

PERSONAL CARE ANTIBACTERIAL HAND- chloroxylenol liquid
Delta Brands & Products LLC

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.

Drug Facts

Active ingredient

Chloroxylenol 0.3%

Purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product

■ avoid contact with the eyes. In case of eye contact, flush with water.

Stop use and ask a doctor if

■ irritation and redness develops

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ pump into hands, wet as needed ■ lather vigorously for at least 15 seconds ■ wash skin, rinse thoroughly and dry

Inactive ingredients

water (aqua), ammonium lauryl sulfate, cocamidopropyl betaine, ammonium chloride, DMDM hydantoin, fragrance, citric acid, tetrasodium EDTA, FD&C yellow no. 5, FD&C red no. 40

Package Label



PERSONAL CARE ANTIBACTERIAL HAND

chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72133-151
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
WATER (UNII: 059QF0K00R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72133-151-75	221.8 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/16/2018	
2	NDC:72133-151-15	444 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/16/2018	

Labeler - Delta Brands & Products LLC (080999173)

Revised: 4/2018

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