



MATERIAL SAFETY DATA SHEET

Revision date: 09-Feb-2011

Version: 2.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Phenzelzine Sulfate Tablets

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

2. HAZARDS IDENTIFICATION

Appearance: Orange film-coated tablets
Signal Word: WARNING

Statement of Hazard: May damage fertility.

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:



EU Risk Phrases:

R60 - May impair fertility.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Phenelzine hydrogen sulphate	156-51-4	205-856-0	Xn;R22 T;Repr.Cat1;R60	9.9

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

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.
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.

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.
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- 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:** 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). Wash hands and any exposed skin after removal of PPE. 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.
- Storage Conditions:** Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Phenzine hydrogen sulphate

Pfizer OEL TWA-8 Hr:	50µg/m ³
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- Analytical Method:** Analytical method available for Phenzine Sulfate. Contact Pfizer Inc for further information.
- 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.
- Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.
- 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Film-coated tablets	Color:	Orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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)

Phenzelzine hydrogen sulphate

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

Povidone

Rat Oral LD50 100 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Edetate disodium

Rat Oral LD50 2000-2200 mg/kg

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))

Phenzelzine hydrogen sulphate

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

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

Phenzelzine hydrogen sulphate

Sister Chromatid Exchange Mouse Bone Marrow Positive
In Vivo Direct DNA Damage Mouse Negative
Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Positive without activation

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11. TOXICOLOGICAL INFORMATION

In Vitro Unscheduled DNA Synthesis Rat Hepatocyte Negative
In Vitro Unscheduled DNA Synthesis Mouse Hepatocytes Negative

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

Phenzelzine 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

Phenzelzine 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

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

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:
R60 - May impair fertility.

EU Safety Phrases:

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15. REGULATORY INFORMATION

S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May damage fertility.

Canada - WHMIS: Classifications

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



Povidone

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

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Edetate disodium

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

Croscarmellose sodium

Australia (AICS):	Listed
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Simethicone emulsion

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

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

Phenzelzine hydrogen sulphate

Australia (AICS):	Listed
EU EINECS/ELINCS List	205-856-0

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R60 - May impair fertility.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 11 - Toxicology Information.

Prepared by: Product Stewardship Hazard Communications
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