



# MATERIAL SAFETY DATA SHEET

Revision date: 27-Jun-2012

Version: 2.0

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

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International CHEMTREC (24 hours): +1-703-527-3887

**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	EU 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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
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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.

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### 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. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Chlorhexidine Gluconate

**Pfizer Occupational Exposure Band (OEB):** OEB 4 (control exposure to the range of 1ug/m<sup>3</sup> to <10ug/m<sup>3</sup>)

**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. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**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

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

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

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### 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	Para-periosteal	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
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#### 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
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##### **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**

<i>In Vivo</i> Cytogenetics	Hamster	Negative
<i>In Vivo</i> 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

#### **Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

##### 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.

#### 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

#### 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

#### Chlorhexidine Gluconate

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

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	242-354-0
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#### Nonoxynol-9

Inventory - United States TSCA - Sect. 8(b)	Present
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Australia (AICS):	Present
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### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

**Data Sources:** Publicly available toxicity information.

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**