



MATERIAL SAFETY DATA SHEET

Revision date: 05-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 Powder and Solvent for Oral Solution

Trade Name: Sermion 10 mg/ml Powder and Solvent for Oral Solution
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 | 300 mg#### |
| Tartaric acid | 87-69-4 | 201-766-0 | * |

| Ingredient | CAS Number | EU EINECS List | % |
|---------------|------------|----------------|-------|
| Methylparaben | 99-76-3 | 202-785-7 | 0.1% |
| Water | 7732-18-5 | 231-791-2 | 99.9% |

Additional Information: * Proprietary
per vial/cartridge/ampule
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Powder / Clear, colorless liquid
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.

Additional Hazard Information:
Short Term: May be harmful if swallowed. 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: Harmful

EU Hazard Symbols:

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EU Risk Phrases:

R22 - Harmful if swallowed.

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: | 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: | Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. |
|--------------------------|---|

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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

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/m³ to < 100ug/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:

Hands: 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: Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

| | | | |
|---------------------------|-----------------|--------------------------|-------------------------------|
| Physical State: | Powder / Liquid | Color: | No data available / Colorless |
| 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)

Nicergoline

Rat Oral LD 50 1193 mg/kg

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Methylparaben

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 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.

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: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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 Symbol: 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.

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OSHA Label:

WARNING

May be 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.

Nicergoline

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

Methylparaben

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 202-785-7 |

Water

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 231-791-2 |

Tartaric acid

| | |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS List | 201-766-0 |

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. 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