# MATERIAL SAFETY DATA SHEET



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

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

## Material Name: Nicergoline Powder and Solvent for Injectable Solution and for Infusion

**Trade Name:** Sermion Powder and Solvent for Injectable Solution and for Infusion, 4 mg/2 ml, 4 mg/4 ml
**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 | 4 mg#### |
| Benzalkonium chloride | 8001-54-5 | Not listed | * |

| Ingredient | CAS Number | EU EINECS List | % |
|---|---|---|---|
| Lactose | 63-42-3 | 200-559-2 | * |
| Sodium chloride | 7647-14-5 | 231-598-3 | * |
| Water for injection | 7732-18-5 | 231-791-2 | * |
| Tartaric acid | 87-69-4 | 201-766-0 | * |

**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.

**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:** Harmful

**EU Hazard Symbols:**

**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.

**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/$m^3$ to < 100ug/$m^3$)

**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)**

**Lactose**
Rat Oral LD50 > 10 g/kg

**Sodium chloride**
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

**Benzalkonium chloride**
Rat Oral LD50 240 mg/kg

**Nicergoline**
Rat Oral LD 50 1193 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)**

**Sodium chloride**
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

**Benzalkonium chloride**
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Severe

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

**Sodium chloride**
10 Day(s) Rat Oral 12500 mg/kg LOAEL 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:** 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.

**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 |

**Lactose**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 200-559-2 |

**Sodium chloride**

| | |
|---|---|
| **Inventory - United States TSCA - Sect. 8(b)** | Present |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 231-598-3 |

**Water for injection**

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

**Benzalkonium chloride**

| | |
|---|---|
| **Australia (AICS):** | Present |

| | |
|---|---|
| **Standard for the Uniform Scheduling for Drugs and Poisons:** | Schedule 5<br>Schedule 6 |

**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 2 - Composition / Information on Ingredients. 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
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**End of Safety Data Sheet**