

ANTIMICROBIAL FOAM- 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 FOAM SOAP (67106-7231)

ACTIVE INGREDIENTS

CHLOROXYLENOL 0.45%

PURPOSE

ANTISEPTIC

USES

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

WARNINGS

FOR EXTERNAL USE ONLY. AVOID ANY FOODS CONTAMINATION DURING APPLICATION AND STORAGE.

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 IRRITATION OR REDNESS DEVELOPS OR CONDITION PERSISTS FOR MORE THAN 72 HOURS.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

WET HANDS AND FOREARMS. APPLY A SMALL AMOUNT OF SOAP AND SCRUB THOROUGHLY FOR 1 MINUTE. RINSE THOROUGHLY. DRY HANDS COMPLETELY.

INACTIVE INGREDIENTS

WATER, SODIUM LAURETH SULFATE, PROPYLENE GLYCOL, POLYQUATERNIUM 7, FRAGRANCE, CITRIC ACID, FD&C YELLOW #5 (CAS #1934-21-0), FD&C rED #4 (CAS #548-53-2), D&C RED #33 (CAS #567-66-6), FD&C BLUE #1 (CAS #3844-15-9).

CHEMICAL EMERGENCY #: 1-800-255-3924

ANTIMICROBIAL FOAM SOAP

Drug Facts

Active Ingredients

Chloroxylenol 0.45%

Purpose

Antiseptic

Uses -Helps prevent cross contamination by hand contact to reduce incidence on nosocomial infection.

Warnings

For external use only. Avoid any foods contamination during application and storage

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 irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children.

Condition worsen or irritation persists,
Irritation or redness develops and persisted for more than 72 hours.

Directions -Wet hands and forearms. -Apply a small amount of soap and scrub thoughtfully for 1 minute. - Rinse thoughtfully.

Dry Hands completely.

Inactive Ingredients Water, Sodium Laureth Sulfate, Propylene Glycol, Polyquaternium 7, Fragrance, Citric Acid, FD&C Yellow #5 (CAS#1934-21-0) FD&C Red# 4 (CAS#45853-2), D&C Red# 33 (CAS# 3587-66-6), FD&C Blue# 1 (CAS# 3844-45-9).

Chemical Emergency #: 1-800-255-3924

ANTIMICROBIAL FOAM

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67106-7231
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67106-7231-1	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	03/29/2018	

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(67106-7231)

Revised: 4/2022

Sky Systems Co., Inc