PRIME- benzalkonium chloride soap
Prime Industries Usa, Inc

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.

Active Ingredient

Benzalkonium chloride 0.13% w/v

Purpose

Antibacterial

Use

For handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product, avoid contact with eyes. In case of contact with eyes, flush with water.

Stop use and ask a doctor if irritation or 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 20 seconds. Wash skin, rinse thoroughly and dry

Inactive ingredients

Water, cetrimonium chloride, glycerin, lauramidopropylamine oxide, cocamide MEA, sodium chloride, PEG-120 methyl glucose dioleate, citric acid, tetrasodium EDTA, methylchloroisothiazolinone, methylisothiazolinone.

Package Label - Principal Display Panel

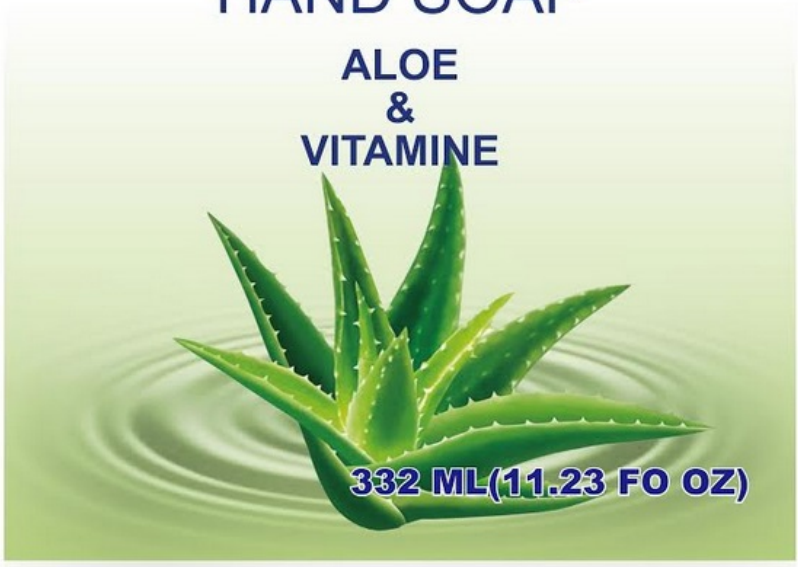
KILLS
99.99% BACTERIAL

Prime

ANTI**BACTERIAL**

HAND SOAP

ALOE
&
VITAMINE



332 ML(11.23 FO OZ)

Drug Facts

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Benzalkonium chloride 0.13%	Antibacterial

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Manufactured for / Distributed By
Prime Industries USA, Inc.
14 Penn Plaza, 9th Floor, New York, NY 10122
Toll-Free: 888-367-1555
www.primeindustryusa.com

Item #01479

6 939563 242586

KILLS
99.99% BACTERIAL

Prime

ANTIBACTERIAL

HAND SOAP

ALOE
&
VITAMINE

400 ML (13.52 FL OZ)

Drug Facts

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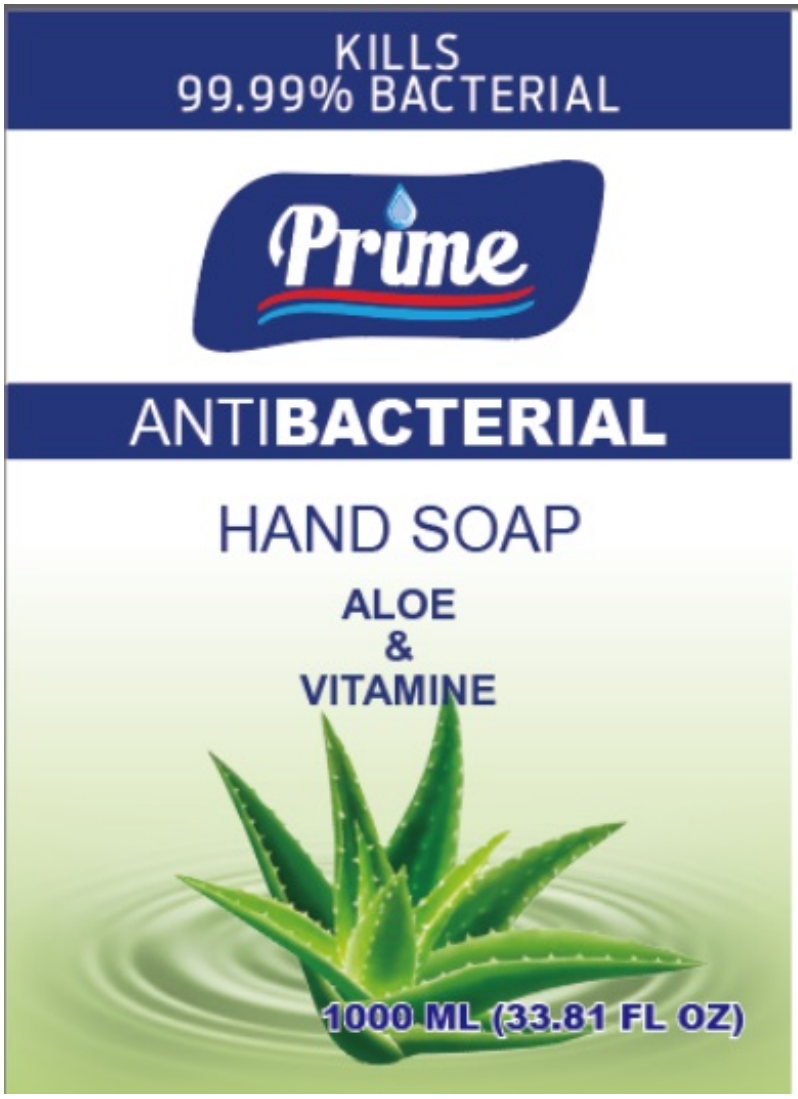

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PRIME

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79382-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
GLYCERIN (UNII: PDC6A3C0OX)	

LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79382-002-01	332 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
2	NDC:79382-002-02	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
3	NDC:79382-002-03	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
4	NDC:79382-002-04	2000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
5	NDC:79382-002-05	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2020	
6	NDC:79382-002-06	100000 mL in 1 DRUM; Type 0: Not a Combination Product	08/04/2020	
7	NDC:79382-002-07	200000 mL in 1 DRUM; Type 0: Not a Combination Product	08/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/04/2020	

Labeler - Prime Industries Usa, Inc (117547551)

Revised: 8/2020 Prime Industries Usa, Inc