



SAFETY DATA SHEET

Revision date: 17-Apr-2015

Version: 2.0

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

Product Identifier

Material Name: Nicergoline Soluble Tablets

Trade Name: Sermion 30 mg Soluble Tablets

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as cognition activator

Details of the Supplier of the Safety Data Sheet

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Nicergoline	27848-84-6	248-694-6	Xn;R22	Acute Tox.4 (H302)	1-5
Tartaric acid	87-69-4	201-766-0	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Mannitol	69-65-8	200-711-8	Not Listed	Not Listed	*
Sodium bicarbonate	144-55-8	205-633-8	Not Listed	Not Listed	*
Aspartame	22839-47-0	245-261-3	Not Listed	Not Listed	*
Cherry flavor, artificial	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*
Leucine	61-90-5	200-522-0	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and bromine-containing compounds

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

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

Specific end use(s): Pharmaceutical product used as cognition activator

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium bicarbonate

Czech Republic OEL - TWA	5 mg/m ³
Latvia OEL - TWA	5 mg/m ³

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL - TWAs	1000 ppm

Leucine

Latvia OEL - TWA	5 mg/m ³
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The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

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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): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Not required for the normal use of this product. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Not required for the normal use of this product. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablets	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Mannitol

No data available

Polyethylene glycol

No data available

Sodium bicarbonate

No data available

Tartaric acid

No data available

Leucine

No data available

Aspartame

No data available

Cherry flavor, artificial

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Nicergoline

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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 therapeutic use include skin rash and gastrointestinal disturbances.

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

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

Sodium bicarbonate

Rat Oral LD50 4220 mg/kg

Mouse Oral LD50 3360mg/kg

Rat Inhalation LC50 > 900mg/m³

Nicergoline

Rat Oral LD 50 1193 mg/kg

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11. TOXICOLOGICAL INFORMATION

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

Sodium bicarbonate

Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Slight

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.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Sodium bicarbonate

Daphnia magna (Water Flea) EC50 48 Hours 2350 mg/L
Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 8250 mg/L
Gambusia affinis (Mosquitofish) LC50 96 Hours 7550 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	248-694-6

Mannitol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Sodium bicarbonate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-633-8
Aspartame	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	245-261-3
Cherry flavor, artificial	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Tartaric acid	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-766-0
Polyethylene glycol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed
Leucine	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-522-0

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

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Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 16 - Other Information.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet