



# MATERIAL SAFETY DATA SHEET

Revision date: 03-Jun-2008

Version: 1.1

Page 1 of 9

## 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: Chlorhexidine in Alcohol 70%

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

## 2. HAZARDS IDENTIFICATION

**Appearance:** Red liquid  
**Signal Word:** WARNING

**Statement of Hazard:** Flammable liquid and vapor.  
Causes severe eye irritation.  
May cause drowsiness or dizziness.

**Additional Hazard Information:**

<b>Short Term:</b>	May cause mild skin irritation (based on animal data). Exposure to high concentrations of gas, vapor, or mist may cause irritation.
<b>Long Term:</b>	Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and, if ingested during pregnancy, congenital malformations.

**EU Indication of danger:** Flammable

**EU Hazard Symbols:**



**EU Risk Phrases:**

R11 - Highly flammable.

**Australian Hazard Classification (NOHSC):**

Dangerous Goods. Hazardous Substance.

# MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 2 of 9  
Version: 1.1

## 2. HAZARDS IDENTIFICATION

**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	%
ETHANOL	64-17-5	200-578-6	F;R11	60-100
Chlorhexidine Gluconate	18472-51-0	242-354-0	Xn;R22	0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Water	7732-18-5	231-791-2	Not Listed	*
Amaranth	915-67-3	213-022-2	Not Listed	*
Carmoisine red E122	3567-69-9	222-657-4	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 with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Water spray, carbon dioxide, dry chemical or foam.

**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.

## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 3 of 9  
Version: 1.1

---

**Fire / Explosion Hazards:** Flammable liquid and vapor. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

**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:** Use only in a well-ventilated area. 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. Keep away from heat, sparks, flame and all other sources of ignition. Releases to the environment should be avoided.

**Storage Conditions:** Store in a cool, dry, well-ventilated area. Keep away from heat, sparks, flame, and other sources of ignition. Keep container tightly closed when not in use.

## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 4 of 9  
Version: 1.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### ETHANOL

ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m <sup>3</sup> TWA
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany - TRGS 900 - TWAs	= 500 ppm TWA = 960 mg/m <sup>3</sup> TWA
Germany (DFG) - MAK	= 500 ppm MAK = 960 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	= 1000 ppm TWA = 1900 mg/m <sup>3</sup> TWA
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	= 1000 ppm TWA = 1900 mg/m <sup>3</sup> TWA
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	= 1000 mg/m <sup>3</sup> LLV = 500 ppm LLV

#### 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.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### Hands:

Wear impervious gloves.

#### Eyes:

Wear safety glasses or goggles if eye contact is possible.

#### Skin:

Wear protective clothing when working with large quantities.

#### 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 5 of 9  
Version: 1.1

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Red
<b>Odor:</b>	Alcohol	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		
<b>Water Solubility:</b>	Soluble:		
<b>Boiling Point (°C):</b>	78.5 based on major component Ethanol		
<b>Vapor Pressure (kPa):</b>	7.91 (Ethanol)		
<b>Vapor Density (g/ml):</b>	1.59 (Ethanol)		
<b>Flash Point (Liquid) (°C):</b>	12.8	Closed cup based on major component (Ethanol)	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	19		
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	3.3		
<b>Polymerization:</b>	Will not occur		

### 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Keep away from heat, spark, flames and all other sources of ignition.
<b>Incompatible Materials:</b>	Strong oxidizing agents and strong inorganic acids

## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 6 of 9  
Version: 1.1

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

**ETHANOL**

Rat Oral LD 50 7060 mg/kg  
Mouse Oral LD 50 3450 mg/kg  
Rat Inhalation LC 50 20000 ppm/10H  
Mouse Inhalation LC 50 39 gm/m<sup>3</sup>/4h

**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

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

**ETHANOL**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

**Chlorhexidine Gluconate**

Eye Irritation Rabbit Moderate

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

**Chlorhexidine Gluconate**

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

**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.

**Amaranth**

**IARC:** Group 3 (Not Classifiable)

**Carmoisine red E122**

**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 7 of 9  
Version: 1.1

### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### ETHANOL

Rainbow Trout	NPDES	LC-50	96 Hours	12900 mg/L
Fingerling Trout	NPDES	LC-50	24 Hours	11200 mg/L
Fathead Minnow	NPDES	LC-50	96 Hours	14200 mg/L

### 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. 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.

### 14. TRANSPORT INFORMATION

This material is regulated for transport under DOT, ADR, IMDG, and IATA regulations.

Proper shipping name:	Ethanol solution
UN / ID No:	UN 1170
Hazard class:	3
Flash Point (°C):	12.8
Packing group:	II

Limited Quantity Exceptions may apply for small quantities packed in combination packaging. See applicable DOT/IATA/IMDG modal regulations for specific instructions.

#### IMDG

IMDG Proper shipping name:	Ethanol solution
IMDG UN / ID No:	UN 1170
IMDG Hazard Class:	3
Flash Point (°C):	12.8
IMDG Packing Group:	II

# MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 8 of 9  
Version: 1.1

## 15. REGULATORY INFORMATION

EU Symbol: F  
EU Indication of danger: Flammable

EU Risk Phrases:  
R11 - Highly flammable.

EU Safety Phrases:  
S 2 - Keep out of the reach of children.  
S 7 - Keep container tightly closed.  
S16 - Keep away from sources of ignition - No smoking.  
S25 - Avoid contact with eyes.

OSHA Label:  
WARNING  
Flammable liquid and vapor.  
Causes severe eye irritation.  
May cause drowsiness or dizziness.

### Canada - WHMIS: Classifications

WHMIS hazard class:  
Class B, Division 2  
Class D, Division 2, Subdivision B



### Water

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

### ETHANOL

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

### Chlorhexidine Gluconate

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



## MATERIAL SAFETY DATA SHEET

Material Name: Chlorhexidine in Alcohol 70%  
Revision date: 03-Jun-2008

Page 9 of 9  
Version: 1.1

### Amaranth

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	213-022-2

### Carmoisine red E122

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	222-657-4

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R11 - Highly flammable.  
R22 - Harmful if swallowed.

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

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

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**End of Safety Data Sheet**