

FOAMING HAND SANITIZER- foaming hand sanitizer liquid
Theochem Laboratories 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.

Foaming Hand Santizer

Active Ingredient

Benzalkonium Chloride 0.1%

Purpose

Antimicrobial

Uses

For hand sanitizing to decrease bacteria on the skin.
Recommended for repeated use.

Warnings

For external use only.
When using this product, avoid contact with eyes. In case of eye contact, flush eyes with water.
Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Pour contents into the Foaming Dispenser reservoir. For first use applications, pump dispenser a few time to prime. Pump a small amount of foam into palm of hand. Rub thoroughly over all surfaces of both hands. Rub hands together briskly until dry.

Other Information

Store below 110 °F (43 °C). May discolor certain fabrics or surfaces.

Inactive Ingredients

Water, dihydroxypropyl PEG-5 linoleammonium chloride, glycereteh-2 cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide, aloe barbadensis leaf juice.

PRINCIPAL DISPLAY PANEL
FOAMING HAND SANITIZER
NET CONTENTS: 3.785 LITERS



THEOCHEM LABORATORIES, INC.
"Solutions for a Cleaner World"™

FOAMING HAND SANITIZER

Alcohol-Free, Fragrance Free
NSF E3 approved for food handlers
Effective against MRSA

NET CONTENTS:
ONE GALLON
(3.785 LITERS)

KEEP OUT OF REACH OF CHILDREN
CAUTION

See side panel for first aid and other precautions.

PROVIDED BY
CHEM•TEL

EMERGENCY RESPONSE
1.800.255.3924



103357813/ea2

Manufactured by:
THEOCHEM
LABORATORIES, INC.
7373 Rowlett Park Drive
Tampa, Florida 33610
www.theochem.com

ADVANTAGES

This product has a unique antibacterial foaming formula with aloe. It is mild on the skin. The foaming action is created by dispensing through our special foaming dispenser.

| | |
|---|---------------------------------|
| Drug Facts | |
| Active Ingredient Benzalkonium Chloride 0.1% | Purpose Antimicrobial |
| Uses: For hand sanitizing to decrease bacteria on the skin. Recommended for repeated use. | |
| Warnings: For external use only. When using this product, avoid contact with eyes. In case of eye contact, rinse eyes with water. Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours. | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Directions: For Use with Dispenser: Pour contents into the Foaming Dispenser reservoir. For first use applications, pump dispenser a few times to prime. Pump a small amount of foam into palm of hand. Rub thoroughly over all surfaces of both hands. Rub hands together briskly until dry. | |
| Other Information: Store below 110°F (43°C). May discolor certain fabrics or surfaces. | |
| Inactive Ingredients: Water, dihydroxypropyl PEG-5 linoleammonium chloride, glycereteh-2 cocoate, behentrimonium chloride, dihydroxyethyl cocamine oxide, aloe barbadensis leaf juice. | |

| | | | |
|--|--------------------------|---------------------------|---------------|
| FOAMING HAND SANITIZER | | | |
| foaming hand sanitizer liquid | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68878-119 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |

| | | |
|--|-----------------------|-------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.1 mg in 1 mL |
|--|-----------------------|-------------------|

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:68878-119-11 | 3785 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 10/01/2008 | |

Labeler - Theochem Laboratories Inc (004100038)

Registrant - Theochem Laboratories Inc (004100038)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Theochem Laboratories Inc | | 004100038 | manufacture(68878-119) |

Revised: 12/2013

Theochem Laboratories Inc