DCN TAP-03-002560-1.0

MATERIAL SAFETY DATA SHEET - Sterile Diluent Lupron Depot

Date Issued: April, 2003 *Supersedes the MSDS dated*: September, 1998

1. COMPANY & PRODUCT IDENTIFICATION

Manufacturer Name:	Takeda Chemical Industries Limited, Osaka, Japan, for TAP Pharmaceutical Products Inc.
Address:	675 North Field Drive, Lake Forest, IL 60045
Phone:	1-800-622-2011 (Medical Information/Pharmacovigilance)
Product Name:	Sterile Diluent Lupron Depot
Chemical Name:	Not applicable
CAS* Number:	Not applicable

* Chemical Abstract Service

2. COMPOSITION/INFORMATION ON INGREDIENTS

Name/Hazardous* Ingredient	Quantity per 2 mL Ampule	Exposure limits OSHA-PEL**	ACGIH-TLV***
d-mannitol (CAS # 69-65-8)	100 mg	Not determined	Not determined

* Hazardous per OSHA criteria

** US Occupational Safety and Health Administration-Permissible Exposure Limit

*** American Conference of Governmental Industrial Hygienists- Threshold Limit Value

3. HAZARDS/ACUTE EXPOSURE INFORMATION

Emergency Overview: This material is a diluent for Lupron Depot. It does not contain leuprolide acetate. Has a low order of toxicity. Based on d-mannitol as the major ingredient, kidneys and eyes are the target organs. Hypersensitivity to d-mannitol may be observed in some individuals.

Primary Routes of Exposure: These have not been determined but based on the dosage form and limited usage the following are an estimation.

Oral: not likely; Dermal: rare; Inhalation: not likely

Acute Toxicity:

Oral:	Not determined for the product. LD_{50} for d-mannitol is 13,500 to 22,000 mg/kg in mice and rats. Ingestion of large quantities of d-mannitol can cause diarrhea with fluid loss and electrolyte imbalance.
Dermal:	Not determined
Inhalation:	Not determined

OTHER HAZARD INFORMATION:

Dermal Irritation:	Not determined
Eye Irritation:	Not determined
Skin Sensitization:	Not determined
Likely Target Organs:	Eyes and kidneys (based on the osmotic diuretic effect of d-mannitol)
Miscellaneous:	Pre-existing kidney or ocular ailments may be aggravated by exposure.

4. FIRST AID MEASURES

Eye : Remove from the source of exposure. Flush eyes with copious amounts of water. If irritation or redness persists, consult a physician.

Skin: Remove from the source of exposure. Flush the area of contact with copious amounts of water. If irritation persists, consult a physician.

Inhalation: Remove from the source of exposure. If difficulty in breathing, provide artificial respiration (if suitable help available). Seek appropriate medical attention.

Ingestion: Remove from the source of exposure. If signs of toxicity occur seek medical attention. Provide symptomatic/supportive care if available.

Note to the Physician: No specific antidotal treatment available. Treat symptomatically. Monitor fluid and electrolytes, if indicated. Pre-existing kidney or ocular ailments may be aggravated.

5. FIRE FIGHTING MEASURES

NFPA* Rating:	1: Health, 0: Flammability, 0: Reactivity
Flammability Class:	Not flammable
Flash Point:	Not applicable
Explosive Limits:	Not applicable
Extinguishing Media:	No special requirements
Special Protective Equipment:	Firefighters should wear full protective clothing including self-contained breathing equipment.
Fire Fighting Procedures:	Normal procedures.
Combustion Products:	Not determined
Unusual Fire or Explosion Hazards:	None known

* National Fire Prevention Association

6. ACCIDENTAL RELEASE MEASURES

Steps to be Taken:	In case of a spill use normal cleaning procedures.
Absorbents:	Clay granules, saw dust, dirt or equivalent.
Incompatibilities:	Not determined.

7. HANDLING PRECAUTIONS

Handling (Personnel):	Use standard safety precautions. Avoid contact with eyes and skin. Safety glasses, gloves or lab coat may be worn during an excessive exposure situation.
Storage Precautions:	Store according to label instructions.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Exposure Limits:	Not established
Ventilation:	Standard ventilation is adequate
Personal Protective Equipment:	Wear standard laboratory clothes, such as, lab coat, safety glasses or gloves when a major spill or exposure is expected.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (color, etc.):	Clear liquid in 2 mL ampules
Odor:	None
Vapor Density(Air =1):	Not known
Vapor Pressure (mm Hg):	Not known
Solubility in Water:	Fully miscible
Specific Gravity:	1.0
pH:	5 to 7 (per label)

10. STABILITY AND REACTIVITY

Stability:	Stable
Hazardous Polymerization:	Not expected to occur
Incompatibility with other Materials:	Not determined
Decomposition Products:	Not determined

11. OTHER TOXICOLOGICAL INFORMATION

Chronic Toxicity:	Not determined /available
Mutagenicity/Carcinogenicity: (for d-mannitol)	Has been referenced (RETECS*) as negative for carcinogenicity (in mouse and rat) per EPA's Genetox program 1988. Negative per NTP** (NTP TR -236.82) also.

* Registry of Toxic Effects of Chemical Substances
** National Toxicology Program

12. ENVIRONMENTAL/ECOLOGICAL INFORMATION

ENVIRONMENTAL FATE:

Hydrolysis:	Not available
Photolysis:	Not available
Soil half-life:	Not available

ECOTOXICITY:

Acute Toxicity -Fish:	Not determined
Acute Toxicity- aquatic invertebrates:	Not determined

13. DISPOSAL PROCEDURES

Waste resulting from use of this product may be disposed of as a pharmaceutical waste.

14. TRANSPORTATION AND SHIPPING INFORMATION

DOT/ 49CFR Description:	Not applicable
Freight Classification:	Pharmaceutical Product

15. REGULATORY INFORMATION

SARA* 311/312
Hazard Categories:

Immediate Heath:	No
Delayed Health:	No
Fire:	No
Sudden Pressure:	No
Reactivity:	No

*Superfund Amendmends and the Reauthorization Act.

16. OTHER INFORMATION

REFERENCES:

1) Health Hazard Evaluation Summary for Sterile Diluent Lupron Depot (HHES Number: 1818.2), Abbott Laboratories, issued 06/09/98,

2) RETECS for toxicity data for d-mannitol.

Prepared By. Drug Safety Department Tap Pharmaceutical Products Inc.