

SECUREMAX ANTIBACTERIAL HAND CLEANSING- ethyl alcohol gel
ATOMIZER KOZMETİK TURİZM VE YAPI SANAYİ TİCARET ANONİM ŞİRKETİ

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.

SECUREMAX Antibacterial Hand Cleansing Gel

Drug Facts

Active Ingredient

Ethyl Alcohol 64.5%

Be sure to read the label before use.

Purpose

Antiseptic

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 and amounts (W/W): 34,25% Deionised Water, 0,75% Glycerin, 0,25% Carbomer, 0,25% Triethanolamine.

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

SECUREMAX Antibacterial hand cleansing gel 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

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+361+353:** 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+313:** If eye irritation persists get medical advice/attention. **P403+235:** Store in a well ventilated place. Keep cool. **P501:** Dispose of contents/container to 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

MADE IN TURKEY

Packaging

Drug Facts

Active Substance: (w/w): 64.5% Ethyl Alcohol (CAS No: 64 17 5)

Be sure to read the label before use

Poisoning Symptoms: None.

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

Antibacterial

Hand Cleansing Gel

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 64.5% Antiseptic

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

Warnings
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 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.

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Application Dose: Ready to Use.
Application Range: It is used as often as desired.

ATTENTION USED EXTERNALLY, NOT DRINKING.
License No and Date: 2020/554 - 21.04.2020
Production Date: 27/04/2020
Expiry Date: 27/04/2022
Lot No: P27042031

ATOMIZER KOZMETIK TURIZM VE YAPI SAN. TIC. A.Ş.
 Esetevler Mah. Korupark Sok. No:1 Ümraniye /İstanbul
 Turkey www.atomizer.com.tr

MADE IN TURKEY

Danger

500 ml e 16,9 fl.oz.

SECUREMAX ANTIBACTERIAL HAND CLEANSING

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78092-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	64.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78092-601-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
2	NDC:78092-601-02	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
3	NDC:78092-601-03	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	

4	NDC:78092-601-04	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
5	NDC:78092-601-05	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
6	NDC:78092-601-06	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
7	NDC:78092-601-07	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
8	NDC:78092-601-08	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
9	NDC:78092-601-09	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
10	NDC:78092-601-10	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
11	NDC:78092-601-11	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
12	NDC:78092-601-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2020	
13	NDC:78092-601-13	5000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/26/2020	
14	NDC:78092-601-14	10000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/26/2020	
15	NDC:78092-601-15	25000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/26/2020	
16	NDC:78092-601-16	30000 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/26/2020	

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(78092-601)

Revised: 5/2020

ATOMIZER KOZMETIK TURIZM VE YAPI SANAYI TICARET ANONIM SIRKETI