

**SECUREMAX ANTIBACTERIAL HAND CLEANSING- ethyl alcohol, benzalkonium chloride solution**

**ATOMIZER KOZMETIK TURIZM VE YAPI SANAYI 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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**SECUREMAX Antibacterial Hand Cleansing Solution**

**Drug Facts**

**Active Ingredient**

Ethyl Alcohol 70 %

Benzalkonium Chloride 0.1 %

Be sure to read the label before use.

**Purpose**

Antiseptic

Antibacterial

**Use**

- To decrease bacteria on the skin and clean hands.
- Recommended for repeated use.

**Warnings**

For external use only. Flammable, keep away from fire or flame. Do not store above 40°C.

**Do not get into eyes.**

If contact occurs, rinse thoroughly with water.

**Discontinue use.**

If irritation or redness develops. If irritation persists for more than 72 hours, consult a doctor.

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

**DIRECTIONS**

- Apply to hands until thoroughly wet.
- Rub vigorously until dry.
- Supervise children in the use of this product.

**Inactive Substances:**

29,15% Deionised water, 0,75% Glycerin.

**KILLS 99,9% OF BACTERIA\* /RINSE-FREE /WITH MOISTURIZER /70 °ETHANOL**

SECUREMAX Antibacterial hand cleansing liquid has been developed especially to ensure effective protection of the hands against tested bacteria. It kills 99.9% of the tested bacteria (\*). It has been proven to provide antibacterial protection against the microorganisms listed below (\*).

(\*) Bacteria type tested under laboratory conditions

**Bacteria Type:** Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae.

**Application Area and Usage:** General Area-Hand and Skin. At least 3 ml solution is applied to the hand without dilution and rubbed until the hands are dry for 60 seconds. It is not necessary to rinse.

**Application Dose:** Ready to Use.

**Application Range:** It is used as often as desired.

**Poisoning Symptoms:** None.

**Ethyl Alcohol:** LD50: Acute oral-rat: 6200 mg/kg. Acute dermal rabbit: 7060 mg/kg

**Benzalkonium Chloride:** LD50: (Acute oral-rat): 795 mg/kg., LD50:(Dermal rat)>5000 mg/kg

Antidote and necessary information: There is no specific antidote known. Toxic for bees. It can be poisonous to fish and aquatic organisms.

**First Aid Measures :**

**If inhaled:** Remove patient to fresh air. If you feel unwell, consult a doctor. **If swallowed:** Rinse mouth with plenty of water and consult a doctor. In case of **Eye Contact:** If contact lenses are present, before washing the eyes, they should be removed. Open the eyelids and wash the eyes immediately with plenty of water. If the discomfort continues, consult a doctor. Hazard Statements and Descriptions: **H225** Highly flammable liquid and vapour. **H319** Causes serious eye irritation. Precautionary statements and Descriptions: **P210:** Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P233:** Keep container tightly closed. **P240:** Ground/bond container and receiving equipment. **P241:** Use explosion-proof electrical/ventilating/lighting/.../equipment. **P303+P361+P353:** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower. **P305+351+338: IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. **P370+378:** In case of fire: Use suitable fire extinguisher to extinguish. **P337+P313:** If eye irritation persists get medical advice/attention. **P403+235:** Store in a well-ventilated place. Keep cool. **P501:** Dispose of contents/container in accordance with regional regulation. Keep away from children, food and animal feeds. Do not inhale vapors or particles. Do not eat or drink anything during application. Do not smoke. Store in the original packaging at a temperature below 30°C. Keep away from sunlight. Follow the instructions for use to avoid risks on human and environmental health. Use the opened product within 6 months. The shelf life of the product is 2 years under suitable storage conditions.

**ATTENTION USED EXTERNALLY, NOT DRINKING.**

**Production Date:**27/04/2020

**Expiry Date:**27/04/2020

**ATOMİZER KOZMETİK TURİZM VE YAPI SAN. TİC. A.Ş.**

Esenevler Mah. Korupark Sok. No:1 Ümraniye/İstanbul, Turkey [www.atomizer.com.tr](http://www.atomizer.com.tr)

**MADE IN TURKEY**

**Packaging**

**Drug Facts**

**Active Substances: (V/V):** 70 % Ethyl Alcohol (CAS No: 64-17-5), 0,1% (w/w) Alkyl (C12-16) dimethylbenzyl ammonium chloride ADBAC / BKC (C12-16) (Benzalkonium Chloride) (Cas No: 68424-85-1)

Be sure to read the label before use

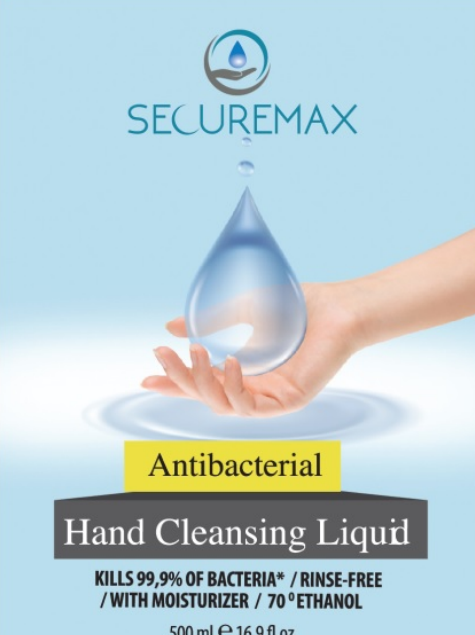
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**Benzalkonium Chloride:** LD50: (Acute oral-rat): 795 mg/kg. LD50: (Dermal rat) >5000 mg/kg  
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**Antibacterial**

**Hand Cleansing Liquid**

**KILLS 99,9% OF BACTERIA\* / RINSE-FREE**  
**/ WITH MOISTURIZER / 70° ETHANOL**

500 ml e 16,9 fl.oz.

**Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 70 %	Antiseptic
Benzalkonium Chloride 0,1%	Antibacterial

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License No and Date: 2020/GS3 - 21.04.2020  
Production Date: 27/04/2020  
Expiry Date: 27/04/2022  
Lot No: P27042030

ATMIZER KOZMETİK  
TURİZM VE YAPIL SAN. TİC. A.Ş.  
Esenler Mah. Karupark Sok. No: 1 Ümraniye / İstanbul  
Turkey www.atmizer.com.tr

**MADE IN TURKEY**

**Danger**

500 ml e 16,9 fl.oz. 8 692 18 1 970597

## SECUREMAX ANTIBACTERIAL HAND CLEANSING

ethyl alcohol, benzalkonium chloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78092-602
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78092-602-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
2	NDC:78092-602-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
3	NDC:78092-602-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	

4	NDC:78092-602-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
5	NDC:78092-602-05	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
6	NDC:78092-602-06	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
7	NDC:78092-602-07	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
8	NDC:78092-602-08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
9	NDC:78092-602-09	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
10	NDC:78092-602-10	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
11	NDC:78092-602-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
12	NDC:78092-602-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/27/2020	
13	NDC:78092-602-13	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/27/2020	
14	NDC:78092-602-14	10000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/27/2020	
15	NDC:78092-602-15	25000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/27/2020	
16	NDC:78092-602-16	30000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/27/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2020	

**Labeler** - ATOMIZER KOZMETIK TURIZM VE YAPI SANAYI TICARET ANONIM SIRKETI (364761135)

## Establishment

Name	Address	ID/FEI	Business Operations
ATOMIZER KOZMETIK TURIZM VE YAPI SANAYI TICARET ANONIM SIRKETI		364761135	manufacture(78092-602)

Revised: 5/2020

ATOMIZER KOZMETIK TURIZM VE YAPI SANAYI TICARET ANONIM SIRKETI