

ALLPURE HAND SANITIZER- alcohol gel
YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET
LIMITED 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.

Active Ingredient

Ethyl Alcohol 70% v/v.

Purpose

Antiseptic

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

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

When using this products 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 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.

Directions

- Place enough product on hands to cover all surfaces.. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store above 15·30C (59·86F)




Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Carbomer, Glycerin, Purified Water, Rosmarinus Officinalis Extract, Triethanolamine

Product label

| | |
|---|------------------------------|
| Drug Facts | |
| Active ingredients Alcohol 70%v/v | Purpose Antiseptic |
| 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. Keep out of reach of children. | |
| 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 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. | |
| Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information • Store above 15-30C (59-85F) • Avoid freezing and excessive heat above 40C (104F) | |
| Inactive ingredients Carbomer, Glycerin, Purified Water, Rosmarinus Officinalis Extract, Triethanolamine | |

Distributed by
CERCI USA INC.
7755 Alabama Ave Unit 10
91304, California, USA

Batch number and expiry date
are printed on the bottle.

FORMULATED IN USA
MADE IN TURKEY

ALLPURE
HAND SANITIZER

with soothing
aloe vera

NATURAL
70% alcohol
maximum protection
antiseptic

100 ml 3.38 fl. oz.

ALLPURE HAND SANITIZER

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:78575-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| ROSEMARY (UNII: IJ67X351P9) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:78575-002-01 | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |

| | | | | |
|---|------------------|---|------------|--|
| 2 | NDC:78575-002-02 | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| 3 | NDC:78575-002-03 | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| 4 | NDC:78575-002-04 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| 5 | NDC:78575-002-05 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| 6 | NDC:78575-002-06 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| 7 | NDC:78575-002-07 | 5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 07/20/2020 | |

Labeler - YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI
(355436838)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI | | 355436838 | manufacture(78575-002) |

Revised: 7/2020

YESILILGAZ KOZMETIK KIMYA INSAAT OTOMOTIV VE GIDA SANAYI TICARET LIMITED SIRKETI