

## **HAND WASH- benzalkonium chloride soap**

**Fred's 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.*

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**freds 403.002-AC**

### ***Active ingredients***

Benzalkonium chloride 0.13%

### ***Purpose***

Antibacterial

### ***Use***

for handwashing to decrease bacteria on the skin

### ***Warnings***

For external use only-hands only

### **When using this product**

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

### **Stop use and ask a doctor if**

- irritation or redness develops
- 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***

- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse thoroughly

### ***Inactive ingredients***

water, lauramine oxide, cocamidopropyl betaine, lauramidopropylamine oxide, sodium chloride, myristamidopropylamine oxide, glycerin, fragrance, disteareth-75 IPDI, PEG-150 distearate, citric acid, tetrasodium EDTA, benzophenone-4, sodium benzoate, red 4, yellow 5

### **Adverse reaction section**

DISTRIBUTED BY: fred's Inc.

4300 NEW GETWELL ROAD

MEMPHIS, TN 38118

[www.fredsinc.com](http://www.fredsinc.com)

100% satisfactiuon guaranteed

Questions or comments: 1-855-331-FRED (3733)

403.002/403AC

**principal display panel**

freds

Pharmacy

CLEAR

AMBER

ANTIBACTERIAL

LIQUID HAND SOAP

Original Scent

Contains Moisturizers

7.5 FL OZ (221 mL)



## HAND WASH

benzalkonium chloride soap

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-403
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>WATER</b> (UNII: 059QF0KO0R)
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4M18W)
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)
<b>LAURAMIDOPROPYLAMINE OXIDE</b> (UNII: I6KX160QTV)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>MYRISTAMIDOPROPYLAMINE OXIDE</b> (UNII: 3HSF539C9T)
<b>glycerin</b> (UNII: PDC6A3C0OX)
<b>DISTEARETH-75 ISOPHORONE DIISOCYANATE</b> (UNII: 5365FJ30SC)
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)
<b>SULISOBENZONE</b> (UNII: 1W6L629B4K)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-403-96	221 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/23/2015	
2	NDC:55315-403-49	443 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/23/2015	
3	NDC:55315-403-64	1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/23/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/23/2015	

**Labeler** - Fred's Inc (005866116)

**Registrant** - Vi-Jon (005866116)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-jon		088520668	manufacture(55315-403)