## LACTONE HAND SANITIZER- alcohol gel 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.

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## Hand sanitizer 606 gallon

## L'ACTONE HAND SANITIZER GEL

**Dermal Disinfectant** 

## **Active Ingredient(s)**

Alcohol 80% v/v. Purpose: Antiseptic

## **Purpose**

Antiseptic, Hand Sanitizer

## Use

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 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.

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## **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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## **Package Label - Principal Display Panel**

Producer

ALL ONE KOZMETIK SAN. DIS. TIC. A. S.

Sutluce Mahallesi

Uzunbayir Sokak No:44/4

Beyoglu/Istanbul

PRD: 01.04.2020

EXP: 01.04.2023

LOT: AL006220

MADE IN TURKEY

Dermal Disinfectant

HAND SANITIZER GEL

Kills 99.9% of germs without water

For External Use Only

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Inactive ingredients Glycerin, Carbomer, Triethanolamine, purified water USP



# L'ACTONE

# **Dermal Disinfectant** HAND SANITIZER GEL

Kills 99.9% of germs without water

For External Use Only

**1US GALLON** 

Active Ingredient(s) Alcohol 80% v/v. Purpose: Antiseptic

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MADE IN TURKEY



alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75348-606	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER 980 (UNII: 4Q93RCW27E)				
WATER (UNII: 059QF0KO0R)				
TRO LAMINE (UNII: 903K93S3TK)				

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75348-606- 19	19000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75348-606- 38	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

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PRD: 81.84.2828 EXP: 81.84.2823 LOT: RL886228

Producer
ALL ONE KOZMETIK SAN. DIS.TIC.A.S.
Sielluse Mahallesi Uzunbayır Sokak No:44/4 Beyoglu / İstanbul

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## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

# **Labeler -** ALL ONE KOZMETIK SANAYI 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(75348-606)	

Revised: 7/2020 ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI