

DEEP FRESH ANTIBACTERIAL HAND SANITIZER GEL- alcohol gel **AKSAN KOZMETIK 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.

DEEP FRESH ANTIBACTERIAL HAND SANITIZER GEL

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) 70%, volume/volume (v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (0.5% v/v).
- c. Carbomer (0.35% v/v).
- d. Triethanolamine (0.1% v/v).
- e. 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)

Alcohol 70% v/v. Purpose: Antibacterial

Purpose

Antibacterial Hand Gel

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 fire, flame, sparks and heat. Keep away from children, food and animal feeds.

Do not use

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

Do not inhale the vapour or grains of the product if occurs. In case of inhaling: If you feel uncomfortable get some fresh air. In case of contact with eyes: If you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. Seek for medical advice if necessary. In case of swallowing: Rinse the patient's mouth with water and drink water. Keep it calm. Do not induce vomiting. Call your local Toxication Center and get medical help.

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

Take some Antibacterial gel in your hand. Rub your hands, between the fingers, all the inner and outer surfaces, the nails, until they dry. It is used for hand cleaning. Do not rinse after use.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

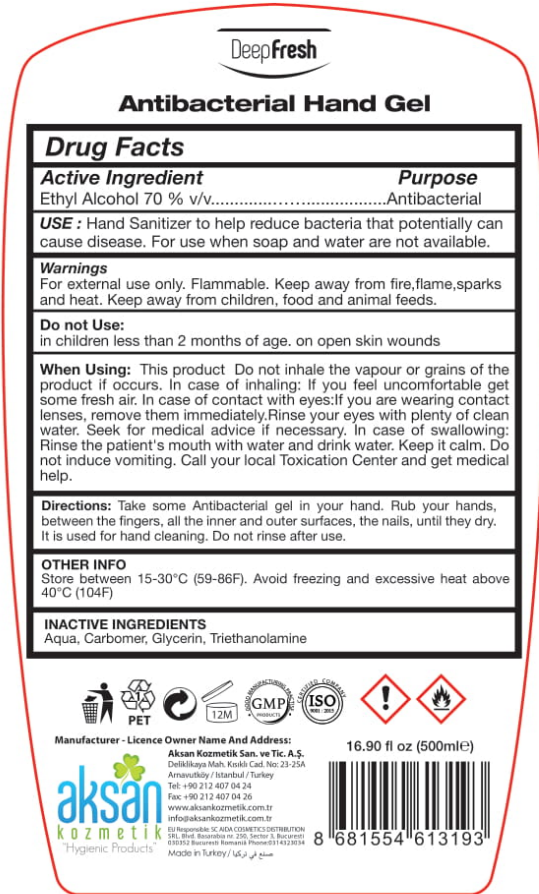
Inactive ingredients

glycerin, Carbomer, purified water USP, Triethanolamine

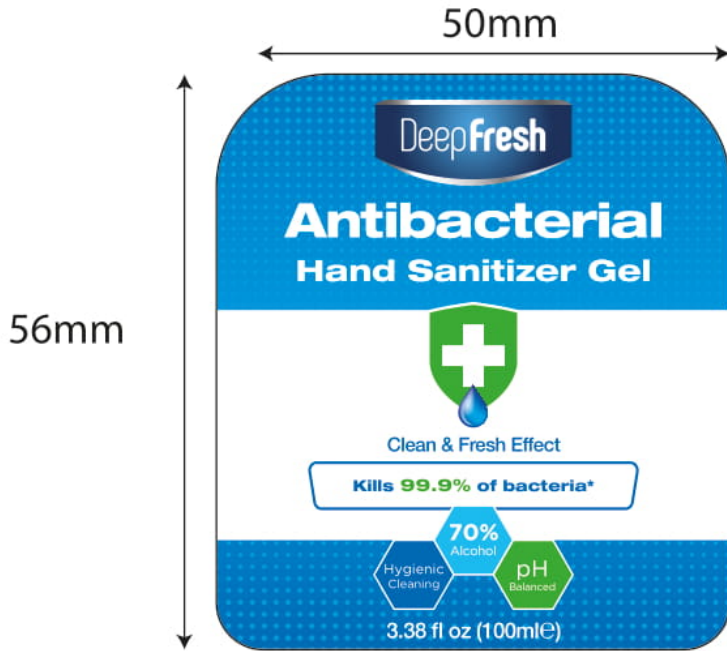
Package Label - Principal Display Panel

1000 mL NDC: 86815-002-04

70x115mm



100 mL NDC: 86815-002-02



Deepfresh
Antibacterial Hand Gel

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70 % v/v	Antibacterial
USE : Reduces bacteria on skin	
Warnings For external use only. Flammable. Keep away from fire, flame, sparks and heat. Keep away from children, food and animal feeds.	
Do not Use in children less than 2 months of age, on open skin wound	
When Using: This product. Do not inhale the vapour or grains of the product if occurs. In case of inhaling: If you feel uncomfortable get some fresh air. In case of contact with eyes: If you are wearing contact lenses, remove them immediately. Rinse your eyes with plenty of clean water. Seek for medical advice if necessary. In case of swallowing: Rinse the patient's mouth with water and drink water. Keep it calm. Do not induce vomiting. Call your local Toxication Center and get medical help.	
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OTHER INFO Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F)	
INACTIVE INGREDIENTS Aqua, Carbomer, Glycerin, Triethanolamine	

Manufacturer - Licence Owner Name And Address:
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 00 000 0000000 00 000 0000000
 00 000 0000000 00 000 0000000
 Made in Turkey / Türkiye

3.38 fl oz (100ml) ±

200 mL NDC: 86815-002-03

142mm




111mm

Deepfresh

Antibacterial Hand Gel


Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70 % v/v.....	Antibacterial
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 fire, flame, sparks and heat. Keep away from children, food and animal feeds.	
Do not Use: in children less than 2 months of age. on open skin wounds	
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Manufacturer - Licence Owner Name And Address:
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 SİL. SİL. Bakanlıkça onay. 3152 Sektör 1, Buzdolabı
 501215 Buzdolabı Bermanlı Pnömetri 019422844
 Made in Turkey / صنع في تركيا


Deepfresh

**Antibacterial
Hand Sanitizer Gel**




Clean & Fresh Effect


Kills 99.9% of bacteria*



Hygienic
Cleaning



70%
Alcohol



pH
Balanced

6.76 fl oz (200mL)

DEEP FRESH ANTIBACTERIAL HAND SANITIZER GEL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86815-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 1342 (UNII: 809Y72KV36)	0.35 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL

WATER (UNII: 059QF0KO0R)

29.05 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86815-002-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86815-002-05	2500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86815-002-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:86815-002-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:86815-002-03	200 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(86815-002)

Revised: 1/2022

AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI