

DEEP FRESH ANTIBACTERIAL-ANTISEPTIC DISINFECTANT- alcohol solution
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-ANTISEPTIC DISINFECTANT

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 (0.6% v/v).
- c. 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)

Purpose

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

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

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. 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

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, purified water USP

Package Label - Principal Display Panel

135mm

102mm

Deepfresh

Antibacterial-Antiseptic Disinfectant

Drug Facts	
Active Ingredient	Purpose
Ethyl Alcohol 70 % v/v.....	Antiseptic
USE : Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available	
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INACTIVE INGREDIENTS Glycerin, Water	

Deepfresh

Antibacterial-Antiseptic Disinfectant

70% Alcohol

Kills **99.9%** of bacteria and viruses*

Antiviral

Max Protection

Clean & Fresh Effect

200ml e (6.76 fl oz)

Manufacturer - Licence Owner Name And Address:
Aksan Kozmetik San. ve Tic. A.Ş.
Ortaköy Mah. Raif Cad. No: 29-25A
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Tel: +90 212 607 04 24
Fax: +90 212 607 04 26
www.aksankozmetik.com.tr
info@aksankozmetik.com.tr
Etiler Mah. Beşiktaş / İstanbul / Turkey
KOSGEBE Yatırım Destek Programı ile Desteklenmektedir
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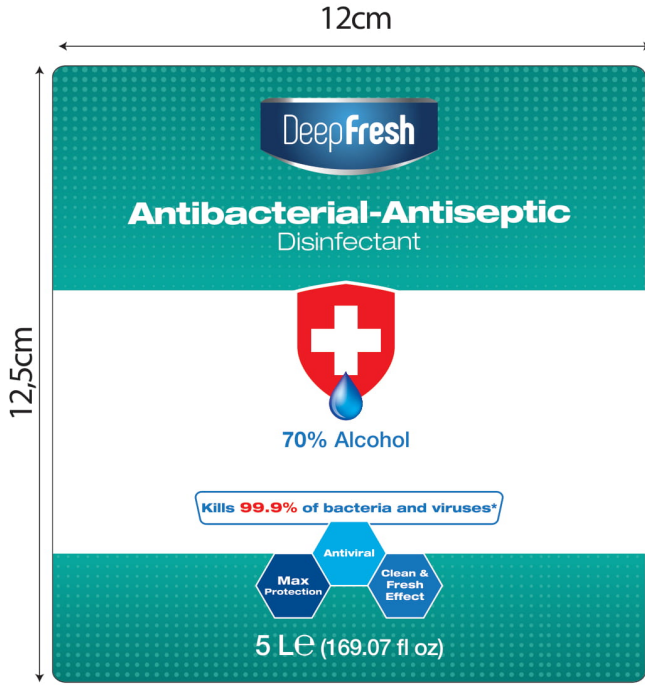
ISO 9001

GMP

HDPE

TQM

8 681554 613889



Deepfresh
Antibacterial-Antiseptic Disinfectant

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INACTIVE INGREDIENTS Glycerin, Water	

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aksan **Kozmetik**
 Akisan Kozmetik San. ve Tic. A.Ş.
 Oskodurca Mah. Sıhhiye Cad. No: 23/25A
 Arnavutköy / İstanbul / Turkey
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 Fax: +90 212 607 04 26
 www.aksankozmetik.com.tr
 info@aksankozmetik.com.tr
 ISO 9001:2015, ISO 13485:2015, ISO 22716:2008, ISO 22717:2008
 Made in Turkey / Üretim Yeri: Türkiye

5 Le (169.07 fl oz)

8 681554 613926



Deepfresh
Antibacterial-Antiseptic Disinfectant

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 ISO 9001:2015, ISO 13485:2015, ISO 22716:2008, ISO 22717:2008
 Made in Turkey / Üretim Yeri: Türkiye

10 Le (338.14 fl oz)

8 681554 613933

118mm

80mm

Deepfresh

Antibacterial-Antiseptic Disinfectant

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 Tugaylar, Products
 Made in Turkey / Türkiye Üretim

Deepfresh

Antibacterial-Antiseptic Disinfectant

70% Alcohol

Kills 99.9% of bacteria and viruses*

100ml (3.38 fl oz)

18 cm

16 cm

Deepfresh

Antibacterial-Antiseptic Disinfectant

70% Alcohol

Kills 99.9% of bacteria and viruses*

20 L (676.28 fl oz)

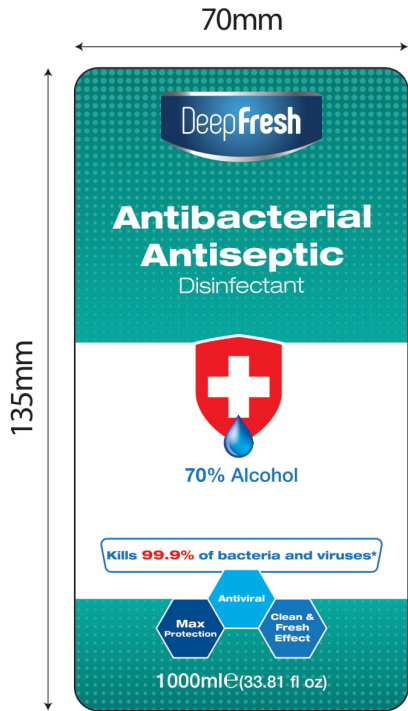
Deepfresh

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20 L (676.28 fl oz)

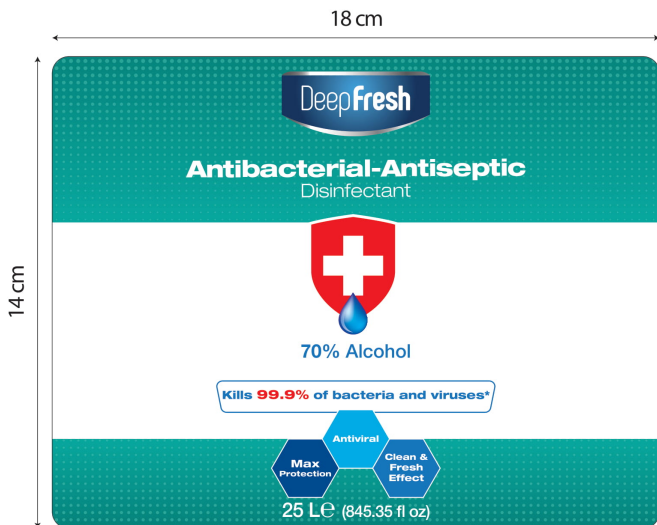


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 info@aksanchem.com.tr
 K 1 2 0 0 1 1 1
 Hygienic Products
 İstanbul - Turkey / İstanbul - Türkiye

1000ml (33.81 fl oz)

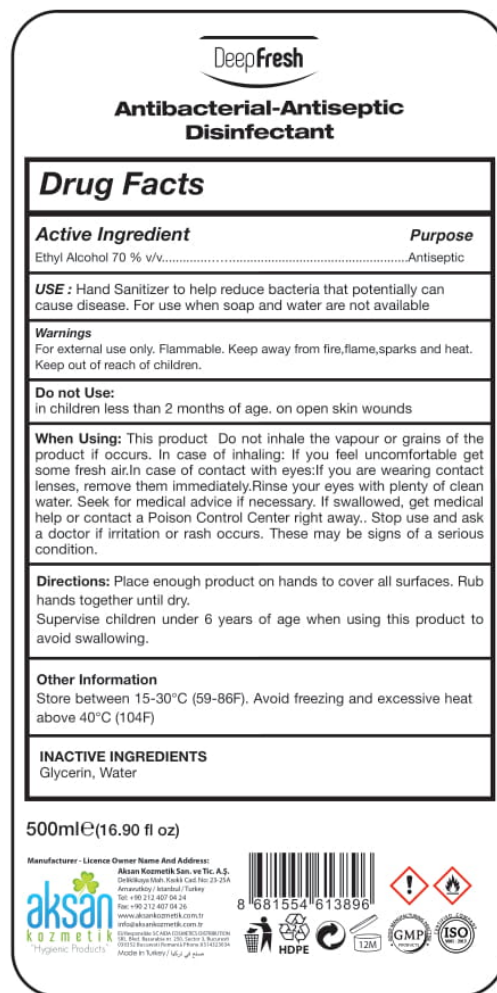


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 K 1 2 0 0 1 1 1
 Hygienic Products
 İstanbul - Turkey / İstanbul - Türkiye

25 L (845.35 fl oz)



DEEP FRESH ANTIBACTERIAL-ANTISEPTIC DISINFECTANT

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86815-004
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		
GLYCERIN (UNII: PDC6A3C0OX)		0.6 mL in 100 mL		
WATER (UNII: 059QF0KO0R)		29.4 mL in 100 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86815-004-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:86815-004-02	200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:86815-004-03	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:86815-004-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:86815-004-05	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:86815-004-06	10000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:86815-004-07	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:86815-004-08	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(86815-004)

Revised: 7/2020

AKSAN KOZMETIK SANAYI VE TICARET ANONIM SIRKETI