BORTEK ANTIBACTERIAL HAND WASH- chloroxylenol liquid Bortek Industries

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.

Bortek Foaming Hand Wash

Drug Facts

Active ingredient

Chloroxylenol 0.3% w/w

Purpose

Antiseptic

Uses

- Handwash to decrease bacteria on the skin that can potentially cause disease.
- Recommended for repeated use.

Warnings

For external use only.

When using this product, keep away from eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands with water and dispense sufficient amount of product into cupped palm of hand.
- Wash both hands thoroughly for 15 seconds.
- Rinse under running water and dry thoroughly.

Inactive Ingredients

Water, Sodium Laureth Sulfate, Cocamide DEA, DMDM Hydantoin, Ethyl Alcohol, Phenoxyethanol, Isopropyl Alcohol, Fragrance, Citric Acid, FD&C Red 4

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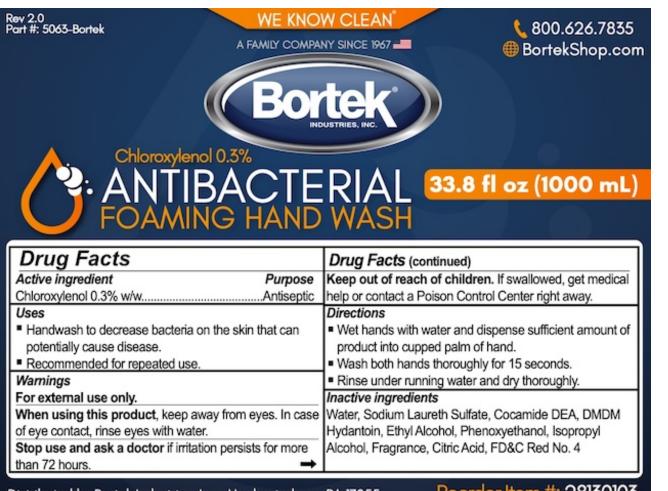
Distributed by Bortek Industries, Inc., Mechanicsburg, PA 17055

Bortek® INDUSTRIES, INC.

Chloroxylenol 0.3%

ANTIBACTERIAL FOAMING HAND WASH

33.8 FL OZ (1000 mL)



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Reorder Item #: 28130103

BORTEK ANTIBACTERIAL HAND WASH									
Product Information									
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:81731-508					
Route of Administration	TOPICAL								
Active Ingredient/Active	Moiety								
Ingredient Name Basis of S					Strength				
CHLOROXYLENOL (UNII: 0F32U78 UNII:0F32U78V2Q)	V2Q) (CHLOROXYLENOL -		CHLOROXYLENOL		0.3 g in 100 ml				
Inactive Ingredients									
	Ingredient Name				Strength				
PHENOXYETHANOL (UNII: HIE492)	ZZ3T)								
FD&C RED NO. 4 (UNII: X3W0AM1)	LX)								
SODIUM LAURETH SULFATE (UN	II: BPV390UAP0)								
WATER (UNII: 059QF0K00R)									

Сľ	TRIC ACID MO	NOH	YDRATE (UNII: 2968PHW8QP)						
СС	CO DIETHAN								
DN	IDM HYDANTC								
AL	COHOL (UNII: 3								
IS	OPROPYL ALC								
Packaging									
#	ltem Code		Package Description		Marketing Start Date	Marketing End Date			
1	NDC:81731- 508-10		1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		04/12/2021	02/19/2022			
2	NDC:81731- 508-11	1000 Prod) mL in 1 POUCH; Type 0: Not a Combination uct		02/19/2022	07/20/2024			
Marketing Information									
Marketing Category			Application Number or Monograph Citation	P	larketing Start Date	Marketing End Date			
OTC monograph not final		not	part333E	04/	/12/2021	07/20/2024			

Labeler - Bortek Industries (014184014)

Revised: 9/2022

Bortek Industries