SOFTSOAP ANTIBACTERIAL CLEAN AND PROTECT COOL SPLASHbenzalkonium chloride liquid Colgate-Palmolive Company

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.

Softsoap® Antibacterial Clean and Protect Cool Splash Drug Facts

Active ingredient

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Use

helps eliminate bacteria on hands

Warnings

For external use only.

When using this product, avoid contact with eyes.

In case of contact, flush with water.

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

Directions

Wet hands and apply soap. Lather front and back, between your fingers, and under your nails. Scrub for at least 20 seconds, rinse then dry.

Inactive ingredients

Water, Cetrimonium Chloride, Glycerin, Lauramidopropylamine Oxide, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Fragrance, Citric Acid, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1, Red 33.

Questions?

1-800-255-7552

DIST. BY: COLGATE-PALMOLIVE COMPANY, NEW YORK, NY 10022 USA

PRINCIPAL DISPLAY PANEL - 332 mL Bottle Label

NEW

Softsoap® brand

Antibacterial Clean & Protect

ELIMINATES 99.9% OF BACTERIA THAT POTENTIALLY CAUSE DISEASE*

ENRICHED WITH MOISTURIZERS

Cool Splash

Hand Soap With Moisturizers

11.25 FL OZ (332 mL)

0013086

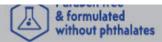


GOOD FOR THE EARTH + BODY











UNIQUE FORMULA: Refill only with Softsoap® Antibacterial Hand Soap Protects skin's natural barrier by retaining skin's natural moisture

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Drug Facts (continued)

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*In a handwashing test vs. the following common harmful bacteria: S. aureus & E. coli.

COLGATE-PALMOLIVE

COLGATE-PALMOLIVE COMPANY, **NEW YORK, NY 10022 USA**

www.softsoap.com



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SOFTSOAP ANTIBACTERIAL CLEAN AND PROTECT COOL SPLASH

benzalkonium chloride liquid

Product Information

HUMAN OTC DRUG **Product Type** Item Code (Source) NDC:35000-096

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	1.33 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)		
GLYCERIN (UNII: PDC6A3C0OX)		
LAURAMIDOPROPYLAMINE OXIDE (UNII: 16KX160QTV)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
COCO MONOETHANOLAMIDE (UNII: C80684146D)		
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
EDETATE SODIUM (UNII: MP1J8420LU)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		332 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333E	11/23/2020		

Labeler - Colgate-Palmolive Company (001344381)

Establishment			
Name	Address	ID/FEI	Business Operations
Colgate-Palmolive Company		079342773	ANALYSIS(35000-096), MANUFACTURE(35000-096), PACK(35000-096), LABEL(35000-096)