

ANTISEPTIC- chloroxylenol soap
Sky Systems Co., 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.

SKY SYSTEMS - ANTISEPTIC LOTION SOAP (67106-7014)

ACTIVE INGREDIENT

CHLOROXYLENOL 0.45%

PURPOSE

ANTISEPTIC

USES

- HELP PREVENT CROSS CONTAMINATION BY HAND CONTACT TO REDUCE INCIDENCE ON NOSOCOMIAL INFECTION.

WARNINGS

- FOR EXTERNAL USE ONLY.

WHEN USING THIS PRODUCT

- AVOID CONTACT WITH EYES. IN CASE OF CONTACT WITH EYES, FLUSH THOROUGHLY WITH WATER.
- AVOID CONTACT WITH BROKEN SKIN.

STOP USE AND ASK A DOCTOR IF

- CONDITIONS WORSEN OR IRRITATION PERSISTS.
- IRRITATION OR REDNESS DEVELOPS AND PERSISTED FOR MORE THAN 72 HOURS.

KEEP OUT OF REACH OF CHILDREN.

- IF SWALLOWED, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- WET HANDS AND FOREARMS.
- APPLY 5 ML (TEASPOONFULL) OR PALMFUL TO HANDS AND FOREARMS.
- SCRUB THOROUGHLY FOR 1 MINUTE. RINSE AND REPEAT.

OTHER INFORMATION

- STORE AT 20-25°C (60 TO 77°F)

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, PROPYLENE GLYCOL, POLYQUATERNIUM 7, GLYCOL STEARATE, SODIUM CHLORIDE, CITRIC ACID.



ANTISEPTIC			
chloroxylenol soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67106-7014
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		CHLOROXYLENOL	0.45 g in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)				
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)				
GLYCOL STEARATE (UNII: 0324G66D0E)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
WATER (UNII: 059QF0KO0R)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67106-7014-1	800 mL in 1 BOX; Type 0: Not a Combination Product	03/29/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part333A		03/27/2018	

Labeler - Sky Systems Co., Inc (621886548)

Registrant - Sky Systems Co., Inc (621886548)

Establishment			
Name	Address	ID/FEI	Business Operations
Sky Systems Co., Inc		621886548	manufacture(67106-7014)