WONVIA ANTIBACTERIAL 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

Purpose

Antiseptic, Antibacterial Hand Disinfectant 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 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 direct 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% resolvent is completed with 27.8% proportion to 100%

Package Label - Principal Display Panel





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, nause, preness of the skin. Ethyl alcohol LD30 (DrAL Rat): 436 mg/kg. Dimetryl benzyl ammonium chloride LD30 (Dral Rat): 410 mg/kg first all ecomemediators. Respirators in the skin. Ethyl alcohol LD30 (DrAL Rat): 435 mg/kg. Dimetryl benzyl ammonium chloride LD30 (Dral Rat): 410 mg/kg first all ecomemediators. Respirators in Tesh all should be taken and see a doctor immediately in case of weakness. Sikin Contacts with the present of the skin and the standard of the skin and the ski

ANTIBACTERIAL HAND DISINFECTANT

GEL

Alcohol Based Hand Disinfectant



1L (33.8 fl oz)









Formulation: Liquid Users Group: People Content: Ethyl alcohol (CAS Nox54-17-5) %58, Isoproply Alcohol (CAS Nox57-63-0) %12, Alkyl dimethyl benzyl ammonium chloride (CAS Nox5198-71-7) %0.2, Softener %1.5, Resolvent %28.19, Fragrance %0.1 Colouring %0.01, Excl plents and its amounts (%): The resolvent is completed with %27.8. Proportion to %10.0, Keep away from children, food and animal feed. Do not use in cleaning of foodstrike, Do not est, drink, or smoke during the application and preparation phase. Follow the instructions to avoid risks to human and environmental health. Empty packaging disposal bispose of properly.

This product is mandetured in Koder Mikalou Kings.



WONVIA



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5L (169 fl oz)







| ected by the pro | Application | Use enough amount of solution to keep your hands wet, Rub |
|----------------------------------|------------------------------|---|
| Il organisms affected by the pro | Application Area & Manner | It is used to clean hands in public and personal |

Formulation: Liquid Users Group: People Content: Ethyl alcohol (CAS No:64-17-5) %58, Isoproply Alcohol (CAS No:57-63-0) %12, Alloyd dimethyl benzyl ammonlum chloride (CAS No:578-87-17-7) %0.2, Softener %1.5, Resolvent %28.19, Fragrance %0.1 Colouring %0.01, Exel plents and its amounts (%): The resolvent is completed with %27.8, Proportion to %10.00. Keep away from children, food and animal feed. Do not use in cleaning of foodstuffs. Do not est, 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 Kodar Makins Kimp.

This product is manufactured in Koçkar Makir San. ve Tic. A.Ş under SAYE brand for Hyglene is the permission certificate of the Ministry of dated 27.03.2020 and numbered E.173538.



Kaplan Distribution LLC **1 888 8WONVIA**

1L NDC: 78876-710-10 5L NDC 78876-710-50

WONVIA ANTIBACTERIAL HAND DISINFECTANT GEL

alcohol gel

| Product Information | roduct Information | | | |
|-------------------------|--------------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78876-710 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | | |
|---|--------------------------|--------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 58 kg in 100 L | | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 12 kg in 100 L | | |
| BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y) | BENZALKONIUM CHLORIDE | 0.2 kg in 100 L | | |

| Inactive Ingredients | | |
|--------------------------|----------|--|
| Ingredient Name | Strength | |
| WATER (UNII: 059QF0KO0R) | | |

| Product Characteristics | | | |
|-------------------------|--------------|--|--|
| Color | Score | | |
| Shape | Size | | |
| Flavor | Imprint Code | | |
| Contains | | | |

| I | Packaging | | | |
|---|----------------------|--|-------------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:78876-710-10 | 1 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/30/2020 | |
| 2 | NDC:78876-710- 50 | 5 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/30/2020 | |
| | | | | |

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Show the product container or label to the doctor.

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Marketing Information

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

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(78876-710)

Revised: 8/2020 KAPLAN DISTRIBUTION LLC