

PREVENT- chloroxylenol soap
Ultra-Chem Inc.

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.

Prevent

Prevent

☐Active Ingredient

Chloroxylenol 0.375%

Prevent

Uses

- ☐☐Antibacterial hand cleaner.
- Use in daycare, hospitals, nursing homes, physicians offices, dental offices and clinics

Prevent

Warnings

- **For external use only.**
- Avoid contact with eyes.
- Children under the age of 6 should be supervised by an adult when using this product.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**

Prevent

Directions

- ☐**Read the entire label before using this product.**
- ☐Dispense 1-2 pumps of product onto wet palm.
- Lather and rinse hands with clean water

Prevent

Inactive Ingredients

☐Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl betadine, Phenoxyethanol, Sodium Laureth Sulfate, Propylene Glycol, Fragrance, DMDM Hydantoin, Glycol Stearate, Lauramide DEA, Glycerine, Tocopheryl Acetate, D&C Green #5, FD&C Yellow #5.

Prevent

Purpose

Antibacterial

Prevent

Winning Hands Antibacterial

KEEP OUT OF REACH OF CHILDREN

Prevent

UltraChem 141

PREVENT

Pearlized Antibacterial Skin Cleanser with Chloroxylonol (PCMX)

DISTRIBUTED BY:

ULTRA-CHEM INC.

8043 Flint St., Lenexa, KS 66214

KANSAS CITY - PHOENIX (800)451-0726

Drug Facts

Active Ingredient.....	Purpose
Chloroxylonol 0.375%	Antibacterial

Uses

- Antibacterial hand cleaner.
- Use in daycare, hospitals, nursing homes, physician offices, dental offices and clinics.

Warnings

- **For external use only.**
- Avoid contact with eyes.
- If contact occurs, rinse thoroughly with water.
- Discontinue use if irritation or redness develops.
- If irritation persists for more than 72 hours, consult a physician.
- **KEEP OUT OF REACH OF CHILDREN.**
- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **Read the entire label before using this product.**
- Dispense 2 pumps of product onto palm of hand and scrub thoroughly over all surfaces of both hands.
- Rinse with clean water.

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Coco MIPA, Phenoxyethanol, Ethanol, Sodium Lauryl Sulfate, Glycol Distearate, Sodium Chloride, Glycerin, Propylene Glycol, Lauramide MIPA, Fragrance, Disodium Cocamidoisopropyl Sulfosuccinate, Sodium Hydroxide, Magnesium Nitrate, Ethoxylated Alcohols, Methylchloroisothiazolinone, Magnesium Chloride, D&C Green #5, FD&C Yellow #5, Methylisothiazolinone.

55 US gal (208 L)

MADE IN USA



RLB8816

0814117

PREVENT

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66077-708
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL BENZOATE (UNII: N863NB338G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYL ANTHRANILATE (UNII: 981I0C1E5W)	
SODIUM ALUMINIUM SILICATE (UNII: 058TS43PSM)	
ETHYL ACETOACETATE (UNII: IZP61H3TB1)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
.GAMMA.-DECALACTONE (UNII: 7HLS05KP9O)	
ETHYLENE OXIDE (UNII: JJH7GNN18P)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYL BUTYRATE (UNII: UFD2LZ005D)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
DIOXANE (UNII: J8A3S10O7S)	
DIMETHYL BENZYL CARBINYL ACETATE (UNII: 6Y9488RL8H)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SODIUM FERROCYANIDE (UNII: 5HT6X21AID)	
LAURIC ISOPROPANOLAMIDE (UNII: 82DUX3RRVU)	
METHYL ALCOHOL (UNII: Y4S76JWI15)	
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
CHLOROACETIC ACID (UNII: 5GD84Y125G)	
DIMETHYL BENZYL CARBINYL BUTYRATE (UNII: 3Q0C60547R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66077-708-55	208 mL in 1 DRUM; Type 0: Not a Combination Product	11/12/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/12/2012	

Labeler - Ultra-Chem Inc. (181772757)**Registrant** - Betco corporation, Ltd. (005050158)**Establishment**

Name	Address	ID/FEI	Business Operations
Betco Corpo, Ltd.		005050158	manufacture(66077-708) , label(66077-708) , pack(66077-708)

Revised: 7/2020

Ultra-Chem Inc.