# DR.OSLER HAND SANITIZER- alcohol gel Corelandmark Inc.

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.

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#### **Drug Facts**

Alcohol

Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylene Glycol, Triethanolamine, Aloe Barbadensis Leaf Extract, Eucalyptus Globulus Leaf Extract, Glycerin, 1,2-Hexanediol, Ethylhexylglycerin, Carbomer, Fragrance

Antiseptic

#### KEEP OUT OF REACH OF THE CHILDREN

For the external use only

For external use only.

Flammable, keep away from fire or flame.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation or sensitization develops.

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

Put enough amount in your palm and rub hands together until dry. Children under 6 years of age should be supervised by adult who is older than 21 years of age.



#### DR.OSLER HAND SANITIZER alcohol gel **Product Information** HUMAN OTC DRUG NDC:78050-0001 Product Type Item Code (Source) **Route of Administration** TOPICAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL 175 mL in 250 mL

| Inactive Ingredients  |          |  |  |
|---|----------|--|--|
| Ingredient Name   | Strength |  |  |
| GLYCERIN (UNII: PDC6 A3C0 OX)                                 |          |  |  |
| WATER (UNII: 059QF0KO0R)                                      |          |  |  |
| CARBOMER HO MO PO LYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) |          |  |  |
| ALOE VERA WHOLE (UNII: KIZ4X2EHYX)                            |          |  |  |

| Packaging |                      |   |                         |                       |
|-----------|----------------------|---|-------------------------|-----------------------|
| #         | Item Code            | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:78050-0001-<br>1 | 250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/01/2020              |                       |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333A                                 | 06/01/2020           |                    |  |
|                         |  |                      |                    |  |

## Labeler - Corelandmark Inc. (688505535)

### Registrant - Corelandmark Inc. (688505535)

| Establishment          |         |           |                         |  |
|------------------------|---------|-----------|-------------------------|--|
| Name                   | Address | ID/FEI    | Business Operations     |  |
| AD Cosmetics Co., Ltd. |         | 688155662 | manufacture(78050-0001) |  |

| Establishment     |         |           |                     |  |
|-------------------|---------|-----------|---------------------|--|
| Name              | Address | ID/FEI    | Business Operations |  |
| Corelandmark Inc. |         | 688505535 | label(78050-0001)   |  |

Revised: 6/2020 Corelandmark Inc.