## HAND SANITIZER- alcohol gel Zermat Internacional S.A. de C.V.

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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#### **Hand Sanitizer Gel**

#### **Drug Facts**

# Active ingredient[s]

Alcohol 80% v/v

## **Purpose**

Antiseptic

#### Use[s]

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 product

keep out 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.

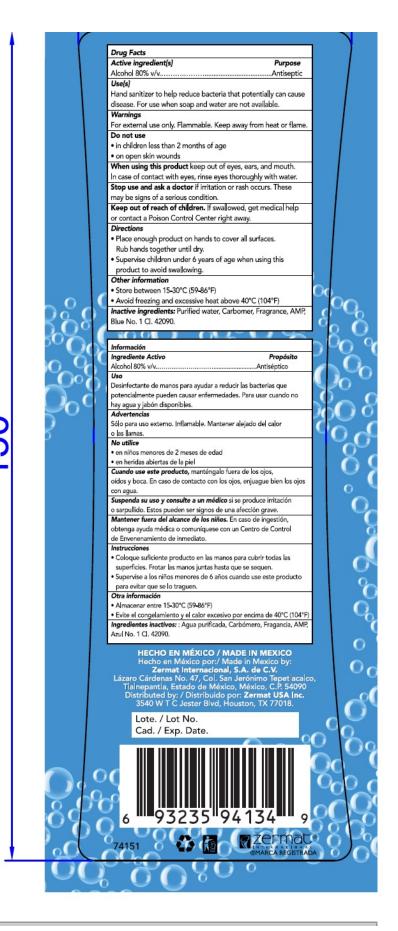
## Other information

- Store between 15-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

#### **Inactive ingredients:**

# **Package Labeling:**





# HAND SANITIZER

alcohol gel

| Duadrick | Information |
|----------|-------------|
| Product  | Information |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:15828-196

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

| ı | Ingredient Name                                        | Basis of Strength | Strength       |
|---|--------------------------------------------------------|-------------------|----------------|
| ı | ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 0.8 mL in 1 mL |

# **Inactive Ingredients**

| industry ingredients                                       |          |  |
|------------------------------------------------------------|----------|--|
| Ingredient Name                                            | Strength |  |
| WATER (UNII: 059QF0KO0R)                                   |          |  |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC) |          |  |
| ADENO SINE PHO SPHATE (UNII: 415SHH325A)                   |          |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                         |          |  |

# Packaging

| 1 | _ | - m              |                                                       |                             |                    |
|---|---|------------------|-------------------------------------------------------|-----------------------------|--------------------|
| ı | # | Item Code        | Package Description                                   | <b>Marketing Start Date</b> | Marketing End Date |
| 1 | 1 | NDC:15828-196-01 | 195 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/24/2020                  |                    |

# **Marketing Information**

| Turneting into mutton   |                                          |                      |                    |  |
|-------------------------|------------------------------------------|----------------------|--------------------|--|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph not final | part333E                                 | 04/24/2020           |                    |  |
|                         |                                          |                      |                    |  |

# Labeler - Zermat Internacional S.A. de C.V. (812820712)

Revised: 4/2020 Zermat Internacional S.A. de C.V.