



MATERIAL SAFETY DATA SHEET

Revision date: 09-Feb-1998

Version: 2.0

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

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Material Name: Thiothixene hydrochloride for intramuscular injection

Trade Name: Not determined
Synonyms: NAVANE® intramuscular for injection , cis-N,N-dimethyl-9-[3-(4-methyl-1-piperazinyl)-propylidene]thioxanthene-2-sulfonamide
Chemical Family: Thioxanthenes, Psychotropics
Intended Use: antipsychotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Thiothixene hydrochloride	22189-31-7	Not listed	*

Ingredient	CAS Number	EU EINECS List	%
Mannitol	69-65-8	200-711-8	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: White powder, lyophilized
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause central nervous system effects and blood disorders May cause liver toxicity

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.

Skin Contact: None known

Inhalation: May cause nose, throat and lung irritation. May cause allergic reaction.

Ingestion: None known

Known Clinical Effects: 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. As with all antipsychotic agents, tardive dyskinesia may appear. Signs and symptoms of overdose 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.

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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. If irritation occurs or persists, 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, hydrogen chloride and other chlorine- and 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: 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 the spill or leak. Wipe up with a damp cloth and place in container for disposal. 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: Review Sections 3, 8 and 12 before proceeding with clean up. Vacuum or sweep material into appropriate recovery container. Close container and move it to a secure holding area.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use only in a well-ventilated area. Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing dust.

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

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Storage Temperature 15-25°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands: None required under normal and foreseeable conditions of use.
Eyes: Not required under normal conditions of use.
Skin: None required under normal and foreseeable conditions of use.
Respiratory protection: None required under normal conditions of use. Use dust mask for dusty conditions.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Powder	Color:	White
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Oxidizers

Hazardous Decomposition Products: No data available See Section 5 - under Hazardous combustion products.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

NTP:	Not classified
IARC:	Not classified
OSHA:	No

Mannitol

Rat	Oral	LD 50	13500 mg/kg
Mouse	Oral	LD 50	22g/kg

Thiothixene hydrochloride

Mouse	Oral	LD50	203 mg/kg
Rat	Oral	LD50	> 100mg/kg

Ingestion Acute Toxicity

The acute oral LD50 for the active ingredient is listed in the table, above. While this formulation has not been tested as a whole, it would not be expected to be acutely toxic by ingestion based on the amount of the active ingredient(s) it contains.

Subchronic Effects

A five day intramuscular (IM) toxicity study in rats at dose levels up to 50 mg/kg/day showed irritation, producing muscle necrosis with localized swelling. There were no other drug-related gross or histopathologic changes.

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Chronic Toxicity	Chronic toxicity was evaluated in dogs at oral doses up to 25 mg/kg/day for one year. High dose animals showed the following liver changes: slight intrahepatic cholestasis, mild central degeneration and/or necrosis with increased accumulation of hepatocellular inclusion bodies. An 18-month feeding toxicity study in rats showed ptosis (drooping of the upper eyelid) and depression of weight gain at 25 and 50 mg/kg/day dose levels. At 100 mg/kg/day, rats showed liver changes.
Chronic Effects/Carcinogenicity	No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.
Reproductive Effects	No drug-related abnormalities were observed in the offspring of rats, rabbits, or monkeys. However, there was a reduction in conception rate, litter size, and number of resorption sites in a fertility and reproductive toxicity studies in rats and rabbits.
Teratogenicity	No teratogenic effects were observed in rats (5 to 15 mg/kg/day), rabbits (3 to 50 mg/kg/day) or monkeys (1 to 3 mg/kg/day). Liver Central nervous system
Carcinogen Status:	Not listed as a carcinogen by IARC, NTP or US OSHA.
At increase risk from exposure:	Individuals who have shown hypersensitivity to this drug or other materials in its chemical class and individuals with circulatory collapse, comatose states, liver dysfunction, central nervous system depression due to any cause, or blood disorder may be susceptible to toxicity in cases of overexposure.
Additional Information:	Alcohol or central nervous system depressants may produce additive effects.

12. ECOLOGICAL INFORMATION

Environmental Overview: No environmental effects data are available.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Thiothixene hydrochloride for intramuscular injection

15. REGULATORY INFORMATION

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OSHA Label:

WARNING

Harmful if swallowed.

May cause central nervous system effects and blood disorders May cause liver toxicity

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

Mannitol

EU EINECS List

200-711-8

Inventory - United States TSCA - Sect. 8(b)

Listed

16. OTHER INFORMATION

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

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