

**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.*

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**Berkley Jensen Liquid Hand Soap With Light Moisturizers**

**Active ingredients**

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

**Purpose**

Antibacterial Hand Soap

**Use**

help eliminate bacteria on hands.

**Warnings**

For external use only: hands only

**When using this product**

- avoid contact with eyes. If contact occurs, rinse eyes 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**

- Except under adult supervision.
- If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

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

Water, Cetrimonium chloride , Cocamidopropyl betaine, Sodium chloride, glycerin,PEG-

Fragrance, Polyquaternium-10 , PEG-8 , Citric Acid, Tetrasodium EDTA, Cocamidopropyl PG-Dimonium Chloride,

Methylchloroisothiazolinone, Methlisothiazolinone, Aloe Vera, Blue 1,Red 33(CI 17200).

**Principal display panel**

**BERKLEY JENSEN 64 OZ ALOE VERA & SILK PROTEINS FOR SOFT SKIN**



<b>ANTIBACTERIAL</b>			
benzalkonium chloride 0.13% liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76772-031
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	1.3 g in 1 mL
<b>Inactive Ingredients</b>			
Ingredient Name			Strength
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)			

<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)
<b>POLYQUATERNIUM-10 (1000 MPAS 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>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-031-18	1890 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(76772-031)

Revised: 7/2021

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