

SAFETY DATA SHEET



Chlorhexidine 0.1% Lube

Item # 10-073

1. SUBSTANCE IDENTITY/COMPANY CONTACT INFORMATION

PRODUCT NAME: Pro-Tec™ Chlorlube
MOLECULAR FORMULA: Mixture
CHEMICAL FAMILY: Lubricant
USE: Ready-to-use chlorhexidine preserved lubricant for topical or intrauterine application.
SUPPLIER:
Aurora Pharmaceutical, LLC
1196 South Highway 3
Northfield, MN 55057
TELEPHONE NUMBERS:
Emergency (Chemtrec 24 hours): (800) 424-9300
Information: (888) 215-1256

2. HAZARDS IDENTIFICATION

Signal word: WARNING

Pictograms



HAZARD STATEMENTS

H318 – Causes serious eye damage
H335 – May cause respiratory irritation

Precautionary statements

P305, P351, P338 – If in eyes; rinse with water for at least 15 minutes. Remove contact lenses. Seek medical attention

OTHER HAZARDS

CARCINOGENIC STATUS: Ingredients are not considered carcinogenic by NTP, IARC, or OSHA.

EFFECTS OF EXPOSURE: May cause skin, eye, and mucous membrane irritation and burns (symptoms such as discomfort, redness, tearing, sneezing, and runny nose). May cause allergic skin reactions. Exposure may cause nausea, vomiting, diarrhea, cramps, and colitis.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

3. COMPOSITION/INFORMATION OF INGREDIENTS

Mixture of the substances listed in this section.

INGREDIENT 1

COMMON NAME: Water
CAS: 7732-18-5
% BY WEIGHT: >80%
EXPOSURE LIMIT(S):

INGREDIENT 2

COMMON NAME: Chlorhexidine Gluconate
CAS: 18472-51-10
% BY WEIGHT: 0.1%
EXPOSURE LIMIT(S): Not established.

INGREDIENT 3

COMMON NAME: Alcohol, SDA-35A
CAS: 64-17-5 & 141-78-6
% BY WEIGHT: Trade secret
EXPOSURE LIMIT(S): Not established.

INGREDIENT 4

COMMON NAME: Hydroxyethyl Cellulose
CAS: mixture
% BY WEIGHT: Trade secret
EXPOSURE LIMIT(S): Not established.

Additional ingredients are present in < 1% of the formulation and are not considered carcinogens.

EXPOSURE LIMIT(S) FOR THE MATERIAL:
Not established.

4. FIRST AID MEASURES

EYES: Remove contact lenses, if present. Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. If irritation persists, obtain medical attention.

SKIN: Wash off with soap and water. If reaction occurs, seek medical attention.

INHALATION: Move to fresh air.

INGESTION: Contact a physician or poison control center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not applicable (predominantly water).

LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.

FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and full-body protective equipment.

UNUSUAL FIRE OR EXPLOSION HAZARDS:
None known.

HAZARDOUS COMBUSTION PRODUCTS:
Carbon monoxide, carbon dioxide

6. ACCIDENTAL RELEASE MEASURES

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PERSONAL PRECAUTIONS: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

ENVIRONMENTAL PRECAUTIONS: Do not let product enter drains. Do not flush into surface water. Do not flush to groundwater and soil.

METHODS FOR CLEANING UP: Absorb the liquid with suitable material, then transfer into a suitable container for disposal.

7. HANDLING AND STORAGE

HANDLING: Use with adequate ventilation. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Launder contaminated clothing before reuse.

STORAGE: Store at room temperature. Store in a dry area away from direct sunlight, heat, and incompatible materials. Protect from freezing and physical damage. Reseal containers immediately after use. Store away from food and beverages. Keep out of reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required under normal conditions of use.

VENTILATION: Good general ventilation should suffice.

HAND PROTECTION: Not normally required.

EYE PROTECTION: Safety glasses. Care should be taken to avoid accidental exposure.

OTHER PROTECTIVE EQUIPMENT: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, green, viscous gel

Odor: Not available.

pH: 5.0-7.0

Flash Point: NA

Auto ignition Temperature: NA

Boiling Point/Range: NA

Melting Point/Range: NA

Flammability (solid, gas): NA

Upper/Lower Flammability: NA

Vapor Pressure: NA

Vapor Density: NA

Specific Gravity: NA

Water Solubility: Soluble

Reactivity in Water: NA

Decomposition Temperature: NA

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

PHYSICAL CONDITIONS TO AVOID: Heat - high temperature.

INCOMPATIBILITY WITH OTHER

MATERIALS: Do not clean with anionic detergents that will precipitate the chlorhexidine into a water insoluble residue.

HAZARDOUS DECOMPOSITION PRODUCTS: No data.

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

No data is available for the 0.1% product. The following is for Chlorhexidine Gluconate:

LD₅₀ Oral rat 2000mg/kg

LD₅₀ Oral mouse: 1260mg/kg

CHRONIC TOXICITY:

No known chronic effects.

REPRODUCTIVE/DEVELOPMENTAL TOXICITY:

Non-teratogenic.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable local and national regulations.

14. TRANSPORT REGULATIONS

Not regulated by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA).

15. REGULATORY INFORMATION

Federal

TSCA: All of the components are listed in the United States TSCA (Toxic Substances Control Act) inventory.

SARA: No component is listed

State

California Prop 65: No components listed under Prop 65

16. OTHER INFORMATION

Revision Date: 12/15/15

The information and recommendations presented in this SDS are based on sources believed to be accurate. Aurora Pharmaceutical, LLC assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the information for their particular purposes.