

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.

Bath & Beauty Antibacterial Liquid Hand Soap

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 sulfate , cocamidopropyl betaine, sodium chloride, glycerin,

fragrance, polyquaternium-10 , PEG-8 , citric acid, tetrasodium EDTA, cocamidopropyl pg-dimonium chrolide,

methylchloroisothiazolinone , methlisothiazolinone, Orange (CI 15985).

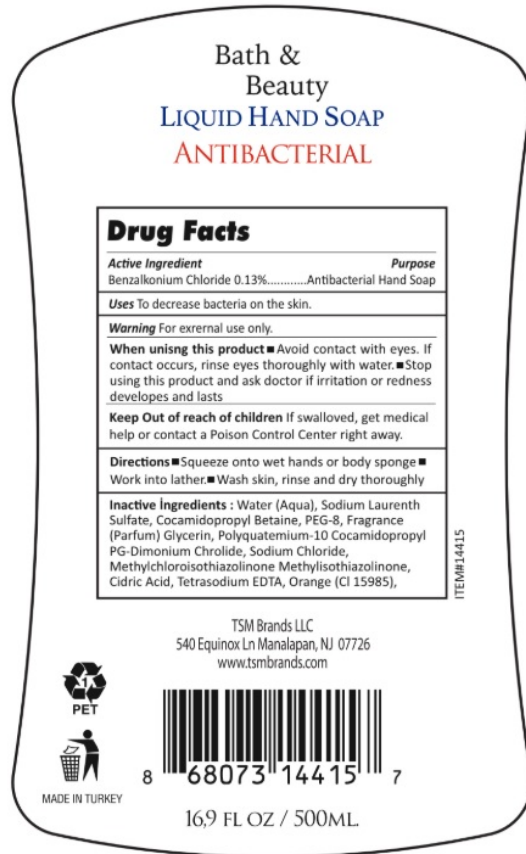
Adverse Reactions

TSM BRANDS LLC

540 Equinox Ln Manlapan, NJ 07726

Made in TURKEY.

principal display panel



Bath & Beauty

LIQUID HAND SOAP

ANTIBACTERIAL



23 FL OZ / 680ML

Bath & Beauty LIQUID HAND SOAP ANTIBACTERIAL

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.13%	Antibacterial Hand Soap

Uses To decrease bacteria on the skin.

Warning For external use only.

When using this product ■ Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. ■ Stop using this product and ask doctor if irritation or redness develops and lasts.

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

Inactive Ingredients : Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, PEG-8, Fragrance (Parfum) Glycerin, Polyquaternium-10 Cocamidopropyl PG-Dimonium Chloride, Sodium Chloride, Methylchloroisothiazolinone Methylisothiazolinone, Citric Acid, Tetrasodium EDTA, Orange (CI 15985),

ITEM#6520

TSM Brands LLC
540 Equinox Ln Manalapan, NJ 07726
www.tsmbrands.com



PET



MADE IN TURKEY



23 FL OZ / 680ML.

Bath & Beauty

LIQUID HAND SOAP

ANTIBACTERIAL



11.25 FL OZ / 333 ML

Bath & Beauty

LIQUID HAND SOAP

ANTIBACTERIAL

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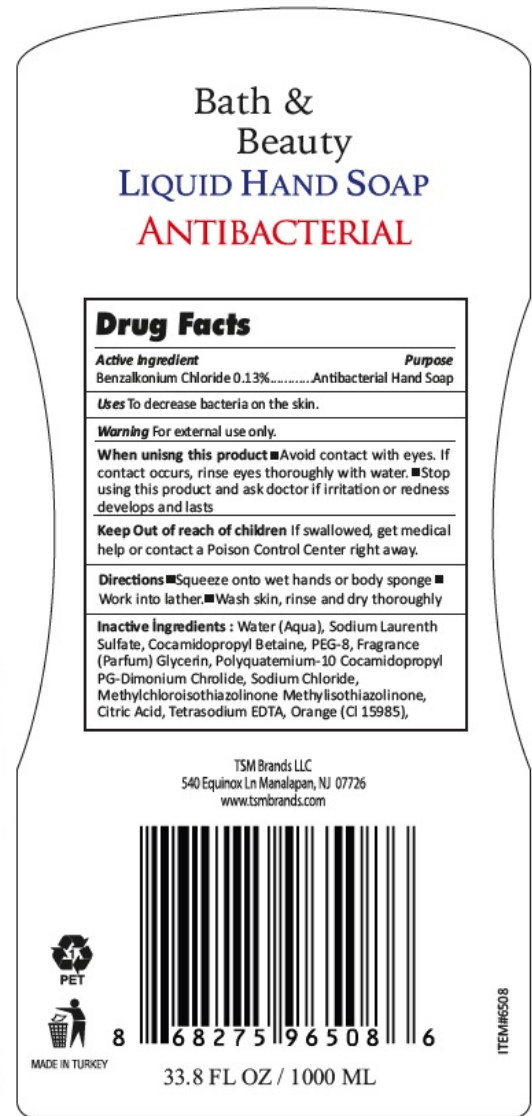


MADE IN TURKEY



11.25 FL OZ / 333 ML

ITEM#6504



ANTIBACTERIAL

benzalkonium chloride 0.13% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76772-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
POLYQUATERNIUM-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
GLYCERIN (UNII: PDC6A3C0OX)
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE (UNII: 205Z54J075)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
CITRIC ACID ACETATE (UNII: DSO12WL7AU)
EDETIC ACID (UNII: 9G34HU7RV0)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76772-010-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
2	NDC:76772-010-68	680 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
3	NDC:76772-010-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	
4	NDC:76772-010-33	333 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/10/2020	

Labeler - TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Establishment

Name	Address	ID/FEI	Business Operations
TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-010)

Revised: 9/2020

TSMITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI