

LEMON DROP GENTLE ANTISEPTIC- chloroxylenol liquid
Woodbine Products Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Choroxylenol 0.3%

Purpose

Antibacterial

Uses:

For hand washing to decrease bacteria on the skin.

Warnings:

For external use only

When using this product avoid contact with eyes.

In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

If swallowed, get medical help or contact a Poison control Center right away.

Directions:

Apply to hands, add small amount of water and lather.

Work until soil is emulsified, rinse and wipe dry.

Other Information:

Store at 20 to 25 C (68 to 77 F)

Inactive Ingredients:

Water, Sodium Lauryl Sulfate, Lauryl Glucoside, Cocamidopropyl Betaine, Propylene Glycol, Sodium Chloride, Fragrance and Glycerin.

PK

Lemon Drop

gentle lotion soap

antiseptic

Woodbine Products Company

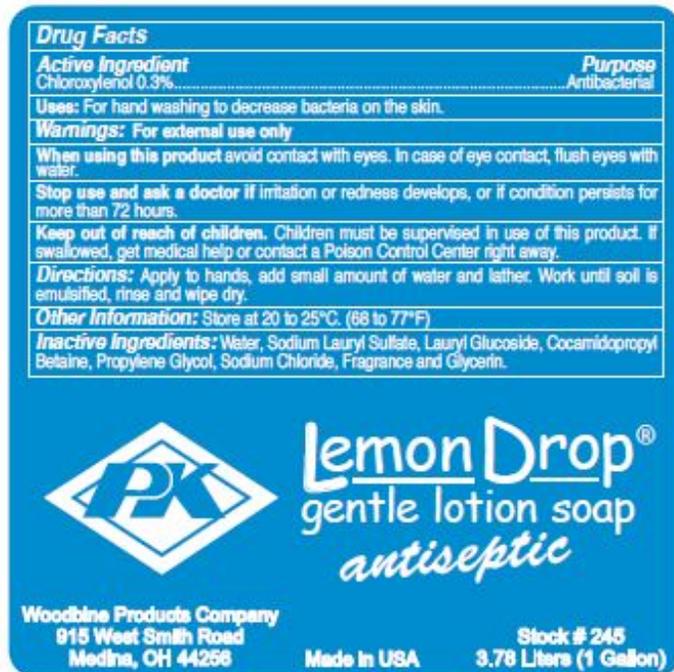
915 West Smith Road

Medina, OH 44256

Made in USA

Stock # 245

3.78 Liters (1 Gallon)



LEMON DROP GENTLE ANTISEPTIC

chloroxylenol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11429-1006 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q) | CHLOROXYLENOL | 3 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| LAURYL GLUCOSIDE (UNII: 76LN7P7UCU) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

SODIUM CHLORIDE (UNII: 451W47IQ8X)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:11429-1006-1 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/16/2014 | |
| 2 | NDC:11429-1006-2 | 800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/16/2014 | |
| 3 | NDC:11429-1006-4 | 2125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/16/2014 | |
| 4 | NDC:11429-1006-5 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/16/2014 | |
| 5 | NDC:11429-1006-3 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 04/16/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 04/16/2014 | |

Labeler - Woodbine Products Company (004220323)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|-------------------------|
| Woodbine Products Company | | 004220323 | manufacture(11429-1006) |

Revised: 6/2022

Woodbine Products Company