

ANTIBACTERIAL WIPES- benzalkonium chloride cloth
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 %0.25 w/w. Purpose : Antibacterial

Purpose

Antibacterial, Wet Wipes

Use

Antibacterial wet wipes helps reduce bacteria (organisms).

Effective on bacterias :

Staphylococcus aureus ATCC 6538,

Pseudomonas aeruginosa ATCC 15442,

Enterococcus hirae ATCC 10541,

Escherichia coli ATCC 10536

Warnings

Keep away from children and direct sunlight. Children should not use this product without an adult supervision. For external use only. In case of poisoning, call the National Toxication Information Center. Avoid contact with eyes.

Do not use

Do not use with eyes. For external use only.

In case of inhaling: If you feel uncomfortable get some fresh air. In case of skin Irritation: Occurs stop using the wipes immediately and wash the affected area with water and soap for at least 15 minutes. People with sensitive skin, pregnant women, breastfeeding women and children under the age of 12 should consult a doctor/pharmacist before using the product. Seek for medical advice if necessary. In case of contact with eyes: If you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. In case of swallowing: Call your local Toxication Center and get medical help. There is no specific antidote therefore treatment must be done according to symptoms. Treatment: Treatment is indicated according to the indication. CALL YOUR LOCAL POISON CENTER.

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Keep out of reach of children. Children should not use this product without an adult supervision.

Directions

Provides practical cleaning without need of water and soap. Used for hand cleaning. Open the adhesive label and pick up a wipe. Gently wipe your hands with antibacterial wipe. No rinsing required. User group : General public

Other Information

Store in a cool and dry place.

Inactive Ingredients

Aqua, Parfum, C12-15 Pareth-12, Glycerin, Polysorbate 20, Propylene Glycol, Tetrasodium EDTA, Piroctone Olamine, Tocopheryl Acetate, Panthenol, Citric Acid

Package Label - Principal Display Panel

Distributed by
 Oceanline LLC
 2 Andrews Dr. Ste 5
 Woodland Park, NJ 07424
 +1-201-562-8403
 info@oceanlinebrands.com

ISO9001
 CERTIFIED



8 694965 1538597
 Manufactured by TAT Chemical Co.
 Product of Turkey

7.1 in x 5.9 in (18 cm x 15 cm)



Use anytime, anywhere



- ✓ **ULTRA PROTECTION**
- ✓ Alcohol Free
- ✓ Paraben Free
- ✓ Dermatologically Tested



7.1 in x 5.9 in (18 cm x 15 cm)



Use anytime, anywhere

Drug Facts		Other Information
Active Ingredient Benzalkonium Chloride 0.13% w/w.....Antibacterial	Purpose Antibacterial	Production date, expiration date, and lot number are printed on the package.
Uses To decrease bacteria on the skin.	Directions * Open the lid, remove the band, and pull out the wipe. After use, reseal the band and close the lid to maintain wetness. * Adult and children 2 years and over: apply to hands. Children under 2 years: ask a doctor before use. * Do NOT flush wipes, trash only. * Store at room temperature and protect from sun exposure.	Inactive Ingredients Aqua, C12-15 Pareth-12, Glycerin, Polysorbate 20, Propylene Glycol, Tetrasodium EDTA, Piroctone Olamina, Tocopheryl Acetate, Panthenol, Fragrance, Citric Acid.
Warnings For external use only Do not use if you are allergic to any of the product's ingredients.		
When using this product , keep it out of eyes. If it contacts eyes, rinse thoroughly with water.		

* Kills 99.9% of germs that may cause illness.

ANTIBACTERIAL WIPES

benzalkonium chloride cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76964-200
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
C12-15 PARETH-12 (UNII: 131316X18L)	0.35 g in 100 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.2 g in 100 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.2 g in 100 g
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	0.1 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	0.25 g in 100 g
EDETATE SODIUM (UNII: MP1J8420LU)	0.1 g in 100 g
PANTHENOL (UNII: WW9CM0O67Z)	0.001 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.001 g in 100 g
WATER (UNII: 059QF0K00R)	98.66 g in 100 g
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.008 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76964-200-11	60 in 1 PACKAGE	06/03/2020	
1		5 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/03/2020	

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(76964-200)

Revised: 7/2022

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