CETYLPYRIDINIUM CHLORIDE
Catalog Number: 1104006  Package Size: 500 mg  Revision Date: June 24, 2003

EMERGENCY OVERVIEW - Toxic. This material is irritating to mucous membranes, skin and respiratory tract.

SECTION 1 - IDENTIFICATION

Common Name: Cetylpyridinium Chloride  
Formula: C21H38ClN.H2O

Synonym: n/f

Chemical Name: Pyridinium, 1-hexadecyl-, chloride, monohydrate

CAS Number: 6004-24-6; 123-03-5 (anhydrous)  
RTECS Number: UU5075000; UU4900000 (anhydrous)

Chemical Family: Pyridine derivative

Therapeutic Category: Anti-infective, topical; pharmaceutic aid (preservative)

SECTION 2 - INGREDIENT INFORMATION

<table>
<thead>
<tr>
<th>Principle Components</th>
<th>Percent</th>
<th>Exposure Limits</th>
</tr>
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<tbody>
<tr>
<td>Cetylpyridinium Chloride</td>
<td>Pure Material</td>
<td>n/f</td>
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</tbody>
</table>

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of cetylpyridinium chloride is 0.33 to 3 mg as a lozenge or as a 0.05 to 0.1% solution in a mouthwash. It is also used topically.

Adverse Effects: Adverse effects may include respiratory/muscular paralysis, nausea, vomiting, collapse, convulsions, and coma. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects include those described in adverse effects above.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
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Chronic: Possible hypersensitization.
Inhalation: Causes irritation. Avoid inhalation. Remove to fresh air.
Eye: Causes irritation. Avoid contact. Flush with copious quantities of water.
Skin: Causes irritation. Avoid contact. Flush with copious quantities of water.
Ingestion: May cause irritation and toxicity. Avoid ingestion. Flush out mouth with water.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material and dermatitis.

Cross Sensitivity: n/f
Pregnancy Comments: n/f
Pregnancy Category: n/f

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment of overdose should be symptomatic and supportive. For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: 200 mg/kg (anhydrous)
Oral Mouse: LD50: 108 mg/kg (anhydrous)
Irritancy Data: [RTECS] - Rabbit/Skin: moderate; Rabbit/Eye: reaction not reported. (anhydrous)
Target Organ(s): n/f
Listed as a Carcinogen? NTP: No  IARC: No  OSHA: No
Other: No

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f  Upper Flammable Limit: n/f
Auto-Ignition Temperature: 420° - 450° C  Lower Flammable Limit: n/f
Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.
Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: n/f
Incompatibilities: Strong oxidizing or reducing agents, and anionic detergents.
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Decomposition Products: When heated to decomposition material emits very toxic fumes of Cl- and NOx. Emits toxic fumes under fire conditions.

Stable? Yes  Hazardous Polymerization? No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Ventilation: Recommended.

Gloves: Rubber

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White powder; slight characteristic odor.

Melting Point: 77 - 84°F

Solubility in Water: Freely soluble

Boiling Point: n/f

Specific Gravity: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Evaporation Rate: n/f

Reactivity in Water: n/f

% Volatile by Volume: n/f