



MATERIAL SAFETY DATA SHEET

Revision date: 17-Jan-2007

Version: 1.1

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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

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: Ethacrynic Acid Tablets

Trade Name: Reomax
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as diuretic.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ethacrynic Acid	58-54-8	200-384-1	33
Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver (based on components) .

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include loss of appetite (anorexia), abdominal pain, changes in electrolytes, inability to swallow (dysphagia), nausea, vomiting, thirst, diarrhea. Clinical use has resulted in liver effects. Symptoms may include jaundice, liver function test abnormalities, and hepatitis. May cause adverse effects on the kidney. Other less common effects include allergic reaction, effects on hearing, vision. Drowsiness, fatigue, or headache are also possible.

EU Indication of danger: Harmful

EU Hazard Symbols:

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EU Risk Phrases:

R22 - Harmful if swallowed.

Australian Hazard Classification (NOHSC):

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 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:

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

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:

May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-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.

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7. HANDLING AND STORAGE

General Handling: Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch

OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA	total
	= 5 mg/m ³ TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	
Australia TWA	= 10 mg/m ³ TWA	

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.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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:	Not required for the normal use of this product. 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:	Not applicable
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None for the normal use of this material
Incompatible Materials: Incompatible with acids.

11. TOXICOLOGICAL INFORMATION

General Information: The information in this section describes the potential hazards of the individual ingredients and the formulation.

Product Level Toxicity Data

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Repeated Dose Toxicity

Duration	Species	Route	Dose (mg/kg/day)	End Point	Target Organ(s)
6 Month(s)	Mouse	Oral	10 mg/kg	NOAEL	None identified

Ingredients:

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

Ethacrynic Acid

Mouse	Oral	LD 50	627 mg/kg
Rat	Oral	LD 50	1000 mg/kg
Mouse	IV	LD50	175 mg/kg
Rat	IP	LD50	43 mg/kg
Guinea pig	Intravenous	Maximally Symptomatic Dose	80 mg/kg

Lactose

Rat	Oral	LD50	> 10 g/kg
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Magnesium stearate

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

Starch

Mouse	IP	LD50	6600 mg/kg
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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.

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

Ethacrynic Acid

21 Day(s)	Mouse	Oral	100 mg/kg/day	LOAEL	Liver
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Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ethacrynic Acid

Embryo / Fetal Development	Rat	No route specified	100 mg/kg	NOAEL	Not teratogenic
Fertility and Embryonic Development	Rat	No route specified	20 mg/kg/day	NOAEL	No effects at maximum dose
Fertility and Embryonic Development	Dog	No route specified	5 mg/kg/day	NOAEL	No effects at maximum dose

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

Ethacrynic Acid

79 Week(s)	Rat	No route specified	45 times human dose	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.

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

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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: Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.

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.

Ingredients:

Ethacrynic Acid	
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-384-1

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Starch

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

Lactose

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

Magnesium stearate

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

16. OTHER INFORMATION

Reasons for Revision: Updated Section 10 - Stability and Reactivity.

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

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