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MATERIAL SAFETY DATA SHEET

ABBOTT LABORATORIES CHEMICAL &  
AGRICULTURAL PRODUCTS DIVISION  
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EMERGENCY TELEPHONE 1-312-937-6100  
CHEMTREC 1-800-424-9300  
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 PEL	ACGIH TLV	ABBOTT LIMIT (AIRBORNE)
Leuprolide acetate* (74381-53-6)	NL	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  
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.



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

(R) = a registered trademark of Abbott Laboratories

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