

**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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**LACTONE HAND SANITIZER**

**Active ingredient(s)**

Alcohol 80% v/v

**Purpose**

Antiseptic

**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**

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

**STOP USE**

Stop use and ask a doctor if irritation or rash occurs. These may be signs of 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 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

**Inactive ingredients**

Glycerin, Carbomer, Triethanolamine, purified water USP

**Kills 99.9% of germs without water**

**For External Use Only**

**MADE IN TURKEY**

Producer

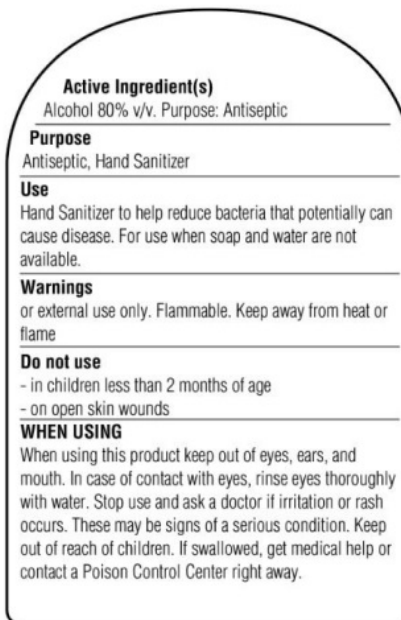
**ALL ONE KOZMETIK SAN. DIS. TIC.A.S.**

Sutluce Mahallesi Uzunbayir Sokak No. 44/4 Beyoglu / Istanbul

PRD: 01.04.2020

EXP: 01.04.2023

## Packaging





## LACTONE HAND SANITIZER

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: PDC6 A3C0 OX)	
CARBOMER HO MO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM30 7FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0 KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75348-606-05	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
2	NDC:75348-606-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
3	NDC:75348-606-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

**Labeler** - ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI (519983719)

## Establishment

Name	Address	ID/FEI	Business Operations
ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI		519983719	manufacture(75348-606)

Revised: 4/2020

ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI