



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 3.1

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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: Thiothixene capsules

Trade Name:	NAVANE®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antipsychotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Thiothixene	5591-45-7	227-001-0	0.5-5.0
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not listed	*
Starch	9005-25-8	232-679-6	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Capsules: greenish-blue/yellow or /white, orange/yellow or /white, blue/green
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
Antipsychotic drug: causes central nervous system effects

Additional Hazard Information:
Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, blood and blood forming organs.

Known Clinical Effects: As with all antipsychotic agents, tardive dyskinesia may appear. Ingestion of this material may cause effects similar to those seen in clinical use including effects on cardiovascular system, central nervous system, liver, allergic reactions, endocrine, and autonomic system. Signs and symptoms of overdosage include muscular twitching, drowsiness, dizziness, CNS depression, rigidity, weakness, deformity of the neck (torticollis), tremor, salivation, inability to swallow (dysphagia), low blood pressure, disturbance of gait, or coma. This syndrome is characterized by rhythmical involuntary movements of the tongue, face, mouth, or jaw.

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: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. Get 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, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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, skin, and clothing.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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Starch

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

The purpose of the Occupational Exposure Band (OEB) is to separate substances into different hazard categories and provide an exposure control and containment strategy for the compound as detailed in this section. The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to alteration when new information becomes available.

Thiothixene

Pfizer Occupational Exposure Band (OEB): OEB3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

Analytical Method: Analytical method available for thiothixene. Contact Pfizer Inc for further information.

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:	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:	Capsule	Color:	Greenish-blue/yellow or /white, orange/yellow or /white, blue/green
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.
Polymerization:	Will not occur

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)

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Thiothixene

Mouse Oral LD50 400 mg/kg

Rat Oral LD50 720 mg/kg

Lactose

Rat Oral LD50 > 10 g/kg

Starch

Mouse IP LD50 6600 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.

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

Thiothixene

7 Month(s) Dog Oral 50 mg/kg/day LOAEL Blood, Blood forming organs

1 Year(s) Dog Oral 25 mg/kg/day LOAEL Liver

18 Month(s) Dog Oral 25 mg/kg/day LOAEL Central Nervous System, Liver

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

Thiothixene

Prenatal & Postnatal Development Rat Oral 15 mg/kg/day NOAEL Not teratogenic

Prenatal & Postnatal Development Rabbit Oral 50 mg/kg/day NOAEL Not Teratogenic

Prenatal & Postnatal Development Monkey Oral 3 mg/kg/day NOAEL Not Teratogenic

Fertility and Embryonic Development Mouse Oral 540 mg/kg/day LOAEL Fetotoxicity, Reproductive toxicity

Fertility and Embryonic Development Rabbit Oral 810 mg/kg/day LOAEL Fetotoxicity, Fertility

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

The environmental characteristics of this material have not been fully evaluated. 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.

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15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

WARNING

May be harmful if swallowed.

Antipsychotic drug: causes central nervous system effects

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.

Thiothixene

EU EINECS List	227-001-0
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Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Lactose

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

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

Prepared by:

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

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End of Safety Data Sheet