

**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**

**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, Carbomer, Thiethanlamine, purified water USP



alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75348-606
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 980 (UNII: 4Q93RCW27E)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75348-606-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
2	NDC:75348-606-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
3	NDC:75348-606-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
4	NDC:75348-606-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	
5	NDC:75348-606-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/22/2020	

**L'ACTONE**  
 Dermal Disinfectant  
**HAND SANITIZER GEL**  
 Kills 99.9% of germs without water  
 For External Use Only

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

**Purpose**  
 Antiseptic, Hand Sanitizer

**Use**  
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**Warnings**  
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 - on open skin wounds

**WHEN USING**  
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**Other information**  
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**Inactive ingredients**  
 Glycerin, Carbomer, Triethanolamine, purified water USP

PRD: 01.04.2020  
 EXP: 01.04.2023 LCT: FL096220

Product: ALL ONE KOZMETIK SAN. DIS. TIC. A.Ş. Sultuk Mahallesi Yenibayır Sokak No:443 Beşyüzyıl / İstanbul  
 MADE IN TURKEY

8 694 587 576557

946ml/ 32 FL OZ

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473ml/ 16 FL OZ

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 For External Use Only

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 Alcohol 80% v/v, Purpose: Antiseptic

**Purpose**  
 Antiseptic, Hand Sanitizer

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Product: ALL ONE KOZMETIK SAN. DIS. TIC. A.Ş. Sultuk Mahallesi Yenibayır Sokak No:443 Beşyüzyıl / İstanbul  
 MADE IN TURKEY

110ml/ 4 FL OZ

**L'ACTONE**  
 Dermal Disinfectant  
**HAND SANITIZER GEL**  
 Kills 99.9% of germs without water  
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 Alcohol 80% v/v, Purpose: Antiseptic

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Product: ALL ONE KOZMETIK SAN. DIS. TIC. A.Ş. Sultuk Mahallesi Yenibayır Sokak No:443 Beşyüzyıl / İstanbul  
 MADE IN TURKEY

8 694 587 576557

238ml/ 8 FL OZ

**L'ACTONE**  
 Dermal Disinfectant  
**HAND SANITIZER GEL**  
 Kills 99.9% of germs without water  
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 Alcohol 80% v/v, Purpose: Antiseptic

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 Antiseptic, Hand Sanitizer

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 MADE IN TURKEY

8 694 587 576519

**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.  
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 MADE IN TURKEY

58ml/ 2 FL OZ

**Marketing Information**

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 SANAYI DIS TICARET ANONIM SIRKETI (519983719)

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

**Establishment**

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

Revised: 6/2020

ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI