

#### **SECTION 1: IDENTIFICATION**

PRODUCT NAME:	Mupirocin Cream USP, 2% PRODUCT No.: 21922-029
Distributor:	Encube Ethicals Private Limited
	803, B wing, HDIL Kaledonia, Sahar Road, Andheri East, Mumbai-400069
Recommended Use:	Mupirocin Cream USP, 2% is indicated for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm <sup>2</sup> in area) due to susceptible isolates of <i>Staphylococcus aureus (S.aureus)</i> and <i>Streptococcus pyogenes (S. pyogenes)</i> .
Restrictions on Use:	Mupirocin cream is contraindicated in patients with known hypersensitivity to mupirocin or any of the excipients of mupirocin cream.
Substance Class:	Anti-bacterial Agent
Formula:	$(C_{26}H_{43}O_9)2Ca\cdot 2H_2O$
<b>M.W.:</b>	500.6

# **SECTION 2: HAZARD(S) IDENTIFICATION**

Health Hazards: Caution - Pharmaceutical agent.

Exposure might occur via ingestion; skin; eyes.

Health effects information is based on hazards of components.

Flammability Hazards: This product is classified as a non-combustible solid and will not support propagating combustion. Environmental Hazards: No information is available about the potential of this product to produce adverse environmental effects.

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

	Xanthan Gum	
Inactive Ingredients:	Benzyl Alcohol, Polyoxyl 20 Cetostearyl Ether, Mono- And Di- Glycerides, Mineral Oil, Phenoxyethanol, Purified Water And	
Active Ingredient:	Mupirocin Calcium 2%	CAS#: 115074-43-6

Wash immediately with clean and gently flowing water. Continue for at least 15 Eye:



minutes. Obtain medical attention.

- **Skin:** Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
- **Ingestion:** Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation: Physical form suggests that risk of inhalation exposure is negligible.

SECTION 5. FIRE-FIGHTING WEASURES		
Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.	
Extinguishing Media:	Water is recommended for fires involving packaging.	
Special Fire Fighting Procedures:	For single units (packages): No special requirements needed.	
	For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.	
Hazardous Combustion Products:	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.	

# **SECTION 5: FIRE-FIGHTING MEASURES**

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear p hazard	protective clothing and equipment consistent with the degree of
<b>Environmental Precaut</b>		For large spills, take precautions to prevent entry into waterways, , or surface drainage systems.
Clean-up Methods:	Collect and place it in a suitable, properly labelled container for recovery or disposal.	
Decontamination Proce	decont	Detergent solutions can be used for clean-up and amination operations. No specific decontamination or fication procedures have been identified for this product.



### **SECTION 7: HANDLING AND STORAGE**

Handling General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage:	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
	SECTION & EXPOSUDE CONTROL S/DEDSONAL DEOTECTION

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS	An Exposure Control Approach (ECA) is established for
Exposure Controls:	operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them

# **Other Equipment or Procedures** Wash hands and arms thoroughly after handling. None required for normal handling.

OCCUPATIONAL EXPOSURE LIMITS

**INGREDIENT** MUPIROCIN CALCIUM

**Occupational Exposure Limit** 5000 mcg/m3 (8 HR TWA)

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Cream.

Appearance

**Physical Form** 

Flash Point

120 °C (Closed Cup).

# SECTION 10: STABILITY AND REACTIVITY

Stability:

This product is expected to be stable.

**Conditions to Avoid:** 

None for normal handling of this product.

# SECTION 11: TOXICOLOGICAL INFORMATION

**Pharmacological Effects**: This preparation contains ingredient(s) with the following activity: an



antibiotic.

# **Routes of Exposure**

<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Minor irritation might occur following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b> No adverse effects have been reported following extensive use or exposure in humans.	
Other Adverse Effects None known for occupational exposure	
	SECTION 12. ECOLOCICAL INFORMATION

#### **SECTION 12: ECOLOGICAL INFORMATION**

Summary	This material has had limited testing. There is insufficient information to determine the scope of the environmental effects this material may cause. Local regulations and procedures should be consulted prior to environmental release.	
ECOTOXICITY		
Aquatic		
Daphnid	This material contains an active pharmaceutical ingredient that is not toxic to daphnids.	
	EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Nominal	
	NOEC: 1000 mg/l	
MOBILITY		
Solubility	This material contains an active ingredient that for environmental fate predictions has solubility in water.	

# SECTION 13: DISPOSAL CONSIDERATIONS



**Disposal Recommendations** Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

**Regulatory Requirements** Observe all local and national regulations when disposing of this product.

### SECTION 14: TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

#### **UN Classification and Labelling**

**Transport Information** 

Not regulated in transport.

### SECTION 15: REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

#### **EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

#### **Other US Regulations**

TSCA Status Exempt

#### **SECTION 16: OTHER INFORMATION**

Contact: Encube Ethicals Private Limited 803, B wing, HDIL Kaledonia,

Sahar Road, Andheri East, Mumbai-400069

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