



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Phenelzine Sulfate Tablets

Trade Name:	NARDIL®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antidepressant

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium stearate	557-04-0	209-150-3	*
Phenelzine hydrogen sulphate	156-51-4	205-856-0	9.9

Ingredient	CAS Number	EU EINECS List	%
Povidone	9003-39-8	Not listed	*
Mannitol	69-65-8	200-711-8	*
Opadry orange	NOT ASSIGNED	Not listed	*
Croscarmellose sodium	74811-65-7	Not listed	*
Edetate disodium	139-33-3	205-358-3	*
Simethicone emulsion	67762-90-7	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Orange film-coated tablets
Signal Word: WARNING

Statement of Hazard: May cause nervous system, cardiovascular system and reproductive effects

Additional Hazard Information:

Short Term: Active ingredient may be harmful if swallowed.

Known Clinical Effects: Clinical use may cause an increase in blood pressure (hypertension). Dry mouth, increased sweating, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Can produce impotence and other sexual disturbances in men.

EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:

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EU Risk Phrases:

R60 - May impair fertility.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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:	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
Skin Contact:	Remove contaminated clothing and wash the affected area with soap and water. Seek medical attention if unusual symptoms occur.
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:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.
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.
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Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Phenelzine hydrogen sulphate

Pfizer OEL TWA-8 Hr: 0.05 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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: 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:	Film-coated tablets	Color:	Orange
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.

Hazardous Decomposition Products: Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur.

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)

Phenelzine hydrogen sulphate

Rat	Oral	LD50	210 mg/kg
Mouse	Oral	LD50	156 mg/kg

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Povidone

Rat Oral LD50 100 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/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.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Phenelzine hydrogen sulphate

Reproductive & Fertility Mouse Subcutaneous 25 mg/kg/day Fertility, Not teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Phenelzine hydrogen sulphate

Sister Chromatid Exchange Mouse Bone Marrow Positive

Direct DNA Damage Mouse Positive

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Phenelzine hydrogen sulphate

100 Week(s) Mouse Female Oral 0.015 % Malignant tumors, Lungs, Blood vessels

110 Week(s) Mouse Male Oral 0.015 % Benign tumors, Lungs

Carcinogen Status:

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

Phenelzine hydrogen sulphate

IARC: Group 3

Povidone

IARC: Group 3

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.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1
EU Risk Phrases: R60 - May impair fertility.
EU Safety Phrases: S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause nervous system, cardiovascular system and reproductive effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

Croscarmellose sodium

Australia (AICS):	Present
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Edetate disodium

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-358-3

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
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Australia (AICS):	Present
EU EINECS List	209-150-3
Simethicone emulsion	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Phenelzine hydrogen sulphate	
Australia (AICS):	Present
EU EINECS List	205-856-0

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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