

DEEPFRESH ANTIBACTERIAL SOAP- benzalkonium chloride soap
AKSAN KOZMETİK SANAYİ VE TİCARET ANONİM ŞİRKETİ

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.

DEEP FRESH ANTIBACTERIAL LIQUID SOAP

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Benzalkonium Chloride (0.23% w/v) (active ingredient)
- b. Glycerol (2 % v/v)
- c. Lauramine Oxide (1,5 % v/v)
- d. Disodium Cocoamphodiacetate (2 % v/v)
- e. Hexylene Glycol (1 % v/v)
- f. Sodium Chloride (0.4% v/v)
- g. PEG-150 Distearate (3% v/v)
- h. Cocamidopropyl Betaine (5% v/v)
- i. Cetrimonium Chloride (0.3% v/v)
- j. Magnesium Nitrate (0.0018% v/v)
- k. Methylchlorisothiazolinone and Methylisothiazolinone (0.0014% v/v)
- l. Tetrasodium EDTA (0.03% v/v)
- m. Citric Acid (0.05% v/v)
- n. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Benzalkonium Chloride 0,23% w/v. Purpose: Antibacterial / Antifungal

Purpose

Antibacterial / Antifungal, Hand Sanitizer

Use

Antibacterial Liquid Soap helps to reduce bacteria that potentially can cause disease.

Warnings

For external use only.

Do not use

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

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

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

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.

Directions

- Wet your hands with clean water. Take some Deepfresh Antibacterial liquid soap and foam it. Thoroughly rub your hands between fingers, all inside and outside surfaces, nails. Rinse your hands with clean water.

Other information

- Store the product dry, cool, clean place and keep away from direct sunlight.
- Keep away from children and pets.

Inactive ingredients

Glycerol, Lauramine Oxide, Disodium Cocoamphodiacetate, Hexylene Glycol, Sodium Chloride, PEG-150 Distearate, Cocamidopropyl Betaine, Cetrimonium Chloride, Magnesium Nitrate, Methylchloroisothiazolinone and Methylisothiazolinone, Tetrasodium EDTA, Citric Acid, Sterile distilled water or boiled cold water.

Package Label - Principal Display Panel



Deepfresh

Antibacterial Liquid Hand Soap

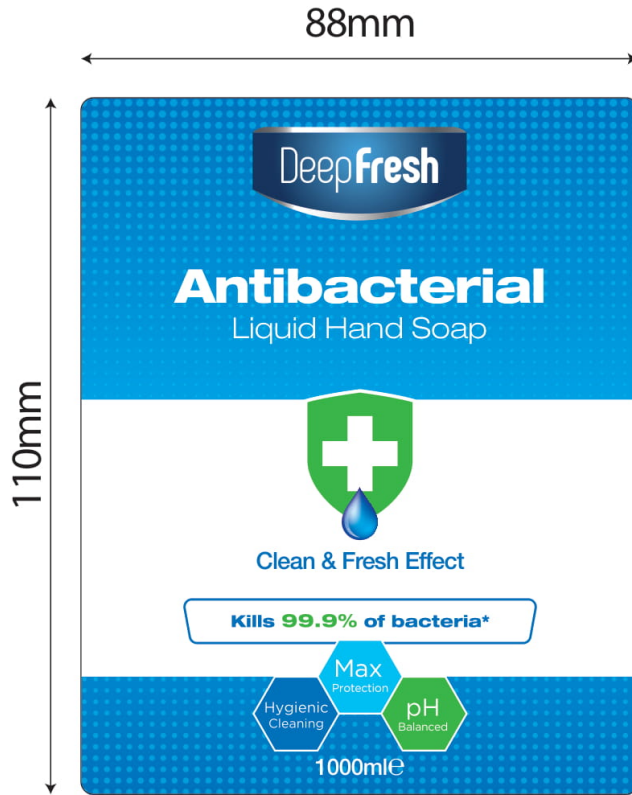
Drug Facts	
Active Ingredient	Purpose
Benzalkonium Chloride 0,23 %.....	Antibacterial / Antifungal
USE : Antibacterial liquid soap helps to reduce bacteria that potentially can cause disease.	
Warnings For external use only.	
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Other Information Store the product dry, cool, clean place and keep away from direct sunlight. Keep away from children and pets.	
INACTIVE INGREDIENTS Cetrimonium Chloride, Citric Acid, Cocamidopropyl Betaine, Disodium Cocoamphodiacetate, Fragrance, Hexylene Glycol, Glycerin, Lauramine Oxide, Magnesium Nitrate, Methylchlorisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Chloride, Tetrasodium EDTA, Water	

Manufacturer - Licence Owner Name And Address:
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2500ml e

aksan kozmetik

GMP ISO PET 12M DİKKAT / ATTENTION



Deepfresh

Antibacterial Liquid Hand Soap

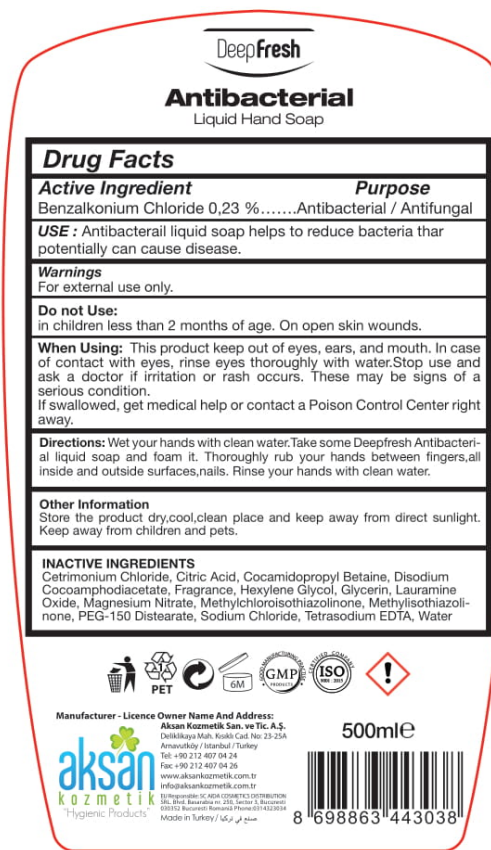
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1000ml e

aksan kozmetik

GMP ISO PET 12M DİKKAT / ATTENTION



DEEPFRESH ANTIBACTERIAL SOAP

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86815-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.23 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	1 mL in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.4 mL in 100 mL

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	5 mL in 100 mL
DISODIUM OLEAMIDO MIPA-SULFOSUCCINATE (UNII: 0MBZ20845F)	2 mL in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.05 mL in 100 mL
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	3 mL in 100 mL
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	1.5 mL in 100 mL
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	0.3 mL in 100 mL
MAGNESIUM NITRATE (UNII: 77CBG3UN78)	0.0018 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 100 mL
WATER (UNII: 059QF0KO0R)	84.49 mL in 100 mL
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	0.03 mL in 100 mL
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	0.0014 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86815-005-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86815-005-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86815-005-03	2500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (365577706)

Registrant - AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (365577706)

Establishment

Name	Address	ID/FEI	Business Operations
AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		365577706	manufacture(86815-005)

Revised: 1/2022

AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI