

**ANTIBACTERIAL- benzalkonium chloride 0.13% liquid**  
**TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI**

*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.*

-----  
**Berkley Jensen Antibacterial Liquid Hand Soap - Lemon**

**Active ingredients**

Benzalkonium chloride 0.13%.....Anitbacterial Hand soap

**Purpose**

Antibacterial Hand Soap

**Use**

helps eliminate bacteria on hands.

**Warnings**

For external use only: hands only

**When using this product**

- avoid contact with eyes.
- In case of contact,
- flush 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**

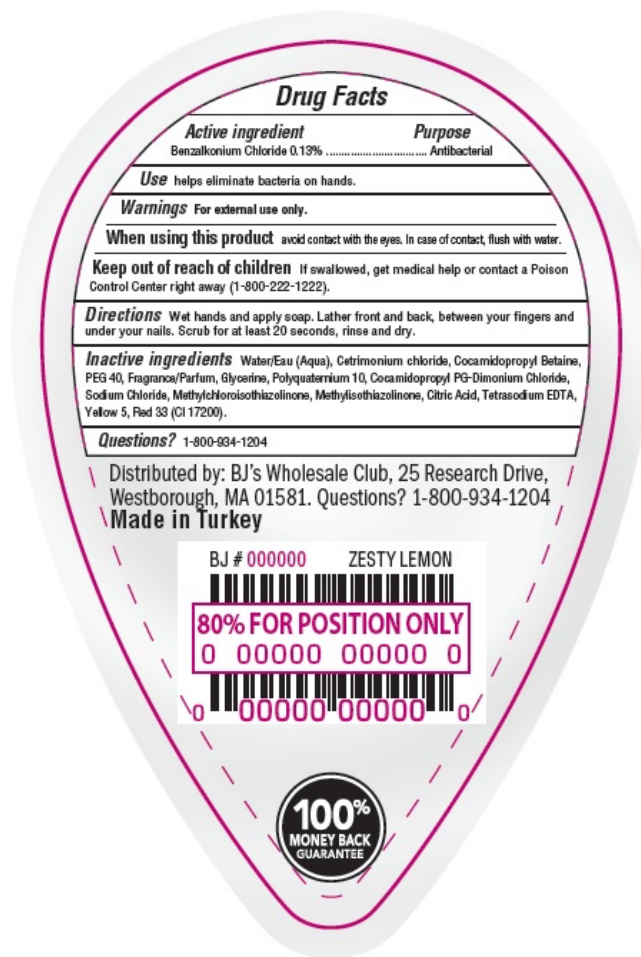
If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

- Wet hands and apply soap.
- Lather front and back, between your fingers and under your nails.
- Scrub for at least 20 seconds
- rinse and dry

Water, Cetrimonium Chloride , Cocamidopropyl Betaine, Sodium Chloride, Glycerin, Fragrance, Polyquaternium-10 , PEG-8 , Citric Acid, Tetrasodium EDTA, Cocamidopropyl PG-Dimonium Chloride, Methylchloroisothiazolinone, Methlisothiazolinone, Yellow (CI 19140),Red 33

## Principal display panel



### ANTIBACTERIAL

benzalkonium chloride 0.13% liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76772-034
<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	1.3 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>POLYQUATERNIUM-10 (1000 MPA.S AT 2%)</b> (UNII: GMR4PEN8PK)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>COCAMIDOPROPYL PG-DIMONIUM CHLORIDE</b> (UNII: 205Z54J075)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>CITRIC ACID ACETATE</b> (UNII: DSO12WL7AU)	
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-034-33	332 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/16/2021	

**Labeler** - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

**Registrant** - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

## Establishment

Name	Address	ID/FEI	Business Operations
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-034)

Revised: 7/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI