## CARE ON HAND SANITIZER GEL- alcohol gel WELCRON HEALTHCARE CO., LTD

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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70416-2001

#### **Active Ingredients**

Ethyl Alcohol 70%

#### **Purpose**

Antiseptic

#### Use

Hand sanitizer to help reduce bacteria on the skin.

#### 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 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**

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using care on Hand Sanitizer gel.

#### Other information

- Store below 33.8-86F(1-30C)
- May discolor certain fabrics or surfaces.

#### **Inactive ingredients**

Water, Glycerin, Carbomer, Triethanolamine, Aloe Barbadensis Leaf Extract, Camellia Sinensis Leaf Extract, Glycyrrhiza Extract, Rosemary Extract

#### **Package Label**





# CARE ON HAND SANITIZER GEL alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70416-2001

| Route of Administra | tion |
|---------------------|------|

TOPICAL

| Active Ingredient/Active Moiety                           |                   |                 |  |
|---|-------------------|-----------------|--|
| Ingredient Name   | Basis of Strength | Strength        |  |
| ALCOHOL (LINII: 3K9958V90M) (ALCOHOL - LINII: 3K9958V90M) | AT COHOI          | 70 mI in 100 mI |  |

| Inactive Ingredients                                       |          |  |  |
|--|----------|--|--|
| Ingredient Name  | Strength |  |  |
| WATER (UNII: 059QF0KO0R)                                   |          |  |  |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) |          |  |  |
| TROLAMINE (UNII: 9O3K93S3TK)                               |          |  |  |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)                       |          |  |  |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)                          |          |  |  |
| LICORICE (UNII: 61ZBX54883)                                |          |  |  |
| ROSEMARY (UNII: IJ67X351P9)                                |          |  |  |
| GLYCERIN (UNII: PDC6 A3C0 OX)                              |          |  |  |

| ] | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | t Item Code          | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:70416-2001-      | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 09/28/2020              |                       |  |
| 2 | NDC:70416-2001-<br>2 | 100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 11/20/2020              |                       |  |

| Marketing Information   |  |                      |                    |  |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333A                                 | 09/28/2020           |                    |  |
|                         |  |                      |                    |  |

## Labeler - welcron healthcare co., Ltd (688301944)

## Registrant - Devolver Cosmetics Co., Ltd (695733244)

| Establishment               |         |           |                         |  |
|-----------------------------|---------|-----------|-------------------------|--|
| Name                        | Address | ID/FEI    | Business Operations     |  |
| Devolver Cosmetics Co., Ltd |         | 695733244 | manufacture(70416-2001) |  |