

ANTIBACTERIAL HAND- antiseptic hand soap soap
US Chemical Corporation

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.

US Chem F060

Directions 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.

Inactive Ingredients Water, Tall Oil Acide, Potassium Hydroxide, Coconut Acid, Phenoxyethanol, Cocamide DIPA, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Tetrasodium EDTA, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance, Sodium Sulfate, Iodopropynl, Butylcarbamate, Yellow 5, Red 33.

Uses Handwash to help decrease bacteria on the skin.

Active Ingredient Chloroxylonol 0.3% w/w

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

Purpose Antibacterial Agent

Warnings For external use only. Avoid contact with eyes. In case of contact, flush with plenty of water. Stop use, and ask a doctor if irritation or rash appears and persists.

Drug Facts		Drug Facts (continued)	
Active Ingredient	Purpose	Directions	
Chloroxylenol 0.3 % w/w.....	Antibacterial Agent	<ul style="list-style-type: none"> ■ 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. 	
Uses		Inactive Ingredients	
<ul style="list-style-type: none"> ■ Handwash to help decrease bacteria on the skin. 		<p>Water, Tall Oil Acid, Potassium Hydroxide, Coconut Acid, Phenoxyethanol, Cocamide DIPA, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Tetrasodium EDTA, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Fragrance, Sodium Sulfate, Iodopropynyl Butylcarbamate, Yellow 5, Red 33.</p>	
Warnings			
For external use only.			
<p>Avoid contact with eyes. In case of contact, flush with plenty of water.</p>			
<p>Stop use and ask a doctor if irritation or rash appears and persists.</p>			
<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>			

antiseptic hand soap soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61307-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TALL OIL ACID (UNII: H9HR63474M)	
COCONUT ACID (UNII: 40U37V505D)	
ACID RED 35 (UNII: 02BXM5Q7GE)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM LAURETH-12 SULFATE (UNII: 8M492LDU23)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
DISODIUM ETHYLENE DICOCAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61307-060-09	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/13/2013	

Labeler - US Chemical Corporation (031457842)

Registrant - KutoI Products Company (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
KutoI Products Company		004236139	manufacture(61307-060)

Revised: 8/2023

US Chemical Corporation