#### LACTONE HAND SANITIZER WIPE- alcohol cloth ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM 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.

-----

#### Hand Sanitizer Wipes

#### **Active Ingredient(s)**

Ethyl Alcohol 80%

# Purpose

Antiseptic

# Use

Use for hand-washing to decrease bacteria on the skin, only when water is not available

#### Warnings

Flammable, keep away from heat and flames. For external use only

When using this product

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash occurs.

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

# Directions

wet hands thorougly with product and allow to dry without wiping

#### **Inactive ingredients**

water, Aloe Barbadensis Leaf Extract and propylene glycol

# Package Label - Principal Display Panel

Producer ALL ONE KOZMETIK SAN. VE DIS. TIC. A. S. Sutluce Mahallesi Uzunbayır Sokak No:44/4 Beyoglu/Istanbul Net weight: 5 gr MADE IN TURKEY Hand Sanitizer Wipe Kills 99.99% of E. coli, Salmonella enterica and Staphylococcus aureus (MRSA) with ALOE VERA FRAGRANCE For External Use only LACTONE HAND SANITIZING WIPES- alcohol cloth





# LACTONE HAND SANITIZER WIPE

alcohol cloth

| Product Informat          | ion   |   |                 |                    |  |  |   |               |
|---------------------------|---|---|-----------------|--------------------|--|--|---|---------------|
| Product Type              | HUMAN OTC DRUG  |   |                 | Item Code (Source) |  |  | NDC:75348-888   |               |
| Route of Administra       | tion  | TOPICAL   |                 |                    |  |  |   |               |
| Active Ingredient         | /Active Moie  | ty  |                 |                    |  |  |   |               |
|                           | Ingre   | dient Name  |                 |                    |  | Basis of Stren   | gth   | Strength      |
| ALCOHOL (UNII: 3K99       | 958V90M) (ALC   | OHOL - UNII:3K  | (9958V90M)      |                    |  | ALCOHOL  |   | 800 mg in 1 g |
| Inactive Ingredie         | nts   |   |                 |                    |  |  |   |               |
| 0                         |   | Ingredient  | t Name          |                    |  |  |   | Strength      |
| ALOE VERA LEAF (UI        | NII: ZY81Z83H0X   | )   |                 |                    |  |  |   | -             |
| PROPYLENE GLYCO           | L (UNII: 6DC9Q1   | 67V3)   |                 |                    |  |  |   |               |
| WATER (UNII: 059QF0       | KO0R)   |   |                 |                    |  |  |   |               |
|                           |   |   |                 |                    |  |  |   |               |
| Product Characte          | ristics   |   | 2               |                    |  |  |   |               |
|                           | olor Score  |   |                 |                    |  |  |   |               |
| Shape                     |   |   |                 |                    |  |  |   |               |
| Flavor<br>Contains        | Flavor Imprint Code   |   |                 |                    |  |  |   |               |
| Packaging                 |   |   |                 |                    |  |  |   |               |
| # Item Code               | I   | Package Desc  | ription         |                    | Mark   | eting Start Date   | Mar   | keting End Da |
| <b>1</b> NDC:75348-888-05 | 5 g in 1 POUCH  | Type 0: Not a C   | Combination Pro | duct               | 05/22/2  | 020  |   |               |
|                           | L'ACT<br>Hand Sanit<br>Kills 99.99% of E. coli, Sa<br>Staphylococcus a<br>%80 ALC | <b>izer Wipe</b><br>Imonella enterica and<br>Ireus (MRSA) |                 |                    | L'ACTO<br>Hand Sanitia<br>(ills 99,99% of E. (<br>ills 99,99% of E. (<br>MRSA)<br>In UR (194 MASAING<br>or External Use Only<br>(Internal Use Only<br>(Internal Use Only)<br>(Internal Use Only) | Zer Wipe<br>The for hardweaking to<br>the science of the science of th | om fire and flames<br>use eyes thoroughly<br>or if<br>dren, if swallowed,<br>cct a Poison Contro<br>th product and allo |               |
|                           | with ALOE VERA  | FRAGRANCE   |                 | _                  | ANE IN TURKEY Net Wei  | yac uyi  |   |               |

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A                                 | 05/22/2020           |                    |

# Labeler - All one kozmetik sanayı dis ticaret anonim sirketi (519983719)

# **Registrant** - HARDAL GLOBAL CONSULTING LLC. (123584960)

# Establishment

| Name   | Address | ID/FEI    | <b>Business Operations</b> |
|--|---------|-----------|----------------------------|
| ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI |         | 519983719 | manufacture(75348-888)     |

Revised: 6/2020

ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI