#### MATERIAL SAFETY DATA SHEET

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FOR: TAP PHARMACEUTICALS INC DEERFIELD, IL 60015

1-800-622-2011

TSCA STATUS: Exempt

LIST/CODE: 5508/41450, 41558

PRODUCT NAME; Leuprolide acetate

CHEMICAL NAME; 5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-D-leucyl-L-leucyl-L-arginyl-N-ethyl-L-prolinamide acetate

DOT CLASSIFICATION: Not regulated

HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

NAME (CAS NO.)

OSHA ACGIH ABBOTT
PEL TLV LIMIT
(AIRBORNE)

NI. \*\*

Leuprolide acetate\* (74381-53-6) NL

\* = Hazardous per OSHA criteria
 \*\* = Internal guideline 0.1
mcg/m3 (8-hr TWA)

(Women of child bearing potential must be excluded from working directly with product which is not package in closed container.)

#### PHYSICAL PROPERTIES

Appearance: White, flocculent powder

Solubility; Completely soluble in water

Boiling Point: N/A Melting Point: N/D Vapor Density. N/A pH: N/A Vapor Pressure; N/A Density: N/A

pH: N/A Viscosity; N/A

FIRE AND EXPLOSION DATA

### Flash Point; N/A

Extinguishing Media: Use appropriate media for underlying cause of fire.

Special Fire Fighting Procedures; Wear protective clothing and self-contained breathing apparatus.

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PRODUCT NAME:

Leuprolide acetate

#### REACTIVITY

Incompatibility; Hypochlorite solutions

Hazardous Decomposition or By-products: N/D

Conditions to Avoid; N/D

#### HEALTH HAZARD DATA

Routes of Entry; Inhalation - YES Skin - POORLY
Ingestion - YES Intranasal - YES Injection - YES

Oral Toxicity; N/D Leuprolide acetate is not active when given orally.

Dermal Toxicity; N/D. SC LD50 > 100 mg/kg in rats and mice. Skin application has produced pharmacologic responses in animals.

Inhalation Toxicity; N/D. Intranasal application has produced pharmacologic responses in men and women.

Corrosiveness: No

Dermal Irritation: Not irritating to the skin

Ocular Irritation: N/D

Dermal Sensitization: N/D

Special Target Organ Effects: In clinical use, continuous administration of therapeutic doses acts as a potent, but reversible inhibitor of gonadotropin secretion by the pituitary, resulting in inhibition of ovarian and testicular steroid production. In rabbits, subcutaneous dosages as low as 0.1 mcg/kg produced embryolethality while dosages of 10 mcg/kg produced fetal resorptions in rats.

Carcinogenicity: NTP - NL IARC - NL OSHA - NL ACGIH - NL

In rats, a dose-related increase of benign pituitary hyperplasia and benign pituitary adenomas was noted at 24 months when the drug was administered subcutaneously at high daily doses (0.6 to 4 mg/kg). There was a significant but not dose-related increase of pancreatic islet-cell adenomas in females and of testes interstitial cell adenomas in males (highest incidence in the low dose group). In mice, no leuprolide acetate-induced tumors or pituitary abnormalities were observed at a dose as high as 60 mg/kg for two years. Patients have been treated with leuprolide acetate for up to three years with doses as high as 10 mg/day and for two years with doses as high as 20 mg/day without demonstrable pituitary abnormalities.

PRODUCT NAME:

Leuprolide acetate

## HEALTH HAZARD DATA (cont)

Signs and Symptoms of Exposure: N/D. In clinical use, the initial response to leuprolide acetate is an increase in LH, FSH, and male and female sex hormones (e.g. testosterone and estrogens). Continued use leads to reductions in these hormones to castrate or menopausal levels. Adverse reactions due to the physiologic effect of decreased sex hormones include hot flashes/sweats (both male and female), impotence (male), decreased libido (both), decreased testicular size, headache (both), mood changes (female), amenorrhea, vaginal dryness, fertility suppression (both), and decreased bone density (females). Other reactions not due to decreased sex steroids have been reported and are described in the package inserts for the finished products.

Medical Conditions Aggravated by Exposure: N/D. Due to a temporary increase of sex hormone levels during the first few weeks of treatment, isolated cases of worsening of signs and symptoms of hormonally-dependent conditions have been reported.

Emergency and First Aid Procedures: Remove from source of exposure. If skin or eye contact occurs, flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. There is no known antidote. Provide symptomatic and/or supportive care, monitoring hormone/sexual function as necessary.

# SPECIAL PROTECTION INFORMATION

Ventilation: Use local ventilation to control dust at its source.

Respirator: Approved respirator with high efficiency particulate filter or supplied-air (if handling powder).

Gloves: Rubber

Eve Protection: Safety glasses/goggles

Other Protection: Avoid skin contact with the solid or its solutions.

### SPECIAL HANDLING AND STORAGE

Special Precautions: Store only in containers approved for storage of this material.

Spill or Release Procedures: Wear approved respirator and chemically compatible gloves. Sweep up spillage. Avoid dust. Place in appropriate container for disposal. Ventilate and wash spill area.

Waste Disposal: Dispose of material in accordance with applicable federal, state and local regulations.

Other Handling: N/D

PRODUCT NAME: Leuprolide Acetate

# Legend:

N/A = not applicable

N/D = not determined

NL = not listed

L = listed

C = ceiling

S = short term

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