



MATERIAL SAFETY DATA SHEET

Revision date: 13-Dec-2006

Version: 2.0

Page 1 of 7

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

Pfizer Ltd
Ramsgate Road
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: Polythiazide tablets (2 mg)

Trade Name: RENESE(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as diuretic, antihypertensive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Polythiazide	346-18-9	206-468-4	0.5
Magnesium stearate	557-04-0	209-150-3	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Starch	9005-25-8	232-679-6	*

Ingredient	CAS Number	EU EINECS List	%
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	*
Polyethylene glycol	25322-68-3	Not listed	*
Lactose	63-42-3	200-559-2	*
Vanillin	121-33-5	204-465-2	*
FD&C Yellow No. 10	Not assigned	Not listed	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*

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

3. HAZARDS IDENTIFICATION

Appearance: Yellow tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Can cause effects on gastrointestinal tract, cardiovascular system, and central nervous system.

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 2 of 7
Version: 2.0

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal system, central nervous system, blood, and cardiovascular system. Signs and symptoms might include nausea, vomiting, cramps, dizziness, headache, vertigo, low blood pressure on standing, rash, urticaria, photosensitivity, electrolyte imbalance, muscle spasm, weakness, and restlessness.

EU Indication of danger: Not classified

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: Wash skin with soap and water. If irritation occurs or persists, get 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, hydrogen chloride and other chlorine-, fluorine-, and sulfur-containing compounds

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.

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 3 of 7
Version: 2.0

Storage Conditions: Store as directed by product packaging.

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

Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Polythiazide

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: 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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	Yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: None known

Hazardous Decomposition Products: See Section 5 - under Hazardous combustion products.

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 4 of 7
Version: 2.0

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient and/or of a chemically-related material. The remaining information describes the potential hazards of the individual ingredients.

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

Lactose

Rat Oral LD50 > 10 g/kg

Starch

Mouse IP LD50 6600 mg/kg

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg

Mouse Oral LD50 > 6,000 mg/kg

Polythiazide

Mouse Oral LD50 > 5000 mg/kg

Rat Intraperitoneal LD50 400 mg/kg

Dog Oral LD50 450 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg

Rat Intraperitoneal LD 50 210 mg/kg

Vanillin

Rat Oral LD 50 1580 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

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

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

Chlorothiazide

Reproductive & Fertility-Females Rat No route specified 60 mg/kg NOAEL No effects at maximum dose

Reproductive & Fertility-Males Rat No route specified 40 mg/kg NOAEL No effects at maximum dose

Embryo / Fetal Development Rabbit No route specified 50 mg/kg NOAEL No effects at maximum dose

Embryo / Fetal Development Rat No route specified 60 mg/kg No effects at maximum dose

Embryo / Fetal Development Mouse No route specified 500 mg/kg NOAEL No effects at maximum dose

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 5 of 7
Version: 2.0

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

Chlorothiazide

Bacterial Mutagenicity (Ames) Bacteria Negative

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

Chlorothiazide

18 Month(s) Rat No route specified 2850 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

FD&C Yellow No. 6; (Sunset yellow)

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: 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 Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 6 of 7
Version: 2.0

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.

Polythiazide

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	206-468-4

Calcium phosphate dibasic, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-826-1

Magnesium stearate

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

Polyethylene glycol

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

Sodium Lauryl Sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Vanillin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-465-2

FD&C Yellow No. 6; (Sunset yellow)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients.

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

MATERIAL SAFETY DATA SHEET

Material Name: Polythiazide tablets (2 mg)
Revision date: 13-Dec-2006

Page 7 of 7
Version: 2.0

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