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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number: 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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Dibasic calcium phosphate, dihydrate USP</td>
<td>7789-77-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>PIIMAA</td>
<td>7440-21-3</td>
<td>231-130-8</td>
<td>*</td>
</tr>
</tbody>
</table>

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³ TWA</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³ TWA</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Magnesium stearate

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<tr>
<th>Source</th>
<th>Threshold Limit</th>
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<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
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<td>Australia TWA</td>
<td>10 mg/m³ TWA</td>
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</tbody>
</table>

Microcrystalline cellulose

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</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³ TWA</td>
</tr>
</tbody>
</table>

Iron oxide

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PIIMAA

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<td>Australia TWA</td>
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</tr>
</tbody>
</table>

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 >10µg/m³ to < 100µg/m³)

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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hands</td>
<td>Not required for the normal use of this product. Wear protective gloves when working with large quantities.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.</td>
</tr>
<tr>
<td>Skin</td>
<td>Not required for the normal use of this product. Wear protective clothing when working with large quantities.</td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>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.</td>
</tr>
</tbody>
</table>
Material Name: Nicergoline Film-Coated Tablets
Revision date: 02-Jan-2007

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablets
Molecular Formula: Mixture
Color: No data available.
Molecular Weight: 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/m³

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

Hypermellose
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
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:
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

**Hyromellose**

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
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