# SAFETY DATA SHEET

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

**Product Identifier**

- **Material Name:** Thiothixene capsules
- **Trade Name:** NAVANE®
- **Chemical Family:** Mixture

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

**Intended Use:** Pharmaceutical product used as antipsychotic

**Details of the Supplier of the Safety Data Sheet**

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-800-879-3477</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Emergency telephone number:</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>CHEMTREC (24 hours): 1-800-424-9300</td>
<td>Emergency telephone number:</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td>International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

**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**

- **Australian Hazard Classification (NOHSC):**

**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**
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiothixene</td>
<td>5591-45-7</td>
<td>227-001-0</td>
<td>Xn;R22</td>
<td>Acute Tox.4(H302)</td>
<td>0.5-5.0</td>
</tr>
<tr>
<td>Magnesium stearate/sodium lauryl sulfate blend</td>
<td>MIXTURE</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Lactose 63-42-3 200-559-2 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.

4. FIRST AID MEASURES

Description of 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. |

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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

| Hazardous Combustion Products: | Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds. |

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

Advice for Fire-Fighters

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

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

Specific end use(s): Pharmaceutical product used as antipsychotic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
          5 mg/m³
Ireland OEL - TWAs 10 mg/m³
          4 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 3 mg/m³

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.

Thiothixene
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


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: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory Protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Capsule

Color: Greenish-blue/yellow or white, orange/yellow or white, blue/green

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)

Thiothixene

No data available

Lactose

No data available

Starch

No data available

Magnesium stearate/sodium lauryl sulfate blend

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 (°C): No data available

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

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

Polymerization: Will not occur

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: None known
   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.
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.

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
<th>LOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>400 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>720 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>LOAEL</td>
<td>Blood, Blood forming organs</td>
</tr>
<tr>
<td>1 Year(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>18 Month(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>LOAEL</td>
<td>Central Nervous System, Liver</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>15 mg/kg/day</td>
<td>NOAEL</td>
<td>Not teratogenic</td>
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<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>50 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Monkey</td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Fertility and Embryonic Development</td>
<td>Mouse</td>
<td>Oral</td>
<td>540 mg/kg/day</td>
<td>NOAEL</td>
<td>Fetotoxicity, Reproductive toxicity</td>
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<tr>
<td>Fertility and Embryonic Development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>810 mg/kg/day</td>
<td>NOAEL</td>
<td>Fetotoxicity, Fertility</td>
</tr>
</tbody>
</table>

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
11. TOXICOLOGICAL INFORMATION

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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.
15. REGULATORY INFORMATION

Thiothixene

<table>
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<tr>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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</tr>
<tr>
<td>California Proposition 65</td>
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Magnesium stearate/sodium lauryl sulfate blend

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<tr>
<td>California Proposition 65</td>
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</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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Lactose

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<td>EU EINECS/ELINCS List</td>
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</tbody>
</table>

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.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 03-Apr-2015

Prepared by: Product Stewardship Hazard Communication

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet