CARROLLCLEAN- chloroxylenol (pcmx) soap CarrollCLEAN LCC

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.

Pink antimicrobial soap

Active ingredient

Chloroxylenol 0.25% w/v

Purpose

Antimicrobial

Uses

• hand washing in public washrooms, work areas, healthcare facilities, office buildings, food service facilities, and whatever cleanliness and antimicrobial properties are desired.

Warnings

For external use only

When using this product

• do not use in or near eyes

Keep out of reach of children

In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

Directions

- apply small amount of product to hands
- hold hands under water and work cleaner into lather
- rinse with water and wipe clean

Other information

• store at room temperature

Inactive ingredients section

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Dimethylol-5,5-dimethylhydantoin, Linear Ethoxylated Alcohol, Propylene Glycol, Polyethylene Glycol Distereate, Fragance, Tetrasodium EDTA, Methylchloroisothiazolinone (and) Methyllisothiazolinone, Isopropyl Myristate, Citric acid, FD & C Red #40, D & C Red #33

Package label



ANTIMICROBIAL Antimicrobial Pink Hand Soap

Drug Facts

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524 20130313 GJ#01-0314-2



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Manufactured By:

CARROLLCLEAN

2900 W. Kingsley Rd., • Garland, Texas 75041 • 800.527.5722 www.CarrollCLEAN.com

CARROLLCLEAN

chloroxylenol (pcmx) soap

Prod	nict 1	Info	rmat	tion
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:73708-524

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2O) (CHLOROXYLENOL - UNII:0F32U78V2O)	CHLOROXYLENOL	0.282 mg in 100 mL

Inactive Ingredients	
Ingredient Name	Strength

SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	7.85 mL in 100 mL
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)	0.099 mL in 100 mL
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)	4.132 mL in 100 mL
C9-11 PARETH-8 (UNII: 80E6PSE1XL)	0.242 mL in 100 mL
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	0.005 mL in 100 mL
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	0.317 mL in 100 mL
WATER (UNII: 059QF0KO0R)	84.307 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.026 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	2.146 mL in 100 mL
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	0.0004 mL in 100 mL
EDETATE SO DIUM TETRAHYDRATE (UNII: L13NHD21X6)	0.038 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.221 mL in 100 mL
FD&C RED NO. 40 (UNII: WZB9127XOA)	0.0002 mL in 100 mL
DMDM HYDANTO IN (UNII: BYR0546 TOW)	0.334 mL in 100 mL

Packaging					
ı	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
ı	1 N	NDC:73708-524-17	800 mL in 1 BAG; Type 0: Not a Combination Product	11/06/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/06/2020		

Labeler - CarrollCLEAN LCC (081222623)

Registrant - CarrollCLEAN LCC (081222623)

Establishment				
Name	Address	ID/FEI	Business Operations	
CarrollCLEAN		081222623	manufacture(73708-524)	

Revised: 11/2020 CarrollCLEAN LCC