

CHORHEXIDINE GLUCONATE & ETHYL ALCOHOL SOLUTION - BACTORUB

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Chlorhexidine Gluconate & Ethyl Alcohol Solution (BACTORUB)

PRODUCT USE

Effective Antiseptic Solution for external use.

MANUFACTURED BY:

T.M. Thakore Pharmaceutical Laboratories.

Address:

15-A, Premson's Industrial Estate, Caves Road, Jogeshwari-East, Mumbai-400060. India

Telephone: .022-28246058 Tele Fax: 91-22-2824 0855 E-mail: <u>internal@tmtpharma.in</u>

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

Hazardous substance. Dangerous goods.







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Hazard statement(s)

Highly flammable liquid and vapour Causes serious eye irritation

Precautionary statement(s) Prevention

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

In case of fire: Use alcohol resistant foam or normal protein foam for extinction.

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 ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Precautionary statement(s) Storage

Store in a well-ventilated place. Keep cool. Precautionary statement(s) Disposal Dispose of contents/container in accordance with local regulations.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME

Chlorhexidine Gluconate Solution I.P 2.5% v/v Equivalent to Chlorhexidine Gluconate 0.5 % w/v Ethyl Alcohol I.P 70% v/v With emollient and moisturizer

Colour: Carmoisine

Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down Position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced Awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as Casualty can comfortably drink.
- Seek medical advice.





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EYE

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

No adverse effects anticipated from normal use.

If skin irritation occurs:

- Immediately remove all contaminated clothing, including footwear
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

NOTES TO PHYSICIAN

For acute or short term repeated exposures to ethanol:

- Acute ingestion in non-tolerant patients usually responds to supportive care with special attention to prevention of aspiration, replacement of fluid and correction of nutritional deficiencies (magnesium, thiamine pyrodoxine, Vitamins C K)
- Give 50% dextrose (50-100 ml) IV to obtunded patients following blood draw for glucose etermination.
- Comatose patients should be treated with initial attention to airway, breathing, circulation and drugs of immediate importance (glucose, thiamine)
- Decontamination is probably unnecessary more than 1 hour after a single observed ingestion. Cathartics and charcoal may be given but are probably not effective in single ingestions.
- Fructose administration is contra-indicated due to side effects. Emesis is contraindicated as the product will foam.





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Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- May be violently or explosively reactive.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course. Consider evacuation (or protect in place).
- Fight fire from a safe distance, with adequate cover.
- If safe, switch off electrical equipment until vapour fire hazard removed.
- Use water delivered as a fine spray to control the fire and cool adjacent area.
- Avoid spraying water onto liquid pools.
- Do not approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 500 metres in all directions.

FIRE/EXPLOSION HAZARD

- Liquid and vapour are highly flammable.
- Severe fire hazard when exposed to heat, flame and/or oxidisers.
- Vapour forms an explosive mixture with air.
- Severe explosion hazard, in the form of vapour, when exposed to flame or spark.
- Vapour may travel a considerable distance to source of ignition.
- Heating may cause expansion / decomposition with violent rupture of containers.
- On combustion, may emit toxic fumes of carbon monoxide (CO). Decomposition products include chloroaniline.

FIRE INCOMPATIBILITY

Avoid contamination with strong oxidising agents as ignition may result.

Avoid reaction with strong acids and strong alkalis.

Personal Protective Equipment

Gas tight chemical resistant suit.

Limit exposure duration to 1 BA set 30 mins.





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Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

MINOR SPILLS

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eye Control personal contact by using protective equipment.
- Contain and absorb small quantities with vermiculite or other absorbent material. Wipe up.
- Collect residues in a flammable waste container.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- May be violently or explosively reactive.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.
- Consider evacuation (or protect in place).
- No smoking, naked lights or ignition sources.
- Increase ventilation.
- Stop leak if safe to do so.
- Water spray or fog may be used to disperse /absorb vapour.
- Contain spill with sand, earth or vermiculite.
- Use only spark-free shovels and explosion proof equipment.
- Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite. Collect solid residues and seal in labelled drums for disposal.
- Wash area and prevent runoff into drains. If contamination of drains or waterways occurs, advise emergency services.

FOOTNOTES

1. PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapour plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.

2 PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapour concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.





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3 INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localised wind reversal may expose nearly all persons without appropriate protection to life-threatening concentrations of the material.

4 SMALL SPILLS involve a leaking package of 200 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres and compressed gas leaking from a small cylinder are also considered "small spills".

LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one-tonne" Compressed gas cylinder.

EMERGENCY RESPONSE PLANNING GUIDELINES (ERPG)

The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour WITHOUT experiencing or developing life-threatening health effects is: ethanol 3300 ppm , glycerol 500 mg/ m³ , water 500 mg/m³ irreversible or other serious effects or symptoms which could impair an individual's ability to take protective action is: ethanol 3300 ppm , glycerol 500 mg/ m³ , water 500 mg/m³ other than mild, transient adverse effects without perceiving a clearly defined odour is: ethanol 3000 ppm , glycerol 500 mg/ m³ , water 500 mg/m³ The threshold concentration below which most people. will experience no appreciable risk of health effects: ethanol 1000 ppm , glycerol 500 mg/ m³ , water 500 mg/m³ American Industrial Hygiene Association (AIHA) Ingredients considered according to the following cutoffs Very Toxic (T+) >= 0.1% Toxic (T) >= 3.0% R50 >= 0.25% Corrosive (C) >= 5.0% R51 >= 2.5% else >= 10% where percentage is percentage of ingredient found in the mixture SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

+X+X0+		

- +: May be stored together
- -: May be stored together with specific preventions
- X: Must not be stored together Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING BULK OR LARGE QUANTITIES

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps
- DO NOT enter confined spaces until atmosphere has been checked.
- Avoid smoking, naked lights, heat or ignition sources.





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- When handling, DO NOT eat, drink or smoke.
- Vapour may ignite on pumping or pouring due to static electricity.
- DO NOT use plastic buckets.
- Earth and secure metal containers when dispensing or pouring product.
- Use spark-free tools when handling.
- Avoid contact with incompatible materials.
- Keep containers securely sealed.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions.

SUITABLE CONTAINER

Packing as supplied by manufacturer. Plastic containers may only be used if approved for flammable liquid. Check that containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

Avoid storage with oxidisers strong alkalis and strong acids.

STORAGE REQUIREMENTS

- Store in original containers in approved flame-proof area.
- No smoking, naked lights, heat or ignition sources.
- DO NOT store in pits, depressions, basements or areas where vapours may be trapped. Keep containers securely sealed.
- Store away from incompatible materials in a cool, dry well ventilated area.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storing and handling recommendations. Keep cool. Store below 25 deg. C.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTION

EYE

- Safety glasses with side shields.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation





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immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly.

HANDS/FEET

No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves, eg. PVC. OTHER

- Overalls.
- Eyewash unit.

ENGINEERING CONTROLS

General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Pink colour liquid.

PHYSICAL PROPERTIES

Liquid.

Mixes with water. Molecular Weight: Not applicable Boiling Range (C): 78 °C (ethanol) Melting Range (C): Not available Weight per mL : 0.89gm/ml Solubility in water (g/L): Miscible pH : 6.20 ± 0.5 pH (1% solution): Not available Vapour Pressure (kPa): 5.85 @ 20 deg C Volatile Component (%vol): Not available Evaporation Rate: Not available Relative Vapour Density (air=1): Not available Flash Point (C): 22 (ethanol) Lower Explosive Limit (%): 3.5 (ethanol) Upper Explosive Limit (%): 19.0 (ethanol) Autoignition Temp (C): Not available Decomposition Temp (°C): Not available State: Liquid Viscosity: Not available

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.





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Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS ACUTE HEALTH EFFECTS SWALLOWED

The liquid is highly discomforting and harmful if swallowed in quantity and may cause dizziness, disorientation, mental confusion, slurred speech.

Ingestion may result in nausea, abdominal irritation, pain and vomiting.

Ingestion may result in intoxication, drunkenness.

EYE

The liquid may produce eye discomfort causing transient smarting, blinking. The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

SKIN

The material may be discomforting to the skin and may be capable of causing skin reactions which may lead to dermatitis.

Sensitisation may result in allergic dermatitis responses including rash, itching, hives or swelling of extremities.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis.

Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

Not considered to cause discomfort through normal use.

INHALED

The vapour is discomforting to the upper respiratory tract.

Inhalation hazard is increased at higher temperatures.

Acute effects from inhalation of high concentrations of vapour are pulmonary irritation, including coughing, with nausea; central nervous system depression - characterised by headache and dizziness, increased reaction time, fatigue and loss of co-ordination with dizziness, disorientation, mental confusion, slurred speech.

CHRONIC HEALTH EFFECTS

The principal routes of exposure are by skin contact with the material. Prolonged or continuous skin contact with the liquid may cause defatting with drying, cracking, irritation and dermatitis following. Chronic ingestion of chlorhexidine gluconate may result in liver or kidney damage.



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TOXICITY AND IRRITATION

Not available.

Section 12 – ECOLOGICAL INFORMATION

NOT AVALIABLE

Chlorhexidine Gluconate Solution IP - NA

Ethyl Alcohol IP - NA

Section 13 - DISPOSAL CONSIDERATIONS

- Consult manufacturer for recycling options and recycle where possible.
- Consult State Land Waste Management Authority for disposal.
- Incinerate residue at an approved site.
- Recycle containers if possible, or dispose of in an authorized landfill.

Section 14 – TRANSPORTATION INFORMATION

Labels Required Flammable liquid

Dangerous Goods Class: 3 Subrisk: None

Part Number: 1910

• Part Title: Occupational Safety and Health Standards

• Subpart: H

• Subpart Title: Hazardous Materials

• Standard Number: 1910.106

• Title: Flammable liquids.

• GPO Source: <u>e-CFR</u>



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Category 3 is for ethyl Alcohol because the flash point is below 100°F.

Generally, a flammable liquid is a combustible liquid that can easily catch fire. However, it is not the liquid itself that burns, but the vapor cloud above the liquid that will burn if the vapor's concentration in air is between the lower flammable limit (LFL) and upper flammable limit (UFL) of the liquid. Class 3 Flammable liquids are liquids, or mixtures of liquids, or liquids containing solids in solution or suspension (for example, paints, varnishes, lacquers, etc., but not including substances otherwise classified on account of their dangerous characteristics) which give off a flammable vapour at temperatures of not more than 60°C, closed-cup test, or not more than 65.6°C, open-cup test, normally referred to as the flash point. This class also includes:

Liquids offered for transport at temperatures at or above their flash point; and

1. Substances that are transported or offered for transport at elevated temperatures in a liquid state and which give off a flammable vapour at a temperature at or below the maximum transport temperature.



Section 15 – REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

ETHANOL (64-17-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

CHLORHEXIDINE GLUCONATE (18472-51-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS



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Australia Inventory of Chemical Substances (AICS)

WATER (7732-18-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

Section 16 - OTHER INFORMATION

* BACTORUB is a trademark of Raman & Weil Pvt. Ltd. Manufactured By: - T.M. Thakore Pharmaceutical Laboratories

The MSDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For complaints or Suggestions: RW Customer care cell 022 – 22049527 / 022 – 22856397.