

QCBG-2020-0102

Quito DM, 1 de diciembre de 2020

Señor (s)  
Ciudad.-

**REF.: BIOSEGURIDAD: DISPONIBILIDAD DE CLOROHEXIDINA**

**Estimado (s)**

Reciba un cordial saludo desde **Químicos CBG**, empresa perteneciente al Grupo Químico Indu-Quim, con trayectoria de 32 años en el mercado nacional e internacional entregando productos químicos genéricos y especialidades de elevada calidad y efectividad.

La presente tiene por finalidad poner a vuestra amable consideración el agente químico de bioseguridad (importado) denominado Clorohexidina, CH, en la forma de Gluconato de Clorohexidina al 20%.

Clorhexidina se encuentra a disposición de nuestros clientes en las siguientes presentaciones:

- a) Canecas de 5 galones (20 L, 20 kg)
- b) Galoneras (3,785 L)
- c) Frascos de 1000 mL
- d) Frascos de 500 mL
- e) Frascos de 100 mL
- f) O, según requiera el cliente

Adjunto, como corresponde, sírvase encontrar la respectiva información técnica del producto químico aquí propuesto, así como una tabla detallando los precios de venta según el tipo de empaque que se requiera.

CUADRO DE PRECIOS PARA COMERCIALIZACIÓN DE  
CLORHEXIDINA 20%

ITEM	DESCRIPCIÓN	PRESENTACIÓN	CANTIDAD	PRECIO UNITARIO	P.V.P + IVA	P.V.P
1	GLUCONATO DE CLORHEXIDINA 20%	100 ml	100 ml	5,77	5,77	6,46
		500 ml	500 ml	20,3	20,3	22,74
		1 Litro	1000 ml	32,73	32,73	36,66
		GALON	3,785 L	31,17	117,99	132,15
		CANECA	20 L	26,55	531,05	594,78

Aprovechamos la oportunidad para saludarlos con respeto y consideración, esperando poder servirlo(s) dentro del ambiente de alta calidad de los Procesos de su Empresa.

Cordialmente,



Ing. Carlos M. Batallas G.  
Director Técnico  
Grupo Químico Indu-Quim & Bioquimec S.A.  
CBG/cbg

# **OZZIE CHEMICAL(DALIAN) CO., LTD.**

Add: NO.20 GANGWAN STREET, ZHONGSHAN DIST, DALIAN, CHINA.

TEL : (0086 ) 411 82592911

FAX : (0086) 411 82592915

Email : sales@ozziechemical.com

Website : www.ozziechemical.com

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## **Chlorhexidine Gluconate Solution**

**Product Name:Chlorhexidine Gluconate Solution**

**CAS RN:18472-51-0**

**Molecular Formula:C<sub>22</sub>H<sub>30</sub>Cl<sub>2</sub>N<sub>10</sub>·2C<sub>6</sub>H<sub>12</sub>O**

**Molecular Weight:897.56**

**Quality Standard:EP 9.0**

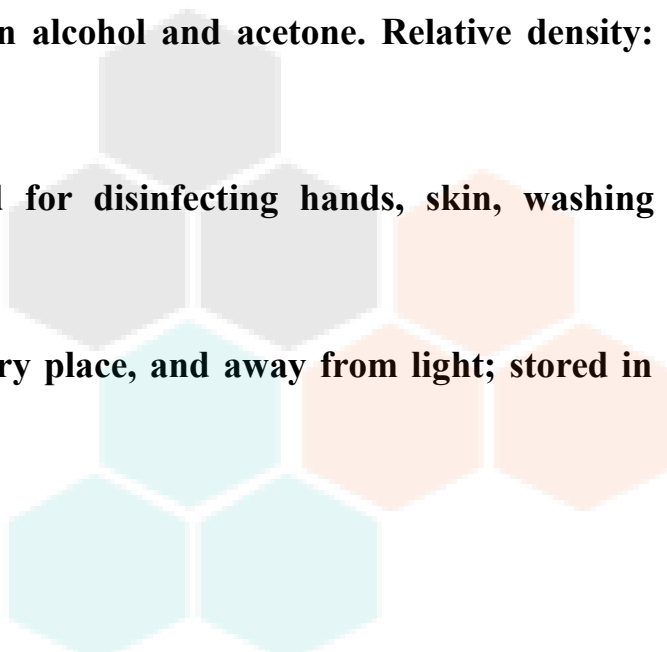
**Properties:**An almost colorless or pale-yellow transparent liquid, odorless, miscible with water, sparingly soluble in alcohol and acetone. Relative density: 1.060~1.070g/ml (25℃) .

**Uses:**It is an antiseptic medicine used for disinfecting hands, skin, washing wounds.

**Storage:**It should be kept in cool and dry place, and away from light; stored in sealed containers.

**Packing:**25KG, 200KG or 1000KG IBC

QUÍMICOS  
CBG



# Material Safety Data Sheet

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Revision Date 22-Feb-2020  
Version 3

## Chlorhexidine digluconate, 20% w/v aqueous solution, non-sterile

### SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**Product Description:** Chlorhexidine digluconate, 20% w/v aqueous solution, non-sterile

**Molecular Formula** C<sub>22</sub> H<sub>30</sub> Cl<sub>2</sub> N<sub>10</sub> · 2 C<sub>6</sub> H<sub>12</sub> O<sub>7</sub>

**Supplier** OZZIE CHEMICAL(DALIAN) CO.,LTD  
NO.20 GANGWAN STREET,ZHONGSHAN DIST,DALIAN,CHINA.  
TEL: 86 411 82592911  
FAX: 86 411 82592915

**Emergency Telephone Number** Call Carechem 24 at  
+86 177 411 32291(English only)

**E-mail address** sales@ozziechemical.com

**Recommended Use** Medicines.  
**Uses advised against** For pharyngitis and canker sores

### SECTION 2. HAZARD IDENTIFICATION

**Physical State**  
Liquid

**Appearance**  
No information available

**Odor**  
No information available

**Emergency Overview**  
The product contains no substances which at their given concentration are considered to be hazardous to health.

#### Classification of the substance or mixture

Based on available data, the classification criteria are not met

#### Label Elements

None required

#### **Physical and Chemical Hazards**

None identified.

#### **Health Hazards**

The product contains no substances which at their given concentration are considered to be hazardous to health.

#### **Environmental hazards**

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants. .

# Material Safety Data Sheet

Chlorhexidine digluconate, 20% w/v aqueous solution, non-sterile

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS-No	Weight %
Water	7732-18-5	80
Chlorohexidine digluconate	18472-51-0	20

## SECTION 4. FIRST AID MEASURES

### Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

### Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention.

### Inhalation

Move to fresh air. Obtain medical attention. If not breathing, give artificial respiration.

### Ingestion

Do not induce vomiting. Obtain medical attention.

### Most important symptoms and effects

Causes severe eye damage.

### Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

### Notes to Physician

Treat symptomatically.

## SECTION 5. FIRE-FIGHTING MEASURES

### Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### Extinguishing media which must not be used for safety reasons

No information available.

### Specific Hazards Arising from the Chemical

Do not allow run-off from fire fighting to enter drains or water courses.

### Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions

Ensure adequate ventilation. Use personal protective equipment.

### Environmental Precautions

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.

# Material Safety Data Sheet

Chlorhexidine digluconate, 20% w/v aqueous solution, non-sterile

## Methods for Containment and Clean Up

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7. HANDLING AND STORAGE

### Handling

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation.

### Storage

Keep containers tightly closed in a dry, cool and well-ventilated place.

### Specific Use(s)

Use in laboratories

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control Parameters

### Exposure Controls

#### Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source.

#### Personal protective equipment

**Eye Protection** Goggles (European standard - EN 166)

**Hand Protection** Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Natural rubber	See manufacturers	-	EN 374	(minimum requirement)
Nitrile rubber	recommendations			
Neoprene				
PVC				

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Skin and body protection** Long sleeved clothing

**Respiratory Protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

**Large scale/emergency use** Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced  
**Recommended Filter type:** Particulates filter conforming to EN 143

# Material Safety Data Sheet

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**Small scale/Laboratory use** Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.  
**Recommended half mask:-** Particle filtering: EN149:2001  
When RPE is used a face piece Fit Test should be conducted

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** Prevent product from entering drains. Do not allow material to contaminate ground water system. Local authorities should be advised if significant spillages cannot be contained.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	
<b>Physical State</b>	Liquid
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No data available
<b>pH</b>	No information available
<b>Melting Point/Range</b>	No data available
<b>Softening Point</b>	No data available
<b>Boiling Point/Range</b>	No information available
<b>Flash Point</b>	No information available
<b>Evaporation Rate</b>	No data available
<b>Flammability (solid,gas)</b>	Not applicable
<b>Explosion Limits</b>	No data available
<b>Vapor Pressure</b>	No data available
<b>Vapor Density</b>	No data available
<b>Specific Gravity / Density</b>	1.06
<b>Bulk Density</b>	Not applicable
<b>Water Solubility</b>	No information available
<b>Solubility in other solvents</b>	No information available
<b>Partition Coefficient (n-octanol/water)</b>	
<b>Autoignition Temperature</b>	No data available
<b>Decomposition Temperature</b>	No data available
<b>Viscosity</b>	No data available
<b>Explosive Properties</b>	No information available
<b>Oxidizing Properties</b>	No information available
<b>Molecular Formula</b>	C <sub>22</sub> H <sub>30</sub> Cl <sub>2</sub> N <sub>10</sub> . 2 C <sub>6</sub> H <sub>12</sub> O <sub>7</sub>
<b>Molecular Weight</b>	897.77

**Method -** No information available

Liquid  
(Air = 1.0)  
Liquid

## SECTION 10. STABILITY AND REACTIVITY

**Stability** Stable under normal conditions.

**Hazardous Reactions** None under normal processing.  
**Hazardous Polymerization** Hazardous polymerization does not occur.

**Conditions to Avoid** Incompatible products. Excess heat.

**Materials to avoid** Strong oxidizing agents.

**Hazardous Decomposition Products** None under normal use conditions.

## SECTION 11. TOXICOLOGICAL INFORMATION

# Material Safety Data Sheet

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## Product Information

### (a) acute toxicity; Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Water	-		
Chlorhexidine digluconate	2 g/kg ( Rat ) 1260 mg/kg ( Mouse )		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; Category 1

(d) respiratory or skin sensitization;  
Respiratory No data available  
Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available  
There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available  
Target Organs None known.

(j) aspiration hazard; No data available

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and delayed No information available

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity effects** Very toxic to aquatic organisms. The product contains following substances which are hazardous for the environment.

**Persistence and Degradability**  
**Degradation in sewage treatment plant** No information available  
Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

**Bioaccumulative Potential** No information available

**Mobility in soil** No information available



# Material Safety Data Sheet

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**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors  
**Persistent Organic Pollutant** This product does not contain any known or suspected substance  
**Ozone Depletion Potential** This product does not contain any known or suspected substance

## SECTION 13. DISPOSAL CONSIDERATIONS

**Waste from Residues / Unused Products** Should not be released into the environment. Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

**Contaminated Packaging** Dispose of this container to hazardous or special waste collection point.

**Other Information** Do not dispose of waste into sewer. Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains. Do not let this chemical enter the environment.

## SECTION 14. TRANSPORT INFORMATION

### Road and Rail Transport

**UN-No** UN3082  
**Proper Shipping Name** Environmentally hazardous substance, liquid, n.o.s  
**Hazard Class** 9  
**Packing Group** III

### IMDG/IMO

**UN-No** UN3082  
**Proper Shipping Name** Environmentally hazardous substance, liquid, n.o.s  
**Hazard Class** 9  
**Packing Group** III

### IATA

**UN-No** UN3082  
**Proper Shipping Name** Environmentally hazardous substance, liquid, n.o.s  
**Hazard Class** 9  
**Packing Group** III

**Special Precautions for User** No special precautions required

## SECTION 15. REGULATORY INFORMATION

**International Inventories** X = listed

Component	The Inventory of Hazardous Chemicals (2015 Edition)	List of dangerous goods GB 12268 - 2012	Taiwan Toxic Chemical Substances Inventory	IECSC	EINECS	TSCA	DSL	PICCS	ENCS	AICS	KECL
Water	-	-	X	X	231-791-2	X	X	X	-	X	X
Chlorhexidine digluconate	-	-	X	X	242-354-0	X	X	-	-	X	X

# Material Safety Data Sheet

Chlorhexidine digluconate, 20% w/v aqueous solution, non-sterile

## National Regulations

### SECTION 16. OTHER INFORMATION

**Prepared By** Health, Safety and Environmental Department  
**Creation Date** 23-Nov-2012  
**Revision Date** 22-Feb-2018  
**Revision Summary** SDS authoring systems update, replaces ChemGes SDS No. 347.

**Training Advice**  
Chemical incident response training.

#### Legend

**CAS** - Chemical Abstracts Service  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**IECSC** - Chinese Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**WEL** - Workplace Exposure Limit  
**ACGIH** - American Conference of Governmental Industrial Hygienists  
**DNEL** - Derived No Effect Level  
**RPE** - Respiratory Protective Equipment  
**LC50** - Lethal Concentration 50%  
**NOEC** - No Observed Effect Concentration  
**PBT** - Persistent, Bioaccumulative, Toxic  
**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road  
**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code  
**OECD** - Organisation for Economic Co-operation and Development  
**BCF** - Bioconcentration factor

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**ENCS** - Japanese Existing and New Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TWA** - Time Weighted Average  
**IARC** - International Agency for Research on Cancer  
**PNEC** - Predicted No Effect Concentration  
**LD50** - Lethal Dose 50%  
**EC50** - Effective Concentration 50%  
**POW** - Partition coefficient Octanol:Water  
**vPvB** - very Persistent, very Bioaccumulative  
**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association  
**MARPOL** - International Convention for the Prevention of Pollution from Ships  
**ATE** - Acute Toxicity Estimate  
**VOC** - Volatile Organic Compounds

**Key literature references and sources for data**  
Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**Physical hazards** On basis of test data  
**Health Hazards** Calculation method  
**Environmental hazards** Calculation method

#### Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Material Safety Data Sheet**

# OZZIE CHEMICAL(DALIAN) CO.,LTD

## Certificate Of Analysis

<b>Product Name</b>	Chlorhexidine digluconate 20% Solution	<b>Batch No.</b>	2003181140
<b>Sample Qty Base</b>	8600KGS	<b>Date of Production</b>	2020.03.18
<b>Analysis Date</b>	2020.03.18	<b>Expiry Date</b>	2024.03.17
<b>Standard</b>	EP 9.0	<b>CAS NO</b>	18472-51-0
<b>Item</b>	<b>Standard</b>		<b>Test Results</b>
<b>Appearance</b>	Almost colourless or pale yellowish liquid		Complies
<b>Solubility</b>	Miscible with water,with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96%)		Complies
	Miscible with glacial acetic acid and with water, miscible with three times its volume of acetone and with five times its volume of dehydrated alcohol; further addition of acetone or dehydrated alcohol yields a white turbidity		Complies
<b>Identification</b>	A.The IR Spectrum obtained with sample should correspond with that of standard		Complies
	B.The principal spot in the chromatogram obtained with the test solution should be similar in position, color and size to the principal spot in the chromatogram obtained with the reference solutuion		Complies
	C.The residue meets at 132°C-136°C		134.8°C
	D.A deep red color should be produced		Complies
<b>Specific Gravity</b>	1.06 ~ 1.07		1.065
<b>PH(5%,v/v)</b>	5.5 ~ 7.0		6.5
<b>Related substances</b>	Chlorhexidine Oxazinone Analog(Impurity L)	≤0.2%	BDL
	Specified unidentified impurity 1(Impurity Q)	≤0.2%	BDL
	Chlorhexidine Amine(Impurity G)	≤0.3%	BDL
	Chlorhexidine Guanidine(Impurity N)	≤1.0%	BDL
	Chlorhexidine Urea(Impurity B)	≤0.2%	BDL
	p-Chlorophenyl Urea(Impurity F)	≤0.2%	ND
	Chlorhexidine nitrile(Impurity A)	≤0.4%	BDL
	Chlorhexidine dimer(Impurity H)	≤0.5%	BDL
	o-Chlorhexidine and specified unidentified impurity 2	≤0.4%	BDL
	Chlorhexidine Glucityl Triazine(Impurity J)	≤0.4%	BDL
	Oxochlorhexidine(Impurity K)	≤0.4%	BDL
	Any individual unspecified impurity	≤0.1%	BDL
	Total impurities	≤3.0%	BDL
	<b>p-Chloroaniline</b>	≤500 ppm	
<b>Content</b>	190 g/l-210 g/l		208.8 g/l
<b>Residual Solvent</b>	Methanol	≤3000 ppm	89 ppm
	Butanol	≤5000 ppm	18 ppm
<b>Color Absorbance</b>	≤0.005, by UV at 480nm 1% w/v solution		0.001
<b>Microbial Enumeration test</b>	Total aerobic microbial count	≤100 CFU/ml	Nil
	Total yeasts and molds count	≤100 CFU/ml	Nil
	Other Specific micro organism	Absent per 10ml	Complies
<b>Storage</b>	Store in a well closed containers and protected from light		
<b>Conclusion</b>	The batch conforms to the EP 9.0 standard		

