


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CHLORHEXIDINE GLUCONATE SOLUTION, USP (20%)
PRODUCT CODE	2755
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Eye Damage (Category 1) Sensitization - Respiratory (Category 1) Sensitization - Skin (Category 1) Chronic Aquatic Toxicity (Category 1)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	May be harmful if swallowed. May cause skin irritation. Causes severe eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable

PRECAUTIONARY STATEMENT(S)	Prevention	Wear eye and face protection protection. Wash hands thoroughly after handling. Do not touch eyes. Avoid breathing dust, fume, gas, mist, vapors, spray. In case of inadequate ventilation wear respiratory protection. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. Avoid release to the environment		
	Response	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. COLLECT SPILLAGE		
	Storage	Not applicable		
	Disposal	Dispose of contents in accordance with local regulation).		
HMIS CLASSIFICATION	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Not applicable								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	Not applicable								
CHEMICAL FAMILY	Biguanide								
CAS NUMBER	Not applicable								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	Not applicable								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>CHLORHEXIDINE GLUCONATE</td> <td>18472-51-0</td> <td>242-354-0</td> <td>19-21</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	CHLORHEXIDINE GLUCONATE	18472-51-0	242-354-0	19-21
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT						
CHLORHEXIDINE GLUCONATE	18472-51-0	242-354-0	19-21						
NOTES	<p>There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.</p> <p>Balance is water</p>								

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CHLORHEXIDINE GLUCONATE CAS #: 18472-51-0

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

CHLORHEXIDINE GLUCONATE:

USP ELV: Industrial: TWA 10 micrograms/m³

CEL TWA: 0.0027 ppm; 0.1 mg/m³** [AstraZeneca]

CHLORHEXIDINE GLUCONATE SOLUTION (20%):

Composite Exposure Standard for Mixture (TWA) (mg/m³): 0.1 mg/m³

Component Breathing zone Mixture Conc:

Chlorhexidine gluconate 0.00 ppm, 0.1000 mg/m³, 20.0 %

Composite Exposure Standard for Mixture: (TWA) (mg/m³): 20 mg/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Liquid				
DESCRIPTION	Almost colorless or pale yellow, clear liquid. Is odorless or almost odorless.				
SOLUBILITY	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.				
ODOR	Odorless or almost odorless.				
FLAMMABILITY	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	100°C, 212°F	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	Not available
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.5 - 7.0
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	1.06 - 1.07	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	2.66	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures. Light sensitive.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

CHLORHEXIDINE GLUCONATE SOLUTION (20%)*:

Oral: Rat: LD50: (mg/kg): 10,000

Dermal: Rabbit LD50: (mg/kg): Not available

Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE
IRRITATION**

Causes serious eye damage.

Cases of irreversible corneal damage resulting from contact with solutions of this material have been reported.

Controlled irritancy study: 3 hours: Rabbit: Corneal de-epithelialization, conjunctival chemosis, and anterior stromal edema.

CHLORHEXIDINE GLUCONATE:

Eye irritancy: Rabbit: Moderately irritating

Eye irritancy in unspecified animals, 20% solution: Severely irritating.

RESPIRATORY SENSITIZATION

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Anaphylactic reactions have been reported.

SKIN SENSITIZATION

May cause an allergic skin reaction.

CHLORHEXIDINE GLUCONATE:

Chlorhexidine Gluconate Skin sensitization: Guinea pig: Weakly sensitizing.

Contact dermatitis and occupational asthma following exposure to this material have been reported.

Individuals with eczema, leg ulcers, or leg eczema are more prone to chlorhexidine allergies.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

Chromosomal aberration in Chinese hamster ovary cells: Negative.

In vitro Ames test: Negative.

In vivo cytogenetics assay in hamsters: Negative.

In vivo dominant lethal assay in mice: Negative.

In vivo mouse micronucleus test: Negative.

CARCINOGENICITY

OSHA No component of this product, present at $\geq 0.1\%$, is listed.

NTP No component of this product, present at $\geq 0.1\%$, is listed.

IARC No component of this product, present at $\geq 0.1\%$ has been evaluated.

California Proposition No component of this product, present at $\geq 0.1\%$ is known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**ADDITIONAL CARCINOGENICITY
INFORMATION**

Due to lack of data the classification is not possible.

CHLORHEXIDINE GLUCONATE:

Long-term carcinogenicity, administered in drinking water: Rat: 2 years: 50 mg/kg/day: No evidence of carcinogenicity

REPRODUCTIVE TOXICITY

Due to lack of data the classification is not possible.

CHLORHEXIDINE GLUCONATE:

Fertility study, administered as base: Rat: 100 mg/kg/day: Fertility not impaired.

Reproductivity study, administered by gavage: Rat: 300 mg/kg/day: No fetal harm.

Reproductivity study, administered by gavage: Rabbit: 40 mg/kg/day: No fetal harm.

Reproductivity study, administered orally: Rat: 68 mg/kg/day: Not teratogenic.

**SPECIFIC TARGET ORGAN
TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN
TOXICITY - REPEATED
EXPOSURE**

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF
EXPOSURE****ROUTES OF EXPOSURE:**

Oral, dermal, inhalation, eyes

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Liver damage. Swollen glands.

Symptoms related to the physical, chemical, and toxicological characteristics:

Permanent eye damage including blindness could result. Permanent eye damage including blindness.

Sore

throat. Taste perversion. Staining of teeth. Mouth sores. Swollen gums. Dry mouth. Vomiting. Cough.

Medical conditions aggravated by exposure:

Dermatitis. Asthma. Eczema

POTENTIAL HEALTH EFFECTS**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.**Ingestion** May be harmful if swallowed.**Skin** May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction.**Eyes** Causes serious eye damage.**NOTES**

*Values for mixture are calculated based on known values for toxicity of the components.

SECTION 12: ECOLOGICAL INFORMATION**ECOTOXICITY****CHLORHEXIDINE GLUCONATE SOLUTION (20%)*:**

EC50: 48 Hr: Crustacea (Daphnia magna): (mg/L): 0.225

LC50: 96 Hr: Fish: (mg/L): Not available

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND
DEGRADABILITY**

CHLORHEXIDINE is not readily degradable.

BIOACCUMULATIVE POTENTIAL

Not available

MOBILITY IN SOIL

Soluble in water.

OTHER ADVERSE EFFECTS

Very toxic to aquatic life with long lasting effects

This product is not intended to be released into the environment

NOTES

*Values for mixture are calculated based on known values for toxicity of the components.

SECTION 13: DISPOSAL CONSIDERATIONS**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION**UN PROPER SHIPPING NAME**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

UN NUMBER

3082

CLASS

9

PACKING GROUP III

AUSTRALIA
HAZCHEM 2Z

EU
**TRANSPORT IN BULK ACCORDING
TO ANNEX II OF MARPOL 73/78
AND THE IBC CODE** Not Listed

ENVIRONMENTAL HAZARDS Not available

**SPECIAL SHIPPING
INFORMATION** Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
CHLORHEXIDINE GLUCONATE 18472-51-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
CHLORHEXIDINE GLUCONATE 18472-51-0	N/L	Listed as Schedule 7*	N/L	Listed*	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
CHLORHEXIDINE GLUCONATE 18472-51-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT** Not applicable

NOTES *Listed as the base

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

06/2023

SUPERSEDES

02/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.