³
Latvia OEL - TWA	5 ppm 8 mg/m ³
Lithuania OEL - TWA	5 ppm 8 mg/m ³
Luxembourg OEL - TWA	5 ppm 8 mg/m ³
Malta OEL - TWA	5 ppm 8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 ppm 8 mg/m ³
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³
Slovenia OEL - TWA	5 ppm 8 mg/m ³
Spain OEL - TWA	5 ppm 7.6 mg/m ³
Benzyl Alcohol	
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm 45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

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).

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 5 of 8
Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands: Wear impervious gloves as minimum protection.
Eyes: Wear safety glasses as minimum protection.
Skin: Wear impervious protective clothing when handling this compound.
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:	Sterile solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
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)

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Dinoprost Tromethamine

Rat Oral LD 50 665 mg/kg
Rat Para-periosteal LD 50 101 mg/kg
Mouse Oral LD 50 711 mg/kg
Mouse Intravenous LD 50 331 mg/kg

Benzyl Alcohol

Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53 mg/kg
Rat Inhalation LC50 46 mg/m³

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

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe
Eye Irritation Severe

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 6 of 8
Version: 1.0

11. TOXICOLOGICAL INFORMATION

Dinoprost Tromethamine

Eye Irritation Rabbit Severe
Skin Irritation Rat No effect
Skin Sensitization - GPMT Guinea Pig Negative

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dinoprost Tromethamine

6 Month(s) Rat Intraperitoneal 32.8 mg/kg LOEL Male reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Dinoprost Tromethamine

Reproductive & Fertility Rat 1-3 mg/kg/day NOEL Fertility
Embryo / Fetal Development Rat Subcutaneous 0.5 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat 1-3 mg/kg/day LOEL Fetotoxicity

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

Dinoprost Tromethamine

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Direct DNA Interaction Negative

Carcinogen Status:

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

Hydrochloric Acid

IARC:

Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 7 of 8
Version: 1.0

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Dinoprost Tromethamine

Australia (AICS):	Present
EU EINECS/ELINCS List	254-002-3

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

MATERIAL SAFETY DATA SHEET

Material Name: Dinoprost Tromethamine Sterile Solution
Revision date: 14-Jul-2011

Page 8 of 8
Version: 1.0

15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R61 - May cause harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity 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