

WONVIA ANTIBACTERIAL HAND DISINFECTANT- 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)

Alcohol 70% Purpose: Antibacterial Hand Disinfectant

Purpose

Antibacterial 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+/-2C) of the product is 2 years.

Inactive ingredients

Softener 1.5%, resolvent 28.19%, fragrance 0.1%, colouring 0.01%
resolcent 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

70% Alcohol

CE

MADE IN TURKEY

ATTENTION!

FLAMMABLE

Harmful organisms affected by the product	
Type Of Pest	Application Area & manner of use
Escherichia coli Salmonella Staphylococcus aureus Bacillus cereus Serratia	Use the amount of solution to keep your hands wet. Rub your hands at least 20 seconds.
	When Required

Formulation: GEL
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, Excipients 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.

Distributed by:
Kaplan Distribution LLC
828 N. OLDEN AVE. TRENTON, NJ 08630 USA
1 888 8WONVIA
www.wonvia.com

200 mL NDC: 78876-711-02

WONVIA ANTIBACTERIAL HAND DISINFECTANT

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78876-711
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	12 g in 100 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78876-711-02	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/30/2020	

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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(78876-711)