MATERIAL SAFETY DATA SHEET

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: Ethacrynate Sodium Powder for Solution for Injection

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ethacrynate Sodium	Not assigned	Not listed	5

Ingredient	CAS Number	EU EINECS List	%
Glucose	50-99-7	200-075-1	*
Mannitol	69-65-8	200-711-8	*

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

3. HAZARDS IDENTIFICATION

Appearance: Powder for reconstitution plus sterile diluent
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: 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 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.

7. HANDLING AND STORAGE

General Handling: Avoid generating airborne dust. When handling, use proper personal protective equipment as specified in Section 8.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

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

Personal Protective Equipment:

Hands: Chemical protective gloves
Eyes: Safety glasses or goggles
Skin: Wear protective clothing when working with large quantities.
Respiratory protection: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Powder plus sterile diluent	**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.

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

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

Mannitol
Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

Glucose
Rat Oral LD50 25800 mg/kg

Ethacrynate Sodium
Mouse Oral LD 50 627
Rat Oral LD 50 1000
Mouse IV LD50 175
Rat IP LD50 43
Guinea pig Intravenous Maximally Symptomatic Dose 80

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

Ethacrynate Sodium
21 Day(s) Mouse Oral 100 mg/kg/day LOAEL Liver

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

Ethacrynate Sodium
Embryo / Fetal Development Rat No route specified 100 mg/kg/day 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))

Ethacrynate Sodium
79 Week(s) Rat No route specified 45 times human dose NOAEL Not carcinogenic

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.

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:
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.

Glucose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-075-1

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-711-8

16. OTHER INFORMATION

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

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

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End of Safety Data Sheet