ULTIMA DET ANTISEPTIC- chloroxylenol liquid ATLANTIC CARE CHEMICALS PRIVATE LIMITED

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.

ultima DET Concentrated Antiseptic Hand wash

Drug Facts

Purpose: Antiseptic

ACTIVE INGREDIENTS

Component

Chloroxylenol - 5 %

INACTIVE INGREDIENTS

Isopropyl alcohol, Castor oil, Pine oil, Lauryl alcohol ethoxylate, Methyl ester sulfonate, Water, Caramel colour E150d

Use: This product is a specially formulated hand wash soap for hygiene hand washing to decrease microbes on the skin. This concentrated antiseptic hand wash liquid should be diluted with water (1:5 ml) before use.

Directions: Wet hand with fresh water and apply soap. Rub hand together for 20 sec. Rinse hands thoroughly with fresh water.

When using this product: keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor: if irritation occurs, please consult a doctor.

Do not use

- In children less than 2 months of age.
- On open skin wounds.

Warning

- For external use only
- Keep out of Reach of Children

Other information

- Store between 15-30°C (59-86F)
- Avoid freezing and excessive heat above 50°C (104F)

Manufactured by:

Atlantic Care Chemicals. Pvt. Ltd Industrial Development Plot, Alappuzha, Kerala, India.

9001:2015

ISO CERTIFIED COMPANY

PASSION FOR INNOVATION

care@atlanticchemicals.com www.atlanticchemicals.com

MADE IN INDIA

Packaging

ultima

7724910745

DET

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care@atlanticchemicals.com www.atlanticchemicals.com Net Qty:5 L (169.07 fl oz)

MADE IN INDIA

ULTIMA DET ANTISEPTIC

chloroxylenol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77249-107	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety					
	Ingredient Name	Basis of Strength	Strength			
	CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	50 g in 1 L			

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
CASTOR OIL (UNII: D5340 Y2I9G)			
WHITE PINE OIL (UNII: HA5CX6676U)			
LAURYL ALCOHOL (UNII: 178 A96 NLP2)			
S-METHYL METHANETHIO SULFO NATE (UNII: 0906Z2356U)			
WATER (UNII: 059QF0KO0R)			
CARAMEL (UNII: T9 D99 G2B1R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77249-107-45	5 L in 1 CAN; Type 0: Not a Combination Product	05/15/2020	
2	NDC:77249-107-01	0.1 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
3	NDC:77249-107-02	0.2 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	
4	NDC:77249-107-05	0.5 L in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/15/2020		

Labeler - ATLANTIC CARE CHEMICALS PRIVATE LIMITED (861499902)

Establishment				
Name	Address	ID/FEI	Business Operations	
ATLANTIC CARE CHEMICALS PRIVATE LIMITED		861499902	manufacture(77249-107)	

Revised: 5/2020 ATLANTIC CARE CHEMICALS PRIVATE LIMITED