

## **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

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

aloe barbadensis (aloe vera) leaf juice

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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: 76665-020-08

| Drug Facts   |                |
|--|----------------|
| <b>Active ingredient</b>   | <b>Purpose</b> |
| Benzalkonium chloride  | Antimicrobial  |
| <b>Use(s)</b>  |                |
| - for handwashing to decrease bacteria on skin   |                |
| - <b>not recommended for repeated use</b>  |                |
| <b>Warnings</b>  |                |
| For external use only.   |                |
| <b>Do not use</b>  |                |
| - in children less than 2 months old   |                |
| - on open skin wounds  |                |
| <b>When using this product</b> keep out of eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.   |                |
| <b>Stop use and ask a doctor if</b>  |                |
| - irritation and redness develop   |                |
| - condition persists more than 72 hours  |                |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.  |                |
| <b>Directions</b>  |                |
| - Dispense lotion onto hands and rub into skin until absorbed.   |                |
| - Supervise children under 6 years of age when using this product to avoid swallowing.   |                |
| <b>Other information</b>   |                |
| - Store between 15-30° C (59-86°F).  |                |
| - Avoid freezing and excessive heat above 40° C (104°F).   |                |
| <b>Inactive ingredients:</b> Water (aqua), glycerin, C12-15 alkyl benzoate, propylene glycol, hexylene glycol, stearyl alcohol, cetyl alcohol, petrolatum, aloe barbadensis (aloe vera) leaf juice, retinyl palmitate, vitamin A, tocopheryl acetate, vitamin E, dimethicone, sodium acrylate, acrylyldimethylsulfonate copolymer, polysorbate 80, isohexadecane, polysorbate 60, acrylates/C10-30 allyl acrylate cross polymer, xanthan gum, sodium hydroxide, phenoxyethanol, caprylyl glycol, ethylhexylglycerin, fragrance (parfum). |                |

HYDRATE - APPLY LOTION - STAY SMOOTH

**fundamentals**  
by CBC

**ANTIBACTERIAL**  
Kills 99.9% of Germs

Moisturizing lotion for active hands

Lightly scented infused with aloe vera

FRESH OCEAN SCENT

Helps reduce germs on skin

Our formula is Cruelty-free and vegan

Produced in FDA registered facility NDC 76665-020-08

**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: 76665-020-02

**Drug Facts**

**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 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**

• 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, 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).

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HYDRATE - PROTECT - STAY SMOOTH

fundamentals  
by CBC

**ANTIBACTERIAL**

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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# 76665-020-02

**HAND LOTION**

2 FL OZ | e60 mL

473 ml NDC: 76665-020-16

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**

**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 alkyl benzoate, propylene glycol, hexylene glycol, stearyl alcohol, cetyl alcohol, petrolatum, 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).

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16 FL OZ | 473 mL



fundamentals  
by CBC

**ANTIBACTERIAL**

Kills 99.9% of Germs

Moisturizing lotion for active hands

Lightly scented infused with aloe vera



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 76665-020-16

**HAND LOTION**

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FAS004F011 | LB10-20



3785 ml NDC: 76665-020-01

**fundamentals**  
by CBC

HYDRATE - APPLY LOTION - STAY SMOOTH

**fundamentals**  
by CBC

**ANTIBACTERIAL**  
Kills 99.9% of Germs

Moisturizing lotion for active hands

Lightly scented infused with aloe vera

Helps reduce germs on skin

Our formula is Cruelty-free and vegan

**FRESH OCEAN SCENT**

Produced in FDA registered facility NDC 76665-020-01

**HAND LOTION**

1 GALLON | 3785 mL

**MADE IN THE USA**

Drug Fact  
Active Ingredient  
Purpose  
Indication/Use  
Warnings  
Precautions  
Directions  
Other information  
Inactive ingredients

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## FUNDAMENTALS HANDLOTION

benzalkonium chloride lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:76665-020 |
| <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 CLEAN ORC0600327</b> (UNII: 329LCV5BTF)  | 0.1 mL in 100 mL    |
| <b>WATER</b> (UNII: 059QF0KO0R)   | 78.398 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 ACRYLOYLDIMETHYLAURATE 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: 2KR8914H1Y)   | 2.145 mL in 100 mL  |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)   | 1.852 mL in 100 mL  |

|  |                   |
|--|-------------------|
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) | 0.1 mL in 100 mL  |
| <b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)              | 0.47 mL in 100 mL |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)             | 0.74 mL in 100 mL |
| <b>CARBOMER 1342</b> (UNII: 809Y72KV36)              | 0.2 mL in 100 mL  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                | 0.15 mL in 100 mL |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)           | 0.05 mL in 100 mL |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)         | 0.2 mL in 100 mL  |
| <b>C12-20 ALKYL BENZOATE</b> (UNII: Y15I6XI14C)      | 3.44 mL in 100 mL |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)            | 0.14 mL in 100 mL |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:76665-020-08 | 236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product  | 09/01/2020           |                    |
| 2 | NDC:76665-020-01 | 3785 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 09/01/2020           |                    |
| 3 | NDC:76665-020-02 | 60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product   | 09/01/2020           |                    |
| 4 | NDC:76665-020-16 | 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(76665-020) |

Revised: 12/2020

Clean Beauty Concepts