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

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>Composition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leuprolelin acetate</td>
<td>53714-56-0</td>
<td>Not applicable</td>
<td>11.25 mg/vial</td>
<td>R48/61, S36/37/39</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Remainder</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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.
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**

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Use water spray, foam, dry chemical or carbon dioxide.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unsuitable Extinguishing Media</td>
<td>Do NOT use water jet.</td>
</tr>
</tbody>
</table>

**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/m³

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
Avoid contact with skin, eyes and clothing. Conduct a task-specific 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Pharmaceutical powder</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not available</td>
</tr>
<tr>
<td>pH</td>
<td>Not available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Explosion Limits</td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Not available</td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Odor</td>
<td>Not available</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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

Leuprolrelin 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

Leuprolrelin acetate

No Toxicologic Effect
Not applicable

Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Leuprolrelin 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

Leuprolrelin 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