

ANTI-BACTERIAL ALCOHOL-BASED HAND AND SKIN DISINFECTANT- alcohol liquid
DTH SAGLIK HIZMETLERI 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.

Hand Sanitizer Liquid

Active Ingredient(s)

Ethyl alcohol 70% w/w, 2-Propanol 0.5% w/w

Purpose

Antiseptic

Alcohol-based hand disinfectant

Use

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

Warnings

This product is only for external use. Keep away from children, food, and animal feed. Do not swallow.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and 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

Put enough product (app.3-5 ml) on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. Do not rinse or wipe off the hand sanitizer before it's dry; it may not work as well against germs.

Supervise children under 6 years of age when they use hand sanitizer gel to prevent swallowing alcohol, especially in schools and childcare facilities.

Other information

Do not use other disinfectant and cleaning agents. It should be used in its original packaging. Store between 15-30 C (59-86F).Protect from direct sunlight. Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Fragrance, Citric acid, Purified water USP

Package Label - Principal Display Panel

DTH Saglik Hizmetleri Tic. A.S. Merkez: Incek Mehmetcik Cad. 2654. Sk. No:2 Golbasi-Ankara

T: +90 312 211 05 06 F: +90 312 211 05 00

www.dthsaglik.com - www.idkimya.com

I& D sept INTERNATIONAL DISINFECTION

ANTI-BACTERIAL ALCOHOL BASED HAND AND SKIN DISINFECTANT

For External Use Only

KILLS 99,9% of germs without water

KILLS 99,9% VIRUSES & BACTERIA



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| | |
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| <p>ACTIVE INGREDIENTS Ethyl alcohol 70%w/w , 2-Propanol 0.5% w/w. Purpose: Antiseptic</p> <p>PURPOSE Alcohol-based hand disinfectant</p> <p>USE Hand Sanitizer to help reduce bacteria that potentially can cause disease. Effective against bacteria, fungi, viruses. For use when soap and water are not available.</p> <hr/> <p>DO NOT USE</p> <ul style="list-style-type: none">❖ in children less than 2 months of age❖ on open skin wounds <hr/> <p>WHEN USING</p> <p><small>This product is only for external use. Keep away...</small></p> | <p>STOP USE Stop use and ask a doctor if irritation and rash occurs. These may be signs of a serious condition.</p> <p>KEEP OUT OF REACH OF CHILDREN Keep out of reach of children. If accidentally swallowed, get medical help or contact a Poison Control Center right away.</p> <p>DIRECTIONS Put enough product (app.3-5 ml) on hands to cover all surfaces. Rub hands together, until hands feel dry. This should take around 20 seconds. Do not rinse or wipe off the hand sanitizer before it's dry; it may not work as well against germs. Supervise children under 6 years of age when they use hand sanitizer gel to prevent swallowing alcohol, especially in schools and childcare facilities.</p> <p>OTHER INFORMATIONS Do not use other disinfectant and cleaning agents. It should be used in it's original packaging. Store between 15-30 C (59-86F). Protect from direct</p> |
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INACTIVE INGREDIENTS

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PRD:

EXP:

LOT



250ml e 8.45 fl. oz.



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8681889320988



ANTI-BACTERIAL ALCOHOL-BASED HAND AND SKIN DISINFECTANT

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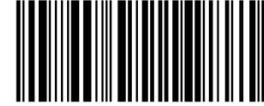
Glycerin, Fragrance, Citric Acid, Purified water USP

PRD:

EXP:

LOT

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8681889320018



ANTI-BACTERIAL ALCOHOL-BASED HAND AND SKIN DISINFECTANT

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KILLS 99,9% of germs without water

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100ml e 3,38 fl.oz



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PRD:

EXP:

LOT



1000ml e 33,8 fl. oz.

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8681889320025

ANTI-BACTERIAL ALCOHOL-BASED HAND AND SKIN DISINFECTANT

alcohol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78992-612 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) | ISOPROPYL ALCOHOL | 0.5 mL in 100 mL |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |

Product Characteristics

| | | | |
|--------|--|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78992-612-01 | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:78992-612-02 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:78992-612-03 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:78992-612-04 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | |



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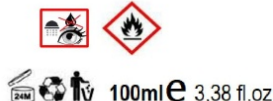
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Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/30/2020 | |

Labeler - DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI (566220129)

Registrant - HARDAL GLOBAL CONSULTING LLC (123584960)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI | | 566220129 | manufacture(78992-612) |

Revised: 6/2020

DTH SAGLIK HIZMETLERI TICARET ANONIM SIRKETI