

**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 *Staphylococcus aureus* (*S.aureus*)and *Streptococcus pyogenes* (*S. pyogenes*).

**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<sub>26</sub>H<sub>43</sub>O<sub>9</sub>)<sub>2</sub>Ca·2H<sub>2</sub>O

**M.W.:**                                 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**

**Active Ingredient:**                Mupirocin Calcium 2%                CAS#: 115074-43-6

**Inactive Ingredients:**            Benzyl Alcohol, Polyoxyl 20 Cetostearyl Ether, Mono- And Di-Glycerides, Mineral Oil, Phenoxyethanol, Purified Water And Xanthan Gum

**SECTION 4: FIRST-AID MEASURES**

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





**SECTION 7: HANDLING AND STORAGE**

**Handling** No special control measures required for the normal handling of this product.  
**General Requirements** 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 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**ENGINEERING CONTROLS** An Exposure Control Approach (ECA) is established for 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..  
**Exposure Controls:**  
**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/m<sup>3</sup> (8 HR TWA)

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** Cream.  
**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**

**Oral Toxicity** 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.

**Reproductive Effects** No adverse effects have been reported following extensive use or exposure in humans.

**Other Adverse Effects** None known for occupational exposure

**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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