



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2010

Version: 2.7

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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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

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CT13 9NJ
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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Procardia® XL (Nifedipine) tablets

Trade Name: Procardia; Procardia XL
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

2. HAZARDS IDENTIFICATION

Appearance: Round, biconvex, rose-pink film coated tablets

Additional Hazard Information:

Short Term: Dust may cause irritation . May be harmful if swallowed. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Exposure to sunlight following contact may result in skin reactions. Antihypertensive drug: has blood pressure-lowering properties

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Nifedipine	21829-25-4	244-598-3	Xn;R22	11
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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Cellulose Acetate	9004-70-0	Not listed	Not Listed	*
Opadry YS-5-7017	NOT ASSIGNED	Not listed	Not Listed	*
Polyethylene oxide NF	25322-68-3	Not listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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.

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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. Releases to the environment should be avoided. 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 at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Nifedipine

Pfizer OEL TWA-8 Hr: 300µg/m³

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	1 mg/m ³ TWA
	5 mg/m ³ TWA
Australia TWA	1 mg/m ³
	5 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	1.5 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	10 mg/m ³
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Polyethylene oxide NF

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

Polyethylene glycol

Austria OEL - MAKs	Listed
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

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

Sodium chloride

Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

Analytical Method:

Analytical method available for Nifedipine. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	Rose-pink
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

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

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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)

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Nifedipine

Mouse Oral LD50 454 mg/kg

Rat Oral LD50 1022 mg/kg

Mouse IV LD50 4.2 mg/kg

Rat IV LD50 15.5 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene glycol

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Polyethylene oxide NF

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

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

Nifedipine

13 Week(s) Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose

13 Week(s) Dog Oral 50 mg/kg/day NOAEL No effects at maximum dose

4 Week(s) Dog Oral 125 mg/kg/day NOAEL No effects at maximum dose

4 Week(s) Dog Intravenous 0.6 mg/kg/day NOAEL No effects at maximum dose

1 Year(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose

Subchronic intravenous and oral toxicity studies revealed no drug-related effects in general behavior, clinical laboratory tests, gross necropsy, or histopathology in any of the dog and rat studies. Oral doses administered demonstrated nifedipine to be without significant toxic effects at doses up to 100 - 125 mg/kg/day.

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

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11. TOXICOLOGICAL INFORMATION

Nifedipine

Reproductive & Fertility	Rat	Oral 3 mg/kg/day	NOAEL	Reproductive toxicity, Embryotoxicity, Postnatal mortality, Maternal toxicity
Peri-/Postnatal Development	Rat	Oral 4 mg/kg/day	NOAEL	Reproductive toxicity, Fetotoxicity, Maternal Toxicity
Peri-/Postnatal Development	Rat	Oral 3 mg/kg/day	NOAEL	Embryotoxicity
Embryo / Fetal Development	Rat	Oral 10 mg/kg/day	NOAEL	Maternal Toxicity, Fetotoxicity, Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral 10 mg/kg/day	LOAEL	Developmental toxicity

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

Nifedipine

In Vivo Dominant Lethal Assay	Mouse	Negative
In Vivo Cytogenetics	Hamster	Negative
In Vivo Micronucleus	Mouse	Negative
Bacterial Mutagenicity (Ames)	Salmonella	Negative

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

Nifedipine

2 Year(s)	Rat	Oral 156-210 mg/kg/day	NOAEL	Not carcinogenic
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Carcinogen Status:

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

Ferric oxide red

IARC:

Group 3

12. ECOLOGICAL INFORMATION

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

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Nifedipine

Brachydanio rerio (Zebra fish)	LC50	96 Hours	> 5.77 mg/L
Daphnia magna (Water Flea)	EC50	48 Hours	> 3.88 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Nifedipine

Activated sludge	EC50	0.5 Hours	> 10000 mg/L
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13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

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.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

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.

Nifedipine

California Proposition 65

developmental toxicity, initial date 1/29/99
female reproductive toxicity, initial date 1/29/99
male reproductive toxicity, initial date 1/29/99

Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:
EU EINECS/ELINCS List

Listed
Schedule 4
244-598-3

Cellulose Acetate

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

Listed
Listed

Ferric oxide red

Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Standard for the Uniform Scheduling
for Drugs and Poisons:

Listed
Listed
Schedule 2
Schedule 4
Schedule 5
Schedule 6
215-168-2

EU EINECS/ELINCS List

Polyethylene oxide NF

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

Listed
Listed

Polyethylene glycol

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Hydroxypropyl methylcellulose	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3
Sodium chloride	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-598-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
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