

FUNDAMENTALS HANDLOTION- benzalkonium chloride lotion

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 lotion is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

Benzalkonium chloride

Water (aqua)

Glycerin³

C12-15 Alkyl benzoate

propylene glycol

stearyl alcohol

cetyl alcohol

Petrolatum

Lemon Oil

aloe barbadensis (aloe vera) leaf juice

retinyl palmitate (vitamin A)

tocopheryl acetate (vitamin E)

dimethicone

sodium acrylate

acryloyldimethyltaurate copolymer

polysorbate 80

isohexadecane

polysorbate 60

acrylates/C10 30 Alkyl acrylate crosspolymer

hexylene glycol

xanthan gum

sodium hydroxide

phenoxyethanol

caprylyl glycol

ethylhexylglycerin

fragrance (parfum)

Active Ingredient(s)

Benzalkonium chloride 0.13% v/v. Purpose: Antimicrobial

Purpose

Antimicrobial

Use

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

Dispense lotion onto hands and rub into skin until absorbed

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)

Glycerin

C12-15 Alkyl benzoate

propylene glycol

stearyl alcohol

cetyl alcohol

Petrolatum

Lemon Oil

aloe barbadensis (aloe vera) leaf juice

retinyl palmitate (vitamin A)

tocopheryl acetate (vitamin E)

dimethicone

sodium acrylate

acryloyldimethyltaurate copolymer

polysorbate 80

isohexadecane

polysorbate 60

acrylates/C10 30 Alkyl acrylate crosspolymer

hexylene glycol

xanthan gum

sodium hydroxide

phenoxyethanol
 caprylyl glycol
 ethylhexylglycerin
 fragrance (parfum)

Do not Use

Do not Use
 in children less than 2 months old
 on open skin wounds

Package Label - Principal Display Panel

NDC 76665-021-08 236 ml

HYDRATE - APPLY LOTION - STAY SMOOTH

fundamentals
by CBC

ANTIBACTERIAL
Kills 99.9% of Germs

LEMON SCENT

Moisturizing lotion for active hands
 Lightly scented infused with aloe vera
 Helps reduce germs on skin
 Our formula is Cruelty-free and vegan

Produced in FDA registered facility NDC 76665-021-08

HAND LOTION

fundamentals
by CBC

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

Info@cleanbeautyconcepts.com
 www.cleanbeautyconcepts.com

8 FL OZ | e236 mL

MADE IN THE USA

Drug Fact	
Active ingredient Benzalkonium chloride	Purpose Antimicrobial
Use(s) - Decrease bacteria on skin - Recommended for repeated use	
Warnings For external use only.	
Do not use - 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 - 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 - Dispense lotion onto hands and rub into skin until absorbed. - 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), glycerin, C12-15 aliphatic benzoate, propylene glycol, hexylene glycol, stearyl alcohol, cetyl alcohol, petrolatum, citrus limon (lemon) fruit extract, aloe barbadensis (aloe vera) leaf juice, retinyl palmitate (vitamin A), tocopheryl acetate (vitamin E), dimethicone, sodium acrylate, acrylyl dimethyl itaure copolymer, polysorbate 80, isohexadecane, polysorbate 60, acrylates/C10-30 alkyl acrylate cross polymer, xanthan gum, sodium hydroxide, phenoxyethanol, caprylyl glycol, ethylhexylglycerin, fragrance (parfum).	

76665-021-01 3785 ml

fundamentals by CBC

HYDRATE - APPLY LOTION - STAY SMOOTH

fundamentals by CBC

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Kills 99.9% of Germs

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LEMON SCENT

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Produced in FDA registered facility - NDC 76665-021-01

HAND LOTION

1 GALLON | 3785 mL

MADE IN THE USA

Drug Fact	Purpose
Active Ingredient Benzalkonium chloride	Antimicrobial
Use(s) • 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, 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 • Dispense lotion onto hands and rub into skin until absorbed. • 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), glycerin, C12-15 alkyl benzoate, propylene glycol, hexylene glycol, stearyl alcohol, cetyl alcohol, petrolatum, citrus limon (lemon) fruit extract, aloe barbadensis (aloe vera) leaf juice, retinyl palmitate (vitamin A), tocopheryl acetate (vitamin E), dimethicone, sodium acrylate, acryloyldimethyltaurate copolymer, polysorbate 80, isohexadecane, polysorbate 60, acrylates/C10-30 alkyl acrylate crosspolymer, xanthan gum, sodium hydroxide, phenoxyethanol, caprylyl glycol, ethylhexylglycerin, fragrance (parfum).	

Manufactured & Distributed By:
CLEAN BEAUTY CONCEPTS LLC Gardena, CA 90248
info@cleanbeautyconcepts.com www.cleanbeautyconcepts.com

76665-021-02 60 ml

HYDRATE - PROTECT - STAY SMOOTH

fundamentals by CBC

ANTIBACTERIAL
Kills 99.9% of Germs

Moisturizing lotion for active hands

Lightly scented infused with aloe vera

LEMON SCENT

Helps reduce germs on skin

Our formula is Cruelty-free and vegan

Produced in FDA registered facility NDC# 76665-021-02

HAND LOTION

2 FL OZ | e60 mL

Drug Facts
Active Ingredient Benzalkonium chloride
Purpose Antimicrobial
Use(s) • 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
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MADE IN THE USA

1 95248 00253 3

76665-021-16 473 ml

fundamentals
by CBC

HYDRATE - APPLY LOTION - STAY SMOOTH

Drug Fact

Active Ingredient **Purpose**

Benzalkonium chloride Antimicrobial

Use(s)

- Decrease bacteria on skin
- Recommended for repeated use

Warnings

For external use only.

- Do not use
- 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

- 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

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Inactive Ingredients Water (aqua), glycerin, C12-15 alkyl benzoate, propylene glycol, hexylene glycol, stearyl alcohol, cetyl alcohol, petrolatum, dnis limon/lemon fruit extract, aloe barbadensis (aloe vera) leaf juice, retinyl palmitate (vitamin A), tocopheryl acetate (vitamin E), dimethicone, sodium acrylate, acryloyldimethylacrylate copolymer, polysorbate 80, behenic acid, polysorbate 60, acrylates/C10-30 alkyl acrylate crosspolymer, xanthan gum, sodium hydroxide, phenylethanol, caprylyl glycol, ethylhexylglycerin, fragrance (parfum).

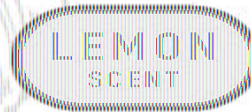
fundamentals
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ANTIBACTERIAL

Kills 99.9% of Germs

Moisturizing lotion for active hands

Helps reduce germs on skin



Lightly scented infused with aloe vera

Our formula is Cruelty-free and vegan

Produced in FDA registered facility NDC 76665-021-16

HAND LOTION

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CLEAN BEAUTY CONCEPTS LLC
Gardena, CA 90248

Info@cleanbeautyconcepts.com
www.cleanbeautyconcepts.com

1.6 FL OZ | 47.3 mL



FUNDAMENTALS HANDLOTION

benzalkonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76665-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.1 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.12 mL in 100 mL
PETROLATUM (UNII: 4T6H12BN9U)	1.4 mL in 100 mL
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.1 mL in 100 mL
WATER (UNII: 0590EQK0DP)	78.798 mL

WATER (UNII: 059QF0R00R)	in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	3.15 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	4.85 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.15 mL in 100 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.85 mL in 100 mL
DIMETHICONE (UNII: 92RU3N3Y1O)	0.34 mL in 100 mL
SODIUM ACRYLATE (UNII: 7C98FKB43H)	0.14 mL in 100 mL
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	0.145 mL in 100 mL
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	0.14 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.1 mL in 100 mL
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	2.145 mL in 100 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	1.852 mL in 100 mL
LEMON OIL (UNII: I9GRO824LL)	0.1 mL in 100 mL
ISOHEXADECANE (UNII: 918X10UF1E)	0.47 mL in 100 mL
POLYSORBATE 60 (UNII: CAL22UVI4M)	0.74 mL in 100 mL
CARBOMER 1342 (UNII: 809Y72KV36)	0.2 mL in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.15 mL in 100 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.05 mL in 100 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.2 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.14 mL in 100 mL
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	3.44 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-021-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
2	NDC:76665-021-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
3	NDC:76665-021-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
4	NDC:76665-021-16	473 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - Clean Beauty Concepts (117491649)

Establishment

Name	Address	ID/FEI	Business Operations
Clean Beauty Concepts		117491649	manufacture(76665-021)