

MATERIAL SAFETY DATA SHEET

Document No.: PSK/MSDS/104

Revision No.: 00

Revised Date: 01.04.2017

This MSDS has been prepared by PSK Pharma Pvt. Ltd., Quality Control Dept.

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution

COMPANY:

PSK Pharma Private Limited

121/22, Mahajenahalli, Post Box No. 21

Shimoga Road, Harihar – 577 601

Karnataka, India

Tel: +91 8192 24 0317, +91 8192 24 0318

Fax: +91 8192 24 0002

E-mail: weprotect@pskpharma.com

Website: www.pskpharma.com

RECOMMENDED USE: Skin Antiseptic

2. COMPOSITION

Ingredient Name	CAS No.	Percentage
Ethyl Alcohol	64-17-5	80% w/w
Chlorhexidine Gluconate (CHG)	18472-51-0	2% w/w
Preservative	-	< 0.5% w/w
Purified water	7732-18-5	qs to 100%

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)

3. HAZARDS IDENTIFICATION

NOTE: DANGEROUS GOODS. NON-HAZARDOUS SUBSTANCE.

POISONS SCHEDULE NONE ALLOCATED

Information pertaining to particular dangers for man and environment

R 10 Flammable.

R 41 Risk of serious damage to eyes.

R 67 Vapours may cause drowsiness and dizziness.

Classification System

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information by supplier companies.

4. FIRST AID MEASURES

IF SWALLOWED

The liquid may cause acute discomfort and is harmful if swallowed in large quantity and may cause dizziness, disorientation, mental confusion, slurred speech. Ingestion of the liquid may result in nausea, abdominal irritation, pain and vomiting. It may also result in intoxication and drunkenness.

EYE CONTACT

The liquid may cause severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure may produce conjunctivitis.

SKIN CONTACT

The liquid may cause skin irritation after prolonged or repeated exposure. It may produce skin redness, swelling, production of vesicles, scaling and thickening of the skin on contact. It is not considered to be an irritant through normal use.

IF INHALED

The vapor may cause discomfort. Hazard due to inhalation is increased at higher temperatures. Inhalation of higher concentrations of the vapor causes lung irritation with coughing and nausea, central nervous depression with headache and dizziness, slowing of reflexes, fatigue and loss of coordination with dizziness, disorientation and slurring of speech.

5. FIRE FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA

Alcohol stable foam, dry chemical powder, carbon dioxide

FIRE FIGHTING PROCEDURES

- Wear breathing apparatus plus protective gloves.
- If safe, switch off electrical equipment until vapour fire hazard removed.
- Use water delivered as a fine spray to control 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.

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)

FIRE FIGHTING PROCEDURES

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

COMBUSTION PRODUCTS FROM FIRE

Carbon Monoxide
Carbon Dioxide

HAZCHEM CODE 2[Y]

6. ACCIDENTAL RELEASE MEASURES (SPILL)

Person-related safety precautions:

Ensure adequate ventilation
Keep away from ignition sources

Measures for environmental protection:

Do not allow product to reach sewage system or water bodies.
Dilute with much water.

SPILL RESPONSE

Minor Spills

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid breathing vapours and contact with skin and eyes.
- 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.
- 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.

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)

7. HANDLING AND STORAGE

Precautions for Safe Handling

- Wear protective clothing when risk of overexposure 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 or ignition sources.
- Avoid generation of static electricity.
- DO NOT use plastic buckets.
- Earth all lines and equipment.
- Use spark-free tools when handling.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- 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.

Conditions for Safe Storage

- 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.
- Avoid storage with oxidisers, strong alkalis and strong acids.
- 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.

EXPLOSION AVOIDANCE

Flammable liquid and vapour. Keep away from heat, sparks, open flame, pilot lights and other sources of ignition.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components with critical values that require monitoring at the workplace:	
Ethyl Alcohol	64-17-5
ACGIH Threshold Limit Value (TWA) = 1000 ppm TWA NIOSH = 1000 ppm TWA; 1900 mg/m³ TWA 3300 ppm IDLH OSHA - Final PELs = 1000 ppm TWA; 1900 mg/m³ TWA	
Chlorhexidine Gluconate (CHG)	18472-51-0
Not Available	

Additional information: The lists that were valid during the compilation were used as basis.

Special Information, Exposure/Protection

The extent to which the following recommendations for exposure control and protection are observed should depend on the risk assessment undertaken for the specific conditions under which this product is used, including occupational hygiene measurements.

Recommended Ventilation

Use in a well-ventilated area.

Eye Protection

Avoid eye contact with vapour, spray, or mist.

Hand Protection

Not applicable.

Respiratory Protection

Avoid breathing vapours, mists or spray.

Prevention of Accidental Ingestion

Do not ingest. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Form:	Fluid
Colour:	Dark blue
Smell:	Pleasant
pH	5.5 – 7.5
Density	0.85 – 0.90 g/ml

Change in condition

Flash Point	22°C
Boiling Point	78°C
Solubility	100% in water
Vapor Density	1.6 (Air = 1) for ethanol
Vapor Pressure	43 mm Hg (0 °C)

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)

10 STABILITY AND REACTIVITY

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Dangerous reactions: No dangerous reactions known.

Dangerous products of decomposition: May produce chloroaniline on decomposition.

11. TOXICOLOGICAL INFORMATION

LD/LC50 values that are relevant for classification:

ETHANOL

TOXICITY

Oral (rat) LD50: 7060 mg/kg Skin (rabbit):20 mg/24hr- Moderate
Oral (human) LDLo: 1400 mg/kg Skin (rabbit):400 mg (open)- Mild
Oral (man) TDLo: 50 mg/kg Eye (rabbit):100mg/24hr- Moderate
Oral (man) TDLo: 1.40 mg/kg Eye (rabbit): 500 mg SEVERE
Oral (woman) TDLo: 256 mg/kg/12 wks
Inhalation (rat) LC50: 20, 000 ppm/10h
Inhalation (rat) LC50: 64000 ppm/4h

IRRITATION

Skin (rabbit):20 mg/24hr- Moderate
Skin (rabbit):400 mg (open)- Mild
Eye (rabbit):100mg/24hr- Moderate
Eye (rabbit): 500 mg SEVERE

The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

CHLORHEXIDINE GLUCONATE

TOXICITY

Oral (rat) LD50: 2000 mg/kg Nil Reported
Subcutaneous (rat) LD50: 3320 mg/kg
Intravenous (rat) LD50: 24.2 mg/kg

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

IRRITATION

Nil Reported

The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:

12. ECOLOGICAL INFORMATION

Information about elimination (persistence and degradability):

DO NOT discharge into sewer or waterways.

Refer to data for ingredients, which follows:

ETHANOL:

Fish LC50 (96hr.) (mg/l): 13480

Algae IC50 (72hr.) (mg/l): 1450

log Kow (Sangster 1997): - 0.3

BOD5: 63%

ThOD: 2.1

Half- life Soil - High (hours): 24

Half- life Soil - Low (hours): 2.6

Half- life Air - High (hours): 122

Half- life Air - Low (hours): 12.2

Half- life Surface water - High (hours): 26

Half- life Surface water - Low (hours): 6.5

Half- life Ground water - High (hours): 52

Half- life Ground water - Low (hours): 13

Aqueous biodegradation - Aerobic - High (hours): 26

Aqueous biodegradation - Aerobic - Low (hours): 6.5

Aqueous biodegradation - Anaerobic - High (hours): 104

Aqueous biodegradation - Anaerobic - Low (hours): 26

Aqueous biodegradation - Removal secondary treatment - High (hours): 67%

Photooxidation half- life water - High (hours): 3.20E+05

Photooxidation half- life water - Low (hours): 8020

Photooxidation half- life air - High (hours): 122

Photooxidation half- life air - Low (hours): 12.2

DO NOT discharge into sewer or waterways.

log Kow: -0.31- -0.32

Half-life (hr) air: 144

Half-life (hr) H2O surface water: 144

Henry's atm m³ /mol: 6.29E-06

BOD 5 if unstated: 0.93-1.67,63%

COD: 1.99-2.11,97%

ThOD: 2.1

When ethanol is released into the soil it readily and quickly biodegrades but may leach into ground water; most is lost by evaporation. When released into water the material readily evaporates and is biodegradable. Ethanol does not bioaccumulate to an appreciable extent. The material is readily degraded by reaction with photochemically produced hydroxyl radicals; release into air will result in photodegradation and wet deposition.

CHLORHEXIDINE GLUCONATE:

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

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.

14. TRANSPORT INFORMATION

Labels Required: FLAMMABLE LIQUID
HAZCHEM: 2[Y]
UNDG:
Dangerous Goods 3 Subrisk: None
Class:
UN Number: 1170 Packing Group: III
Shipping Name: ETHANOL SOLUTION

Air Transport IATA:

ICAO/IATA Class: 3 ICAO/IATA Subrisk: None
UN/ID Number: 1170 Packing Group: III
Special provisions: A3 A58 A148
Shipping Name: ETHANOL

Maritime Transport IMDG:

IMDG Class: 3 IMDG Subrisk: None
UN Number: 1170 Packing Group: III
EMS Number: F- E, S- D Special provisions: 144 223 330
Limited Quantities: 5 L
Shipping Name: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION
(ETHYL ALCOHOL SOLUTION)

15. REGULATORY INFORMATION

Designation according to EC guidelines:

As a drug/ cosmetic preparation, the product is not subject to the provisions of the Chemical Law and the Ordinance on Hazardous Materials. However, normal safety regulations should be observed.

Risk phrases:

10 Flammable.
41 Risk of serious damages to eyes.
67 Vapours may cause drowsiness and dizziness.

Safety phrases:

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
46 If swallowed, seek medical advice immediately and show container or label.

16. OTHER INFORMATION

Relevant R-phrases:

11 Highly flammable
22 Harmful if swallowed
36 Irritating to eyes.
38 Irritating to skin.

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)



PSK PHARMA PRIVATE LIMITED
PSK/MSDS/104

- 41 Risk of serious damage to eyes.
- 67 Vapours may cause drowsiness and dizziness.

The information on this data sheet represents our current data and best opinion as to the proper use in handling of this product under normal conditions. Any use of the product which is not in conformance with this data sheet, which involves using the product, or otherwise that in accordance with instructions of use on product packaging is the responsibility of the user. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact the Quality Control In-charge at +91 8192 240 318.

CUTAPREP-CHG HIGHLIGHT

Ethyl Alcohol & Chlorhexidine Gluconate Solution (Skin Antiseptic)