MATERIAL SAFETY DATA SHEET

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

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Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Metergoline Tablets

Trade Name: LISERDOL
Synonyms: None
Chemical Family: Not determined
Intended Use: Anti-prolactin

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Metergoline	17692-51-2	241-686-3	4 mg***
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium stearate	557-04-0	209-150-3	*
Starch	9005-25-8	232-679-6	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Povidone	9003-39-8	Not listed	*
Lactose	63-42-3	200-559-2	*
Hydroxypropyl methylcellulose	9004-65-3	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White round biconvex tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation.
Skin Contact: No data available
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Ingestion: Accidental or incidental ingestion of this material may cause headache, nausea, vomiting, dizziness, and gastrointestinal irritation.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness. The most common adverse effects observed with the clinical use of this drug were headache, nausea, and somnolence. Occasional, transient changes reported in liver function tests, but no liver damage seen.

EU Indication of danger: Harmful

EU Hazard Symbols:

EU Risk Phrases:

R22 - Harmful if swallowed.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: If irritation occurs or persists, get medical attention. Flush eyes with water for at least 15 minutes.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust.
Storage Conditions:	Store in a cool, dry, well-ventilated area. Protect from heat and light.
Storage Temperature	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

OSHA - Final PELS - TWAs	15 mg/m³ total dust
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Starch

OSHA - Final PELS - TWAs	15 mg/m³ total dust 5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls:	Local exhaust ventilation (LEV) should used to control airborne levels. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Carboxymethylcellulose sodium
Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000mg/kg
Rabbit Dermal LD50 > 2000mg/kg

Povidone
Rat Oral LD50 100 g/kg

Lactose
Rat Oral LD50 > 10 g/kg

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Starch
Mouse IP LD50 6600 mg/kg

Metergoline
Rat Oral LD 50 680 mg/kg
Mouse Oral LD 50 430 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Carboxymethylcellulose sodium
13 Week(s) Rat Oral =227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Metergoline
40 Day(s) Rat Oral 5 mg/kg/day NOEL No effects at maximum dose
90 Day(s) Rat Oral 20 mg/kg/day NOEL No effects at maximum dose
98 Day(s) Rat Oral 32 mg/kg/day NOEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Carboxymethylcellulose sodium
Reproductive & Fertility-Males Rat Oral =140 mg/kg LOEL Fertility

Metergoline

Embryo / Fetal Development	Rat	Oral	4.5 mg/kg/day	NOEL	Not teratogenic
Embryo / Fetal Development	Mouse	Oral	4.5 mg/kg/day	NOEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	1 mg/kg/day	NOEL	Not Teratogenic

Carcinogen Status: See below

Povidone
IARC: Group 3

Titanium dioxide
IARC: Group 3

Silicon dioxide, colloidal NF
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Labeling: Xn
EU Indication of danger: Harmful
EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S22 - Do not breathe dust.
S24/25 - Avoid contact with skin and eyes.

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Metergoline
EU EINECS List 241-686-3

Carboxymethylcellulose sodium
Inventory - United States TSCA - Sect. 8(b) Listed

Povidone
Inventory - United States TSCA - Sect. 8(b) Listed

Lactose
EU EINECS List 200-559-2
Inventory - United States TSCA - Sect. 8(b) Listed

Hydroxypropyl methylcellulose
Inventory - United States TSCA - Sect. 8(b) Listed

Titanium dioxide
EU EINECS List 236-675-5
Inventory - United States TSCA - Sect. 8(b) Listed

Magnesium stearate
EU EINECS List 209-150-3
Inventory - United States TSCA - Sect. 8(b) Listed

Starch
EU EINECS List 232-679-6
Inventory - United States TSCA - Sect. 8(b) Listed

Polyethylene glycol
Inventory - United States TSCA - Sect. 8(b) Listed

Silicon dioxide, colloidal NF
EU EINECS List 231-545-4
Inventory - United States TSCA - Sect. 8(b) Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet