

TOPCARE AMBER ANTIBACTERIAL HAND- benzalkonium chloride soap
Abaco Partners LLC DBA Surefil

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.

TopCare ® Amber Antibacterial Hand Soap

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

for hand washing, reduces germs on skin

Warnings

For external use only-hands only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly 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

- Wash hands and rinse.

Other information

store at 20°C - 25°C (68°F - 77°F)

Inactive Ingredients

Purified Water, Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Cocamide MEA, Sodium Chloride, PEG-120 Methyl Glucose Dioleate, Fragrance, Citric Acid, Tetrasodium EDTA, Methylchloroisoithiazolinone, Methylisoithiazolinone, FD&C Red #4,

FD&C Yellow #5.

QUESTIONS?

1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 221 mL Bottle Label

TopCare®

TRICLOSAN FREE

ANTIBACTERIAL

**hand
soap**

AMBER

**7.5 FL OZ
(221 mL)**

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1-888-423-0139
topcare@topco.com
PRODUCT OF USA



TOPCARE AMBER ANTIBACTERIAL HAND

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20890-0050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20890-0050-1	221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/15/2014	
2	NDC:20890-0050-2	1180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/15/2014	07/08/2019
3	NDC:20890-0050-3	1650 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/15/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/15/2014	

Labeler - Abaco Partners LLC DBA Surefil (964809417)

Establishment

Name	Address	ID/FEI	Business Operations
Abaco Partners LLC DBA Surefil		964809417	manufacture(20890-0050)