

ANTIMICROBIAL- 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 - ANTIMICROBIAL LOTION SOAP (67106-7031)

ACTIVE INGREDIENT

CHLOROXYLENOL @ 0.45%

TRICLOSAN @ 0.06%

PURPOSE

ANTISEPTIC

USES

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

WARNINGS

- FOR EXTERNAL USE ONLY. AVOID FOOD CONTAMINATION DURING APPLICATION AND STORAGE.

WHEN USING THIS PRODUCT

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

STOP USE OF THIS PRODUCT 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 A SMALL AMOUNT OF SOAP AND SCRUB THOROUGHLY FOR 1 MINUTE.
- RINSE THOROUGHLY.
- DRY HANDS COMPLETELY.

OTHER INFORMATION

- STORE AT 20-25°C (60 TO 77°F)

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, PROPYLENE GLYCOL, POLYQUATERNIUM-7, FRAGRANCE, SODIUM CHLORIDE, CITRIC ACID, COLOR DYE.

QUESTIONS?

CALL 909-923-7040



ANTIMICROBIAL

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67106-7031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Product of

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.06 g in 100 mL
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.45 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67106-7031-8	12 in 1 BOX	12/10/1990	
1	NDC:67106-7031-1	800 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/10/1990	

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(67106-7031)

Revised: 12/2022

Sky Systems Co., Inc