

PEARLESCENT- chloroxylenol soap

Boelter Companies 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.

Pearlescent

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☐Active Ingredient

Chloroxylenol 0.375%

Pearlescent

Uses

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

Pearlescent

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.**

Pearlescent

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

Pearlescent

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.

Pearlescent

Purpose

Antibacterial

Pearlescent

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PEARLESCENT

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57468-708
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
WATER (UNII: 059QF0KO0R)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MYRCENE (UNII: 3M39CZS25B)	
LAURIC DIETHANOLAMIDE (UNII: I29I2VHG38)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
DIMETHYL BENZYL CARBINYL BUTYRATE (UNII: 3Q0C60547R)	
BENZYL BENZOATE (UNII: N863NB338G)	
DIOXANE (UNII: J8A3S10O7S)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL ALCOHOL (UNII: Y4S76JW115)	
.GAMMA.-DECALACTONE (UNII: 7HLS05KP9O)	
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	
SODIUM ALUMINIUM SILICATE (UNII: 058TS43PSM)	
SODIUM FERRO CYANIDE (UNII: 5HT6X21AID)	
ETHYL ACETOACETATE (UNII: IZP61H3TB1)	
LAURIC ISOPROPANOLAMIDE (UNII: 82DUX3RRVU)	
DIMETHYL BENZYL CARBINYL ACETATE (UNII: 6Y9488RL8H)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
METHYL ANTHRANILATE (UNII: 981I0C1E5W)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)	
ETHYL BUTYRATE (UNII: UFD2LZ005D)	
ETHYLENE OXIDE (UNII: JJH7GNN18P)	
CHLOROACETIC ACID (UNII: 5GD84Y125G)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57468-708-05	3780 mL in 1 JUG; Type 0: Not a Combination Product	03/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/18/2013	

Labeler - Boelter Companies Inc. (006436299)

Registrant - Betco corporation, Ltd. (024492831)

Establishment

Name	Address	ID/FEI	Business Operations
Betco Corporation, Ltd.		024492831	manufacture(57468-708) , pack(57468-708) , label(57468-708)

Revised: 7/2020

Boelter Companies Inc.