BIOORBIL ANTIBACTERIAL HANDSOAP- benzalkonium chloride liquid ASILNUR GIDA VE KIMYA SANAYI 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.

Identity

BioOrbil ANTIBACTERIAL HAND SOAP

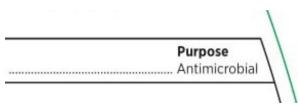


Active Ingredient(s)

Benzalkonium Chloride 0.13%

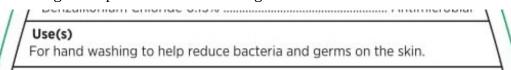
Purpose

Antimicrobial



Use(s)

For hand washing to help reduce bacteria and germs on the skin.



Warnings

- For external use only.
- Not edible. Don't drink.

• Prolonged skin contact may cause temporary irritation.

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DO NOT USE

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

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When using this product

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

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Stop use and ask a doctor

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

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Keep out of reach of children

Direction

- Pump into hands, wet as needed.
- Lather vigorously for at least 15 seconds.
- Wash hands, rinse thoroughly and dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

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Other Information

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Inactive Ingredients

Aqua, Cocamidopropyl Betaine, Coco-Glucoside, Glycerin, Peg 150 Distearate, Cocomide MIPA, Sodium Benzoate, Polyquaternium 7, Disodium EDTA, Lime Oil, Phenoxyethanol, Citric Acid, Tocopheryl Acetate, Panthenol.

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Dosage and Administration



Usage Section

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Packaging

INSTANT EFFECT-PLUS FORMULA

Clean, Sanitize and Moisture

Free of paraben, dye and phthalates

ANTIBACTERIAL LIQUID SOAP

- Sanitizing formula to help reduce cross-contamination
- Hands feel smooth, soft and refreshed

Distributed by

PBITTS LLC

836 Foster Ave Bensenville

ILLINOIS 60106

Manufacturing Company

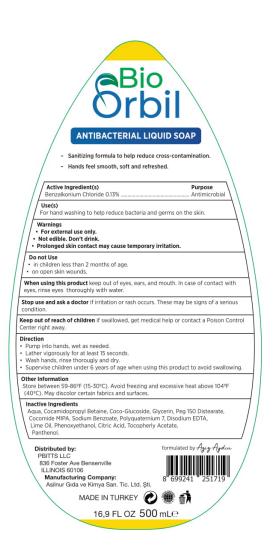
Asilnur Gıda ve Kimya San. Tic. Ltd. Şti.

formulated by: Aziz Aydın

MADE IN TURKEY

Packaging





BIOORBIL ANTIBACTERIAL HANDSOAP

benzalkonium chloride liquid

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81396-101		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
SO DIUM CHLO RIDE (UNII: 451W47IQ8X)				
LIME OIL (UNII: UZH29 XGA8 G)				
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)				
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0 VTB1)				
GLYCERIN (UNII: PDC6A3C0OX)				
EDETIC ACID (UNII: 9G34HU7RV0)				
COCO GLUCOSIDE (UNII: ICS790225B)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)				
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600000 MW) (UNII: 0L414VCS5Y)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	LIME	Imprint Code		
Contains				

ı	Packag	ing			
ı	# Ite	m Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:8	1396-101-50	$500\ mL$ in $1BOTTLE;$ Type $0\colon Nota$ Combination Product	01/31/2021	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	01/31/2021			

Labeler - ASILNUR GIDA VE KIMYA SANAYI TICARET LIMITED SIRKETI (503002931)

Establishment				
Name	Address	ID/FEI	Business Operations	
ASILNUR GIDA VE KIMYA SANAYI TICARET LIMITED SIRKETI		503002931	manufacture (8 1396-101)	