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# IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

**Product Identifier** 

Material Name: Chlorhexidine in Alcohol 70%

Trade Name: Not applicable **Chemical Family:** Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antiseptic, disinfectant

Details of the Supplier of the Safety Data Sheet

Pfizer Inc **Pfizer Pharmaceuticals Group** 235 East 42nd Street New York, New York 10017

1-800-879-3477

**Emergency telephone number (North America):** CHEMTREC (24 hours): 1-800-424-9300 Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Global Manufacturing

38-42 Wharf Road

West Ryde, New South Wales 2114

Australia (02) 9850 3333

Ask for Environmental Health & Safety Manager

**Emergency telephone number (Australia):** 

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

# **HAZARDS IDENTIFICATION**

Classification of the Substance or Mixture **GHS - Classification** 

Flammable liquids- Category 2

**Label Elements** 

Signal Word: Danger

**Hazard Statements:** H225 - Highly flammable liquid and vapor



Other Hazards No data available

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the

potential risk. The precautionary statements and warning included may not apply in all cases.

Your needs may vary depending upon the potential for exposure in your workplace.

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# 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### **Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Chlorhexidine Gluconate	18472-51-0	242-354-0	Acute Tox. 4 (H302)	0.5
ETHANOL	64-17-5	200-578-6	Flam. Liq. 2 (H225)	60-100

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Amaranth	915-67-3	213-022-2	Not Listed	*
Water	7732-18-5	231-791-2	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.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has

been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of For information on potential signs and symptoms of exposure, See Section 2 - Hazards

**Exposure:** Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

# 5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion** Formation of toxic gases is possible during heating or fire. May include oxides of carbon,

**Products:** nitrogen and products of chlorine.

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Fire / Explosion Hazards: Flammable liquid and vapor. Vapors are heavier than air and may travel along surfaces to

remote ignition sources and flash back.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

# 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

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.

#### **Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill

**Collecting:** area thoroughly.

Additional Consideration for Non-essential personnel should be evacuated from affected area. Report emergency

**Large Spills:** situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### **Precautions for Safe 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. 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.

### Conditions for Safe Storage, Including any Incompatibilities

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.

Storage Temperature: Store as directed by product packaging.

Incompatible Materials: Strong oxidizing agents and strong inorganic acids

Specific end use(s): Pharmaceutical product

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### **Control Parameters**

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

### **ETHANOL**

1000 ppm
1000 ppm
1880 mg/m <sup>3</sup>
1000 ppm
1900 mg/m <sup>3</sup>
1000 ppm
1907 mg/m <sup>3</sup>
1000 mg/m <sup>3</sup>
1000 mg/m <sup>3</sup>

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# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA 1000 ppm 1900 mg/m<sup>3</sup> **Estonia OEL - TWA** 500 ppm 1000 mg/m<sup>3</sup> **Finland OEL - TWA** 1000 ppm 1900 mg/m<sup>3</sup> France OEL - TWA 1000 ppm 1900 mg/m<sup>3</sup> Germany - TRGS 900 - TWAs 500 ppm 960 mg/m<sup>3</sup> 500 ppm Germany (DFG) - MAK 960 mg/m<sup>3</sup> **Greece OEL - TWA** 1000 ppm 1900 mg/m<sup>3</sup> **Hungary OEL - TWA** 1900 mg/m<sup>3</sup> Latvia OEL - TWA 1000 mg/m<sup>3</sup> 500 ppm Lithuania OEL - TWA 1000 mg/m<sup>3</sup> **Netherlands OEL - TWA** 260 mg/m<sup>3</sup> **OSHA - Final PELS - TWAs:** 1000 ppm 1900 mg/m<sup>3</sup> **Poland OEL - TWA** 1900 mg/m<sup>3</sup> Portugal OEL - TWA 1000 ppm Romania OEL - TWA 1000 ppm 1900 mg/m<sup>3</sup> **Russia OEL - TWA** 1000 mg/m<sup>3</sup> Slovakia OEL - TWA 500 ppm 960 mg/m<sup>3</sup> 1000 ppm Slovenia OEL - TWA 1900 mg/m<sup>3</sup> **Sweden OEL - TWAs** 500 ppm 1000 mg/m<sup>3</sup> 500 ppm **Switzerland OEL -TWAs** 960 mg/m<sup>3</sup> 1000 mg/m<sup>3</sup> Vietnam OEL - TWAs

### **Chlorhexidine Gluconate**

Pfizer Occupational Exposure OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Band (OEB):

**Exposure Controls** 

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 Refer to applicable national standards and regulations in the selection and use of personal

**Equipment:** 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.

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# 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid Color: Pink

Odor: Alcohol Odor Threshold: No data available.

Molecular Formula: Mixture Molecular Weight: Mixture

Solvent Solubility: No data available

Water Solubility: Soluble

pH: No data available. Melting/Freezing Point (°C): No data available

**Boiling Point (°C):** 78.5 based on major component Ethanol

Partition Coefficient: (Method, pH, Endpoint, Value)

**ETHANOL**No data available

Water

No data available

**Chlorhexidine Gluconate** 

No data available

**Amaranth** 

No data available

Carmoisine red E122

No data available

**Decomposition Temperature (°C):** No data available.

Evaporation Rate (Gram/s):

Vapor Pressure (kPa):

Vapor Density (g/ml):

Relative Density:

No data available

1.59 (Ethanol)

No data available

Viscosity:

No data available

Flammablity:

Autoİgnition Temperature (Solid) (°C):

No data available
Flammability (Solids):

No data available

Flash Point (Liquid) (°C): 12.8 Closed cup based on major component (Ethanol)

Upper Explosive Limits (Liquid) (% by Vol.): 19 Lower Explosive Limits (Liquid) (% by Vol.): 3.3

Polymerization: Will not occur

# 10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

**Possibility of Hazardous Reactions** 

Oxidizing Properties: No data available

**Conditions to Avoid:** Keep away from heat, spark, flames and all other sources of ignition.

Incompatible Materials: Strong oxidizing agents and strong inorganic acids

Hazardous Decomposition No data available

**Products:** 

# 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the

potential hazards of the individual ingredients.

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# 11. TOXICOLOGICAL INFORMATION

Short Term: May cause mild skin irritation (based on animal data). Exposure to high concentrations of gas,

vapor, or mist may cause irritation.

Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver

cirrhosis, and, if ingested during pregnancy, congenital malformations.

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

#### **ETHANOL**

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

### **Chlorhexidine Gluconate**

Rat Oral LD50 2000 mg/kg
Rat Para-periosteal LD50 24.2mg/kg
Mouse Oral LD50 1260mg/kg
Mouse Intravenous LD50 12.9mg/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.

**ETHANOL** 

IARC: Group 1 (Carcinogenic to Humans)

**Amaranth** 

IARC: Group 3 (Not Classifiable)

Carmoisine red E122

IARC: Group 3 (Not Classifiable)

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# 12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to

the environment should be avoided.

Toxicity:

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

**ETHANOL** 

Oncorhynchus mykiss (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

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

# 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.

# 14. TRANSPORT INFORMATION

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

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

UN number: UN 1170

UN proper shipping name: Ethanol solution

Transport hazard class(es): 3
Packing group: 3

Flash Point (°C): 12.8

Flash Point (°C): 12.8

# 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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# 15. REGULATORY INFORMATION

**Chlorhexidine Gluconate** 

**CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Not Listed Present Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Present **EU EINECS/ELINCS List** 242-354-0

**Amaranth** 

**CERCLA/SARA 313 Emission reporting** Not Listed Not Listed **California Proposition 65** Inventory - United States TSCA - Sect. 8(b) Present Present Australia (AICS): **EU EINECS/ELINCS List** 213-022-2

**ETHANOL** 

Not Listed **CERCLA/SARA 313 Emission reporting** 

carcinogen 4/29/2011 in alcoholic beverages **California Proposition 65** 

developmental toxicity 10/1/1987 in alcoholic beverages

Inventory - United States TSCA - Sect. 8(b) Present Present Australia (AICS): **EU EINECS/ELINCS List** 200-578-6

Water

Not Listed **CERCLA/SARA 313 Emission reporting** Not Listed California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **REACH - Annex IV - Exemptions from the** Present

obligations of Register:

231-791-2 **EU EINECS/ELINCS List** 

Carmoisine red E122

**CERCLA/SARA 313 Emission reporting** Not Listed **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 222-657-4

# 16. OTHER INFORMATION

# Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

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

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Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other

Information. Updated Section 9 - Physical and Chemical Properties. Updated Section 2 -

Hazard Identification.

Revision date: 24-Jun-2016

Prepared by:

Product Stewardship Hazard Communications 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** 

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