DEX ANTIBACTERIAL WIPES- benzalkonium chloride cloth Fuson LLC

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

Benzalkonium Chloride .13% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Antibacterial Wet Hand 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. Use only on hands and away from eyes.

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 Toxitation Information Center. Avoid contact with eyes. This product consists of nonwoven fabric (solid) impregnated with a flammable liquid solution that has an estimated flashpoint of approximately 120 degrees fahrenheit; keep away from heat, sparks, open flames, and hot surfaces. Do not smoke near this product or while using. Keep container tightly closed when not in use.

Do Not Use

Do not use if allergic to any of its ingredients. Do not use near eyes. Consult a doctor before use if pregnant, breastfeeding, have sensitive skin, or are under the age of 12. Do not buy opened and/or damaged products.

When Using

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. Rince your eyes with plenty of clean water. In case of swallowing: Call your local Toxication Center and get medical help.

Stop Using

Stop use if rednedd or irritation occurs and persists for longer than 48 hours and contact a healthcare professional.

Keep away from children. Children should not use this product without 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.

Other Information

Do not ingest the product internally. Store in a cool, dry place. Store away from oxidizing agents and food.

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

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Tel: 0 (342) 337 39 00 Fax: 0 (342) 337 39 09 MADE IN TURKEY

9. Organize Sanayi Bolgesi Vali Muammer Güler Bulvarı No: 33 Şehlilkamil/Gaziantep/TÜRKİYE





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Tocopheryl Acetate, Panthenol, Citric Acid, (Active Matter Name and Amount % Benzalkonium Chloride %0,25 w/w (CAS: 68424-85-1), Aqua, Parfum, C12-15 Pareth-12, Glycerin, Polysorbate 20, Propylene Glycol, Benzalkonium Chloride, Tetrasodium EDTA, Piroctone Olamine Ingredients / Içindekiler :

TÜKETICI DANIŞMAHATTI



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- **Alcohol Free**
- Paraben Free
- Dermatologically Tested











GB: Antibacterial Wet Wines

GB: Antibacterial Wet Wipes
PRODUCT TYPE (1) Biocidal product related to human hygiene. Poisoning symptom: No data available. Quaternary
ammonium compounds, benzyl (C12-C16) alkyl dimethyl, chlorides LD50 Rat Acute Oral= 240 mg/kg. First ald guide
and emergency treatment instructions. In case of inhaling: If you feel uncomfortable get some fresh ait. 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. Rince 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, WARNING RISK PHRASES AND HAZARD STATEMENTS: FOR EXTERNEL USE
DNILY DO NOT SWALL OW POINTS TO CORNIFIER WHEN LISS AND STORAGE THE PRODUCTS Read to lead carefully to CALL YOUR LOCAL POISON CENTER. WARKING RISK PHRASES AND HAZARD STATEMENTS: FOR EXTENDLUSE ONLY. DO NOT SWALLOW, POINTS TO CONSIDER WHEN USE AND STORAGE THE PRODUCT: Read the label carefully before using the product. Do not use the product if you have hypersensitivity to any of the ingredients used in the product. The product can be used until be expiration date packaging. Do not buy opened and/or damaged products. Storage: Store the product dry, cool, clean place and keep away from direct sunlight. Close the label after using the product to prevent it getting dry. May be toxic for fishes and aquatic organisms. Toxic for bees, PRECAUTIONARY STATEMENTS AND SAFETY PHRASES: P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children, P103: Read label before use.

Directions: Provides practical cleaning wiyhout the need of water and soaps. It is used for hand cleaning. Open the adhesive label and pick up a wipe. Gently wipe your hands with antibactial wipe. No rinsing required. User Group: General Public. READ THE LABEL. BEFORE USING, Warnings: Keep away from children and direct sunlight. Store in a cool and dry place. Children should not use this product without an adult supervision. For external use only. In case of poisoning, call the national toxiation information center. Avoid contact with eyes. Do not use with eyes. Best before 3 years from manufacturing date. Use within 3 monts after opening the package.

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ORGANISMS		APPLICATION DOSAGE/TIME	
OKGANISMS	APPLICATION		
Staphylococcus aureus ATCC 6538	The product is used for wiping hands.	Wet wipe, 1 Pcs.	WHEN NEEDED
Pseudomonas aeruginosa ATCC 15442			
Enterococcus hirae ATCC 10541	lialius.		
Escherichia coli ATCC 10536			

DEX ANTIBACTERIAL WIPES

benzalkonium chloride cloth

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78141-800
Flouuct Lype	HOMEHY O'L'C DICCO	nem coue (source)	1100.70141 000

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZALKO NIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUMUNII:7N6 JUD5X6Y) BENZALKONIUM CHLORIDE 0.13 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
C12-15 PARETH-12 (UNII: 131316 X18 L)		
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)		
EDETATE SO DIUM (UNII: MP1J8420 LU)		
PANTHENOL (UNII: WV9CM0O67Z)		
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)		
POLYSORBATE 20 (UNII: 7T1F30 V5YH)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

Product Characteristics			
Color	white	Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:78141-800-02	100 g in 1 POUCH; Type 0: Not a Combination Product	07/22/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/22/2020	

Revised: 7/2020 Fuson LLC