Safety Data Sheet
European Format

Prostap

Preparation Date 06-Jul-2007 **Revision Date** 08-Sep-2008 **Revision Number** 1

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

Product Name Prostap
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
Product Use Pharmaceutical product
Classification Sex Hormones and their Modulators

Supplier
Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number
Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Leuprorelin acetate	53714-56-0	Not applicable	11.25 mg/vial	R48/61, S36/37/39
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable

3. HAZARDS IDENTIFICATION

Emergency Overview
This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical powder **Physical State** Solid **Odor** Not available

Potential Physical Hazards
Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes Not available
Skin Not available
Inhalation Not available
Ingestion Not available
Other The most common effects may include fast or irregular heartbeat, anaphylactic reactions, dizziness, pain, mental depression, emotional liability, headache, lethargy, asthenia/weakness, fatigue, insomnia, irritability, anxiety, personality disorder, delusions, mood swings, nervousness, memory disorder, paresthesia, peripheral neuropathy, numbness, and syncope/blackouts. In females, common effects may include androgenic effects such as deepening of voice and hair growth, and changes in menstruation. In males, common effects may include chest pain, shortness of breath, thrombophlebitis, and impotency.

May cause harm to the unborn child. May cause harm to breastfed babies. May cause cancer.

	Please see Patient Package Insert for further information.
Therapeutic Target Organ(s)	Systemic.
	Not listed by OSHA, NTP or IARC.
Potential Environmental Effects	There is no known ecological information for this product.

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	**Exposure Guideline**
Leuprorelin acetate	60 mcg/m^3

Engineering Controls Enclose operations to prevent aerosol generation. Use HEPA filtered, externally vented, biosafety cabinet when preparing or handling this product.

Personal Protective Equipment

Eye/face Protection Wear safety glasses with side-shields.

Skin Protection Wear double gloves or "chemotherapy" gloves. Immediately change gloves when torn, punctured, or contaminated. Wear closed-front, low-permeability protective gowns with tight-fitting wrist cuffs when working with this product.

Respiratory Protection Base respirator selection on a risk assessment.

General Hygiene Considerations Avoid contact with skin, eyes and clothing. Conduct a task-specifc risk assessment prior to authorizing work with this product. Wash hands before breaks and immediately after handling this product.

Other Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical powder	**Physical State**	Solid
Color	White	**Odor**	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not applicable
Partition Coefficient (n-octanol/water)	Not available	**Vapor Density**	Not applicable
Vapor Pressure	Not applicable		
Boiling Point	Not applicable	**Autoignition Temperature**	Not applicable
Flash Point	Not applicable	**Melting Point**	Not available
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Leuprorelin acetate

LD50 Oral	>5 g/kg rats >5 g/kg mice
Acute Dermal Irritation	Not applicable
Primary Eye Irritation	Not applicable
Sensitization	Not applicable

Multiple Dose Toxicity

Leuprorelin acetate

No Toxicologic Effect Dose/Species/Study Length:	Not applicable

Maximum Tolerated Dose (MTD), Oral

Leuprorelin acetate

Carcinogenicity	In a 24-month carcinogenicity study in rats, a dose-dependent increase in benign pituitary tumors was produced at subcutaneous doses ranging from 0.6 to 4 mg/kg/day. No increase in tumors was found in mice treated up to 60 mg/kg/day for 24 months or in patients treated up to 10 mg/day for 3 years or 20 mg/kg for 2 years.
Genetic Toxicity	Negative in a battery of genotoxicity tests.
Reproductive Toxicity	Reproduction studies in rats and rabbits resulted in increased fetal mortality and fetal abnormalities.
Developmental Toxicity	See Reproductive Toxicity

Leuprorelin acetate

Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information	Not available
Ecotoxicity	Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References See Patient Package Insert for more information.
Revision Summary Changes to Section 1

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End of MSDS