

KANDESN- alcohol gel
Sunrider Manufacturing L.P.

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.

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use throughout the day

Warnings

For external use only

Flammable. Keep away from fire or flame.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product in your palm to cover hands, rub hands together briskly until dry
- Children under 6 years of age should be supervised when using this product

Other information

Store below 110°F (43°C)

- May discolor certain fabrics or surfaces

Inactive ingredients

Water (Deionized), Salix Alba (Willow) Bark Extract, Ammonium Acryloyldimethyltaurate/VP Copolymer, Camellia Sinensis Leaf Extract, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Laurus Nobilis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, PEG-40 Hydrogenated Castor Oil, Oleth-20, Fragrance

Questions or comments?

Call 1-310-781-8096

Principal Display Panel – 60 mL Bottle Label

KANDESN®

**HAND
CLEANSING
GEL**

70% Alcohol

SUNRIDER®

NET WT.

2 fl. oz. (60 mL)

| | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------------------|------------|------------------------------------------|
| <p>Drug Facts</p> | <p>MANUFACTURED BY SUNRIDER MANUFACTURING, L.P. TORRANCE, CALIFORNIA 90501 • USA</p>  <p>2 010034 015718</p> | <p>KANDESN®</p> | | | | |
| <table border="0"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Ethyl Alcohol 70%</td> <td>Antiseptic</td> </tr> </table> | | Active Ingredient | Purpose | Ethyl Alcohol 70% | Antiseptic | <p>HAND CLEANSING GEL</p> |
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| Ethyl Alcohol 70% | | Antiseptic | | | | |
| <p>Uses • For handwashing to decrease bacteria on the skin • Recommended for repeated use throughout the day</p> | | <p>70% Alcohol</p> | | | | |
| <p>Warnings For external use only</p> | |  <p>SUNRIDER®</p> | | | | |
| <p>Flammable. Keep away from fire or flame.</p> | | | <p>NET WT. 2 fl. oz. (60 mL)</p> | | | |
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| <p>Stop use and ask a doctor if irritation or rash appears and lasts</p> | | | | | | |
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| <p>Questions or comments? Call 1-310-781-8096</p> | | | | | | |



US B875230134

KANDESN

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62191-085 |
| 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: 059QF0KO0R) | |
| Salix Alba Bark (UNII: 205MXS71H7) | |
| Ammonium Acryloyldimethyltaurate/VP Copolymer (UNII: W59H9296ZG) | |
| Green Tea leaf (UNII: W2ZU1RY8B0) | |
| Menthol, Unspecified Form (UNII: L7T10EIP3A) | |
| Tea Tree Oil (UNII: VIF565UC2G) | |
| Bay Leaf (UNII: WS0Y3M85RF) | |
| Rosemary (UNII: IJ67X351P9) | |
| Polyoxyl 40 Hydrogenated Castor Oil (UNII: 7YC686GQ8F) | |
| Oleth-20 (UNII: YTH167I2AG) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:62191-085-08 | 60 mL in 1 TUBE; Type 0: Not a Combination Product | 04/22/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part333A | 04/22/2020 | |

Labeler - Sunrider Manufacturing L.P. (786951475)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|------------------------|
| Sunrider Manufacturing L.P. | | 786951475 | MANUFACTURE(62191-085) |

Revised: 4/2020

Sunrider Manufacturing L.P.