



MATERIAL SAFETY DATA SHEET

Revision date: 01-Dec-2007

Version: 1.0

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

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

Material Name: Chlorhexidine Aqueous Irrigations 0.1% w/v

Trade Name: Not established
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as disinfectant, antiseptic

2. HAZARDS IDENTIFICATION

Appearance: Clear blue liquid

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	%
Methylene Blue	61-73-4	200-515-2	Xn;R22	0-0.01
Chlorhexidine Gluconate	18472-51-0	242-354-0	Xn;R22	0-1

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water for injection	7732-18-5	231-791-2	Not Listed	*
Nonoxynol-9	26027-38-3	Not listed	Not Listed	0-0.01

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, nitrogen and products of chlorine.

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

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. 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: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Liquid	Color:	Blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Water solubility:	23 mg/L@37C		
Vapor Pressure (kPa):	17.535 mmHg@20C		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None
Incompatible Materials: Strong oxidizing agents, strong bases

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)

Chlorhexidine Gluconate

Rat Oral LD50 2000 mg/kg
Rat Intravenous LD50 24.2 mg/kg
Mouse Oral LD50 1260 mg/kg
Mouse Intravenous LD50 12.9 mg/kg

Methylene Blue

Rat Oral LD50 1180 mg/kg

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

Chlorhexidine Gluconate

Eye Irritation Rabbit Moderate

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

Chlorhexidine Gluconate

Embryo / Fetal Development Rat Oral 68 mg/kg/day NOAEL Not teratogenic

Methylene Blue

Fertility and Embryonic Development Rat Oral 125 mg/kg/day NOAEL Developmental toxicity

Fertility and Embryonic Development Rat Oral 50 mg/kg/day LOAEL Maternal Toxicity

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

Chlorhexidine Gluconate

In Vivo Cytogenetics Hamster Negative

In Vivo Dominant Lethal Assay Mouse Negative

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

EU Indication of danger:

Not classified

OSHA Label:

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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

Methylene Blue

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5 Schedule 7
EU EINECS/ELINCS List	200-515-2

Chlorhexidine Gluconate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	242-354-0

Nonoxynol-9

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

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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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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet