

HOPS ANTIBACTERIAL WET WIPES- benzalkonium chloride 0.10% cloth
Sapro Temizlik Urunleri Sanayi ve Ticaret Anonim Sirketi

OTC product listing

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information








- Store between 15-30C (59-86F)

- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

240x300 mm

15 mm											
47,5 mm		<p>Drug Facts</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Active Ingredient Benzalkonium Chloride 0,10 % (w/w)</td> <td style="width: 50%;">Purpose Anti-Bacterial</td> </tr> <tr> <td>Uses • For hand cleaning to kill bacteria on the skin. • May be used on arms and legs. • Kills 99.9% of tested bacteria • Antibacterial protection against the tested gram negative and gram positive bacteria.</td> <td>Distributed by: SAPRO USA INC 2513 Shallowford Rd, Ste 200 Marietta, GA Cobb County</td> </tr> <tr> <td>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.</td> <td>Question or Comments? +90 212 735 3808</td> </tr> </table>	Active Ingredient Benzalkonium Chloride 0,10 % (w/w)	Purpose Anti-Bacterial	Uses • For hand cleaning to kill bacteria on the skin. • May be used on arms and legs. • Kills 99.9% of tested bacteria • Antibacterial protection against the tested gram negative and gram positive bacteria.	Distributed by: SAPRO USA INC 2513 Shallowford Rd, Ste 200 Marietta, GA Cobb County	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.	Question or Comments? +90 212 735 3808			
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	15 mm	25 mm	160 mm	25 mm	15 mm						

HOPS ANTIBACTERIAL WET WIPES

benzalkonium chloride 0.10% cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81990-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 U in 100 U

Inactive Ingredients

Ingredient Name	Strength
SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	0.12 U in 100 U
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	0.068 U in 100 U
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.01 U in 100 U
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.68 U in 100 U
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.5 U in 100 U
WATER (UNII: 059QF0KO0R)	98.02 U in 100 U
BENZOIC ACID (UNII: 8SKN0B0MIM)	0.102 U in 100 U
SODIUM GLUCONATE (UNII: R6Q3791S76)	0.1 U in 100 U
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.05 U in 100 U


















Product Characteristics

Color		Score	
Shape	RECTANGLE (Wet wipes)	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81990-001-01	60 U in 1 POUCH; Type 0: Not a Combination Product	07/01/2021	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	505G(a)(3)	07/01/2021	
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Labeler - Sapro Temizlik Urunleri Sanayi ve Ticaret Anonim Sirketi (365536965)

Registrant - Sapro Temizlik Urunleri Sanayi ve Ticaret Anonim Sirketi (365536965)

Establishment

Name	Address	ID/FEI	Business Operations
Sapro Temizlik Urunleri Sanayi ve Ticaret Anonim Sirketi		365536965	manufacture(81990-001)

Revised: 12/2023

Sapro Temizlik Urunleri Sanayi ve Ticaret Anonim Sirketi