

FUNDAMENTALS- benzalkonium chloride soap

Clean Beauty Concepts

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.

The hand soap is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

Benzalkonium chloride

Water(aqua)

Sodium alpha olefin sulfonate

Cocamide DIPA

Cocamidopropyl betaine

Glycerin

Polyquaternium-7

Phenoxyethanol

Aloe barbadensis (aloe vera) leaf juice

Sodium benzoate

Citric acid

Sodium chloride

Tetrasodium EDTA

Fragrance (parfum)

Active Ingredient(s)

Benzalkonium chloride 0.13% v/v. Purpose: Antibacterial

Purpose

Antibacterial

Use

For handwashing to decrease bacteria on skin

Recommended for repeat use

Warnings

For external use only.

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 or redness develop

Condition persists 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, apply palmful to hands, scrub thoroughly, rinse thoroughly
- Supervise children under 6 years of age when using this product to avoid swallowing

Other information

- Store between 15-30°C (59-86°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive ingredients

Water(aqua)

Sodium alpha olefin sulfonate

Cocamide DIPA

Cocamidopropyl betaine

Glycerin

Polyquaternium-7

Phenoxyethanol

Aloe barbadensis (aloe vera) leaf juice

Sodium benzoate

Citric acid

Sodium chloride

Tetrasodium EDTA

Fragrance (parfum)

Package Label - Principal Display Panel

236 mL NDC: 76665-016-08

fundamentals
by CBC

KEEP CLEAN - WASH YOUR HANDS - STAY SAFE

Kills most common germs that may make you sick

Drug Fact	
Active ingredient	Purpose
Benzalkonium chloride	Antibacterial
Use(s)	
<ul style="list-style-type: none"> • for handwashing to decrease bacteria on skin • recommended for repeated use 	
Warnings	
For external use only.	
Do not use	
<ul style="list-style-type: none"> • in children less than 2 months old • on open skin wounds 	
When using this product keep out of eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation and redness develop • condition persists more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Wet hands, apply palmful to hands, scrub thoroughly, rinse thoroughly. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30° C (59-86° F). • Avoid freezing and excessive heat above 40° C (104° F). 	
Inactive ingredients Water(aqua), sodium alpha olefin sulfonate, cocamidopropyl betaine, glycerin, cocamide DIPA, aloe barbadensis (aloe vera) leaf juice, polyquaternium-7, phenoxethanol, sodium benzoate, citric acid, sodium chloride, tetrasodium EDTA, fragrance (parfum).	

fundamentals

by CBC

ANTIBACTERIAL

Moisturizing
non-drying soap
for active
hands



Our formula is
Cruelty-free
not tested on
animals and vegan

Our scents are
energizing cool
and crisp

Feel the
softness and
smell the
cleanness

Our wonderful liquid soap lathers and cleanses wonderfully and leaves your skin feeling clean yet moisturized. Blended with several natural ingredients, our deep cleansing formula is safe, gentle, and extremely effective. Absolutely no chlorine, no ammonia, no synthetic colors, no phthalates, and no sodium laureth sulfate. Proudly made in USA. Wet your hands and apply enough liquid soap. Rub your hands together to create a good lather. For best cleansing rub palms together, the back of hands, interlink of fingers and thumbs, and scrub for at least 30 seconds. Rinse your hands well under clean and running water. Keep out of reach of children and pets. External use only.



Produced in FDA registered facility NDC#76665-016-08

HAND SOAP

FOLLOW US @



8 FL OZ | 236 mL



Manufactured & Distributed By:
CLEAN BEAUTY CONCEPTS LLC
Gardena, CA 90248



Info@cleanbeautyconcepts.com
www.cleanbeautyconcepts.com

473 mL NDC: 76665-016-16

fundamentals
by CBC

KEEP CLEAN - WASH YOUR HANDS - STAY SAFE

Drug Fact	
Active ingredient	Purpose
Benzalkonium chloride	Antibacterial
Use(s)	
<ul style="list-style-type: none"> • for handwashing to decrease bacteria on skin • recommended for repeated use 	
Warnings	
For external use only.	
Do not use	
<ul style="list-style-type: none"> • in children less than 2 months old • on open skin wounds 	
When using this product keep out of eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation and redness develop • condition persists more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Wet hands, apply palmful to hands, scrub thoroughly, rinse thoroughly. • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30° C (59-86° F). • Avoid freezing and excessive heat above 40° C (104° F). 	
Inactive ingredients Water(aqua), sodium alpha olefin sulfonate, cocamidopropyl betaine, glycerin, cocamide DIPA, aloe barbadensis (aloe vera) leaf juice, polyquaternium-7, phenoxethanol, sodium benzoate, citric acid, sodium chloride, tetrasodium EDTA, fragrance (parfum).	

fundamentals

by CBC

ANTIBACTERIAL

Kills 99.9% of Germs

Moisturizing
non-drying soap
for active hands



Our formula is
Cruelty-free
not tested on
animals and
vegan

Our scents are
energizing
cool and crisp

Feel the
softness and
smell the
cleanness

Our wonderful liquid soap lathers and cleanses wonderfully and leaves your skin feeling clean yet moisturized. Blended with several natural ingredients, our deep cleansing formula is safe, gentle, and extremely effective. Absolutely no chlorine, no ammonia, no synthetic colors, no phthalates, and no sodium laureth sulfate. Proudly made in USA. Wet your hands and apply enough liquid soap. Rub your hands together to create a good lather. For best cleansing rub palms together, the back of hands, interlink of fingers and thumbs, and scrub for at least 20 seconds. Rinse your hands well under clean and running water. Keep out of reach of children and pets. External use only.



Produced in FDA registered facility NDC 76665-016-16

HAND SOAP

Manufactured & Distributed By:
CLEAN BEAUTY CONCEPTS LLC
Gardena, CA 90248

Info@cleanbeautyconcepts.com
www.cleanbeautyconcepts.com

16 FL OZ | 473 mL



FOLLOW US @



60 mL NDC: 76665-016-02

Drug Facts		<p>KEEP CLEAN - WASH YOUR HANDS - STAY SAFE</p> <p>fundamentals by CBC</p> <p>ANTIBACTERIAL</p> <p>Kills 99.9% of Germs</p> <p>Moisturizing non-drying soap for active hands</p> <p>Our formula is Cruelty-free not tested on animals and vegan</p> <p>Our scents are energizing cool and crisp</p> <p>Feel the softness and smell the cleanness</p> <p>Produced in FDA registered facility NDC#76665-016-02</p> <p>2 FL OZ e60 mL</p>
Active ingredient	Purpose	
Benzalkonium chloride	Antibacterial	
Use[s]	• for handwashing to decrease bacteria on skin • recommended for repeated use	
Warnings		
For external use only.		
Do not use	• in children less than 2 months of age • on open skin wounds	
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 and redness develop • condition persists 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, apply palmful to hands, scrub thoroughly, rinse thoroughly. • Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information	• Store between 15-30°C (59-86°F). • Avoid freezing and excessive heat above 40°C (104°F).	
Inactive ingredients	Water (aqua), sodium alpha olefin sulfonate, cocamidopropyl betaine, glycerin, cocamide DIPA, aloe barbadensis (aloe vera) leaf juice, polyquaternium-7, phenoxyethanol, sodium benzoate, citric acid, sodium chloride, tetrasodium EDTA, fragrance (parfum).	
<p>Manufactured & Distributed By: CLEAN BEAUTY CONCEPTS LLC Gardena, CA 90248 Info@cleanbeautyconcepts.com www.cleanbeautyconcepts.com</p>   		

3785mL NDC: 76665-016-01

FUNDAMENTALS

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76665-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mg in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 160000 MW) (UNII: 0L414VCS5Y)	0.35 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.3 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.15 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	75.71 mL in 100 mL
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	3.42 mL in 100 mL
EDETATE SODIUM (UNII: MP1J8420LU)	0.01 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.35 mL in 100 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 mL in 100 mL
DISODIUM ETHYLENE DICOAMIDE PEG-15 DISULFATE (UNII: QI9A6U005W)	8.47 mL in 100 mL
ALOE VERA LEAF POLYSACCHARIDES (UNII: W21O437517)	0.1 mL in 100 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.02 mL in 100 mL
SODIUM C12 OLEFIN SULFONATE (UNII: K7QRZ05DE3)	10.79 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-016-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	
2	NDC:76665-016-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	
3	NDC:76665-016-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	
4	NDC:76665-016-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2020	

Labeler - Clean Beauty Concepts (117491649)

Establishment

Name	Address	ID/FEI	Business Operations
Clean Beauty Concepts		117491649	manufacture(76665-016)