



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

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

### Material Name: Nicergoline Film-Coated Tablets

**Trade Name:** Sermion Film-Coated Tablets  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as cognition activator

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Nicergoline	27848-84-6	248-694-6	30 mg***
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium stearate	557-04-0	209-150-3	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Iron oxide	1309-37-1	215-168-2	*

Ingredient	CAS Number	EU EINECS List	%
Hypromellose	9004-65-3	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Dibasic calcium phosphate, dihydrate USP	7789-77-7	Not listed	*
PII/MAA	7440-21-3	231-130-8	*

### 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:** Yellow tablet

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Short Term:** May cause drowsiness, insomnia, nervousness, and dizziness.  
**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. Adverse effects associated with the therapeutic use include skin rash and gastrointestinal disturbances.

**EU Indication of danger:** Not classified

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**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 as a precaution

**Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get 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:** Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and bromine-containing compounds

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

**Fire / Explosion Hazards:** Not applicable

### 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.

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**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 5 mg/m<sup>3</sup> TWA  
Australia TWA = 5 mg/m<sup>3</sup> TWA

#### PIIMAA

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### Nicergoline

**Pfizer Occupational Exposure Band (OEB):** OEB3 (control exposure to the range of >10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.  
**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.  
**Respiratory protection:** None required under normal conditions of use. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Tablets	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Not determined  
**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)

#### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

#### **Carboxymethylcellulose sodium**

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

#### **Nicergoline**

Rat Oral LD 50 1193 mg/kg

#### **Hypromellose**

Rat Oral LD50 > 10,000 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)

#### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

#### **Polyethylene glycol**

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

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### 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

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

#### **Nicergoline**

Embryo / Fetal Development	Rat	Oral	Not teratogenic
Embryo / Fetal Development	Rabbit		Fetotoxicity
Embryo / Fetal Development	Rat	Intramuscular	Not Teratogenic

**Carcinogen Status:** See below

#### **Titanium dioxide**

**IARC:** Group 2B  
**OSHA:** Present

#### **Iron oxide**

**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:** 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 Indication of danger:** Not classified

**OSHA Label:**

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Non-hazardous in accordance with international standards for workplace safety.

## 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.

### Nicergoline

Standard for the Uniform Scheduling  
for Drugs and Poisons: Schedule 4  
EU EINECS List 248-694-6

### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 236-675-5

### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 209-150-3

### Hypromellose

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present  
Standard for the Uniform Scheduling  
for Drugs and Poisons: Schedule 4

### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present  
EU EINECS List 232-674-9

### Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present

### Carboxymethylcellulose sodium

Inventory - United States TSCA - Sect. 8(b) XU  
Australia (AICS): Present

### Iron oxide

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 215-168-2

### Dibasic calcium phosphate, dihydrate USP

Australia (AICS): Present

### PIIMAA

Inventory - United States TSCA - Sect. 8(b) Present  
Australia (AICS): Present  
EU EINECS List 231-130-8

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### 16. OTHER INFORMATION

**Reasons for Revision:**

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

**Prepared by:**

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**