

WONVIA HAND DISINFECTANT GEL- alcohol gel
KAPLAN DISTRIBUTION LLC

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.

Active Ingredient(s)

Ethyl Alcohol 58%, Isopropyl Alcohol 12%, Alkyl dimethyl benzyl ammonium chloride 0.2%

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

- keep away from children
- on open skin wounds
- do not use in the cleaning of foodstuffs

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with plenty of 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. Do not breathe directly.

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Directions

- Use enough amount of solution to keep your hands wet. Rub hands together for 30 seconds.
- keep away from children, food, and animal feed.
- follow the instructions to avoid risks to human and environmental health.

Other information

- Store between 15-30C (59-86F) in its original packaging upright in a cool dry place that does not receive sunlight.
- Avoid freezing and excessive heat above 40C (104F)
- do not store more than 4 boxes in a row.

- dispose of the container P501 in accordance with local regulations.
- use the unpacked product within 1 month.
- shelf life (25+/-2°C) of the product is 2 years.

Inactive ingredients

Softener 1.5%, resolvent 28.19%, fragrance 0.1%, colouring 0.01%
resolvent is completed with 27.8% proportion to 100%

Package Label - Principal Display Panel




ATTENTION! ONLY FOR EXTERNAL USE. DO NOT DRINK
Usage area and way: It is a disinfectant formulated for use in areas requiring high hygiene standards. It's a hand rub product. No rinsing required. Special formula does not irritate or dry skin. It saves time and ease of use.
Type of product : Product related to human hygiene. Symptoms of poisoning: Dizziness, nausea, redness of the skin. Ethyl alcohol LD50 (ORAL Rat): 3450mg/kg, Dimethyl benzyl ammonium chloride LD50 (Oral Rat): 410 mg/kg First aid recommendations: Respiratory: Fresh air should be taken and see a doctor immediately in case of weakness. Skin Contact: No impact is expected. However, in case of redness, burning or itching on the skin, wash and rinse with plenty of water. Contact your doctor if irritation persists. Eye Contact: Wash with plenty of water while keeping the eyelids open. Contact your doctor if eye irritation persists. Swallow: Rinse the mouth and then drink 1-2 cups of water or milk. Do not vomit patient. See a doctor if symptoms persist.
Show the product container or label to the doctor.
Antidote and necessary information: It has no specific antidote. Treatment is performed according to the symptoms. In cases of poisoning, call National Poison Advisory Centre or your doctor. It can be poisonous to fish and aquatic organisms. It's toxic to bees. Things to consider while using and storing the product: Store in its original packaging upright in a cool dry place that does not receive sunlight. Do not store more than 4 boxes in a row. Risk statement and explanation: P305+P351+P338 In case of eye contact: Rinse carefully with water for a few minutes. If you have contact lenses, remove them and keep rinsing. Do not use in areas where pregnant women, infants and people with respiratory problems are present. Do not swallow. Dispose of container P501 in accordance with local regulations. Avoid prolonged contact to protect your skin. Keep away from foodstuffs. Keep out of reach of children. It can cause allergies. Do not breathe directly. Use the unpacked product within 1 month. Shelf life (25+/- 2°C) of the product is 2 years. Manufacture date and lot no is on the package.

**ANTIBACTERIAL
HAND DISINFECTANT
GEL**

Alcohol Based Hand Disinfectant




8 698657 587382

100ml (3.38 fl oz)

**70%
Alcohol**

CE

MADE IN TURKEY



Harmful organisms affected by the product

Type Of Pest	Application Area & Manner	Application Range
Escherichia coli Staphylococcus aureus Salmonella typhimurium, Bacillus cereus - Spores	Use to clean hands in public and personal areas. It does not require rinsing.	When Required

Formulation: Liquid
Users Group: People
Content: Ethyl alcohol (CAS No:64-17-5) %58, Isopropyl Alcohol (CAS No:57-63-0) %12, Alkyl dimethyl benzyl ammonium chloride (CAS No:51789-71-7) %0.2, Softener %1.5, Resolvent %28.19, Fragrance %0.1 Colouring %0.01, Exel pients and its amounts (%): The resolvent is completed with %27.8. Proportion to %100. Keep away from children, food and animal feed. Do not use in cleaning of foodstuffs. Do not eat, drink, or smoke during the application and preparation phase. Follow the instructions to avoid risks to human and environmental health. Empty packaging disposal: Dispose of properly.

This product is manufactured in Koşar Makina Kimya San. ve Tic. A.Ş under SAİYE brand for Hygiene Plus with the permission certificate of the Ministry of Health dated 27.03.2020 and numbered E.173936.
Address: Koşar Mah. 9008 Sk. No:121
AYAZLI / SAKARYA / TURKEY



Kaplan Distribution LLC
828 N. OLDEN AVE. TRENTON, NJ 08638 USA
1 888 8WONVIA
www.wonvia.com

100 mL NDC: 78876-708-01

WONVIA HAND DISINFECTANT GEL			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78876-708
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 g	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	12 g in 100 g	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58 g in 100 g	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78876-708-01	100 g in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	

WONVIA



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ANTIBACTERIAL HAND DISINFECTANT

GEL

Alcohol Based Hand Disinfectant



100ml (3.38 fl oz)

70%
Alcohol

CE

MADE IN TURKEY



Harmful organisms affected by the product		Application Range	When Required
Type Of Pest	Application Area	Use enough amount of solution to keep your hands wet. Rub for 30 seconds.	Required
E. coli Salmonella, Bacteroides Staphylococcus Serratias	It is used to clean hands in public and personal hygiene areas requires rinsing.		

Formulation: Liquid
Users Group: People
Content: Ethyl alcohol (CAS No:64-17-5) %58, Isopropyl Alcohol (CAS No:67-63-0) %12, Alkyl dimethyl benzyl ammonium chloride (CAS No:61789-71-7) %0.2, Softener %1.5, Resolvent %28.19, Fragrance %0.1 Colouring %0.01, Exipients and its amounts (%). The resolvent is completed with %27.8. Proportion to %100. Keep away from children, food and animal feed. Do not use in cleaning of foodstuffs. Do not eat, drink, or smoke during the application and preparation phase. Follow the instructions to avoid risks to human and environmental health. Empty packaging disposal: Dispose of properly.

This product is manufactured in Kodkar Makina Kimya San. ve Tic. A.Ş. under SAİE brand for Hygiene Plus with the permission certificate of the Ministry of Health dated 27.03.2020 and numbered E.17338.
Address: İstikbal Mah. 0908 Sk. No:121
Alyazir / Sakarya / TURKEY

Kaplan Distribution LLC
828 N. OLDEN AVE. TRENTON, NJ 08638 USA
1 888 8WONVIA
www.wonvia.com

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

Labeler - KAPLAN DISTRIBUTION LLC (117548994)

Registrant - KAPLAN DISTRIBUTION LLC (117548994)

Establishment

Name	Address	ID/FEI	Business Operations
RKS GROUP YAPI KIMYASALLARI SANAYI VE TICARET LIMITED SIRKETI		520136931	manufacture(78876-708)

Revised: 8/2020

KAPLAN DISTRIBUTION LLC