

DEX- benzalkonium chloride liquid

TAT KIMYA SABUN VE GLISERIN SANAYI VE TICARET ANONIM 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.

Active Ingredient(s)

Benzalkonium Chloride %0.13....Purpose: Antibacterial

Purpose

Antibacterial, Liquid Soap

Use

It helps eliminate bacteria on hands.

Warnings

For external use only. When using this product, avoid contact with eyes. In case of contact, flush with water.

Do not use

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

When using this product, avoid contact with eyes. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- wash hands and rinse

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Aqua, Lauramine Oxide, Cetrimonium Chloride, Glycerin, PEG - 150 Distearate,

Fragrance, Citric Acid, Tetrasodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1(CI 42051)

Package Label - Principal Display Panel

DEX			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76964-300
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
Inactive Ingredients			
	Ingredient Name		Strength

LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	8 g in 100 g
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	3 g in 100 g
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.4 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g
WATER (UNII: 059QF0KO0R)	84.37 g in 100 g
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	2 g in 100 g
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)	0.1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76964-300-01	500 g in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/01/2020	

Labeler - TAT KIMYA SABUN VE GLISERIN SANAYI VE TICARET ANONIM SIRKETI (535142780)

Registrant - TAT KIMYA SABUN VE GLISERIN SANAYI VE TICARET ANONIM SIRKETI (535142780)

Establishment

Name	Address	ID/FEI	Business Operations
TAT KIMYA SABUN VE GLISERIN SANAYI VE TICARET ANONIM SIRKETI		535142780	manufacture(76964-300)

Revised: 12/2022

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