

## **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.*

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

Benzalkonium chloride

Water (aqua)

Glycerin

C12-15 Alkyl benzoate

propylene glycol

stearyl alcohol

cetyl alcohol

Petrolatum

Lavendar 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**

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Glycerin

C12-15 Alkyl benzoate

propylene glycol

stearyl alcohol

cetyl alcohol

Petrolatum

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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**

236 mL NDC: 76665-022-08

**Drug Facts**

Active ingredient	Purpose
Benzalkonium chloride	Antimicrobial

**Use(s)**

- Decrease bacteria on skin
- Recommended for repeated use

**Warnings**

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HYDRATE - APPLY LOTION - STAY SMOOTH

**fundamentals**  
by CBC

**ANTIBACTERIAL**  
Kills 99.9% of Germs

**LAVENDER SCENT**

Moisturizing lotion for active hands

Lightly scented infused with aloe vera

Helps reduce germs on skin

Our formula is Cruelty-free and vegan

NDC Produced in FDA registered facility NDC 76665-022-08

**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**

60 mL NDC: 76665-022-02

**Drug Facts**

**Active ingredient** Purpose  
Benzalkonium chloride ..... Antimicrobial

**Use[s]** • Decrease bacteria on skin • Recommended for repeated use

**Warnings**

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**Do not use** • in children less than 2 months of age • on open skin wounds

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HYDRATE - PROTECT - STAY SMOOTH

**fundamentals**  
by CBC

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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#76665-022-02

**HAND LOTION**

2 FL OZ | e60 mL

473 ml NDC: 76665-022-16

**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**

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**fundamentals**  
by CBC

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Moisturizing lotion for active hands

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Helps reduce germs on skin

Our formula is Cruelty-free and vegan

**NO MORE ITCHY, IRRITATED, OR DRY SKIN**

Environmental toxins, sanitizers, frequent hand-washing, and irritants are found in harsh cleaning products. Fundamentals Antibacterial Hand Lotion is an unparalleled relief for dry and cracked skin. It is a long-lasting hydrating protection while at home, shopping, traveling or at your workplace. This lotion is non-greasy and fast absorbing. Its formula is hypoallergenic, suitable for all skin types. It is vegan, cruelty-free, and does not contain harmful synthetic parabens, SLS, SLES, gluten or harsh dyes. Apply a small amount on clean, dry skin; reapply every 4 to 12 hours. Proudly made in the USA in safe, clean and cruelty free facilities.



Produced in FDA registered facility NDC 76665-022-16

**HAND LOTION**

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

Info@cleanbeautyconcepts.com  
www.cleanbeautyconcepts.com



16 FL OZ | 473 mL



FAS003F011 | LB10-20



3785 ml NDC: 76665-022-01

## FUNDAMENTALS HANDLOTION

benzalkonium chloride lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76665-022
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	0.1 mL in 100 mL
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.12 mL in 100 mL
<b>FRAGRANCE LAVENDER ORC1800979</b> (UNII: 1B40MIN2W5)	0.1 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	78.273 mL in 100 mL
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	3.15 mL in 100 mL
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	1.9 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	4.85 mL in 100 mL
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	0.15 mL in 100 mL
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	0.34 mL in 100 mL
<b>SODIUM ACRYLATE</b> (UNII: 7C98FKB43H)	0.14 mL in 100 mL
<b>SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW)</b> (UNII: 1DXE3F3OZX)	0.145 mL in 100 mL
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	0.85 mL in 100 mL
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	0.14 mL in 100 mL
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	2.145 mL in 100 mL
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	1.852 mL in 100 mL

LAVENDER OIL (UNII: ZBP1YXW0H8)	0.125 mL in 100 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	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
C12-20 ALKYL BENZOATE (UNII: Y15I6XI14C)	3.44 mL in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.14 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76665-022-08	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
2	NDC:76665-022-01	3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
3	NDC:76665-022-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
4	NDC:76665-022-16	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(76665-022)

Revised: 12/2020

Clean Beauty Concepts