



MATERIAL SAFETY DATA SHEET

Revision date: 09-Jun-2005

Version: 1.0

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

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

Material Name: Diltiazem Hydrochloride Film Coated Tablets - 120 and 180 mg

Trade Name: Not determined
Synonyms: None
Chemical Family: Calcium channel blocker
Intended Use: Antianginal; antihypertensive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Diltiazem Hydrochloride	33286-22-5	251-443-3	26.44-39.32
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Titanium dioxide	13463-67-7	236-675-5	*
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	*
Hydroxypropyl methylcellulose	9004-65-3	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Macrogol 6000	Not assigned	Not listed	*
Silicone antifoam agent S 184	Not assigned	Not listed	*
Water, purified	7732-18-5	231-791-2	*
Hydrogenated castor oil	8001-78-3	232-292-2	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Tablet
Signal Word: WARNING

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

Eye Contact: None known; however, direct contact with any foreign material may cause eye irritation.
Skin Contact: No data available

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Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

Ingestion: May be harmful if swallowed (based on animal data).

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.

Potential Health Effects: Animal studies have shown a potential to cause adverse effects on the fetus. 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.

EU Indication of danger: Harmful
Toxic to Reproduction: Category 2



R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

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. 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. 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: 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.

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Measures for Cleaning / Collecting: 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: Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust. Transfer all waste to a labeled container and move it to a secure holding area.

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

Talc (non-asbestiform)
OSHA - Final PELs - Table Z-3 Mineral D TWA-20 mppcf
ACGIH Threshold Limit Value (TWA) 2 mg/m³ TWA

Titanium dioxide
OSHA - Final PELs - TWAs 15 mg/m³ total dust
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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: Tablets
Color: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

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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: 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 > 5000mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Carboxymethylcellulose sodium

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

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Magnesium stearate

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

Stearic acid

Skin Irritation Rabbit Mild

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

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Embryo / Fetal Development Rabbit Intraperitoneal 125 mg/kg LOEL Fetotoxicity, Teratogenic

Carboxymethylcellulose sodium

Reproductive & Fertility-Males Rat Oral =140 mg/kg LOEL Fertility

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 NOEL Not carcinogenic

24 Month(s) Rat Oral 100 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: See below

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Labeling: T
EU Indication of danger: Harmful
Toxic to Reproduction: Category 2

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EU Risk Phrases:

R22 - Harmful if swallowed.
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

EU EINECS List

Listed - Developmental Toxicity
251-443-3

Stearic acid

EU EINECS List

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

200-313-4
Listed

Talc (non-asbestiform)

EU EINECS List

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

238-877-9
Listed

Hydroxypropyl methylcellulose

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

Listed

Carboxymethylcellulose sodium

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

Listed

Titanium dioxide

EU EINECS List

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

236-675-5
Listed

Magnesium stearate

EU EINECS List

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

209-150-3
Listed

Water, purified

EU EINECS List

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

231-791-2
Listed

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Hydrogenated castor oil

EU EINECS List

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

232-292-2

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 warranty of any kind, expressed or implied.

End of Safety Data Sheet