

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 Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

For hand washing to decrease bacteria on the skin.

Warnings:

Flammable. Keep away from fire or flame. For External use only

When using this product,

keep out of eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor

if irritation and redness develops and persists.

Keep out of reach of children.

If swallowed, get medical help promptly and contact poison Control.

Directions

Wet hands thoroughly with product allow to dry without wiping.

Other Information

Store at 20°C (68°-77°F).

Inactive Ingredients:

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl acetate, Triethanolamine, Water.

Package Labeling:120ml

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Distributed by: Sweda Co., LLC

4oz/120ml Made in China

ANTIBACTERIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90121-003
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
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90121-003-12	120 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	

Labeler - Sweda Company LLC (081729899)

Revised: 8/2020

Sweda Company LLC