

SOFT AND SILKY ANTISEPTIC- antiseptic lotion soap solution
Kutol Products Company, 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.

F025F Soft and Silky Antiseptic

Chloroxylenol 0.1% w/w.....Antibacterial Handwashing

Water, Tall Oil Acid, Potassium Hydroxide, Coconut Acid, Sodium Lauryl Sulfate, Cocamide DIPA, Phenoxyethanol, Tetrasodium EDTA, Sodium Chloride, Styrene/Acrylates Copolymer, Fragrance, Iodopropynyl Butylcarbamate.

Handwash to help decrease bacteria on the skin.

USDA E-1

For external use only.

Do not use in the eyes. In case of contact, immediately flush with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Apply a small amount, covering hands with product for 30 seconds. Add water, lather and rinse.

Children under 6 years of age should be supervised when using this product.

Handwash to help decrease bacteria on the skin.

USDA E-1

Do not use in the eyes. In case of contact, immediately flush with water.

Stop use and ask a doctor if irritation or redness appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



50865-025-65.jpg

SOFT AND SILKY ANTISEPTIC

antiseptic lotion soap solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50865-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3.82 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
METHACRYLATE/METHOXY PEG-10 MALEATE/STYRENE COPOLYMER (UNII: 39DK5WQ2PR)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
TALL OIL (UNII: 1GX6Z36A79)	

COCONUT ACID (UNII: 40U37V505D)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIISOPROPANOLAMIDE (UNII: S485AM948Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50865-025-03	208175 mL in 1 DRUM; Type 0: Not a Combination Product	11/04/2013	
2	NDC:50865-025-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/04/2013	05/10/2017
3	NDC:50865-025-09	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/04/2013	
4	NDC:50865-025-12	1200 mL in 1 BAG; Type 0: Not a Combination Product	11/04/2013	05/10/2017
5	NDC:50865-025-18	500 mL in 1 BAG; Type 0: Not a Combination Product	11/04/2013	
6	NDC:50865-025-65	800 mL in 1 BAG; Type 0: Not a Combination Product	11/04/2013	
7	NDC:50865-025-80	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/04/2013	05/10/2017
8	NDC:50865-025-82	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/04/2013	05/10/2017
9	NDC:50865-025-93	1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/04/2013	05/10/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/04/2013	

Labeler - Kutol Products Company, Inc. (004236139)

Registrant - Kutol Products Company (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company Inc.		004236139	manufacture(50865-025)