According to Regulation (EC) No 1907/2006 (REACH)

Trade name: Chlorhexidine Gluconate Solution 0.75% Antiseptic

Product No: 414

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

:

1.1 Product Identifier:

Trade Name / Designation : Chlorhexidine Gluconate Solution 0.75%

Antiseptic

Other means of Identification

Chlorhexidine Gluconate Solution, 0.75%

Recommended Use

: Skin Antiseptic

1.2 Company Contact Information:

Bajaj Medical, LLC 415 W Pershing Rd Chicago IL 60609-2760 USA +1.855.680.0101

1.3 Emergency Telephone Number: In case of emergency, contact your local poison

control center.

If in the USA, contact <u>+1.800.222.1222</u> to reach the American Association of Poison Control

Centers

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture:

GHS-US classification in accordance with 29 CFR 1910 (OSHA HCS)

Causes Skin Irritation (Category 2), H315

Causes Serious Eye Damage (Category 1), H318

Suspected of causing cancer (Category 2), H351

For the full text of the H-Statements mentioned in this section, refer Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP/GHS]

Hazard pictograms:







Signal word (GHS-US):

Danger

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Hazard statements (GHS-US):

H315 Causes skin irritation

H318 Causes serious eye damage H351 Suspected of causing cancer

Precautionary statements (GHS-US):

P201 Obtain special instructions before use

P202 Do not handle until all safety precautions have been read and

understood

P264 Wash hand thoroughly after handling

P302 + P352 If on skin: wash with plenty of soap and water

P305 + P351 + P338 If in eyes: rinse cautiously with water for several minutes. Remove

Contact lenses, if present and easy to do. Continue rinsing

P308 + P313 If exposed or concerned: Get medical advice / attention
P310 Immediately call a poison center or doctor / physician
P332 + P313 If skin irritation occurs: Get medical advice / attention
P362 Take off contaminated clothing and wash before use

P405 Store locked up

P501 Dispose of contents / container in accordance with concerned

regulations

Supplemental Hazard information:

No data available

2.3 Other hazards

No data available

SECTION 3. Composition / Information on Ingredients

3.1 Mixtures

Description of the mixture:

Aqueous solution of 0.75% Chlorhexidine Gluconate

Ingredients:

Name		Identifier	Classification	Concentration
Common/Trade	IUPAC (Preferred)	CAS Number	GHS – US Classification	% w/w
Water	Water, Oxidane	7732-18-5	Not Classified	83.00 - 85.00
amides, coco, n,n- bis(hydroxyethyl)	Cocamide DEA, Cocamide Diethanolamine	68603-42-9	Carc. 2, H351	2.5
Chlorhexidine Digluconate Solution	(1E)-2-[6-[[amino-[(E)- [amino-(4- chloroanilino)methylidene]a mino]methylidene]amino]he xyl]-1-[amino-(4- chloroanilino)methylidene]g uanidine;(2R,3S,4R,5R)- 2,3,4,5,6- pentahydroxyhexanoic acid	18472-51-0	Skin Irr. 2, H315	0.75
Isopropyl Alcohol	Propan-2-ol	67-63-0	Flam. Liq. 2, H225	4 – 5

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SECTION 4: First Aid Measures

4.1 Description of first aid measures

General advice

In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

Inhalation

Get medical attention if syptoms occur.

Skin Contact

Rinse with water.

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for atleast 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention.

If Swallowed

Rinse mouth. Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation

None under normal use.

Skin

Causes skin irritation.

Eye

Causes serious eye damage.

Ingestion

May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.

Unsuitable extinguishing media:

None.

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5.2 Special hazards arising from the substance or mixture

Fire Hazard:

Not flammable. Thermal decomposition may produce toxic fumes of ammonia, hydrogen chloride and oxides of carbon and nitrogen.

Explosion Hazard:

None Known.

5.3 Advice for fire-fighters

Protection during firefighting:

Firefighter should wear full protective gear.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure clean-up is conducted by trained personnel only. Refer ro protective measures in Sections 7 and 8.

6.2 Environmental precautions:

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Stop the flow of material, if this is without risk. Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federeal regulations.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

Avoid contact with eyes. Wash thoroughly after handling.

7.2 Conditions for Safe Storage, including any Incompatibilities

Keep away from open flames, hot surfaces and sources of ignition. Store at temperature not exceeding 37°C.

7.3 Specific end uses:

Pharmaceutical Agent.

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SECTION 8: Exposure Controls / Personal Protection

8.1 Control parameters

8.1.1 Occupational exposure limits:

Source	Substance name	EC-No.	CAS-No.	Occupational exposure limit value
USA ACGIH	Isopropyl Alcohol	200-661-7	67-63-0	TWA: 200 ppm
USA ACGIH	Isopropyl Alcohol	200-661-7	67-63-0	STEL: 400 ppm
USA OSHA	Isopropyl Alcohol	200-661-7	67-63-0	TWA: 980 mg/m3
USA OSHA	Isopropyl Alcohol	200-661-7	67-63-0	TWA: 400 ppm

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Provide adequate general and local exhaust ventilation.

8.2.2 Personal protective equipment

Eye / Face protection:

Chemical goggles or face shield with safety glasses.

Skin and Body protection:

Wear suitable working clothes.

Hand protection:

Wear impervious gloves to minimize skin contact.

Respiratory protection:

None required under normal product handling conditions.

SECTION 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid		
Colour	Colorless		
Odour	No Data Available		
Odour Threshold	No Data Available		
pH	No Data Available		
Relative evaporation rate (butylacetate=1)	No Data Available		
Melting Point	No Data Available		
Freezing Point	No Data Available		
Boiling Point	97°C		
Flash Point	>200°F		
Self Ignition Temperature	No Data Available		
Decomposition Temperature	No Data Available		
Flammability (solid, gas)	No Data Available		
Vapour Pressure	No Data Available		

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Relative Vapour Density at 20°C	No Data Available		
Specific Gravity	1.06		
Solubility	Water Soluble		
Log Pow	No Data Available		
Log Kow	No Data Available		
Viscosity, Kinematic	No Data Available		
Viscosity, Dynamic	No Data Available		
Explosive Properties	No Data Available		
Oxidising Properties	No Data Available		
Explosive Limits	No Data Available		

9.2 Other information:

No other relevant information.

SECTION 10: Stability and Reactivity

10.1 Reactivity

No additional information available.

10.2 Chemical stability

The product is stable at normal handling and storage conditions.

10.3 Possibility of hazardous reactions

Will not occur.

10.4 Conditions to avoid:

Storage in excess heat (104 ° F) over a long period of time.

10.5 Incompatible materials:

None.

10.6 Hazardous decomposition products:

Thermal decomposition may produce toxic fumes of ammonia, hydrogen chloride and oxides of carbon and nitrogen.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

Information on likely routes of exposure:

Inhalation, Eye Contact, Skin Contact.

11.2 Potential Health Effects

Eyes:

Causes serious eye irritation.

Skin:

Do not use in the perineal or eyelid areas. Do not instil in the middle ear – may cause deafness if ear drum is perforated.

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Ingestion:

Health injuries are not known or expected under normal use.

Inhalation:

Health injuries are not known or expected under normal use.

Chronic Exposure:

Suspected of causing cancer.

11.3 Experience with human exposure

Eye contact:

Redness, Pain, Irritation

Skin contact:

No symptoms known or expected.

Ingestion:

No symptoms known or expected.

Inhalation:

No symptoms known or expected.

11.4 Toxicity

Acute oral toxicity:

Acute toxicity estimate: > 5,000 mg/kg

Acute inhalation toxicity:

4 h acute toxicity estimate: 23.64 mg/l

Acute dermal toxicity:

No Data Available

Skin Corrosion / Irritation:

No Data Available

Serious eye damage / Eye Irritation:

No Data Available

Respiratory or skin sensitization:

No Data Available

11.5 <u>Carcinogenicity</u>

IARC:

Group 2B: Possibly carcinogenic to humans amides, coco, n,n-bis(hydroxyethyl) 68603-42-9

OSHA.

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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NTP:

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive effects:

No Data Available

Germ cell mutagenicity:

No Data Available

Teratogenicity:

No Data Available

STOT-single exposure:

No Data Available

STOT-repeated exposure:

No Data Available

Aspiration toxicity:

No Data Available

11.6 Ingredients

Acute dermal toxicity:

propan-2-ol LD50 rabbit: 12,870 mg/kg Chlorhexidine gluconate LD50 rabbit: > 2,000 mg/kg amides, coco, n,n-bis(hydroxyethyl) LD50 rat: > 2,000 mg/kg

SECTION 12: Ecological Information

12.1 Ecotoxicity

Environmental Effects:

Toxic to aquatic life.

12.2 Product

Toxicity to fish:

No Data Available

Toxicity to daphnia and other aquatic invertebrates:

No Data Available

Toxicity to algae:

No Data Available

12.3 Ingredients

Toxicity to fish:

propan-2-ol

96 h LC50 Fish: 9,640 mg/l

amides, coco, n,n-bis(hydroxyethyl)

96 h LC50 Fish: 3.6 mg/l

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Toxicity to daphnia and other aquatic invertebrates:

Chlorhexidine gluconate 48 h EC50: 0.06 mg/l

12.4 Persistence and degradability

No Data Available

12.5 Bio-accumulative potential

No Data Available

12.6 Mobility in soil

No Data Available

12.7 Other adverse effects:

No Data Available

SECTION 13: Disposal Considerations

13.1 Disposal Methods:

The product should not be allowed to enter drains, water courses or the soil. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

13.2 Disposal Considerations:

Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re- use empty containers.

SECTION 14: Transport Information

The shipper/consignor/sender is responsible to ensure that the packaging, labelling, and markings are in compliance with the selected mode of transport.

14.1 Land transport (DOT)

Not dangerous goods

14.2 Sea transport (IMDG/IMO)

Not dangerous goods

SECTION 15: Regulatory Information

15.1 EPCRA

Emergency Planning and Community Right-to-Know

15.2 SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

15.3 SARA 311/312 Hazards:

Fire Hazard, Acute Health Hazard, Chronic Health Hazard

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15.4 SARA 302:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

15.5 SARA 313:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

15.6 California Prop 65:

WARNING! This product contains a chemical known in the State of California to cause cancer. amides, coco, n,n-bis(hydroxyethyl) CAS#: 68603-42-9

SECTION 16: Other Information

16.1 Full text of H-phrases:

Acute Tox. 4 (Oral) Carc. 2

Eye Dam. 1 Flam. Liq. 2 Flam. Liq. 3 Skin Corr. 1B Skin Irrit. 2

Skin Irrit. H225 H315

H318 H351 Acute toxicity (oral) Category 4
Carcinogenicity Category 2

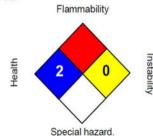
Serious eye damage/eye irritation Category 1

Flammable liquids Category 2
Flammable liquids Category 3
skin corrosion/irritation Category 1B
skin corrosion/irritation Category 2
Highly flammable liquid and vapour

Causes skin irritation

Causes serious eye damage Suspected of causing cancer

NFPA:



HMIS III:

HEALTH	2*
FLAMMABILITY	2
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight, 2 = Moderate, 3 = High

4 = Extreme, * = Chronic

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