

ANTIBACTERIAL HAND SANITIZER- alcohol gel

Sweda Company LLC

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.

Antibacterial Hand Sanitizer

Drug Facts

Active Ingredients

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses:

Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.

Warnings:

For external use only.

Flammable. Keep away from heat and flame. Do not apply around eyes

Do not use in ears & mouth.

When using this product,

avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor

if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

Directions:

Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry

Other information:

Store at 20°C (68°-77°F). May discolor fabrics

Inactive Ingredients:

water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, carbomer, fragrance.

Drug Facts Antibacterial Hand Sanitizer

Active Ingredients.....Purpose

Ethyl Alcohol 62%Antiseptic

Uses: Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.

Warnings: For external use only. Flammable. Keep away from fire or flame. Do not apply around eyes, Do not use in ears & mouth.

When using this product, avoid contact with eyes. In case of contact flush eyes with water. Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children. Children must be supervised in use of this product.

Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry

Other Information: Store at 20°C (68° to 77°F). May discolor fabrics

Inactive Ingredients: water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, carbomer, fragrance.

Distributed By: Sweda Company, LLC, 17411 Valley Blvd.,
City of Industry, CA 91744

MADE IN CHINA

0.5oz / 15ml

Drug Facts Antibacterial Hand Sanitizer

Active Ingredients.....Purpose

Ethyl Alcohol 62%Antiseptic

Uses: Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.

Warnings: For external use only.
Flammable. Keep away from fire or flame.
Do not apply around eyes, Do not use in ears & mouth.

When using this product, avoid contact with eyes.
In case of contact flush eyes with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children.
Children must be supervised in use of this product.

Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry

Other Information:

Store at 20°C (68° to 77°F). May discolor fabrics

Inactive Ingredients:
water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, carbomer, fragrance.

Distributed By: Sweda Company, LLC, 17411 Valley Blvd.,
City of Industry, CA 91744

MADE IN CHINA

1oz / 30ml

Drug Facts Antibacterial Hand Sanitizer

Active Ingredients.....Purpose
Ethyl Alcohol 62%Antiseptic
Uses: Hand sanitizer to help decrease bacteria on the skin. When water, soap & towel are not available. Recommended for repeated use.
Warnings: For external use only. Flammable. Keep away from fire or flame. Do not apply around eyes, Do not use in ears & mouth.
When using this product, avoid contact with eyes. In case of contact flush eyes with water. Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours. Keep out of reach of children. Children must be supervised in use of this product.
Directions: Squirt as needed into your palms and thoroughly spread on both hands. Rub into skin until dry
Other Information: Store at 20°C (68° to 77°F). May discolor fabrics
Inactive Ingredients: water, triethanolamine, glycerin, propylene glycol, tocopheryl acetate, carbomer, fragrance.

Distributed By: Sweda Company, LLC, 17411 Valley Blvd.,
City of Industry, CA 91744

MADE IN CHINA

2oz / 59ml

ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90121-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90121-002-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
2	NDC:90121-002-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
3	NDC:90121-002-59	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/30/2020	

