ANTIBACTERIAL HAND DISINFECTANT SOLUTION- ethyl alcohol liquid KOCKAR MAKINA KIMYA 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.

WIEBERR[®] ANTIBACTERIAL HAND DISINFECTANT SOLUTION

Drug Facts

Active ingredient

Content: Ethyl alcohol (CAS No: 64-17-5) %70, Alkyl dimethyl benzyl ammonium chloride (CAS No: 61789-71-7) % 0.2

Purpose: Antiseptic

Uses: 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.

Warnings: Symptoms of poisoning: Dizziness, nausea, redness of the skin. Ethyl alcohol LD50(OrAL Rat):

3450mg/kg, Dimethyl benzyl ammonium chloride LD50(OraL Rat): 410mg/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.

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.

Avoid prolonged contact to protect your skin. Keep away from foodstuffs.

Do not breathe directly.

Keep out of reach of children. It can cause allergies.

Directions:

| Harmfu | l organisms a | iffected by th | ne product |
|--|--|--|----------------------|
| Type of Pest | Application Area Mananer & | Application dose | Application Range |
| Esherichia coli Salmonella, typhi murium, Bacillus cereus S.aereus. | It is used to clean hands in public and personal areas. It does not require rinsing. | Use enough amount of solution to keep your hands wet. Rub your hands at least 30 seconds. | When. Required. |

Other information: 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.

Dispose of 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.

Excipients and its amounts (%):

Water % 27.5, Glycerine % 2.0, Carbomer %1.0

Quality in our chemistry

% 70 Alcohol

ATTENTION! ONLY FOR EXTERNAL USE. DO NOT DRINK

Type of product: Product related to human hygiene.

Manufacture date and lot no is on the package.

MADE IN TURKEY

Formulation: Liquid

Users Group: People

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 way of dispose: Properly dispose of accordance the rule.

Ministry of Health License

Date and Number 04.06.2020/G181

Manufacturer and Licensee Firm and Name and Address:

KOCKAR

Makina Kimya san. ve Tic. A. S.

Tel: 0 264 418 18 67 - Fax: 418 48 69

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Packaging



ANTIBACTERIAL HAND DISINFECTANT SOLUTION

ethyl alcohol liquid

| Product Information | | | | | | |
|--------------------------------------|-----------------------|-----------|-------------------------------------|-----------------------------|--|--|
| Product T ype | HUMAN OTC DRUG | Item Code | (Source) | NDC:78433-201 | | |
| Route of Administration | TOPICAL | | | | | |
| | | | | | | |
| | | | | | | |
| Active Ingradiant/Active Me | : | | | | | |
| Active Ingredient/Active Mo | iety | | | | | |
| Active Ingredient/Active Mo Ingre | vie ty odient Name | | Basis of Strength | Strength | | |
| | dient Name | | Basis of Strength ALCOHOL | Strength 70 mL in 100 mL | | |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)

| Packaging | | | | | | |
|-----------------------|--|---------------------------------------|------------------------------|-------------------------|-----------------------|--|
| # | Item Code | Package I | Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:78433-201- 01 | 5 mL in 1 BOTTLE; Type 0: No | ot a Combination Product | 07/21/2020 | | |
| 2 | NDC:78433-201- 02 | 10 mL in 1 BOTTLE; Type 1: C | onvenience Kit of Co-Package | e 07/21/2020 | | |
| 3 | NDC:78433-201- 03 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | | 07/21/2020 | | | |
| 4 | NDC:78433-201- 04 | 100 mL in 1 BOTTLE; Type 0: | Not a Combination Product | 07/21/2020 | | |
| 5 | NDC:78433-201- 05 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | | 07/21/2020 | | | |
| 6 | NDC:78433-201- 06 | 250 mL in 1 BOTTLE; Type 0: | Not a Combination Product | 07/21/2020 | | |
| 7 | NDC:78433-201- 07 | 500 mL in 1 BOTTLE; Type 0: | Not a Combination Product | 07/21/2020 | | |
| 8 | NDC:78433-201- 08 750 mL in 1 BOTTLE; Type 0: Not a Combination Product | | 07/21/2020 | | | |
| 9 | NDC:78433-201- 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | | 07/21/2020 | | | |
| 10 | NDC:78433-201- 10 | 5000 mL in 1 BOTTLE; Type 0 |): Not a Combination Product | 07/21/2020 | | |
| 11 | NDC:78433-201- 11 | 20000 mL in 1 CONTAINER; T Product | ype 0: Not a Combination | 07/21/2020 | | |
| 12 | NDC:78433-201- 12 | 1000000 mL in 1 CONTAINEF Product | ; Type 0: Not a Combination | 07/21/2020 | | |
| | | | | | | |
| Marketing Information | | | | | | |
| | Aarketing Catego | | or Monograph Citation | Marketing Start Date | Marketing End Date | |
| | C monograph not f | | | 07/21/2020 | | |

Labeler - Kockar Makina kimya sanayi ve ticaret anonim sirketi (533111210)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|----------------------------|
| KOCKAR MAKINA KIMYA SANAYI VE TICARET ANONIM SIRKETI | | 533111210 | manufacture(78433-201) |

KOCKAR MAKINA KIMYA SANAYI VE TICARET ANONIM SIRKETI