



MATERIAL SAFETY DATA SHEET

Revision date: 03-Dec-2007

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: Urological Solution for Irrigation

Trade Name: Not established
Chemical Family: Mixture
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution

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

Additional Hazard Information:

Short Term: May cause eye irritation (based on components).
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Magnesium oxide	1309-48-4	215-171-9	Not Listed	*
SODIUM CARBONATE	497-19-8	207-838-8	Xi;R36	*
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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: Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

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 spill with absorbent material. 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 breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Magnesium oxide

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Austria OEL - MAKs	= 6 mg/m ³ MAK
Belgium OEL - TWA	= 10 mg/m ³ TWA
Bulgaria OEL - TWA	= 10.0 mg/m ³ TWA
Czech Republic OEL - TWA	= 5 mg/m ³ TWA
Denmark OEL - TWA	= 6 mg/m ³ TWA
Estonia OEL - TWA	= 0.5 mg/m ³ TWA
	= 1 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Greece OEL - TWA	= 10 mg/m ³ TWA
	= 5 mg/m ³ TWA
Hungary OEL - TWA	= 6 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
	= 5 mg/m ³ TWA
Lithuania OEL - TWA	= 4 mg/m ³ IPRV
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
Poland OEL - TWA	= 10 mg/m ³ NDS
	= 5 mg/m ³ NDS
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 5 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

SODIUM CARBONATE

Romania OEL - TWA	= 1 mg/m ³ TWA
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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:	Wear impervious gloves.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear impervious protective clothing to prevent skin contact.
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:	Liquid	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

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

Citric acid, anhydrous
Rat Oral LD50 3000 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Citric acid, anhydrous
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

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EU Indication of danger: Not classified

OSHA Label:

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

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.

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Magnesium oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-171-9

SODIUM CARBONATE

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	207-838-8

Citric acid, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.

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Data Sources: Publicly available toxicity information.

Reasons for Revision: New data sheet.

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

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End of Safety Data Sheet