

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 1 of 15

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
BACTOPREP

SYNONYMS
Chlorhexidine Gluconate and Alcohol Skin Disinfectant

PRODUCT USE
Hand and skin antiseptic solution for external use.

SUPPLIER
Company: T.M.Thakore Pharmaceutical Laboratories.
Address:
15-A, Premson's Industrial Estate,
Caves Road, Jogeshwari-East,
Mumbai-400060.
India
Telephone: .022-2824 6058
Tele Fax: 91-22-2834 1385
E-mail: tmtlab@ tmtlab.biz

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

POISONS SCHEDULE
None

RISK
Irritating to eyes.

SAFETY
Do not breathe gas/fumes/vapour/spray.
Wear eye/face protection for large volumes or spills.
Use only in well ventilated areas.
Keep container in a well ventilated place.
To clean the floor and all objects contaminated by this material, use water.
Keep container tightly closed.

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 2 of 15

Section 2 – HAZARDS IDENTIFICATION

Take off immediately all contaminated clothing.

In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.

If swallowed, IMMEDIATELY contact Doctor.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME

Chlorhexidine Gluconate Solution I.P

Equivalent to Chlorhexidine Gluconate 2 % w/v

Ethanol I.P (95%) 80% v/v

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.

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.

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 3 of 15

Section 4 - FIRST AID MEASURES

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 determination.
 - 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.

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.

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 4 of 15

Section 5 - FIRE FIGHTING MEASURES

- 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.

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 eyes.

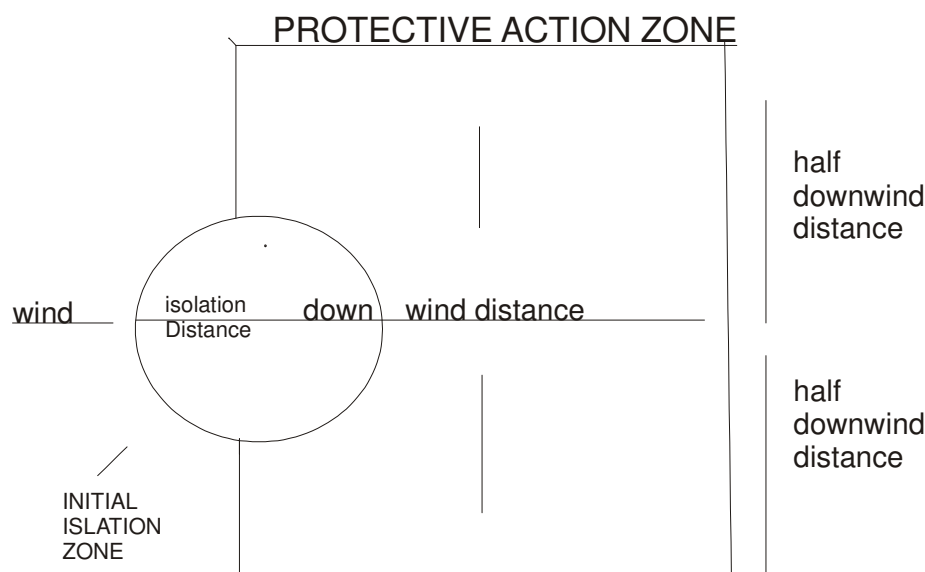
continued...

Section 6 - ACCIDENTAL RELEASE MEASURES

- 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.



continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 6 of 15

Section 6 - ACCIDENTAL RELEASE MEASURES

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.
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/m ³
water	500 mg/m ³

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 7 of 15

Section 6 - ACCIDENTAL RELEASE MEASURES

irreversible or other serious effects or symptoms which could impair an individual's ability to take protective action is:

ethanol 3300 ppm
glycerol 50 mg/m³
water 500 mg/m³

other than mild, transient adverse effects without perceiving a clearly defined odour is:

ethanol 3000 ppm
glycerol 30 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 15 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



+: 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.

RAMAN & WEIL PVT. LTD. BACTOPREP**Material Safety Data Sheet**

Issue Date: 10-March-2013

Page 8 of 15

Section 7 - HANDLING AND STORAGE

- DO NOT enter confined spaces until atmosphere has been checked.
- Avoid smoking, naked lights, heat or ignition sources.
- 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

ODOUR SAFETY FACTOR (OSF)

OSF=6 (ETHANOL)

Exposed individuals are NOT reasonably expected to be warned, by smell, that the Exposure Standard is being exceeded.

Odour Safety Factor (OSF) is determined to fall into either Class C, D or E.

The Odour Safety Factor (OSF) is defined as:

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 9 of 15

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

OSF= Exposure Standard (TWA) ppm/ Odour Threshold Value (OTV) ppm
 Classification into classes follows:

Class	OSF	Description
A	550	Over 90% of exposed individuals are aware by smell that the Exposure Standard (TLV-TWA for example) is being reached, even when distracted by working activities
B	26-550	As "A" for 50-90% of persons being distracted
C	1-26	As "A" for less than 50% of persons being distracted
D	0.18-1	10-50% of persons aware of being tested perceive by smell that the Exposure Standard is being reached
E	<0.18	As "D" for less than 10% of persons aware of being tested

EXPOSURE STANDARDS FOR MIXTURE

"Worst Case" computer-aided prediction of vapour components/concentrations:

"Worst Case" computer-aided prediction of vapour components/concentrations:

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

"Worst Case" computer-aided prediction of vapour components/concentrations:

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

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.

Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc: (%)

Component	Breathing zone (ppm)	Breathing Zone (mg/m ³)	Mixture Conc (%)
chlorhexidine gluconate	0.00	0.1000	2.5

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 10 of 15

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.
Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc: (%).
Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.
"Worst Case" computer-aided prediction of vapour components/concentrations:
Composite Exposure Standard for Mixture (TWA) (mg/m³):

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.
Component Breathing Zone ppm Breathing Zone mg/m³ Mixture Conc: (%).
Operations which produce a spray/mist or fume/dust, introduce particulates to the breathing zone.

If the breathing zone concentration of ANY of the components listed below is exceeded, "Worst Case" considerations deem the individual to be overexposed.
At the "Composite Exposure Standard for Mixture" (TWA) (mg/m³): 2.5 mg/m³

INGREDIENT DATA

ETHANOL:

Odour Threshold Value: 49-716 ppm (detection), 101 ppm (recognition)
Eye and respiratory tract irritation do not appear to occur at exposure levels of less than 5000 ppm and the TLV-TWA is thought to provide an adequate margin of safety against such effects.

Experiments in man show that inhalation of 1000 ppm caused slight symptoms of poisoning and 5000 ppm caused strong stupor and morbid sleepiness.

Subjects exposed to 5000 ppm to 10000 ppm experienced smarting of the eyes and nose and coughing. Symptoms disappeared within minutes.

Inhalation also causes local irritating effects to the eyes and upper respiratory tract, headaches, sensation of heat intraocular tension, stupor, fatigue and a need to sleep.

At 15000 ppm there was continuous lachrymation and coughing.

CHLORHEXIDINE GLUCONATE:

CEL TWA: 0.0027 ppm; 0.1 mg/m³

GLYCEROL:

The mist is considered to be a nuisance particulate which appears to have little adverse effect on the lung and does produce significant organic disease or toxic effects. OSHA concluded that this limit would protect the worker from kidney damage and perhaps, testicular effects.

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 11 of 15

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

WATER:

No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION

EYE

No special equipment for minor exposure i.e. when handling small quantities.

- OTHERWISE:

- 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 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

Colourless , highly flammable liquid; mixes with water.

continued...

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

Molecular Weight: Not applicable

Melting Range (C): Not available

Solubility in water (g/L): Miscible

pH (1% solution): Not available

Volatile Component (%vol): Not available

Relative Vapour Density (air=1): Not available

Lower Explosive Limit (%): 3.5 (ethanol)

Autoignition Temp (C): Not available

State: Liquid

Boiling Range (C): 78°C (ethanol)

Weight per mL : 0.89gm/ml

pH : 6.0 -7.0

Vapour Pressure (kPa): 5.85 @ 20 deg C

Evaporation Rate: Not available

Flash Point (C): 22 (ethanol)

Upper Explosive Limit (%): 19.0 (ethanol)

Decomposition Temp (°C): Not available

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.

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.

continued...

Section 11 - TOXICOLOGICAL INFORMATION

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.

TOXICITY AND IRRITATION

Not available. Refer to individual constituents.

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

ETHANOL:

TOXICITY

Oral (rat) LD50: 7060 mg/kg

Oral (human) LDLo: 1400 mg/kg

Oral (man) TDLo: 50 mg/kg

Oral (man) TDLo: 1.40 mg/kg

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

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 14 of 15

Section 11 - TOXICOLOGICAL INFORMATION

CHLORHEXIDINE GLUCONATE:

TOXICITY

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

IRRITATION

Nil Reported

GLYCEROL:

TOXICITY

Oral (Rat) LD50: 12600 mg/kg

IRRITATION

WATER:

No significant acute toxicological data identified in literature search.

Section 12 - 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 authorised landfill.

Section 13 – TRANSPORTATION INFORMATION



Labels Required

flammable liquid

Land Transport UNDG:

Dangerous Goods Class:

Subrisk:

UN Number:

Packing Group:

Shipping Name: ETHANOL (ETHYL ALCOHOL)

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

continued...

RAMAN & WEIL PVT. LTD. BACTOPREP

Material Safety Data Sheet

Issue Date: 10-March-2013

Page 15 of 15

Section 13 – TRANSPORTATION INFORMATION

Maritime Transport IMDG:

IMDG Class:

IMDG Subrisk:

UN Number:

Packing Group:

EMS Number:

Shipping Name: ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION
(ETHYL ALCOHOL SOLUTION)

Section 14 - OTHER INFORMATION

Issue Date: 10-March-2013

Print Date: 10-March-2013

* BACTOPREP is a trademark of RAMAN & WEIL PVT. LTD.
Manufactured By: - RAMAN & WEIL PVT. LTD.