MATERIAL SAFETY DATA SHEET

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

Pfizer Ltd
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Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Diltiazem Hydrochloride Film Coated Tablets - 90 mg

Trade Name: Dilzem
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for angina, high blood pressure (hypertension)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Diltiazem Hydrochloride	33286-22-5	251-443-3	19.72
Titanium dioxide	13463-67-7	236-675-5	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Lactose Monohydrate	64044-51-5	Not listed	*
Stearic acid	57-11-4	200-313-4	*
Hypromellose	9004-65-3	Not listed	*
Macrogol 6000	Not assigned	Not listed	*
Silicone antifoam agent	Not assigned	Not listed	*
Hydrogenated castor oil	8001-78-3	232-292-2	*
Water, purified	7732-18-5	231-791-2	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May cause harm to the unborn child.

Additional Hazard Information:

Short Term:	Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
Long Term:	Animal studies indicate that this material may cause adverse effects on the fetus.
Known Clinical Effects:	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.
EU Indication of danger:	Toxic to Reproduction: Category 2

EU Hazard Symbols:

EU Risk Phrases:

R61 - May cause harm to the unborn child.

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:	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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:	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.

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. Minimize dust generation and accumulation. Use with adequate ventilation.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Diltiazem Hydrochloride

Pfizer OEL TWA-8 Hr:	1.0 mg/m³

Titanium dioxide

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA	
ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA	
Australia TWA	= 2.5 mg/m^3 TWA	containing no asbestos fibers

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

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

Analytical Method: Analytical method available for Diltiazem Hydrochloride. 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.

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: Tablet **Color:** No data available.

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.

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Diltiazem Hydrochloride
Rat Oral LD50 560 mg/kg
Rat Intravenous LD50 38 mg/kg
Rat Subcutaneous LD50 520 mg/kg
Mouse Oral LD50 508 mg/kg
Mouse Intravenous LD50 58 mg/kg

Lactose Monohydrate
Rat Oral LD 50 29700 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Carboxymethylcellulose sodium
Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Hypromellose
Rat Oral LD50 > 10,000 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)

Stearic acid
Skin Irritation Rabbit Mild

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

Carboxymethylcellulose sodium
13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

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

Diltiazem Hydrochloride
Reproductive & Fertility Rat Oral 100 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Mouse Oral 25 mg/kg LOAEL Embryotoxicity
Embryo / Fetal Development Rat Intraperitoneal 80 mg/kg LOAEL Embryotoxicity, Teratogenic
Embryo / Fetal Development Rabbit Intraperitoneal 125 mg/kg LOAEL Fetotoxicity, Teratogenic

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

Diltiazem Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
In Vivo Mammalian Cell Mutagenicity Negative
In Vitro Mammalian Cell Mutagenicity Negative

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

Diltiazem Hydrochloride
21 Month(s) Mouse Oral 30 mg/kg/day NOAEL Not carcinogenic
24 Month(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: See below

Talc (non-asbestiform)
IARC: Group 3

Titanium dioxide
IARC: Group 2B
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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 2

EU Risk Phrases:
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause harm to the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
D2a very toxic materials

Diltiazem Hydrochloride

California Proposition 65	Listed - Developmental Toxicity
Australia (AICS):	Present
EU EINECS List	251-443-3

Lactose Monohydrate

Australia (AICS):	Present

Stearic acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-313-4

Hypromellose

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

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Hydrogenated castor oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-292-2

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Magnesium stearate

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

Carboxymethylcellulose sodium

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

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet