

**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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**Top Care Antibacterial Liquid Hand Soap - Lemon**

**Active ingredients**

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

**Purpose**

Antibacterial Hand Soap

**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 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**

- Squeeze onto wet hands or body sponge
- Work into lather
- Wash skin,rinse and dry thoroughly

water, sodium laureth sulfata , cocamidopropyl betaine, sodium chloride, glycerin,  
fragrance, polyquatemium-10 , PEG-8 , citric acid, tetrasodium EDTA, cocamidopropyl  
pg-dimonium chrolide,

methylchloroisothiazolinone, methlisothiazolinone, Yellow (CI 19140)

**Principal display panel**



16.9 / 500 mL



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<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:76772-032
<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>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>EDETIC ACID</b> (UNII: 9G34HU7RV0)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-032-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/16/2021	

<b>Marketing Information</b>			
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)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-032)

Revised: 7/2021

TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI